ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

MEXICO

Mexico City, Mexico

26 November to 5 December 2007

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

DEPARTMENT OF TECHNICAL CO-OPERATION Division for Europe, Latin America and West Asia	DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

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 eighty 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 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 for 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.

REPORT

INTEGRATED REGULATORY REVIW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF MEXICO

Mexico City, Mexico
26 November to 5 December 2007

REPORT

INTEGRATED REGULATORY REVIW SERVICE (IRRS)

REPORT TO

THE GOVERNMENT OF MEXICO

Mexico City, Mexico

Mission date: 26 November to 5 December 2007

Regulatory body: CNSNS

Location: CNSNS Headquarters, Mexico City, Mexico

Regulated facilities and practices: Nuclear power plants, research reactors, fuel cycle facilities, medical practices, industrial and research applications, waste facilities, decommissioning and remediation, communication and public information.

Organized by: IAEA

Technical Co-operation Project: MEX/0/016
Technical Co-operation Project: RLA/9/055
Technical Co-operation Project: RLA/9/053

IAEA Review Team:	**ŽIAKOVÁ,** Marta	(Team Leader, Slovak Republic)
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FOREWORD

by Mohamed ElBaradei

Director General

The General Conference Resolution of September 2007 related to the 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, encourages Member States embarking on new nuclear power programmes to take timely and proactive steps to establish and sustain a competent regulatory body with effective independence and the necessary human and financial resources to fulfil its responsibilities and to consider availing themselves of the Secretariat's recently established Integrated Regulatory Review Service (IRRS)… and notes the growing interest of Member States in the IRRS.

The Agency's safety review services use the IAEA safety standards as a reference point, and play an important part in evaluating their effectiveness. Last year we began offering, for the first time, an Integrated Regulatory Review Service (IRRS), which combined previous services ranging from nuclear safety and radiation safety to emergency preparedness and nuclear security.

The Agency conducted the first full scope IRRS in France in November 2006, covering all regulated nuclear and radiation facilities, activities and practices, including nuclear power plants, research reactors, fuel cycle facilities, medical practices, industrial and research activities, waste facilities, decommissioning, remediation and transport. The French Nuclear Safety Authority requested that the mission also cover public information practices. In March, the French Government hosted a workshop, attended by representatives from over 30 countries, so that regulators of other Member States could learn more about the IRRS and experience gained during the mission. The Agency also conducted IRRS missions to Australia and Japan in June 2007. The Spanish Nuclear Safety Council has offered to organize the next workshop, in late 2008 or early 2009, to disseminate information on the results of IRRS missions conducted in 2007 and 2008.

With its modular approach, the IRRS is contributing towards a more active exchange of knowledge among senior regulators and harmonized regulatory approaches worldwide. Future missions are also scheduled for Canada, Germany, Mexico, Pakistan, Russia, Spain, Ukraine and the USA. I would request all countries to take advantage of this service."

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

CONTENTS

EXECUTIVE SUMMARY

At the request of the Government authorities of Mexico, an international team of experts visited the Comision Nacional de Seguridad Nuclear y Salvaguardias (National Commission on Nuclear Safety and Safeguards (CNSNS)), the regulatory body for nuclear and radiation safety, from 26 November to 5 December 2007 to conduct an Integrated Regulatory Review Service (IRRS) mission.

The purpose of the IRRS was to facilitate regulatory improvements in Mexico and throughout the world from the knowledge gained and experiences shared by CNSNS and the reviewers through the evaluation of the effectiveness of Mexico's regulatory body, its regulatory framework and its regulatory activities. The facilities and practices regulated by CNSNS include nuclear power plants, research reactors, medical practices, industrial and research activities, waste facilities, decommissioning, remediation and transport. The IRRS request also included a review of the safety and security of radioactive sources.

The IRRS Review Team consisted of senior, experienced experts from Member States, staff from the IAEA and an IAEA administrative assistant.

The IRRS team carried out a review of the following relevant areas: 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; emergency preparedness; and the management system of the regulatory body.

The mission included a series of interviews and discussions with key personnel at CNSNS and at other organizations, and observation of inspections of several facilities. CNSNS supplied a package of documentation and self-assessment material in advance of the mission and the team presented its findings based on the IAEA safety standards. Additionally, the IRRS team and CNSNS staff discussed policy issues relating to the regulation of nuclear and radiation safety. The results of the discussions will serve as a useful basis for the evolution of future IRRS missions and will assist with continuous improvement in the regulation of nuclear and radiation safety.

The IRRS Review Team noted the open, transparent and learning attitude of CNSNS staff throughout this mission, and it was evident that significant effort had been put into the preparation of the mission. During the review the administrative and logistical support was excellent and the team was extended full cooperation in technical discussions with CNSNS personnel.

The IRRS Review Team appreciates and acknowledges CNSNS's participation in international cooperation activities and encourages CNSNS to continue its active role in the exchange of experience and expertise among regulators.

The IRRS team wants to highlight several major findings:

1) CNSNS is effectively regulating nuclear and radiation safety;
2) Although not legally ("de jure") independent, CNSNS appears to function and regulate independently;
3) The moratorium on standards, in effect since 29 April, 2005, significantly impacts CNSNS ability to upgrade regulatory requirements to continuously improve nuclear and radiation safety;
4) CNSNS faces significant staffing challenges in light of the federally-mandated hiring practices.

The IRRS Review Team identified good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to further strengthen the effectiveness of

regulatory oversight. These recommendations and suggestions will support CNSNS in improving its regulatory performance, and some of them are related to areas in which CNSNS has already initiated actions to address them.

The most relevant good practices identified were:

- The implementation of a nuclear power plant safety performance indicator programme to monitor and track NPP safety performance;
- The periodic summary and assessment of inspection findings provides a good means to monitor licensee safety performance;
- CNSNS staff involved in licensing NPP operators receive the same technical training as the operators;
- The implementation of a training programme for scrap metal recyclers; and
- CNSNS support for the upgrading of the ININ environmental monitoring programme to meet current international standards.

The IRRS Review Team believes that consideration of the following recommendations and suggestions should be given high priority either because they were identified in several areas of review or because the experts considered that they will contribute significantly to the enhancement of the overall performance of the regulatory system:

- The role of CNSNS as the regulatory body in preparing safety regulations and guides should be clarified;
- CNSNS should continue its efforts to address the impacts of human and organizational factors on safety in operation;
- CNSNS should develop a strategic human resources management plan to face future challenges;
- CNSNS should continue the development of its comprehensive management system, including the development and approval of internal operating procedures.

The IRRS Review Team findings are summarized in Appendix V.

I. INTRODUCTION

At the request of CNSNS, an IAEA team consisting of ten experts from eight Member States, four staff members from the IAEA and an IAEA administrative assistant visited Comision Nacional de Seguridad Nuclear y Salvaguardias (CNSNS) 25 November to 5 December 2007 to conduct an Integrated Regulatory Review Service (IRRS) mission. A preparatory meeting had been conducted in June 2007 at CNSNS headquarters in Mexico City to determine the purpose, objectives, scope and schedule for the review.

The purpose of the mission was to conduct a review of the Mexican regulatory framework and the regulatory activities in all regulated facilities and practices, to review the effectiveness of CNSNS and to exchange information and experience in the regulation of the areas considered by IRRS. The areas reviewed included legislative and governmental responsibilities; authority, responsibilities and functions of the regulatory body; organization of the regulatory body; the authorization process; review and assessment process; inspection and enforcement process; the development of regulations and guides; emergency preparedness and the management system of the regulatory body.

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 nuclear and 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 Convention on Nuclear Safety, international conferences and forums and previous IAEA safety review services.

The mission was conducted from 25 November – 5 December 2007. Before and during the mission, CNSNS made available a collection of reference material for the team to review. This material consisted of a large number of legal, regulatory and internal documents, in particular the report on self-assessment including the IRRS questionnaire. During the mission the team performed a systematic review of all topics using the report on self-assessment, the reference material and related presentations, interviews with CNSNS staff and direct observation of their working practices during inspections carried out by CNSNS.

IRRS activities took place mainly at the CNSNS headquarters. Discussions and observations were also conducted at remote locations as noted in Appendix III.

II. OBJECTIVE AND SCOPE

The purpose of the mission was to conduct an IRRS mission to review the Mexican legal and governmental infrastructure for nuclear and radiation safety, the effectiveness of the Mexican regulatory body (CNSNS) and to exchange information and experience among CNSNS and the IRRS team with a view to contributing to harmonizing regulatory approaches and creating mutual learning opportunities among regulators.

The key objectives of this mission were to enhance nuclear and radiation safety by:

- ✓ Providing the host country (regulatory body and governmental authorities) with a review of the discussions of nuclear and radiation safety regulatory technical and policy issues;
- ✓ Providing the host country with an objective evaluation of their nuclear and radiation safety regulatory practices 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 the host country with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing the host country with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review;
- ✓ Providing reviewers from States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field; and
- ✓ Providing the host country, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against international safety standards.

The scope requested by CNSNS for this IRRS mission included:

- Nuclear installations (nuclear power plant and research reactor).
- Radiation protection in industrial practices and research
- Radiation protection in medical practices (excluding diagnostic)
- Transport of radioactive material
- Emergency preparedness
- Control of public exposure
- Radioactive waste management
- Remediation of contaminated sites
- Decommissioning

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

The preparatory work for the mission was conducted by the IRRS Team Coordinator Mr. David Graves, NSNI/IAEA, and by the IRRS Deputy Team Coordinator, Ms. Cynthia Heinberg, NSRW/IAEA. It is important to note that the IRRS Team Leader, Ms. Marta Ziakova, and the IRRS Deputy Team Leader, Mr. Lucian Biro, belong to IAEA Member States rather than being IAEA staff. In accordance with the request from CNSNS, and taking into account the scope as indicated above, it was agreed that the IAEA review team would be comprised of 10 external experts from 8 Member States (see Appendix I) and 5 staff members from IAEA. The working areas and the CNSNS counterparts were distributed according to Appendix V).

During the preparatory period all documents of the advance reference material (ARM) were sent electronically by CNSNS to the IAEA and distributed to the experts. All details and organizational aspects of the mission were defined with the nominated CNSNS Counterpart, Liaison Officer Mr. Jaime Aguirre.

A significant amount of work was carried out by the reviewers and by the IAEA staff before the review in order to prepare the initial impressions about the ARM, to review the answers to the questionnaire sent to CNSNS, to prepare for the interviews and direct observations at the sites and to identify additional relevant material necessary to review during the mission.

An initial team meeting was conducted on 25 November 2007 in Mexico City by the IRRS Team Leader, the IRRS IAEA Coordinator and the IRRS Deputy Coordinator 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. The reviewers also reported their first impression on the advance reference material.

B) REFERENCES FOR THE REVIEW

The main reference documents provided by CNSNS for the review mission are indicated in Appendix VII. The most relevant IAEA Safety Standards and other reference documents used for the review are indicated in Appendix VIII.

C) CONDUCT OF THE REVIEW

During the mission, a systematic review was conducted for all the review areas with the objective of providing CNSNS with recommendations and suggestions as well as of identifying good practices.

The review was conducted through meetings, interviews and discussions with CNSNS personnel; visits to relevant organizations; assessment of the ARM; and direct observations regarding 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 26 November with the participation of CNSNS senior management. Opening remarks were made by Mr. Juan Eibenschutz, Director General of CNSNS, and Ms. Marta Ziakova, IRRS Team Leader.

The exit meeting was held on Wednesday, 5 December with CNSNS authorities, Mr. Juan Eibenschutz, Director General of CNSNS; Division and Department Heads, and other technical and support staff.

Ms. Ziakova, IRRS Team Leader, presented the main conclusions of the mission, and closing remarks were made by Mr. Philippe Jamet, Director, Division of Nuclear Installation Safety, IAEA. A draft Copy of the mission report was provided to CNSNS following the conclusion of the meeting.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1. GENERAL

Legislative and statutory framework

In Mexico the legislative and regulatory framework is based on the Political Constitution of the United Mexican States (Constitution) from which a series of laws, regulations and standards are derived.

Article 25, Paragraph four:

In an exclusive manner, the public sector shall be in charge of strategic areas given in Article 28, paragraph four of the Constitution, maintaining the Federal Government ownership and control over organisms which may be established.

Article 27, Paragraph seven:

It also corresponds to the nation to exploit nuclear fuels for the generation of nuclear energy as well as to regulate its application for other purposes. Nuclear energy may only be used for pacific purposes.

Article 28, Paragraph four:

Functions executed by the State in an exclusive manner and within the following strategic areas shall not constitute monopolies: post office, telegraph and radiotelegraphy; petrol and other hydrocarbons; basic petrochemistry; radioactive minerals and the generation of nuclear energy; electricity and activities expressly determined by the laws issued by the Congress of the Union.

The Constitution in its Article 89, Fraction I empowers the President of the Republic to "promulgate and execute the laws issued by the Congress of the Union, providing the administrative support for allowing its exact observance". It is in this sense that the Federal Executive Branch, through the Department of Energy, regulates and supervises compliance with the provisions on nuclear safety and radiation protection matters, attribution based on Article 33, Fraction X of the Organic Law of Federal Public Administration. Moreover, this Law grants to the Department of Energy, the warrant to exert the rights of the Nation on nuclear energy matters as well as regarding the utilization of products and natural resources required to generate, transmit, transform, distribute and supply electricity having the objective to render public services and "to direct the activity of the state entities whose objective is related to the generation of electric and nuclear energy in attachment to the law on ecological matters" (Article 33, Fractions II and III, respectively).

The Article 17 of the Organic Law on Federal Public Administration, Mexican State Secretaries are authorized to count on semi-autonomous administrative organization under them to offer more effective attention as well as to settle affairs of competence efficiently. Based on this Article, the Comisión Nacional de Seguridad Nuclear y Salvaguardias (CNSNS) was created. CNSNS is a semi-autonomous organism dependent of the Department of Energy and is the Regulatory Body responsible for nuclear safety, radiological safety and security as well as safeguards.

The Regulatory Law of Article 27 of the Constitution on Nuclear Matters (Nuclear Law) entered into effect on February 4, 1985, and awards the Federal Electricity Commission (Comisión Federal de Electricidad: CFE) the responsibility for generating nuclear energy and to coordinate with CNSNS. It also assigns to this institution, the design and construction of nuclear power plants (NPP) taking into account the opinion of the Instituto Nacional de Investigaciones Nucleares: ININ (National Institute for Nuclear Research). The Nuclear Law also establishes that the utilization of nuclear reactors for non-energetic purposes shall only be taken up by the public sector and by universities, institutes and research centers authorized according to the Law. CFE, upon being a parastatal decentralized organization of the Public Administration, has legal and patrimonial

faculties of its own according to provisions foreseen in Article 45 of the Organic Law of Federal Public Administration. As established in Article 17 of the Nuclear Law, being that the nuclear fuel is property of the Nation, the Federal Executive branch may only authorize its use under the terms settled by this Law and continuously under surveillance of CNSNS.

The Nuclear Law establishes in its Article 19 that "safety is the prime importance for all activities involving nuclear energy and it should be considered during planning, design, construction and operation up to the definite shutdown and decommissioning of nuclear and radioactive installations as well as in the disposition and final destination of all the waste". In Article 27, Paragraph Three stipulates that "nuclear installations shall have the required nuclear and radiation safety personnel, and that the head of the corresponding public agency shall be responsible for the strict compliance with the applicable regulations".

Article 23 of the Nuclear Law stipulates that the incidents involving nuclear materials or fuels, radioactive materials or equipment containing them or of conditions that could give rise to such an incident, the Commission shall be notified immediately. In such cases, the Commission may order or carry out the removal of equipment, tools or materials that imply some kind of risk, so that they may be deposited in places with the proper safety conditions.

The Nuclear Law establishes bases for implementing a system for awarding licenses both for nuclear and radioactive installations as well as for the suspension of such licenses in the event of non-compliance with some of the established conditions.

According to provisions established in Article 26 of the Nuclear Law, the actual Department of Energy (former Department of Energy, Mines and Parastatal Industry) is empowered to award authorizations for siting, design, construction, operation, modification, suspension of operations, definitive shutdown and decommissioning of nuclear and radioactive installations. Similarly, it is established in this Article that authorizations for the construction and operation of such installations shall have a fixed validity and their renovation, modification, suspension or cancellation shall be ruled by the respective regulations.

Authorizations for the construction and operation of nuclear installations shall be awarded only when accredited by presenting pertinent information on how the safety objectives are going to be reached and what procedures and methods shall be used during the siting, design, construction, operation, modification, definitive shutdown and decommissioning phases including the corresponding Radiological Emergency Plan. Also, information must be provided on the installation's environmental impact (Article 28 of the Nuclear Law). Additionally, authorization is required for handling, transportation, storage and custody of nuclear materials and fuel, radioactive material and equipment containing them and shall be ruled by regulatory provisions in the Nuclear Law (Article 30). For the license awarding process, the Nuclear Law stipulates that the Commission must forward an opinion on siting, design, construction, operation, modification, suspension of operations, definitive shutdown and decommissioning of nuclear installations, prior to authorization by the Department of Energy, (Article 50 Fraction IV).

To summarize, the principal documents of the Mexican legislation are listed below:

International Treaties

Treaty for the Proscription of Nuclear Weapons in Latin America and the Caribbean (Tlatelolco Treaty), taking effect on September 19, 1967.

Treaty on the Non-Proliferation of Nuclear Weapons (NPT), taking effect on December 7, 1968.

Agreement between the United Mexican States and the International Atomic Energy Agency for the application of safeguards related to the Treaty for the Proscription of Nuclear Weapons in Latin America and the Treaty for the Non-Proliferation of Nuclear Weapons in the Caribbean, taking

effect on March 29, 1973.

Agreement between the International Atomic Energy Agency and government of the United Mexican States (INFCIRC/203), for which the organism shall provide support in the execution of a project related to a nuclear plant. This agreement took effect on February 12, 1974.

Convention on the Prevention of Sea Contamination from the Dumping of Waste and Other Matter, taking effect on July 17, 1975;

Convention on Physical Protection of Nuclear Materials, put into force on June 4, 1988;

Convention on Assistance in the Event of Nuclear Accident or Radiation Emergency, put into force on June 10, 1988;

Convention on Prompt Notification of Nuclear Accidents, put into force on June 10, 1988;

Convention on Civil Liability for Nuclear Damages, put into force on July 25, 1989;

Convention on Nuclear Safety, put into force on October 24, 1996;

National Laws

The Regulatory Law of Article 27 of the Constitution on Nuclear Matters. This Law entered into effect on February 4, 1985;

Law on Civil Liability for Nuclear Damages. This Law entered into effect on January 1, 1975;

General Law of Ecological Equilibrium and Environmental Protection. This Law entered into effect on January 29 1988. It was reformed and entered into effect December 14, 1996.

Chapter VII, Article 154. The Department of Energy and CNSNS, including the participation of the Department of Health, shall assure that the exploration, exploitation and benefit of radioactive minerals, the development of nuclear fuels, the utilization of nuclear energy in general, activities related to the same, are carried out in adherence to official Mexican standards on nuclear, radiation safety and physical security for nuclear or radioactive installations and, in such a manner that human health risks are avoided and the preservation of the ecological equilibrium and environmental protection are ensured. It corresponds to the Department to perform the environmental impact assessment.

Regulations

General Regulations for Radiological Safety. These regulations entered into effect on November 23, 1988.

Regulations for Road Transportation of Hazardous Materials and Wastes. These regulations entered into effect on April 8, 1993.

Safety Standards

From the beginning of the Laguna Verde Nuclear Power Plant (LVNPP) project in 1972, the governmental entities involved in the project made the decision to apply, in addition to the requirements of the IAEA, the regulations of the country of origin of the nuclear steam supply system (General Electric); that is, the regulations of the United States of America. This is contained in Condition No. 3 of the operation license for both LVNPP units. In the above context, Title 10 “Energy” of the Code of Federal Regulations (CFR) of the United States of America was adopted as a primary requirement. In particular, the regulatory framework for licensing LVNPP-1 & 2 was agreed upon between the Regulatory Body and Federal Electricity Commission (CFE), in which is specified the compliance with the 10 CFR Parts, as follows:

Part 20 “Standard for Protection Against Radiation”;

Part 21 “Reporting of Defects and Non-compliance”;

Part 50 “Domestic licensing of production and utilization facilities”;

A “General Design Criteria”;

B “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants”;

E “Production and Utilization Installation Emergency Preparedness and Plans”;

G “Fracture Toughness Requirements”;

H “Vessel Material Surveillance Program Requirements”;

I “Numerical Guide for Design Objectives and Operation Limit Conditions to Satisfy the “As Low As Reasonably Achievable Criteria for Radioactive Materials in Nuclear Power Plant Effluents”;

J “Light-Water-Cooled Reactor Primary Containment Leak Tests”;

K “Emergency Cooling System Assessment Models”.

Part 55 “Operator’s Licenses”;

Part 73 “Physical Protection of Plants and Materials”;

Part 100 “Reactor Site Criteria”.

The series of Regulatory Guides applied to LVNPP are as follows:

Series 1, Power Reactors and Nuclear Installations;

Series 4, Environmental Radiological Surveillance ;

Series 7, Radiation Protection ;

Series 8, Physical Protection;

Series 9, Radioactive Waste Management;

Regarding the Reporting System, a utility - CNSNS interface has been established based on US Nuclear Regulatory Commission (USNRC) regulations. The reports are classified as follows:

Report on Defects in Components: 10 CFR 21

Report on Important Deficiencies (IDI’s): 10 CFR 50.55(e);

Also, CNSNS has published a series of technical standards on diverse topics of nuclear and radiological safety. The Mexican Official Standards applicable to nuclear facilities are presented in Table 1.

Table 1 Official Standards applicable to nuclear facilities in Mexico

Item	Standard	Title	Publication Date
1	NOM-001-NUCL-1994	Dose equivalent calculation factors	Feb-06, 1996
2	NOM-004-NUCL-1994	Classification of radioactive waste	Mar-04, 1996
3	NOM-005-NUCL-1994	Annual radionuclide incorporation limits (LAI) and derived concentrations in air (CDA) for occupationally exposed personnel	Feb-16, 1996
4	NOM-006-NUCL-1994	Criteria for the application of annual incorporation limits for critical public groups	Feb-20, 1996

Item	Standard	Title	Publication Date
5	NOM-018-NUCL-1995	Methods to determine activity	Aug-12, 1996
6	NOM-019-NUCL-1995	Requirements for low level radioactive waste packages for their definitive storage near the Surface	Aug-14, 1996
7	NOM-021-NUCL-1996	Lixiviation tests for solidified radioactive waste Specimens	Aug-04, 1997
8	NOM-024-NUCL-1995	1995 Requirements and calibration of direct reading dosimeters	Aug-05, 1997
9	NOM-026-NUCL-1999	Medical surveillance from occupationally exposed personal to ionising radiation	Jul-05, 1999
10	NOM-028-NUCL-1996	Radioactive waste handling in radioactive facilities that use open sources	Dec-22, 1998
11	NOM-031-NUCL-1999	Requirements for the qualification and training of the occupationally exposed personal to ionising radiations	Dec-28, 1999
12	NOM-034-NUCL-2000	Selection, qualification and training requirements of personnel in nuclear power Plants	Sep-04, 2000
13	NOM-035-NUCL-2000	Limits for considering a solid residue as Radioactive waste	May-19, 2000
14	NOM-036-NUCL-2001	Requirements for facilities for treatment and Conditioning of radioactive waste	Sep-26, 2001
15	NOM-012-NUCL-2002	Requirements and calibration of ionising radiation monitors	Jun-19, 2002
16	NOM-008-NUCL-2003	Radioactive contamination control	Dec-29, 2003
17	NOM-002-NUCL-2004	Leak and tightness tests for sealed sources	Sep-02, 2004

Moratorium on Standards

On May 12, 2004 the Federal Commission for Regulations issued a decision to stop the process of issuing standards. This decision was published in Official Gazette, Primary Section, and entered into force on April 29, 2005. According to this decision, CNSNS was not allowed to issue further regulations and standards within its domain of competences. This moratorium was in force through the duration of the IRRS mission and remains in effect.

1.1.2. Establishment of an effectively independent regulatory body

As was mentioned above, the Department of Energy shall apply the Regulatory Law and in this manner represents the state organization responsible for promotion and utilization of nuclear energy as well as the organization responsible to regulate the safety of nuclear installations.

In this context, CNSNS is not completely independent of organizations and bodies charged with the promotion of nuclear technologies or responsible for facilities or activities, including those listed in GS-R-1 paragraph 1.5.

CNSNS considers itself essentially effectively independent. CNSNS is a small regulatory body, and like many small regulatory bodies, the independence of the organization is de facto. The challenge is whether CNSNS can carry out its main functions without being handicapped.

Originally, regulatory functions were housed in the Commission as well as in the Research Institute. In 1979 the decision was made to attach the nuclear regulatory body to a specific ministry. The Nuclear Law enacted in 1979, which is still the basis for the establishment of different nuclear organizations/installations, gave responsibilities and authorities to the Commission, but at the same time the same authorities were assigned to the Ministry. This article has caused some problems (e.g. with the Convention on Nuclear Safety). CNSNS cannot change the structure of the Mexican

government. CNSNS has proposed modifications to the law to make it clearer.

The Secretary of Energy is also the Chairman of the Board of CFE. This is a potential conflict of interest issue and has been questioned by CNSNS. When the Commission was created in 1979 it was under the Department of National Property. The Secretary of National Property did not chair the board of CFE. The Commission was attached to a ministry where effective independence was not an issue. When the Department of Energy was established, the Secretary of Energy became the chairman of the electric utility and the national oil company.

The Secretary has never interfered in the decisions of CNSNS. The Department of Energy has contacted CNSNS on 3 or 4 occasions asking CNSNS to expedite decisions regarding several issues. However, the Department did not pressure CNSNS to approve or disapprove any specific applications for authorization. CNSNS stated that they have never experienced the slightest hint of intervention. CNSNS has conducted enforcement actions and issued penalties (fines, closed down operations in hospitals, etc.). CNSNS has, on occasion, received calls from influential people but has never been directed by the Department of Energy on what decision to make. CNSNS feels confident that there is not an issue as far as its functional independence is concerned.

Financial and operational independence has also been an issue. In the Government, activities concerned with national security are exempt from the usual budget rules. Agencies designated as essential to national security have guaranteed financial support and are exempt from many of the regulations on bureaucracy. These agencies are accountable to Congress and the Council of National Security. CNSNS believes it should be designated as an organization essential to national security. Obtaining this designation will not be easy, but is one possible solution to address funding challenges. The next step for CNSNS is to convince the Secretary of Energy to propose a decree that can be signed by the Secretary of the Interior who is the chairman of the National Security Cabinet, or possibly by the President, that designates CNSNS as an organization necessary for national security.

The CNSNS budget comes from the Ministry of Finance through the Department of Energy. CNSNS holds discussions with the Finance Ministry but makes the formal request through the Department of Energy. Before 2002, almost 80% of the budget of CNSNS was provided by CFE. The problem with this arrangement was that CNSNS had to sign a contract with CFE for the financing, and CFE had to be satisfied with the quality of CNSNS work prior to releasing the funds. CNSNS decided that it would be better to obtain budget financing from the Minister of Finance than from the utility. However, the CNSNS budget is not sufficient to conduct all of its necessary activities. CNSNS must obtain additional funding from CFE for specific projects or activities such as the Laguna Verde technical specification revision review, although this arrangement must be authorized by the Finance Minister.

The annual budget is closely tied to the number of inspections conducted in the previous year. If the number of inspections conducted by CNSNS declined, the next year's budget would be reduced accordingly. The number of inspections conducted has been severely limited by the available human resources, especially in the radiation protection area. Although Laguna Verde is being inspected appropriately, and the necessary minimum amount of inspection is getting completed (based on discussions with USNRC and Spain), CNSNS feels as though they should do more inspections. CNSNS does not see oversight of Laguna Verde as a serious problem and feels the plant is safe enough, although the overall lack of resources is impacting radiation safety inspections. CNSNS is trying to get increased funding and the authorization to hire more staff.

Fees related to authorizations and licensing for radiation source users are sent to the national treasury. The fees are based on an hourly rate and the number of hours needed to conduct the evaluations. A fee schedule is in place and approved annually by the Minister of Finance. The schedule is posted on the CNSNS website. Even if the revenue collected increases, this does not

directly affect the CNSNS budget. Neither CFE nor the Nuclear Research Institute reactor is charged fees.

Even though a potential conflict of interest exists with the Department of Energy, CNSNS contends that none have occurred. During outages, CFE may ask for exemptions from various rules or technical specifications. The CNSNS position is that CFE must comply with the rules, although the Secretary of Energy may still have the final decision. If CNSNS were to disagree with a decision by the Energy Secretary, it could ask for a legal/judicial ruling. Thus far, the Secretary of Energy has not ruled against any CNSNS decision or recommendation. There are some merits to the utility being government owned because profit is not the primary concern. CNSNS finds this relationship to be very healthy.

1.1.3. Regulatory body - assigned responsibilities, authority, and resources

The Nuclear Law stipulates that the Commission must forward an opinion on siting, design, construction, operation, modification, suspension of operations, definitive shutdown and decommissioning of nuclear installations, prior to authorization by the Department of Energy, (Article 50 Fraction IV). In this context the legislation assigns responsibility to CNSNS for:

Development of standards and regulations.

Licensing of radioactive installations and issuing opinions on safety for licensing of nuclear installations.

Radiological Environmental Surveillance.

Audits, technical visits, and inspections to nuclear and radioactive installations.

Examination and licensing of nuclear reactor operators.

Inspections and audits related to physical security and safeguards.

Licensing of imports, utilization, transportation and storage of radioactive material.

Licensing of radioactive waste repositories.

Participation in international co-operation agreements.

Research and development projects.

National registry of occupationally exposed workers

The Nuclear Law, Articles 17, 29, 32, 33, 34, 35 and 50 assign responsibility to CNSNS for authorization regulatory review and assessment. CNSNS inspection and enforcement activities are covered by Articles: 36, 37, 38, 40 and 50 (XII) of the Nuclear Law. Also, the Nuclear Law, Articles 50 (I), (X) assign to CNSNS the responsibilities in the area of establishing safety principles, criteria, regulations and guides. In the meanwhile, the Federal Executive, through the Head of the Secretariat of Energy may also exercise the attributions contained in the field of CNSNS competences, as per Article 50 of the Nuclear Law.

The CNSNS budget is established through the national budget, as part of the national institutions. The budget is assigned via the Secretary of Energy and is not enough to satisfy the responsibilities of CNSNS as the Nuclear Safety Authority.

The CNSNS budget represents a part of the Department of Energy budget. The budget of CNSNS shall be independent from the budget of the state organizations which are in charge of promotion or utilization of nuclear energy.

By the Regulatory Law CNSNC is in charge of nuclear safety, radiological safety and physical security of radioactive sources and nuclear material.

The Ministry of Health, through the National Health Law, represents the regulatory body in the field

of ionizing sources devoted to medical diagnosis.

In this manner the overlap between competencies is created. There is no agreement between the Ministry of Health and CNSNS how to assure effective co-operation in this field. Due to this fact, diagnostic equipment (X-ray equipment) as well as occupational and personal doses connected with the usage of the equipment are not regulated at all.

The legal and governmental mechanisms which are in place do not ensure adequate infrastructure arrangements for decommissioning, for closeout or closure, site rehabilitation, and safe management of radioactive waste (including spent fuel designated as waste).

The only mention of dismantling of nuclear or radioactive installations is in articles 19, 25, 26, 28, 50 (III) and (IV) of the Nuclear Law, but all of these articles make reference to the requirements, authorizations, safety reports, evaluation process and safety assessment developed by CNSNS. There is no specific mention of any "governmental mechanisms" (provisions) in terms of financial and technical capabilities. Besides the existence of any legal binding document, CNSNS has imposed specific requirements for nuclear installations and for radioactive installations through license conditions.

The "Reglamento General de Seguridad Radiológica" (RGSR) establishes the basic rules for transportation, but the Regulations for the Safe Transport of Radioactive Materials is still pending approval by the legislative advisors of the President.

In accordance with the Nuclear Law, Article 28, the authorization to operate nuclear or radioactive installations requires the establishment of a radiological emergency plan; in Article 124 of the RGSR, it is established that previous to the start of operations, all radioactive installations shall have an Emergency Plan, in accordance with the National Civil Protection System.

The Nuclear Law, Chapter VI, Article 50 stipulates that CNSNS has under its responsibilities the regulations for security of radioactive materials and nuclear and radioactive installations.

Mexico is a signatory to the Convention on Civil Liability for Nuclear Damages, put into force on July 25, 1989. The Law, named "Ley de Responsabilidad Civil por Daños Nucleares" (Liability Nuclear Law), was published on 31 December 1974 and represents the Mexico Government's adherence to the Vienna Convention on Nuclear Liability. Mexico is not party to the Paris and Brussels Conventions on Third Party Indemnity in the event of an accident from a nuclear installation. The Mexico Liability Nuclear Law considers only very low financial limits for compensation. As of December 2007, the Mexico Liability Nuclear Law is not in compliance with the Convention on Civil Liability for Nuclear Damages provisions. For non-nuclear facilities, compensation is available through the Civil Code.

The technological infrastructure necessary for ensuring the safety of facilities and activities is provided primarily by the licensees. The operation license requires the licensee to have personnel, equipment and support organizations in order to fulfil their legal duties on nuclear and radiological safety. The Nuclear Law in Chapter V establishes the responsibilities to provide the technological infrastructure for the country in nuclear and radiological matters.

Operator responsibility

The Nuclear Law, Article 19, establishes that safety is of prime importance to all activities involving nuclear and radiological materials, including radioactive waste.

Legislative requirements

The legislation sets out, partially, effective objectives for protecting individuals, society and the environment from radiation hazards, both for the present and in the future.

The Nuclear Law, Articles 20, 21 and 28, established provisions regarding the protection of the

environment.

Objectives for the protection of individuals (public and occupational exposure) are described in RGSR, Chapter III on Limits for Dose Equivalent.

In the legislation dealing with radiation protection, it is not explicitly established what is excluded from regulatory control. Exemptions are established by Standard (NOM–039-NUCL-2003) issued with the intention to give some orientation on what kind of radioactive material and ionizing equipment is outside of regulatory scope.

The Nuclear Law provides the general regulatory framework and RGSR gives the specific requirements on all kinds of practices and sources involved (considering the risk). For any kind of regulatory action (licences for operation, authorization to import/export nuclear or radioactive materials, etc.), CNSNS must declare in a federal site (COFEMER) which are the steps to get the license, authorization, etc.

The CNSNS authority is not fully in compliance with the authority outlined in GS-R-1 para.2.6. Some examples are presented as follows:

- 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 (only through the Secretary of Energy);
- to communicate independently its regulatory requirements, decisions and opinions and their basis to the public (only if requested under the National Law for Transparency);
- 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 (for the public, only if requested under the National Law for Transparency);
- to liaise and coordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods (only through the Secretary of Energy);

The legislation does not provide for adequate funding of the Regulatory Body. The national budget considers the previous budget assigned as the basis for the current budget authorization. The CNSNS budget is only one part of the Department of Energy budget.

The legislation, through NOM-NUCL-039, specifies the process for removal of a facility or activity from regulatory control. The document takes into account the radiological importance of the sources and gives indications to users.

The General Law for Administrative Matters gives the right for all licensees to appeal any decision taken by CNSNS. In all trials up to now, judges have given the decision to CNSNS, taking into consideration that these are safety issues.

The RGSR has established that any transfer of radioactive material requires a specific authorization. See Articles 58, 154, 190 and 191.

CNSNS does not have a specific independent advisory body. In the case that it needs independent opinions it may obtain assistance via contracts. In this case, specific conditions are established in the contracts to preclude conflicts of interest.

Legislation does not specifically refer to research and development work in areas related to safety, nevertheless CNSNS has undertaken this responsibility and there is a Division (Rules and Technological Support), which conducts some research in safety matters.

The legislation sets out the arrangements for provision of financial security in respect of any liabilities in the case of radioactive waste. In the case of decommissioning, there are no obligations.

For NPPs, CNSNS imposed a requirement for the power plant to maintain the financial capability to provide for decommissioning.

It is not clear how the legislation defines what an offence is, or the corresponding penalties, for NPPs. For radioactive installations the RGSR establishes the list of requirements. In case of a violation of such requirements, CNSNS has the authority to impose sanctions. In this context the Law for Administrative Procedures (which is not included in the information package) also gives the users rights and obligations.

In Mexico, the international Conventions are part of the national legislation once they are approved by the Mexican Senate. Agreements are not part of the legislation but they could be implemented through modifications to standards and regulations.

The legislation does not define how the public and other bodies are involved in the regulatory process.

In the case of nuclear installations there are agreements between CNSNS and the owner of such installations to review and adapt to new regulations. For radioactive installations, during the process to renew the license (two years for Category 1 and 2 sources for example) the new license is issued with the new requirements.

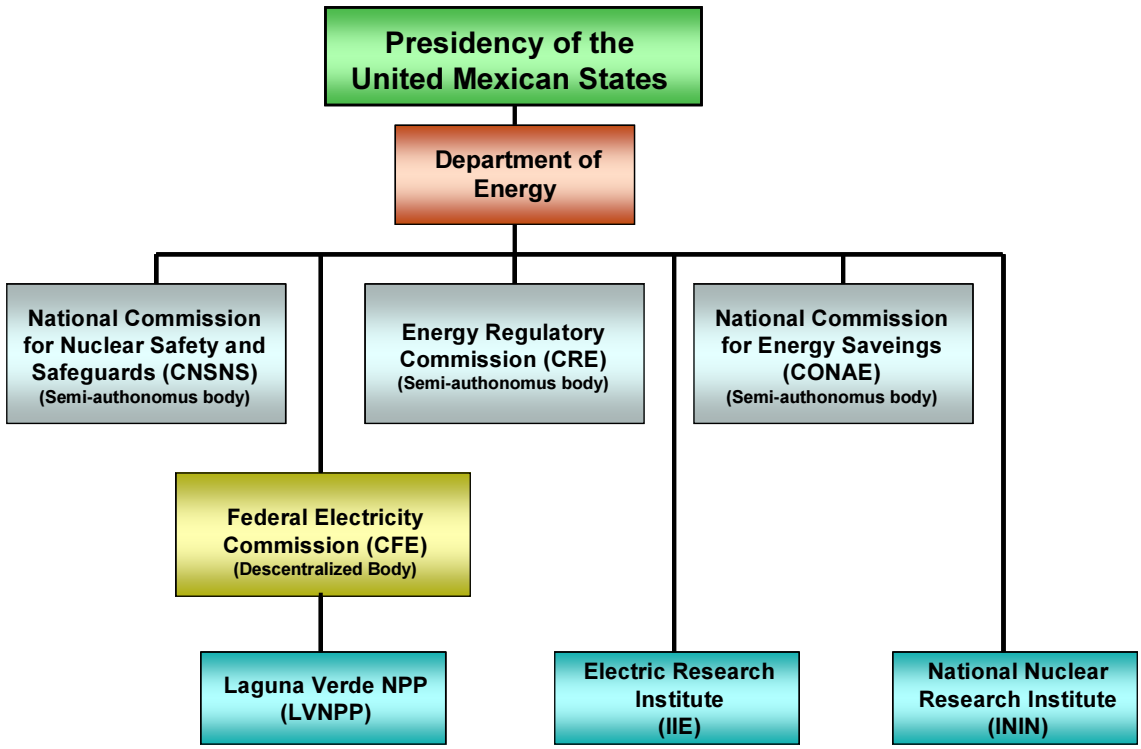

Fig.1 – CNSNS position within Government Structure

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 2.2(2) states *"A regulatory body shall be established and maintained which shall be effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities. This is so that regulatory judgements can be made and enforcement actions taken, without pressure from interests that may conflict with safety".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R1 **Recommendation**: The existing legislation shall be reviewed and revised as necessary to establish a regulatory body effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities.

(1) **BASIS:** GS-R-1 para 2.2(1) states *"A legislative and statutory framework shall be established to regulate the safety of facilities and activities".*

R2 **Recommendation**: Regulations based on provisions of Regulatory Law shall be issued to create a legal framework for the discharge of regulatory responsibilities by CNSNS.

(1) **BASIS:** GS-R-1 para 2.6(2) *"The regulatory body shall have the authority to establish regulations and issue guidance".*

R3 **Recommendation**: The Regulatory Body should be exempted from the provisions of the Decision issued by Federal Commission for Regulations and published in Official Gazette, Primary Section on May 12, 2004 and entered into force on April 29, 2005.

1.2. AUTHORITY OF THE REGULATORY BODY

CNSNS, according to Nuclear Law Article 50, paragraph X and XI, has the authority to develop safety principles and criteria, and to develop regulations and issue guidance in the areas of nuclear and radiological safety, as well as for physical security, nuclear or radioactive installations and safeguards.

CNSNS, according to Nuclear Law Article 50, paragraph XIII, has the authority to require an operator to conduct a safety assessment at any time.

The legislation also gives CNSNS the authority to:

- require an operator to provide any necessary information, including information from its suppliers, even if this information is proprietary. (Nuclear Law Article 50 paragraph XIII);
- issue, amend, suspend or revoke authorizations and to set conditions (Nuclear Law Article 50 paragraph V);
- require the utility to perform a systematic safety reassessment or a periodic safety review over the lifetime of facilities;
- enter a site or facility at any time to carry out an inspection;
- enforce regulatory requirements. CNSNS has the authority to impose sanctions, specifically Articles 37, 38, 39, and 50 paragraph XII; the RGSR in Chapter II is devoted to Sanctions;
- obtain such documents and opinions from private or public organizations or persons as may be necessary and appropriate (Law for Federal Administrative Procedure);
- communicate independently its regulatory requirements, decisions and opinions and their basis to the public, but only in cases where there exists a request invoking the National Law for Transparency of all governmental offices;
- make available to other governmental bodies, national and international organizations information on incidents and abnormal occurrences and other information, as appropriate. Mexico has signed the Conventions on Early Notification of a Nuclear Accident and

Assistance in the Case of a Nuclear Accident or Radiological Emergency. CNSNS has the authority to communicate with other organizations once Conventions are approved by the Senate and they have become national laws;

- make available to the public information on incidents and abnormal occurrences and other information, as appropriate. This is only for cases where there exists a request invoking the National Law for Transparency of all governmental offices;

Through the Secretary of Energy, CNSNS has the authority to:

- liaise and coordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods.
- communicate directly with governmental authorities at higher levels when it is considered necessary for exercising effectively the functions of the Regulatory Body.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

Regulatory Body - Fulfilling Statutory Obligations

CNSNS has not defined policies, safety principles and associated criteria as a basis for its regulatory actions set out in regulations and guides. There is not a clear statement as to how the IAEA safety requirements are incorporated into the CNSNS system of regulations.

CNSNS establishes, promotes or adopts regulations and guides upon which its regulatory actions are based. As was mentioned previously for the nuclear regulations, CNSNS has adopted the regulations from the country of origin of the reactor (USA). For example, all Regulatory Guides, Industrial Standards and the U.S. Code of Federal Regulations (CFR), Part 10, have been adopted by CNSNS. For radiological safety, CNSNS adopted general requirements. All regulations and standards were issued by order of the Secretary of Energy based on proposals by CNSNS.

CNSNS reviews and assesses submissions on safety from the operators both prior to authorization and periodically during operation as required. The RGSR, according to Articles 217, 218, 219, 220, 223, 224, 226, and also the CFR, Part 10, requires that prior to the authorization for operation of any installation, nuclear or radioactive; the solicitor must send a safety report as a basis to support the request. It is also established as a requirement that a safety review report must be submitted to CNSNS in the case of any modification at the installation and prior to the implementation of such modification. For nuclear installations there is a requirement to submit to CNSNS a report every 5 years (periodic safety review).

When issuing, amending, suspending or revoking authorizations, subject to any necessary conditions, CNSNS specifies that:

- the license specifies precisely the type of sources, activities and practice which is authorized;
- the first document in the licensing process satisfies the criteria that all information evaluated should be referenced and the result of the evaluation process notified to the solicitor;
- the license itself contains all requirements to maintain the validity of such license, including the requirement that any modification, if it changes the safety analysis report as it was presented to the regulatory body, must be approved by CNSNS before implementation;
- the license itself contains all requirements to maintain the validity of such license, including equipment, personnel and type and activity of sources under the license;
- limits on discharges are in accordance with NOM-NUCL 06, and characteristics and limits for wastes liberated in liquid form to environment are compliant with RGSR Article 211;
- the licensee has the requirement to immediately notify CNSNS of any event considered as a deviation from the original conditions of the license, specifically any event related with liberations (releases), deviation to Technical Specification for Operation (TSO) in case of nuclear installations, events related with sources, physical security events and personnel (doses), etc.
- the requirements attached to the license specify the kinds of reports that need to be communicated to the regulatory body.
- The requirements attached to the license specify the kind of reports that the operator is required to maintain. By law the minimum time is five years. However, nuclear installations are required to maintain records for the life of the installation. Records for radioactive installations are required to be maintained for the life of the license for discharges, produced radioactive waste, equipment failures, and personnel doses.

- Emergency plans are required as part of the licensing process (RGSR Articles 124, 125, 198, 201, 221 and Nuclear Law Article 28 and 50 paragraph VII)

The requirements for other kind of licenses are not specified in documents issued by CNSNS. There is a general statement that the license is independent of any other requisites from other authorities.

CNSNS carries out regulatory inspections based on yearly plans for inspections.

CNSNS ensures by diverse means that corrective actions impairing safety are implemented and they have the legal authority and attributes to suspend, cancel or take any additional actions to ensure that unsafe conditions do not continue once they are detected. The Nuclear Law empowers CNSNS to apply administrative (suspension, cancellation of licenses) or monetary sanctions (Articles 36, 37, 38 and 50 paragraph XII). Many examples of enforcement actions are in the archives of CNSNS.

CNSNS has not yet established an internal procedure for processing applications, such as applications for the issuing of an authorization, accepting a notification or the granting of an exemption or for removal from regulatory control. Such procedures (applications, authorization) are now in revision (development). For exemptions the solicitor requests directly to CNSNS for such authorization and the same for requesting removal from regulatory control.

CNSNS has not established a process for changing the conditions of an authorization. In case of a request by the licensee to modify the conditions of a license, CNSNS must make the corresponding evaluation and decide to accept or reject the request.

CNSNS provides guidance to the operator on developing and presenting safety assessments and other required safety related information. For nuclear installations the set of Regulatory Guides, specifically R.G. 170, establishes the requirements for the safety related information that needs to be presented to CNSNS. In the case of radioactive installations, the scope of the requested information is in Articles 218, 220, 221, 222, 223, and 224 of the RGSR.

CNSNS ensures that sensitive information, such as personal and proprietary information, is protected by the use of internal directives.

CNSNS provides an explanation of the reasons for the rejection of a submission. As part of the evaluation process, CNSNS prepares a list of issues that were not properly satisfied in the application.

Only case by case and under specific request (connected with Freedom of Information Act) does CNSNS communicate with and provide information to other competent governmental bodies, international organizations, and the public.

CNSNS does not have in place a procedure to ensure that operating experience is appropriately analysed and that lessons to be learned are disseminated. There are two different branches with the responsibility to disseminate information on nuclear and radiological events. From time to time, such information is disseminated through the web page of CNSNS.

There are no established legal requirements for retaining safety related information that could be retrieved in the future. CNSNS carries out regulatory inspections of records. For nuclear installations the digitalization process of all the records has been initiated.

In order to ensure that its regulatory principles and criteria are adequate and valid, CNSNS is participating in different forums with its specialists, confronting and updating ideas and regulatory criteria. Sometimes these criteria are not immediately implemented due to the national process connected with reviewing of regulations.

CNSNS regulatory principles and criteria take into consideration internationally endorsed standards and recommendations through a slow process to modify the standards, rules and regulations. This

process takes too much time to endorse international standards and recommendations. Currently a moratorium on the publication of new standards and regulations is in effect (since 2004).

CNSNS informs the operator of any requirements for systematic safety reassessment or periodic review. For nuclear installations, there is a requirement that the NPP has to conduct a periodic safety review every ten years and send the resulting report to CNSNS. The Licensing Requirements for Operation of Laguna Verde NPP provided such requirements.

CNSNS advises the Government on matters relating to the safety of facilities and activities as required by Nuclear Law in Article 50.

CNSNS directly verifies the competences of senior reactor operators and reactor operators at NPPs. The qualification of other LVNPP staff is verified via evaluation of training programmes and inspections of training. Qualification of personnel as far as concerns radiation protection is assured via certification of organizations involved in training and testing of Safety Radiation Officers and Occupational Exposure Personnel.

CNSNS confirms that safety is managed adequately by the operator through its regulatory actions. In case of any deviation from the operational requirements CNSNS takes necessary steps (enforcement) to maintain the safety of the installations.

Regulatory body – cooperation with other relevant authorities

CNSNS cooperates with other relevant authorities, advises them and provides them information in their respective areas, as necessary. This cooperation is based on requests from these authorities. CNSNS represents the advisory agency for the Federal Government regarding radiological and nuclear safety, and for radiological emergencies. They cooperate with other ministries/governmental departments and authorities during exercises (desk-top and periodic exercises) to test the emergency plans. CNSNS cooperates and coordinates in the following areas:

- Environmental protection: CNSNS personnel take part in the National Committee on Environmental Risks;
- Public and occupational health: CNSNS is part of the Review Committee on standards related with occupational exposure and quality of water and food;
- Emergency planning and preparedness: CNSNS regularly takes part in the Committee for Emergency Preparedness and performs inspections, conducts exercises and evaluations and shares the results with the different Task Forces;
- Radioactive waste management (including determination of national policy): CNSNS works very closely with the responsible personnel at the Department of Energy who have the responsibility to define the policy and strategy for radiological wastes in Mexico;
- Public liability (including implementation of national regulations and international conventions concerning third party liability): CNSNS has promoted a change in the current law to adapt to current times through a proposal to the Congress;
- Water use and consumption of food: CNSNS is the agency responsible for the assessment of the content of radioactive contamination in imported goods.
- Land use and planning: No interaction with any governmental agency up to now;
- Safety in the transport of dangerous goods: CNSNS is part of the Committee on Standards and Norms on Transport of dangerous goods at the Ministry for Communications and Transportation.

Regulatory body – additional functions

CNSNS has additional functions, as follows:

- CNSNS has implemented and operates the National Network for Environmental Radiation Monitoring.
- CNSNS performs evaluations of the impact of radioactive substances on the environment of nuclear and radioactive installations as part of its core responsibilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS*:*** GS-R-1 para 2.6(11) states *"The regulatory body shall have the authority…to communicate independently its regulatory requirements, decisions and opinions and their basis to the public."*

(2) **BASIS*:*** GS-R-1 para 2.6(12) states *"The regulatory body shall have the authority...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 ."*

R4 **Recommendation**: CNSNS shall be empowered to inform the public on any safety issues as appropriate.

3. ORGANIZATION OF THE REGULATORY BODY

3.1. GENERAL ORGANIZATION

The current organizational structure is very new and is in force from November 1, 2007. The official process of approval for organization changes in the state administration is done in two steps and it is not finished yet. The Ministry of Finance approved the new organization but it has not been published in the official government journal. In spite of the fact that the new organization is not officially approved, CNSNS operates with the new organizational structure. The organizational manual, which should support the new organizational structure, is not yet in place.

CNSNS is headed by a Director General and is divided into four divisions:

- Division of Finances and Administration;
- Division of Nuclear Safety;
- Division of Radiological Safety;
- Division of Technology, Regulations, and Services

An independent organizational unit (Controller) discharges the functions of the independent state auditor and reports directly to the "Federal Government Control" unit.

Additionally, the Department of Legal and International Affairs reports directly to the General Director and provides the basis for and reviews the studies, acts, projects or conventions in which the Commission intervenes; passes judgement, advises, reviews, approves and assesses legal ordinances related to the Commission's performance; assesses the legal aspects of enforcement; and establishes bases for formulating agreements on bilateral or multilateral co-operation with institutions and bodies of foreign countries.

The Division of Finances and Administration, in addition to other duties, is primarily responsible for human resources and the budget of CNSNS.

The Division of Technology, Regulation and Services is responsible for maintaining the human capability required by CNSNS to carry out research and technological development. It coordinates the training and standards proposed in the areas of nuclear and radiological safety to support the activities and functions of the Nuclear and Radiological Safety Divisions, and provides technical services as required by these Divisions. It consists of three departments:

- The Department of Regulations and Training, which promotes and coordinates the elaboration of standards on nuclear safety, radiological safety, physical security and safeguards, and organizes their revision so that they correspond to the current status of technological development. It also defines and establishes basic programmes for training, taking into account the present and future needs of CNSNS as well as keeping the document and computer services up to date to support the development of activities of the different Divisions of CNSNS.
- The Department of Technology provides a resource for deterministic and probabilistic evaluation of nuclear and non-nuclear facilities, and provides support for the review and assessment carried out by other Departments at CNSNS.
- The Department of Telematics and Systems is responsible for information technologies used by CNSNS.

The Division of Radiological Safety is responsible for establishing and applying the licensing and surveillance standards for activities involving exposure to ionizing radiation so that such activities are performed under conditions of radiological safety that will not place workers, the population, their property and/or the environment at undue risk. It consists of four departments:

- The Department of Evaluation is responsible for evaluation and licensing of submissions related to the handling, use, possession, transfer, transportation, import and export of radioactive material for industrial, medical (radiotherapy and nuclear medicine) or research purposes as well as for radioactive nuclear fuel cycle facilities and waste management facilities. Similarly, it evaluates and regulates conditions of radiological safety and activities related to the handling, use, possession and importation of radioactive material for industrial, medical and research facilities where X-ray equipment and particle accelerators are used.
- The Department of Inspections is responsible for conducting inspections, audits, check-ups and examinations at industrial and medical facilities to verify if they operate in accordance with the radiological safety standards in force and with the specific licence conditions. It also participates in activities related to radiological emergencies.
- The Department of Environmental Radiological Surveillance and Emergencies conducts activities in support of the regulations related to the environmental radiological surveillance of routine operations at nuclear and licensed radioactive sources within the country.
- The Department of Physical Security and Safeguards is responsible for establishing rules and verifying them in the fields of physical security and safeguards. They also are responsible for the fulfilment of the Mexican international obligations in the area of safeguards.

The Division of Nuclear Safety coordinates the review and assessment of nuclear safety (radiological safety coordination for NPP only) technical reports on nuclear installations, while verifying that such installations satisfy the safety standards imposed by CNSNS. This division is comprised of three departments:

- The Evaluation Department is responsible for review and assessment of nuclear installation safety using safety reports and data generated by such installations. It verifies safety conditions at nuclear installations by evaluating the design basis, operation, and modification of systems, structures and components important to safety. It evaluates both national and international operational experience in relation to its applicability to national installations so as to prevent, or avoid the recurrence of operational events and improve safety levels. They are also responsible for preparing documentation required for issuing of authorizations or altering of licence conditions.
- The Department of Operational Supervision conducts inspections and audits at nuclear facilities, and conducts licensing examinations for nuclear installation operators.
- The Department for Regulatory Actions is responsible for managing and coordinating the safety impact assessment of the violations that occur at nuclear facilities to encourage the nuclear facility's organization to comply with regulatory framework, and to implement new regulations to assure the upgrade of the regulatory framework.

To check compliance with the GS-R-1 requirements, the team examined successively the following items: budget, staffing, training, technical support organization, advisory bodies, relations with the operators and international relations.

Budget and Staffing

The budget of CNSNS is part of the budget of the Department of Energy. The budget in general covers the costs connected with personnel (salaries, taxes, insurance, etc.) and operational costs. The operational costs represent approximately 30 percent of the total budget and do not create enough financial resources required for external contracts in case that CNSNS resources or capabilities are not sufficient to review and assess submissions to CNSNS.

The total number of approved positions is 201 including the general staff. The approved number of technical positions is 120. Due to the requirements of the law on public servants (requirement to

hire fully trained staff as opposed to entry level staff) and lack of qualified applicants to work in this field there are 25 vacancies. Additionally, 25 of the current staff are relative newcomers to the organization and due to the recent change in organizational structure, several other employees work at new positions.

Human Resources and Knowledge Management

CNSNS believes they have the technical capability in-house to conduct most evaluations and analyses to support safe operation. They would like to have more resources. Whenever CNSNS feels like they need assistance in their technical work, other resources are available. Agreements for technical cooperation with USNRC are in place. Similar contacts have occurred with Spain. Technical assistance from IAEA is more difficult to obtain in a timely manner. Although some training and support activities have been provided by outside sources, there have been no major technical issues with radiation facilities that warranted the need for outside assistance.

CNSNS believes the main problem with regard to recruitment is that the previous generation was trained in nuclear engineering and obtained nuclear and radiological experience but given the slowdown in the nuclear industry, the following generation was not as interested in nuclear matters. As a result, there is a gap of 15-20 years where a shortage of qualified and experienced people occurred. When the older generation retires there will be limited availability of qualified staff to replace them. In Europe, post-graduate work centres were developed that would attract students from all over Europe. In Mexico there are only three institutions that have at least some courses in nuclear engineering. Only one actually has a programme in nuclear engineering. Students go into other fields because the future of the nuclear industry and programmes in Mexico is unclear. The challenge for CNSNS is how to address the problem. CNSNS tries to hire new technical staff with a solid basic bachelor's degree in an appropriate field. CNSNS then trains them in situ or sends them abroad for training. Before the civil servants law went into effect, this approach worked well. CNSNS could hire new staff that showed strong potential, and then have them complete specific technical training and integrate them into the technical staff. As a result of the civil servants law, CNSNS is no longer allowed to use this approach. The law says government organizations may only hire people who are already qualified. For this reason, CNSNS has very few applicants and was only able to hire 20 people although there were 50 positions available. This problem was compounded by the loss of experienced people to other agencies. Some of the staff left because of better salaries outside CNSNS. Others left because of limited opportunity for advancement within CNSNS. CFE is not under the same hiring constraints in that they are allowed to hire new staff that are not already fully qualified and then provide the training to acquire the necessary skills. There are also better opportunities for advancement within CFE. Although CFE loses staff through retirement, their hiring and staffing situation is still much better than for CNSNS. Some CNSNS managers are not optimistic about the long-term prospects for hiring due to the current situation with the civil servants law.

There is also a trade union available to non-professional CNSNS staff. Currently at CNSNS, no staff members belong to the union.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 4.1 states *"The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R5 **Recommendation:** CNSNS shall hire to fill current vacancies and ensure staffing levels are adequate to be able to discharge its responsibilities in all appropriate areas.

S1 **Suggestion:** CNSNS should consider methods to improve retention, hiring, motivation of current staff, and career planning where appropriate.

(1) **BASIS:** GS-R-1 para 4.3 states *"If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities for review and assessment or inspection, it shall seek advice or assistance, as appropriate, from consultants…"*

R6 **Recommendation:** Funding shall be made available to allow CNSNS to hire external contractors as necessary.

(1) **BASIS:** GS-R-1 para 4.1 states *"The regulatory body shall be structured so as to ensure that it is capable of discharging its responsibilities and fulfilling its functions effectively and efficiently. The regulatory body shall have an organizational structure and size commensurate with the extent and nature of the facilities and activities it must regulate, and it shall be provided with adequate resources and the necessary authority to discharge its responsibilities..."*

R7 **Recommendation:** To review the organization of the different activities of CNSNS in the area of radioactive waste management and its control in order to harmonize the criteria, the procedures and to enhance the coordination and the performance of the control in this area.

3.2. TRAINING

To assure appropriate qualification of the staff, CNSNS employees undergo training both in the general field connected with public service as well as in specialized fields associated with their respective duties. There is evidence that employees completed various training courses and also that yearly training plans for employees were established. However, qualification requirements for professional staff are not formally established.

The Division of Nuclear Safety began the implementation of a systematic approach to training for its respective employees. A job task analysis was conducted and there is a list of tasks for the division. The design and development of the training associated with the required job tasks should, and is expected to, follow.

Establishing a good safety culture is important to safety. The first way to improve safety culture is through training. CNSNS requires and provides basic training – safety fundamentals on nuclear and radiation safety – for all staff. New staff hired directly from universities may have some limited nuclear or radiation training. Still, CNSNS provides an indoctrination process which includes a review of all areas and issues in which CNSNS is working. Safety culture is not just learned in the classroom but also through experience. CNSNS does not always hire people who are already trained to the necessary knowledge level. In that case, CNSNS provides specific training to address the skill or knowledge gaps. This training may be in other countries. CNSNS receives support from the USNRC Technical Training Center in Chattanooga, Tennessee regarding boiling water reactors. All of CNSNS is committed to train its staff to the level necessary and to invest the necessary resources to produce a highly qualified and productive employee. A large percentage of the 30% of the CNSNS budget for operations is devoted to training. Staff members have attended technical courses

in Buenos Aires as well as at facilities in the US. For the inspectors working directly with the plant (e.g. resident inspector), they complete all of the training courses required of licensed operators.

Today training consists of courses conducted in-house, offered by various certified Mexican organizations as well as from courses organized by IAEA and partner organizations abroad. Most of the training courses attended in 2006 were technical in nature. For the typical training programme, a standard set of courses is specified. The training goal is 120 hours per year but due to the heavy workload, some courses were postponed until 2008. For civil service employees, this training is required and is a fundamental part of being a civil servant. CNSNS decided to use a core set of competencies for training the civil service staff rather than using the courses that the Secretary of Energy recommended. This was determined to be acceptable by the Government for CNSNS civil servants given the highly technical nature of their work.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 4.6 states "*The regulatory body shall employ a sufficient number of personnel with the necessary qualifications, experience and expertise to undertake its functions and responsibilities…The regulatory body shall acquire and maintain the competence to judge, on an overall basis, the safety of facilities and activities and to make the necessary regulatory decisions.*"

R8 **Recommendation:** CNSNS shall establish competencies and training requirements for each position. Staff shall complete required training before being assigned to conduct specific tasks without supervision.

3.3. ADVISORY BODIES AND RESEARCH ORGANIZATIONS

Neither functional advisory nor specialized research organizations are established for CNSNS.

CNSNS has established several agreements on cooperation on a contractual basis with educational and research institutions in the areas of research, technical studies and services. To avoid conflicts of interest if the institutions also work for those utilizing nuclear energy or ionizing sources, specific conditions are established in the contracts. The institutions and the areas of cooperation are as follows:

- Instituto Nacional de Investigaciones Nucleares (National Institute for Nuclear Research): equipment qualification and biological dosimetry;
- Instituto de Investigaciones Electricas (Electrical Research Institute): Piping dynamic analysis;
- Centro Regional de Estudios Nucleares (Regional Centre for Nuclear Studies) of Zacatecas University: Enviromental dosimetry;
- Escuela Superior de Fisica y Matematicas del Instituto Politecnico Nacional (National Polytechnical Institute), Nuclear Engineering Department: Reactor physics; and fuel management;
- Universidad Autonoma Metropolitana (Metropolitan Autonomous University): Core stability analysis, thermal-hydraulic analysis, fuel management and the social impact of national radioactive resources.
- Universidad Nacional Autonoma de Mexico (UNAM – Mexican Autonomous National University). Facultad de Ingenieria: Probabilistic safety assessment, fuel management and neutronic assessment.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 2.4 (9) states *"This legislation…(9) shall allow for the creation of independent advisory bodies to provide expert opinion to, and for consultation by, the government and regulatory body ."*

S2 **Suggestion**: The possibility to create advisory bodies, on a permanent or ad hoc basis, should be allowed by legislation to provide CNSNS independent opinions of experts on technical or non-technical issues.

3.4. RELATIONS WITH LICENSEES AND OTHER ORGANIZATIONS

Relations with the operators

CNSNS aims at an open and frank relationship with the operators. CNSNS representatives meet with operators periodically (usually once per month), in addition to routine regulatory contact (e.g. inspections, authorization issues, etc.). In the field of nuclear safety, given that LVNPP is the only NPP in the country, the regulator has known the licensee well and relationships with the licensee and the operators have been traditionally open and transparent.

International cooperation

CNSNS has relations on a regular basis with various international organizations such as the Ibero-American Forum of Regulators, the Organization for Economic Cooperation and Development/Nuclear Energy Agency (OECD/NEA), the Committee on Nuclear Regulatory Activities (CNRA) and the Committee on the Safety of Nuclear Installations (CSNI). It also represents Mexico in the Review meetings of the Convention on Nuclear Safety. There are also bilateral agreements with USNRC, the regulatory authorities of Spain (CNS), Australia (ASO), Cuba (CSN), and the Ministry of Energy and Mines of Guatemala.

Leadership and management of safety

If an employee at CFE or at CNSNS has a safety concern, they are allowed to talk to either the resident inspector at Laguna Verde or can call CNSNS directly, although this had never happened. Concerns are usually brought to the attention of plant management first. LVNPP safety policy is part of their Quality Assurance programme. Safety is highlighted in their official documentation and is prominently displayed on posters around the plant.

With regard to the CNSNS safety culture, the inspectors share their comments and concerns internally (nuclear safety). Conclusions are collected on 3-month basis and the most important issues are identified for follow-up.

Differences of opinion may arise among the CNSNS staff regarding technical decisions that are made. A differing opinion can be proposed to CNSNS management but it should be based on technical issues. CNSNS tries to resolve the objections by providing additional information so that people are satisfied with proceeding with the decision. Regulatory and safety opinions and conclusions must be based in technical issues and facts. The final decisions rest with the CNSNS manager but always with the respect of the staff's technical opinion.

CNSNS conducted one work environment survey of the CNSNS staff approximately 10 years ago. The questions and results tended to focus more on non-technical issues such as salaries. The survey was only conducted once and did not include questions related to CNSNS internal safety culture or safety focus. CNSNS recognizes that it is not a good idea to just ignore these subjects.

Non-nuclear licensees are surveyed four times a year regarding how they view CNSNS performance, interactions, and regulatory impact. These surveys provide CNSNS a high level of

confidence in the way they conduct their business with licensees. CNSNS also sends emails or letters along with the survey to query the licensees regarding possible corruption. CNSNS reported that 80-90% of the licensees approved of CNSNS performance. The surveys and the results have been audited by the Government's controller. The surveys are part of CNSNS communications with licensees. Additionally, CNSNS communicates important safety information regarding radiological or nuclear accidents to licensees and users by notifying them via email to check the CNSNS website, which will contain more detailed information.

CNSNS staff communicates with LVNPP staff almost daily. Communications are both formal (e.g. application for authorization) and informal (telephone calls). This allows CNSNS to be aware of plant conditions, plant status, technical issues, and events, etc. on an almost continuous basis. CNSNS meets with LVNPP plant management quarterly. CNSNS is taking steps to begin having regular, periodic meetings with plant management specifically to discuss plant performance.

With regard to the potential for worker strikes at Laguna Verde, it was noted that CFE is a public utility and there would be a government intervention if necessary. The unionized staff would not be allowed to leave the plant without at least leaving it in a safe condition (safe shutdown mode). Operators are unionized. The senior operators and non-licensed operators are not unionized and would be available to provide the necessary staffing required for safety.

Use of insights from operation experience feedback (OEF) into the regulatory process

CNSNS monitors all events that occur at LVNPP. Most operational or radiological events are reviewed by the CNSNS staff. If during the review, an issue is found that warrants additional review, evaluation or inspection, CNSNS will conduct the appropriate activity and carry out enforcement as necessary. The enforcement process is not very formal. The information obtained from event follow-ups is used as input to the performance indicators. CNSNS also receives information from the Incident Reporting System (IRS), the Boiling Water Reactor owners group and USNRC event reports. CNSNS reviews all event reports and evaluates those that they determine to be significant.

LVNPP must report events to CNSNS in accordance with CNSNS requirements which are based on the 10 CFR, Part 50 reporting requirements. CNSNS has two staff that evaluate these reports as part of their duties. Reporting requirements are different for nuclear safety and for radiological protection. Users are required to report immediately to CNSNS any loss of a source for appropriate follow-up. CNSNS reports events that reach INES level 2 or higher to the IRS. Although CNSNS is prohibited from reporting event information to the media, this information may be provided to the public upon request.

Problems that are identified with radiological equipment or source equipment are communicated to other users. For example, problems were identified with a container for a radiography source. CNSNS stopped the use of that container at that facility as well as all other facilities unless the user provided tests showing that the container was safe. In another example, a connector started to break which could have lead to a disconnection of the source. This information was provided to other users.

CNSNS inspectors have the authority to shut down activities or facilities (in the radiological area), even though there may be political considerations. At nuclear installations, the inspector has the authority to stop activities. In one instance at Laguna Verde, an operator violated the power-to-flow map for safe operation of the reactor. CNSNS immediately required CFE to stop the power increase and eventually revoked the operator's licence.

Violations (enforcement) are not typically written for operation or conditions outside of the Technical Specifications even though it is written into the license that CFE must comply with the Technical Specifications. The law, however, specifically addresses infringements of requirements but does not specify what constitutes an infringement.

The current regulatory regime is prescriptive but is moving toward risk-informed. For LVNPP, CNSNS approves the quality assurance programme that is then used to develop licensee internal procedures.

CNSNS reviews almost all information provided by radiological users (annual reports, exposure of users, etc.).

Enhancing Regulatory Effectiveness and Competence

CNSNS has conducted a strategic planning effort. Although it is probably not formal enough, they believe they have a vision of where they want to go.

About 70 percent of the CNSNS budget goes to staff salaries. The remaining 30 percent goes to issues that require CNSNS regulatory attention at nuclear and radioactive installations (inspections and consulting for specific issues). About $100K is devoted to this issue, if needed. The radioactive installations are divided into high risk and low risk categories and the funds are divided accordingly. Category 1 and 2 sources are given priority followed by those installations with smaller sources such as nuclear medicine and gauges. Inspections found that procedures for handling unsealed sources were not being followed. This year (2007) CNSNS is focusing on facilities handling unsealed sources and has closed 10-15 facilities. CNSNS is also focusing on two additional challenges: the need to inspect high-risk sources nationwide; and mobile industrial radiography. With regard to the high-risk sources, all inspections were completed this year (2007). With regard to mobile industrial radiography, CNSNS is trying to go directly into the field to inspect the qualification of personnel, procedures, instruments, etc. So far, CNSNS believes they have been effective.

In 2003, CNSNS lost a number of staff due to government mandated reductions. Most of these were in the Radiation Protection area. Since 2003 CNSNS has hired and trained new staff. The new inspectors are typically scheduled to conduct inspections along with experienced inspectors so that the new inspectors benefit more from the inspection. This practice applies to both nuclear and radiation protection inspectors.

CNSNS is also developing a systematic approach to training such that necessary skills are identified, and the appropriate training can be developed to address those needs. This applies to both initial and specialist training.

There is no specific or contingency budget or fund to deal with emergencies. If money is needed it is requested and will be provided by the government. The worst situation would be if an accident occurs at the end of the year because there is little money left in the CNSNS budget.

CNSNS requests Quality Assurance (QA) programmes for major users. In many instances, the users don't know what a QA process or programme is. CNSNS requests procedures, including emergency procedures, from users. Many people (users) do not like to get involved in what they consider philosophical attributes that are actually Quality Assurance issues. Many users just want to be told what to do.

For nuclear installations, CNSNS reviews QA during inspections as well as reviews and approves changes to the licensee's QA Manual.

Efficiency means to perform satisfactory work in an appropriate amount of time. There are two main pillars of CNSNS activities – evaluation and inspection. The CNSNS challenge is to meet the efficiency goals for evaluation and inspection. This is probably the weakest point of CNSNS (according to CNSNS). Ten thousand documents are issued for evaluation each year including permits for construction, authorizations for import and export, transport, exposures to workers, etc. Currently, CNSNS is not meeting its goals. The goal is that import and export authorization requests will be answered in 10 days but CNSNS is not meeting that goal. That is one of the reasons CNSNS

is requesting additional staff. CNSNS established a goal to inspect Category 1 source facilities twice per year. This goal was achieved for sources that were determined to be of high risk such as accelerators, brachytherapy and teletherapy sources. For other sources, a goal of one inspection per year was established. Industrial sources are inspected once every three years. Another way to define efficiency is the avoidance of the use of radioactive material in an unauthorized manner. For the facilities that CNSNS inspected this year, these criteria were met. The challenge with effectiveness is how to measure it. At this time we use the methods described above.

CNSNS has considered the use of regional offices to improve the efficiency of inspecting facilities and activities in parts of the country remote from its headquarters office, but this was determined to not be cost effective (more expensive than paying travel expenses).

The experts pointed out that effectiveness is being able to complete the job you are assigned. Efficiency is optimizing costs. Their organizations have also tried to find indicators to measure efficiency and effectiveness, but it is not easy.

CNSNS is audited by another agency, the internal controller from the Ministry of Public Function. The controller assigned to CNSNS is appointed by the Minister of Public Function. The controller has two functions. One function is a normal auditing function to look into financial accounts and a second function regards the improvement of administrative practices (an efficient bureaucracy). CNSNS is not sure they are achieving administrative efficiency, but that is its goal. The local Public Function unit is forcing CNSNS to be more consistent in its use of procedures. The controller audits operations to determine whether activities are conducted using valid procedures and that there are administrative procedures in place for internal activities. The goals established for CNSNS are also reviewed. Thus far, CNSNS has only established goals related to inspections. Programmes for improvement are established. Most of the improvement programmes are related to radiological safety. Another function of the controller involves transparency and the prevention of corruption. This translates into activities like conducting surveys of users. Questionnaires have been issued to licensees (how they are being treated by the regulator, indications of corruption, are users satisfied with CNSNS performance, are there complaints regarding CNSNS conduct, etc.) The controller unit receives complaints, both internal and external to CNSNS, and are required to follow up on anonymous allegations. Allegations are taken seriously.

A Code of Conduct for public servants was established during the previous administration which included a commitment to good behaviour. This commitment was adopted by CNSNS. The only thing CNSNS does systematically is to make it available over the internet and make sure everyone knows CNSNS is subject to it. The issue of communicating with the public is not addressed directly. The CFE administration is very strongly against releasing information to the public with respect to LVNPP. Thus far they have been successful in preventing information from being released to the public to avoid debates in the media. In general, CFE maintains a very low public profile. However, the population around LVNPP are generally in favour of the NPP.

With regard to lost radioactive sources, CNSNS works with the licensee to determine what information should be released to the public. In the case of events like patient overexposures, CNSNS normally would not issue a press release. When the issue/condition is discovered externally, then a reply would be expected. Normally the hospital (or user) would issue the press release, but typically only after it was brought to the public's attention by someone else.

Typically, requesters for information related to LVNPP would ask the plant directly. If a significant allegation was received, the state governor would call the director of the plant and CFE directly and it is unlikely that CNSNS would be involved.

There have been several examples where information was communicated directly to entities other than CNSNS. A draft WANO report was made public which was against Government policy, and the Ministry began taking compensatory actions. CNSNS was not involved in the process.

4. AUTHORIZATION

This section reviews authorizations for each of the facilities and activities using the requirements of GS-R-1 and the associated guides as the basis.

4.1. LEGAL BASIS

Regarding the authorizing/licensing process, Article 50 of the Nuclear Law derived from Article 27 of the Constitution of México, provides CNSNS with duties in which we have:

*"III.-**Review, assess and authorize the bases for siting, design, construction, operation, modification, end of operations, closure and dismantling of nuclear and radioactive installations;** as well as all aspects of the manufacture, use, handling, storage, reprocessing and transportation of nuclear materials and fuels, radioactive materials and equipment containing the latter; and the processing, conditioning, dumping and storage of radioactive wastes, and the manner in which they are disposed of.*

*IV.-**Issue an opinion prior to any authorization granted by the Minister of Energy, Mines and Para State Industry in connection with the siting, design, construction, operation, modification, end of operations, closure and dismantling of nuclear installations**;*

*V.-**Issue, revalidate, replace, modify, suspend and revoke the permits and licences required for radioactive installations in accordance with the legal provisions, as well as collect and remove, if applicable**, the existing components, equipment and materials, and in general, any contaminated movable property in said installations;*

*VII.-**Prior to the start-up of operations, review, assess and authorize the plans** that should be in place for dealing with anomalous or emergency conditions in nuclear and radioactive installations.*

*XIII.-**Require and verify the information and documentation it deems pertinent** for the exercise of the attributions that this Law confers on it, in accordance with applicable provisions."*

It should be also noted that the Nuclear Law provides for an appeal against an authorization decision in Article 40 by submission of the case to the Secretary of Energy within fifteen days of the date of notification. A decision on the appeal is announced within thirty days. No recourse to further appeal is provided for in the Nuclear Law.

The Secretary of Energy specified in the Official Gazette of the 2nd of June 2005 of the Secretary of Energy (Article 39- section II) that: "CNSNS can issue authorizations, permits, licences, and directions deriving from assessment to nuclear and radioactive installations or contractors, suppliers as well as the personnel that are working in such facilities. Likewise, CNSNS is empowered to revoke, suspend, or modify these documents."

TYPES OF AUTHORIZATIONS

Authorizations related to nuclear installations and for other applications of ionizing radiation and facilities were reviewed and will be documented in separate sections of this report.

4.2.1. Nuclear Installations

For nuclear installations many authorizations are in force for different stages. Such stages are specified in the Law mentioned above: site evaluation, design, construction, operation, modifications, closure and decommissioning. CNSNS divided this licensing process into sub-stages and included "hold-points" to better regulate the licensee such as: different construction permits, fuel loading authorization, Technical Specifications approval, Safety Analysis Report (SAR) approvals and final permit before operation. Since 1975, CNSNS has referred to the US CFRs in different documents signed by the Director General of CNSNS and addressed to the licensee (CFE).

This way of working is currently enforced by several conditions attached to the Licence and was consolidated in 1985 with the promulgation of the Law. As stated before, CNSNS can legally review, assess and authorize the bases for each of the stages mentioned above.

In the conditions attached to the Operation Licence it is stated that the IAEA standards and the vendor country's standards are the bases for safety issues.

Regarding the authorization protocol, nuclear installations submit their authorization application directly to the Secretary of Energy under which both CNSNS and the licensee belong. This could potentially generate a conflict of interest and is addressed in the legislative and governmental responsibilities section in this report.

The Secretary of Energy can, by law, override CNSNS decisions if it deems necessary (for nuclear installations authorizations). Nevertheless, CNSNS has "de facto" full power to refuse and approve modification proposals, Technical Specification or SAR changes. Likewise, the conditions attached to the licence are endorsed and signed by the Director General of CNSNS. By protocol, the operation licence is signed by the Secretary of Energy.

The operation licence contains the validity period (30 years) of the licence, the owner, the responsible organization, the plant location, authorized power, reactor and primary containment types and refers to the Final Safety Analysis Report (FSAR) and attached conditions.

CNSNS can also require additional conditions dealing with safety issues and send directions to the licensee such as corrective actions, the use of operational feedback experience, etc.

In the licensing process of nuclear installations, the final stage dealing with how to release a nuclear installation site from regulatory control has not been established yet.

Regarding the TRIGA MARK III reactor, it was licensed in 1990 for a ten-year period on the same bases as LVNPP regarding the content of the SAR. In 1999, CNSNS agreed with the licensee, the ININ (Instituto Nacional de Investigaciones Nucleares), which is the national institute for nuclear research, on an updated safety analysis based on NUREG-1537. In mid 2000, surveillance checks revealed that the reactor pool liner had to be repaired. This postponed its SAR preparation.

The licence for the TRIGA reactor was due to expire in June 2000 without a new analysis having been provided. As the reactor was shutdown for repair, CNSNS agreed to extend the validity of the licence applying the process set out in 10 CFR 2.109, "Effect of timely renewal application." The new licence was finally issued by the Secretary of Energy on 1 April 2004 for ten more years. The attached conditions were signed by the Director General of CNSNS.

The legal status of the Research Reactor from 2000 to 2004 was not clear although CNSNS was monitoring the Research Reactor under a specific permit. The reactor was, without official licence, undergoing repairs with the fuel in the pool and out of the core. This was not, at the time, compliant with the law.

For nuclear research installations that contain sub-critical assemblies, there is no clear regulatory control regarding radiation and nuclear safety, or for licensing of personnel, ensuring that such assemblies or configurations of assemblies are always sub-critical or are not presenting radiological risks.

The licensee or the applicant for a licence must submit a safety analysis report to apply for any authorization.

The evaluation of applications is conducted for each practice and activity although the process is not guided by internal written and approved procedures. Some procedures are currently being written.

CNSNS has a guide (Regulatory Guide SN-02 – September 2007) referring to relevant CFRs and IAEA standards which take into account the magnitude of the risk. This guide looks appropriate and

comprehensive but deals with Technical Specifications changes only. In addition to this guide CNSNS developed another guide, SN-01 Licence Bases Changes, for other purposes. In practice the lack of synergy and feedback from the inspection team to the evaluation/licensing team could have an impact on the perception of the potential magnitude of the risk.

Additional risks associated with zero power operation and external hazards such as strong winds, hurricanes, tornadoes, fires, transport accidents, floods and earthquakes are not included in the Level 1 and 2 PSA for LVNPP. CNSNS intends to require the licensee (CFE) to submit an IPEEE (Individual Plant Examination for External Events).

Since the 1980's CNSNS has developed and submitted guides for safety analysis reports and for radiation protection procedures. As mentioned above, USNRC documents were "imported" and used by CNSNS for the NPP and Research Reactor as a reference for technical discussions.

During routine operation of LVNPP, CNSNS requires information on safety and operational performance of the plant through daily feedback via the Resident Inspector.

Condition No. 5 of the Operation License indicates that LVNPP must be reviewed periodically (Periodic Safety Review) against the most recent standards, norms and guides, both from the reactor vendor's country as well as from the IAEA. Such PSR shall take place every 10 years. Regarding LVNPP Unit 1, CFE performed its first PSR and submitted it to CNSNS at the end of 1999. Regarding LVNPP Unit 2, CNSNS has requested that the PSR follow the guidelines of IAEA Safety Guide No. NS-G-2.10.

For LVNPP, the licensee sends, on a regular basis, the documents listed in both the conditions of the licence and the relevant US CFRs. The latter was formally addressed to the licensee as requirements for both units in letters signed by the Director General of CNSNS.

Regarding the research reactor, documents are exchanged between CNSNS and the licensee on a regular basis as required by the reactor's licence conditions.

For LVNPP Units 1 and 2, there were many hold points used by CNSNS and derived from the US CFRs including foundation before construction, several construction permits, extension of validity of the permit, preliminary Technical Specifications, final Technical Specifications, nuclear fuel loading, SAR submission, definitive permit, start-up after outages, etc.

For the research reactors there are hold points for site evaluation, design, construction and one combined license for commissioning, start-up and operation. However, for the time being there are no hold points apart from some safety significant modification issues during the ten-year period of the license.

The history showed that all feedback experience from previous stages was taken into account to move forward from one authorization to another.

Following the review and assessment and in granting an authorization CNSNS imposes conditions and limitations on the operator's activities as amendments to the conditions attached to the licence as appropriate.

CNSNS formally records the bases to grant or refuse an authorization following the relevant US CFRs imported by CNSNS.

Regarding LVNPP start-up authorizations following refuelling outages, there is a good draft procedure in force which has been used by CNSNS the last two years. This document should be approved and included in the official procedures of CNSNS.

For other authorizations or licences and for all nuclear installations, there are no formal (written and approved) procedures to amend, renew, revoke or suspend authorizations.

Regarding applications for renewal or amendment of authorizations there is an agreement between CNSNS and the licensee to define the time frame for submitting the corresponding documents.

Long Term Operation and Ageing Nuclear Facilities

In approximately 3 years (2010), CNSNS will start looking at licence renewal for LVNPP Unit 1. The initial licence duration was for 30 years (originally licensed in 1990).

There is no specific programme to address ageing of equipment and facilities associated with radioactive sources. Some Co-60 units are 25 years old or older.

LVNPP is participating in the IAEA programme regarding Plant Life Management with CNSNS observing the process. CNSNS is reviewing USNRC's regulations related to nuclear plant license renewal.

It was noted by the experts that the approach to license renewal for nuclear facilities is similar in most countries. The necessary data related to material ageing are often missing because they were not collected from the beginning of plant operation. It is much easier to make informed decisions regarding ageing if the materials are tested and this information is available from the beginning of plant life.

LVNPP went into operation in 1990. CNSNS will use the IAEA guidance for the periodic safety review (PSR), but will also use the USNRC process for the license renewal. All changes in the plant with safety relevance have to be approved by CNSNS (USNRC approach). The use of PSR is consistent with the European approach, although it will be used in conjunction with the USNRC approach to license renewal. If the results of the PSR are not acceptable or the plant is not willing to make the required upgrades, the plant may be shut down.

The experts noted that there is no single unified approach to plant license renewal or continued operation authorization. PSRs have not been performed from the beginning of nuclear plant operation. Many countries have begun conducting PSRs over the last 5 years. Some countries did not define the lifetime of the plant in the licence. A safety evaluation is conducted to determine if plant operations can continue. This is an approach that has become more widespread and in 5-10 years may/will be common practice. There is a difference in philosophy regarding the approach to safety in Europe versus the U.S. In the U.S. the initial requirements at licensing establish the basis for continued operation of the plant. If serious safety issues are subsequently identified, the licensees will be required to address them. In Europe licensees are expected to continually upgrade to ensure that safety meets new requirements. The use of PSR is helpful in continuously improving safety.

Once CNSNS makes a decision regarding the PSR, the decision does not have to be approved by the Secretary of Energy. Currently, however, there is no budget for conducting the PSR. CFE may be asked to pay for all or part of the reviews. Otherwise, the money will be requested from the national budget.

4.2.2. Application of Ionizing Radiation and Radiation Facilities

The current revision of the regulations "Reglamento General de Seguridad Radiológica" RGSR, (Radiological Safety General Regulations) and rules for radiation facilities should be accelerated. Since the IRRT and the RaSSIA no new version was officially issued. The following aspects of this report are still based on the current regulations mentioned above.

The Regulatory Body ensures that all facilities and activities have in force a formal authorization signed by CNSNS for all radiation facilities. CNSNS also ensures that, before issuing an authorization or an exception for radiation facilities or activities, a formal application is submitted to CNSNS. This is established in the "Reglamento General de Seguridad Radiológica" RGSR, (Radiological Safety General Regulations) Articles 190, 191, 192, 193, 196, 201, 202, 219, 220 and

221. RGSR establishes that an authorization is required for acquiring, import, export, possession, use, transfer, transport, storage or disposal of radioactive materials and ionizing radiation generators. CNSNS issue authorizations for import, export, use including storage, transfer, transport, and services for radiation installations.

All facilities wishing to use radiation for medical, industrial and research purposes or to provide services related with radiation facilities must submit an application for an authorization to CNSNS.

For radiation facilities, the suppliers of services and products must be authorized and regulated by CNSNS.

CNSNS applies the Guidance on the Import and Export of Radioactive Sources of the Code of Conduct on the Safety and Security of Radioactive Sources.

Diagnostic and dental X-ray equipment are under the control of the Ministry of Health and the process for applying for the associated authorizations was not reviewed during the mission.

The application of ionizing radiation installations/facilities are classified, in two types, each one with three classes, as follows:

Type I-A: Class II and IV Irradiators (radioactive source moves out of the shielding) and accelerators with output of 10 MeV or more; mines and treatment plants of radioactive materials, tailing ponds and working zones related with them, temporary storage facilities and repositories for radioactive wastes of low and medium level, places where mobile radiography (X-ray or gamma) are used, well logging and places where patients receive brachytherapy treatment.

Type I-B: Places where therapy X-ray, teletherapy or brachytherapy units are located, class I and III irradiators, accelerators with output of less than 10 MeV, and fixed radiography facilities (X-ray or gamma)

Type I-C: Ophthalmic applicators, nuclear gauges and static eliminators

Type II-A: Radiation facilities with unsealed sources of more than 370 MBq of very high radiotoxicity, more than 3.7 GBq of high radiotoxicity, more than 37 GBq of moderate radiotoxicity or more than 370 GBq low radiotoxicity radionuclides

Type II-B: Radiation facilities with unsealed sources up to 370 MBq of very high radiotoxicity, up to 3.7 GBq of high radiotoxicity, up to 37 GBq of moderate radiotoxicity or up to 370 GBq low radiotoxicity radionuclides

Type II-C: Radiation facilities with unsealed sources up to 370 KBq of very high radiotoxicity, up to 3.7 MBq of high radiotoxicity, up to 37 MBq of moderate radiotoxicity or up to 370 MBq low radiotoxicity radionuclides

CNSNS does not have a system of notification. Authorizations only take the form of licences.

Whatever the facility is, the applicant must submit a safety analysis report to apply for any authorization.

An evaluation is conducted of each application for each practice and activity, although there are not always written procedures for the evaluation process. Some procedures are currently being written.

CNSNS has prepared guidelines for the content of the documents required by the regulations that should include a safety evaluation. These guidance documents are not officially issued.

Evaluation is conducted by specific written procedures, for practices and activities.

The following evaluation procedures were available:

AI-DEL-001: Procedure for evaluation of applications for authorizations of import and export.

AI-DEL-002: General procedure for evaluation applications for permits, authorizations and licenses.

AI-DIR-003: Procedure for evaluation of candidates for radiation protection officer.

AI-DIR-004: Procedure for evaluation of candidates for occupational exposed persons.

AI-DIR-005: Specific procedure for evaluation of applications of nuclear medicine.

AI-DIR-007: Procedure for evaluation applications for deferred braquitherapy.

AI-DIR-011: Procedure for grant consent for import of category 1 (RS-G-1.9) radioactive source.

The procedures listed do not cover all evaluation activities and only two of them (AI-DEL-001 and 002) have been formally approved.

CNSNS stated that the authorization process for nuclear facilities is timely commensurate with the radiological risk of the facility and activity. However, such timeframes are not always established in written procedures.

Since the 1980's CNSNS has developed and submitted guides for safety analysis reports and for radiation protection procedures.

The "Ley Federal de Procedimiento Administrativo" (Federal Law of Administrative Procedures) specifies the time framework regarding the licensing process of radioactive installations.

Hold points, separate permits or separate licences are issued when it is possible to do so. In teletherapy practices, there is an interface between the construction permit and the operation licence. In this case CNSNS takes into account the state of the construction before authorizing the importation of a radioactive source or an accelerator.

For special cases such as new practices, general procedures are applied for safety systems, shielding, calibrations, etc.

CNSNS has prepared some guidelines to the users for completing applications and for the content of the documents required by the regulations. These guidance documents are not officially issued. Application forms, at least for import and export, are published on the CNSNS website.

The information required in the applications is defined in the RGSR.

According to the Administrative procedure federal law, the operators are required to submit or make available to CNSNS all information 30 days before the expiring date of an authorization. This time limit is suspended if the operator is required to provide more information.

There are separate stages of authorization in the case that it is necessary to construct a room to operate equipment or to use the radioactive materials. In this case, a construction and an operation authorization are issued separately.

Each authorization issued by CNSNS, contains an appendix with technical and administrative specifications, such as the period of the leak tests, dosimetry reports, radiation level measurements, list of radiation detector features, calibration aspects, and personnel lists. Any change to the content of an authorization (amendments, renewal, additional authorizations) implies an action from CNSNS. The amount of detailed information contained in authorizations is such that CNSNS must process about 11000 regulatory documents a year. This administrative work may not be always commensurate to the magnitude of the risk.

Following the review and assessment and in granting an authorization, CNSNS has the authority to impose conditions, prescriptions and limitations for the facility or practice in the authorization itself. Conditions are related to the quantity of radioactive material or sources and the requirements of personnel, equipment used and compliance with additional regulations such as TS-R-1 (transport of radioactive material).

Authorizations are issued with expiring time of two years including construction permits. Import and export authorizations have an expiring time of six months.

The bases to grant or refuse authorizations are formally recorded. For granting an authorization the details are established in Articles 189 and 190 of the RGSR and for refusing an authorization, the details are in Articles 253, 227, 232, and 259 of the RGSR. Records are maintained for granted and refused authorizations.

For all radiation facilities and activities, the bases required to amend, renew, suspend or revoke an authorization is contained in Articles 260, 261, 262 and 263 of the RGSR, but there are not yet procedures developed within CNSNS. These procedures are currently being written.

For radiation facilities, applications, authorization amendments or renewal must be submitted 30 days before the expiry date as specified in the regulation (RGSR). After this period is expired, the licensee is prohibited from operating their facility until CNSNS has granted the renewal of their authorizations.

There are no clearly defined written procedures for dealing with any subsequent amendment, renewal, suspension or revocation of an authorization.

Amendment and renewal of an authorization are reviewed according to the guidelines established by each department of CNSNS.

4.2.3. Licensing/Certification of Personnel

CNSNS grants licences to reactor operators on the basis of the Article 50 (section XV) of the Nuclear Law. This article empowers CNSNS to "Establish the requirements to be met by technical training programmes in matters related to nuclear and radiological safety..." in conjunction with Article 50 (sections I and III).

For the NPP operators, CNSNS has defined the requirements in order to license operators. Such requirements are mainly based on the 10 CFR 55. The requirements were agreed between CNSNS and the CFE as part of the NPP licensing.

Although four procedures were drafted for CNSNS licensing of reactor operators at LVNPP, they have not been approved after more than 7 years although such procedures are still used by the CNSNS staff.

- AI-DVO-08, which sets out the requirements for the written exam;
- AI-DVO-10, which sets out the requirements for preparing for the exam;
- AI-DVO-11, which sets out the exam itself; and
- AI-DVO-12, which sets out the requirements for the evaluation of the exam.

For the research reactor, NUREG 1478 is required to be attached as a licence condition. In addition, CNSNS has developed and approved two internal procedures to control the operator licensing process:

- AIDVO-06 (approved), which addresses the personnel issues of reactor operator, is based on USNRC methodology;
- AI-DVO-07(approved), which sets out the requirements for the written exam.

Another procedure has been drafted, AIDVO-09, which sets out the scenarios for the operator test. This procedure will have to be approved and included in the CNSNS management system along with the other currently unapproved procedures.

The terms of reference and the programme of the licensing of personnel is very comprehensive regarding academic aspects as well as the specific knowledge of the position. Furthermore, it should

be underlined that the responsible team in charge of the examination within CNSNS completes the same training process as the licensee's operators. This appears to be a good practice in the light of worldwide practices. The statistics mentioned above, demonstrated the thorough and stringent process put in place by CNSNS.

In addition to providing knowledgeable and well trained operators, the issuing of individual licenses provides a good enforcement tool for CNSNS which may revoke such licences when necessary.

For research reactor the operator licensing process is similar but there is no use of a reactor simulator.

For radioactive facilities and practices the process is different. There are some institutions duly authorized by CNSNS to deliver certificates to different types of radiation users. These certificates are compulsory to get a facility or practice authorization. CNSNS audits the training and the examination process of these institutions and can revoke their authorization if it deems necessary. In the framework of the RGSR revision, CNSNS will be in charge of the examination of the applicants. The training will continue to be performed by the aforementioned institutions

Statistics for Operator Licensing at LVNPP:

2005: one applicant out of seven for Reactor Operator was granted with an Operator Licence. Regarding the others, four succeeded later on and two resigned.

2006: one applicant out of two for Reactor Operator succeeded and the other was granted with the Licence the second time.

Regarding Senior Reactor Operator, six out of eight were granted and the others succeeded the second time.

2007: Two out of three succeeded on the initial exam and the other succeeded later on.

Conclusions:

- CNSNS authorization process does not include the disposal of radioactive materials and ionizing radiation generators as required in the RGSR.
- There is no system of notification as required in SS 115 para. 2.10.
- RGSR defines "the places where radiography is taken" as a radiation facility type I-A. This means that every one of these places requires a license.
- The authorization system does not consider the option of an authorization taking the form of a registration which would provide a graded approach to safety.
- Classification of the applications of ionizing radiation does not fully follow the IAEA recommendations for categorization of sources (RS-G-1.9).
- Written guidelines and evaluation procedures are not available for all practices and activities.
- Most of the existing guidelines and evaluation procedures have not been formally approved.
- Some application forms and guidance documents to users were written and are available but are not yet approved.
- There is a lack of formal written procedures for amendment, renewal, revocation or suspension of an authorization.

For nuclear installations, radiation facilities, activities or practices, there appears to be a disconnection between safety evaluators and inspectors. For nuclear installations, safety evaluators seldom go to the NPP to participate in technical meetings or regulatory oversight. Additionally, it

seems that there is poor synergy and feedback between the inspection and assessment teams, especially for operational experience, modifications, fulfilment of licensing conditions and criteria.

CNSNS works with one division dedicated to Radiation Safety and one division dedicated to Nuclear Safety. Only the radiation safety issues have been formally addressed in the Nuclear Law. To some extent, CNSNS has not been fully empowered yet as the Regulatory Body for nuclear safety. Licenses related to nuclear facilities (namely LVNPP) are issued directly by the Secretary of Energy based on technical evaluations performed by the Nuclear Safety Division of CNSNS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-G-1.2 para 2.3 states *"Management within the regulatory body of the review and assessment process is an important part of the process. … The management of review and assessment should include responsibility for: …Making arrangements for co-ordination between review and assessment activities and inspection activities, as appropriate…"*

S3 **Suggestion**: CNSNS should ensure that there is coordination between review and assessment activities and inspection activities, as appropriate. Safety Evaluators should be provided the opportunity to make site visits as necessary to assess any relevant safety issues at nuclear installations and to participate in inspections and technical meetings with inspectors as appropriate.

(1) **BASIS:** GS-R-1 para 2.2 (4) states *"There are certain prerequisites for the safety of facilities and activities. These give rise to the following requirements for the legislative and governmental mechanisms of States: …The regulatory body shall be provided with adequate authority and power, and it shall be ensured that it has adequate staffing and financial resources to discharge its assigned responsibilities."*

(2) **BASIS:** GS-R-1 para 3.2 (2) states *"In fulfilling its statutory obligations, the regulatory body:…shall review and assess submissions on safety from the operators both prior to authorization and periodically during operation as required."*

R9 **Recommendation**: Adequate staffing and financial resources shall be provided to CNSNS to ensure it can discharge its assigned responsibilities and especially to review and assess submissions on safety from the operators both prior to authorization and during operation as it deems necessary.

(1) **BASIS:** GS-G-1.2 para 2.3 states *"Management within the regulatory body of the review and assessment process is an important part of the process. Consideration should be given to assigning managerial responsibility to a single individual or organizational unit. The management of review and assessment should include responsibility for: …Qualification and training of the personnel engaged in the review and assessment process…"*

G1 **Good practice**: CNSNS staff responsible for licensing of NPP operators receives the same training as licensed operators.

(1) **BASIS:** GS-R-1 para 3.2 (5) states *"In fulfilling its statutory obligations, the regulatory body…shall review and assess submissions on safety from the operators both prior to authorization and periodically during operation as required."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2) **BASIS:** GS-R-1 para 3.3 (12) states *"In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body…shall confirm the competence of personnel responsible for the safe operation of the facility or activity".*

(3) **BASIS:** GS-R-1 para 3.3 (13) states *"In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body……shall confirm that safety is managed adequately by the operator."*

R10 **Recommendation**: Regarding sub-critical assemblies, CNSNS shall ensure that radiation safety, nuclear safety and operator competence are adequate.

(1) **BASIS:** GS-R-1 para 5.25 states *"The system of regulations and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated. Where regulations are not issued by the regulatory body, the legislative and governmental mechanisms shall ensure that such regulations are developed and approved in accordance with appropriate time-scales."*

R11 **Recommendation**: Governmental mechanisms shall be established to ensure that RGSR is reviewed and revised and any other necessary regulations are developed, which are then approved in accordance with appropriate time scales.

(1) **BASIS:** GS-R-1 para 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."*

S4 **Suggestion**: CNSNS should encourage the licensee to analyse the risks associated with LVNPP zero power state as well as external hazards.

(1) **BASIS:** WS-R-5 para 9.2 states *"The facility shall not be released from regulatory control, nor shall authorization be terminated until the operating organization has demonstrated that the end state in the decommissioning plan has been reached and that any additional regulatory requirements have been met. The regulatory body shall evaluate the end state of the site by performing a thorough inspection of the remainder of the facility after decommissioning activities have been completed to ensure that the end point criteria have been met."*

(2) **BASIS:** GS-R-1 para 3.2 (1) states *"In fulfilling its statutory obligations, the regulatory body….shall establish, promote or adopt regulations and guides upon which its regulatory actions are based ."*

(3) **BASIS:** WS-G-2.1 para 2.8 states *"The regulatory framework of a country should include provision for the decommissioning of nuclear installations, in particular nuclear reactors. National regulatory authorities should provide guidance on radiological criteria for the removal of regulatory controls over the decommissioned installations and sites and should ensure that an adequate system is in place for properly managing the removal of controls."*

R12 **Recommendation**: Guidance and criteria to release nuclear sites from regulatory control shall be established. Such criteria shall ensure that adequate systems are in place to properly manage this release.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 5.4 states *"…For complex facilities authorizations may be carried out in several stages, each requiring, hold points, separate permits or licences…each stage subject to review and assessment…"*

S5 **Suggestion**: CNSNS should introduce hold-points for Research Reactors during the 10-year period of the operating licence especially after significant maintenance activities so that CNSNS could review, assess and authorize safe operations to continue.

(1) **BASIS:** GS-R-1 para 5.2 states *"For all facilities, a prior authorization, a notification or an exemption shall be in force..."*

S6 **Suggestion**: Regulations or guidance should be established to deal with the legal situation of a nuclear installation when its licence has expired without a licence renewal or when its licence has been suspended or revoked.

(1) **BASIS**: BSS para 2.7 states *"No practice shall be adopted, introduced, conducted, discontinued or ceased and no source within a practice shall, as applicable, be mined, milled, processed, designed, manufactured, constructed, assembled, acquired, imported, exported, distributed, sold, loaned, hired, received, sited, located, commissioned, possessed, used, operated, maintained, repaired, transferred, decommissioned, disassembled, transported, stored or disposed of, except in accordance with the appropriate requirements of the Standards, unless the exposure from such practice or source is excluded from the Standards or the practice or source is exempted from the requirements of the Standards, including the requirements of notification and authorization."*

R13 **Recommendation**: The authorization system for applications of ionizing radiation shall be reviewed to ensure that it includes all controlled activities.

(1) **BASIS**: BSS para 2.10 states *"Any legal person intending to carry out any of the actions specified under the General Obligations for practices of the Standards (see paras 2.7 and 2.8) shall submit a notification to the Regulatory Authority of such an intention. Notification for consumer products is required only with respect to manufacturing, assembling, importing and distributing."*

R14 **Recommendation**: The authorization process for radiation facilities/installations shall be modified to include notification.

(1) **BASIS:** BSS para 2.11 states *"The legal person responsible for any sealed source, unsealed source or radiation generator shall, unless the source is exempted, apply to the Regulatory Authority for an authorization which shall take the form of either a registration or a licence."*

S7 **Suggestion**: CNSNS should consider modifying the authorization system to include the use of a graded approach to take into account risk (e.g. registration as a type of authorization).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1.9 para 1.8 states *"The objective of this Safety Guide is to provide a simple, logical system for ranking radioactive sources in terms of their potential to cause harm to human health, and for grouping sources and the practices in which they are used into discrete categories. This categorization can assist regulatory bodies in establishing regulatory requirements that ensure an appropriate level of control for each authorized source."*

S8 **Suggestion**: CNSNS should review the authorization system to take into account the IAEA categorization of radioactive sources.

(1) **BASIS**: GS-R-1 para 5.3 states *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures…"*

R15 **Recommendation**: Written guidelines and evaluation procedures for all practices and activities for radiation facilities shall be prepared and formally approved.

(1) **BASIS:** GS-R-1 para 5.4 states *"The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization."*

S9 **Suggestion**: Publishing of application forms and guidance documents should be extended to all practices. This would help to speed the process for submitting the application.

(1) **BASIS**: GS-R-1 para 5.6 states *"Any subsequent amendment, renewal, suspension or revocation of the authorization shall be undertaken in accordance with a clearly defined and established procedure."*

R16 **Recommendation**: Written procedures for dealing with any subsequent amendment, renewal, suspension or revocation of an authorization shall be prepared and formally approved.

5. REVIEW AND ASSESSMENT

This section considers the review and assessment process for the various areas of CNSNS regulatory responsibility.

5.1. GENERAL

CNSNS has developed several procedures dealing with Review and Assessment:

- AI-EVA-03, “Generación de Posiciones Técnicas”;
- AI-EVA-05, “Procedimiento para la Evaluación de Asuntos o Aspectos Técnicos de Seguridad”.

However, certain internal procedures describing what CNSNS is reviewing and assessing on a day-to-day basis are not written down and included in the aforementioned set of procedures.

5.1.1. Nuclear Installations

For nuclear installations, the US CFRs are used and enforced. The review and assessment process is performed in accordance with a given regulatory process as described previously in the authorization section of this report. Furthermore, the potential magnitude and nature of the hazard is implicitly taken into account in the US CFRs which are used by CNSNS as the basis for the review and assessment process.

While the bases documents are made available to the licensees, the criteria in the adopted regulations are not challenged by CNSNS. The CFRs are based on many years of operating reactor-years of experience and may be sufficiently robust. The issue is that CNSNS should be aware of all the relevant bases behind the CFRs’ criteria so that future modifications or maintenance issues can be assessed properly.

For LVNPP all criteria dealing with review and assessment principles and criteria are written down and known by both parties (CFE and CNSNS). Furthermore, meetings are organized on regular basis to discuss any review and assessment issues identified during the review of the licensees’ safety cases.

CNSNS has always followed and used the 10 CFRs to review and assess safety cases. CNSNS can also use the ININ (Instituto Nacional de Investigaciones Nucleares) or National Universities as Technical Support Organizations (TSOs) if necessary. Furthermore, CNSNS satisfies itself that:

- the available information provided by the applicant demonstrates the safety of the facility or proposed activity or practice;
- the information contained in the applicant’s submissions is accurate and sufficient to enable confirmation of compliance;
- CNSNS also uses the experience from other regulatory bodies such as the USNRC, the Spanish CSN, and/or the Canadian CNSC, because the CNSNS’ capability to perform tests and experiments is limited.

However, it should be stressed that the work is mostly accomplished using provided information or documents. Safety evaluators seldom go onto site to check or to investigate such provided information. The communication and synergy between inspectors and safety evaluators seem rather weak.

For nuclear installations there are specific programmes for inspections and also for review and assessment. For the latter programme CNSNS has a list of specific thematics or subjects that must be addressed.

For nuclear installations, US CFRs are used to categorize modifications. The level of review and assessment conducted is based on the categorization which is determined by the level of safety affected by the modification.

For LVNPP, meetings are also organized before outages to discuss all modifications and to become acquainted with all safety issues. Moreover, the list of proposed modifications and safety analyses are submitted to CNSNS for assessment 3 months before the outage.

Regarding modifications, CNSNS has agreements in place with CFE regarding authorizations. CNSNS has also agreed that the process for the authorization of a modification will follow 10 CFR 50.59. Furthermore, after evaluation of a modification, CNSNS regulates LVNPP through licence conditions or Technical Specification amendments without interference from the Secretary of Energy.

5.1.2. Application of Ionizing Radiation and Radiation Facilities

The review and assessment process is performed in accordance with established facility types: A, B or C. These types correspond to the radiological risk. CNSNS performs its review and assessment in accordance with the criteria established in RGSR. As applications of ionizing radiation are classified by risk, the potential magnitude and nature of the hazard associated with the particular facility, activity or practice is taken into account.

The principles and associated criteria used are established in RGSR and in the guide "Normas Oficiales Mexicanas" NOMs (Official Mexican Standards). This guide can be amended based on CNSNS experience and judgement.

The NOM and RGSR are publicly available documents and known by all stakeholders. Moreover, any revision is submitted to professional associations and academic institutions for review.

There is a thorough review and assessment focused on whether facilities, activities or practices comply with guidance, criteria and objectives of normative requirements for radiation protection. Although CNSNS performs a review and assessment of the operator's technical submission, the review team was not able to find adequate evidence of the assessment performed. The only evidence is the final "Dictamen" issued by the evaluator and approved by the Head of the Unit, proposing the issuance or denial of the authorization.

CNSNS satisfies itself that the available information provided by the applicant is what CNSNS has required for the specific facility, activity or practice through a review by the Head of the Unit before the evaluation work is assigned. The evaluator has the responsibility to verify that the information contained in the applicant's submissions is accurate and sufficient to enable confirmation of compliance with regulatory requirements, and the user's technical solutions, and in particular any novel ones, have been proven or qualified by experience or testing or both, and are capable of achieving the required level of safety.

CNSNS has specified, within an internal administrative manual, time periods for reviewing and assessing applications for licenses. License applications should be dealt with in 40 or 50 days after received the license except for those import and export which must be completed within 10 days.

Regarding programmes, there is an annual programme for inspections but not for review and assessment regarding radiation facilities. However, the number and frequency of authorization renewals or amendments is such that the review and assessment process is performed frequently.

Safety related modifications are subject to review and assessment. CNSNS stated that this review and assessment process is commensurate with the potential magnitude and nature of the hazard

thanks to Article 222 of RGSR. This article establishes the content for the safety analysis report for a modification application and requires the reason for the modification, the impact on radiation protection and the dose assessment. However, a lot of non-important for safety detailed information is required by CNSNS for licences of radiation facilities and practices. Any change to the details of a license requires an amendment from CNSNS. This level of administrative actions (involving about 11,000 regulatory documents a year) does not seem to be commensurate with the magnitude of the risk.

Conclusions:

- There are no written procedures for verifying completeness of information.
- Existing procedures have not been formally approved.
- Due to the time of reviewing and assessing being greater than the deadline of the authorization, the facility can stay without authorization for 10 or 20 days.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 4.5 states *"The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken."*

(2) **BASIS** GS-R-1 para 5.3 states *"Prior to the granting of an authorization, the applicant shall be required to submit a detailed demonstration of safety, which shall be reviewed and assessed by the regulatory body in accordance with clearly defined procedures."*

R17 **Recommendation:** CNSNS shall establish and implement arrangements for a systematic approach and should therefore write and approve internal procedures dealing with the CNSNS review and assessment process. Written procedures for all practices and activities shall be prepared and formally approved.

S10 **Suggestion**: CSNSN should make efforts to issue the authorization before its expiry.

6. INSPECTION AND ENFORCEMENT

Introduction

Two Divisions of CNSNS carry out the inspection programme for nuclear and radiation facilities in Mexico. The inspection of nuclear safety is the responsibility of the Division of Nuclear Safety (GSN) while the inspection of radiation facilities, radiation protection, emergency preparedness, physical protection in nuclear installations and safeguards comes under the responsibility of the Division of Radiological Safety (GSR). The CNSNS organizational structure was modified at the beginning of November 2007.

The Division of Nuclear Safety has a staff of 37 positions among the following Departments: Evaluation, Operational Supervision, and Regulatory Implementation. The nuclear safety inspection function is managed by the Department of Operational Supervision, covering routine inspections conducted by the acting resident inspectors located on the site at Laguna Verde NPP, periodic inspections conducted by inspectors from CNSNS Headquarters in accordance with an approved inspection programme, and reactive inspections after significant events. The Department of Operational Supervision is also charged with the review of the training of NPP staff and the licensing of operators. There are normally two resident inspectors at LVNPP responsible for assuring that safety conditions prevail in all operational conditions at the LVNPP and to report any deviation from safe operational conditions to CNSNS Headquarters. For the last several months there has been only one resident inspector, since the more junior inspector took a position at the plant (CFE). The inspector who remains has been a resident inspector at the plant for approximately 18 years. CNSNS is trying to fill this important vacancy.

The Division of Radiological Safety has a staff of 67 positions, with 8 vacancies. It is comprised of the Department for Evaluation, the Department of Inspection, the Department for Environmental Surveillance and Emergencies, and the Department of Physical Security and Safeguards. The radiological safety inspection function is managed by the Department of Inspection.

The objective of the CNSNS inspection programme is: "*To survey that the operations related to nuclear and radiological safety at facilities are carried out according to the rules and regulations established.*" Four IRRS Team Members visited LVNPP on November 30 to interact with the resident inspector, observe an inspection exit, walk down parts of the plant and waste processing and storage installations, and interact with plant management. Team member visits to other facilities are indicated in the text that follows.

6.1. INSPECTION OF NUCLEAR INSTALLATIONS

According with the Regulatory Law of Article 27 of the Constitution on Nuclear Matters, Chapter IV Article 32, and Chapter VI Article 50 fraction XII, CNSNS is empowered to carry out inspections.

Workload for the inspection staff has increased over the last ten years, with the addition of approximately 600 radioactive materials licensees, and the increased inspection workload of physical security and safeguards following the events of September 11, 2001. Both Divisions have experienced staffing shortages and challenges throughout this timeframe. In 2003, a Government-wide early retirement programme resulted in the loss of approximately 35 professional staff from CNSNS.

Human Resource records were reviewed for the years 2006 and 2007. In 2006, four individuals left CNSNS, and 23 were hired. In 2007, five individuals left and two were hired. The hiring process is very cumbersome government-wide, and currently the organization has approximately 25 vacancies. CNSNS does not have the capability to hire contractors for inspections, so the inspection programme is impacted by the staffing shortages (see recommendation on staffing in section 3).

It is difficult to verify that the inspection programme covers all areas of CNSNS regulatory responsibility, since the areas of responsibility are only generally defined. Procedure AI-DVO-01 "Programacion De Inspecciones" lists the following areas which are to be inspected annually at LVNPP:

- Operations;
- Maintenance;
- Radiological Protection;
- Engineering;
- Quality Assurance; and
- Emergency Preparedness.

Additionally, an appendix to this procedure provides a matrix which lists special inspections, with either an annual or biannual requirement.

For the last several years the inspection programme has been proposed and approved on an annual basis. A review of the plans for 2006 and 2007 indicates that several inspections were not completed in accordance with AI-DVO-01. It is clear that the number, schedule, and frequencies of inspections are impacted by staffing shortages. Further evaluation of the inspection programme, with examples of where certain inspections are lacking, is addressed later in this report.

CNSNS ensures through inspections that facilities, equipment and work performance meet necessary requirements. CNSNS staff performs inspections among other activities by conducting relevant field work related to the activity being inspected, by witnessing surveillances where possible, and by conducting routine walk-throughs at the site to check for proper equipment performance. They ensure that relevant documents and instructions are valid and are being complied with by reviewing documents and instructions for proper revision, and verifying that facility personnel are properly following instruction steps.

CNSNS inspectors identify and document deviations, or findings, without establishing corrective actions. The recommendation and implementation of corrective actions are the responsibility of the licensee. CNSNS inspections subsequently verify the implementation of the facility's corrective action programme and their self-assessments.

The inspection and enforcement programme ensures that facilities, equipment, and work performance meet necessary requirements; that relevant documents and instructions are being complied with; persons employed by the operator are appropriately trained and qualified; non-compliances with operating authorizations are complied with in a reasonable time frame; and inspection reports are completed. It is important to note that inspection reports are not routinely released to the public; however, any member of the public can have access to them upon request.

The inspection programme includes an inspection of the training area or training programme in order to verify that individuals have the necessary competence. For example, a review of licensed operator initial examination results was conducted for the last several years. The results of the tests, given by CNSNS to the LVNPP potential operators, indicated that there is a good discrimination of test results (i.e. several operators failed various sections and had to be retrained by the licensee prior to a retest).

CNSNS ensures the quality of services and products for LVNPP by ensuring either that the plant's Quality Assurance Program is followed, or that the supplier has a valid QA Program. CNSNS conducts inspections of the procurement and supplier process. A review of inspections conducted over the last three years indicated that this inspection is normally completed during refuelling

outages. For radioactive installations, the suppliers of services and products must be authorized and regulated by CNSNS.

The inspection programme also includes an inspection of the facility's corrective action programme to check the programme's implementation, effectiveness and timeliness. This inspection was last conducted in January 2007.

For the nuclear installation, the CNSNS inspection programme includes an inspection of the external operating experience area in which they verify that the operator is appropriately applying operating experience. The team reviewed an Inspection Report of the LVNPP Operating Experience Program from September 2007. Although no findings were identified in the report, the report showed a high number of open or pending actions being tracked by the licensee. Approximately 170 items were open or pending, with only 4-6 evaluations being closed by the plant per month. Discussions with GSN management indicate that this is an area of focus, about which they have already communicated with the plant. The inspection report summarized sample actions still open (e.g., Generic Letters, INPO SOER's).

Additionally, CNSNS also uses performance indicators to effectively track plant performance. This programme was developed following the 2001 IAEA IRRT mission, and effectively monitors a variety of indicators on a monthly basis. Plant scrams (with and without loss of the normal heat sink), unplanned power changes, and equipment out of service periods are evaluated monthly. They have expanded on other countries' performance indicators (e.g. including systems in category a.1 under the USNRC Maintenance Rule). A colour is assigned to each indicator based on the calculation for the metric that month. Green, White, Yellow, and Red colours are assigned in order of increasing significance. When the programme was implemented, the plant had one Red, three Yellow, and six White Performance Indicators. A review of the indicators between 2003 and 2006 (four year period) showed steadily increasing performance, as indicated by the performance indicators being primarily Green, with only an occasional White or Yellow indicator. A reactive inspection was recently initiated in accordance with an "Action Matrix" – a tool that categorizes plant performance based on the colour of the indicators (further discussed later in this report under item 5.16).

A part of the annual inspection programme relates to the TRIGA Mark III research reactor owned by the "Instituto Nacional de Investigaciones Nucleares" (ININ). The Department of Operational Verification is responsible for conducting these inspections. The IRRS team had the opportunity to witness part of an inspection performed at this research installation.

As a result of documentation seen, discussions held with personnel of CNSNS and participation as an observer in one regulatory inspection on November 28 to the TRIGA Research Reactor under the area of operation, the IRRS team observed the use of verification lists during this inspection, elaborated according to the procedure AI-DVO-02, rev 0, "Elaboración y Uso de Listas de Verificación**".**

The verification list resulted in a very complete and exhaustive inspection, facilitating an efficient review by the inspector. Additionally, the inspectors informed the ININ counterparts at the end of the inspection of identified good practices (strengths), along with the identified deficiencies and deviations, which were all included in an executive summary report. After the inspection a complete report is sent to the licensee, from which the licensee must respond with proposed corrective actions for the items of non-compliance. The prime responsibility for safety of the operator is not diminished by the regulatory inspections carried out.

CNSNS has, in general, implemented a planned and systematic inspection programme for Laguna Verde NPP. Development of the annual inspection programme is based upon input from implementation of the previous annual programme (which include inspections postponed, in some cases due to lack of resources), key inspection activities which are conducted annually, and other

considered appropriate to be done. However, the final programme appears to be planned based on the available resources, rather than a definitive evaluation of the necessary key/core inspections. CNSNS is engaged in finalizing development and implementation of an integrated inspection system, which should assist this planning process.

CNSNS plans their inspection programme based on a nominal frequency for the conduct of certain types of inspections. The official procedure is AI-DVO-01, "Program of Inspections", which includes a wide variety of inspections (approximately 40 inspection types) with either annual or biennial frequencies. This procedure was last updated in 2000. Currently, inspections have been combined and are planned on a simple spreadsheet for the year. Inspection plans for 2006 and 2007 were reviewed. The 2006 plan had 29 inspections scheduled, for a total of about 38 weeks of inspection activity. The 2007 plan includes 30 inspections, for a total of about 45 weeks of inspection activity (an increase primarily due to a refuelling outage occurring for each unit in 2007). This plan is published monthly and is colour coded to show inspections that are programmed, completed, reprogrammed, and cancelled. With respect to inspections of physical protection and safeguards, no procedure has been developed for defining the scope and plan for the inspections, but there is an approved separate annual list of inspections. With respect to certain areas like corrective actions and human resources, detailed inspection guidance has not been finalized to provide effective oversight of these areas.

In general, the frequency and extent of inspections for the nuclear installation depends on the significance to safety of the inspected area. For example, inspections of key safety systems are performed annually, and other inspections are performed every two years. However, there are no explicit guidelines for the inspector on examples of issues to review for a particular inspection, or on the expected amount of time to spend on an inspection. Inspection checklists, and inspection manual chapters, which are similar to those used for other international BWRs, are used for general guidance.

On a monthly basis the programme is summarized to verify programme execution. However, the monthly metrics are based on what they have determined they will inspect that year, rather than on what the inspection frequency called out in their procedures would require. Additionally, a schedule for a periodic assessment of the inspection programme does not exist.

In the Nuclear Safety field, CNSNS indicated that it is often difficult to accomplish or complete the annual programme. Approximately 85% of the inspection programme was completed during 2006, with the rest of the programme deferred to the following year.

Although a procedure exists for the inspection programme of LVNPP, the actual implementation is largely driven by available resources. CNSNS has put a priority on completing inspections at LVNPP. However, it could not be clearly determined, especially when comparing the inspections performed 5 years ago with this year's programme, whether a complete set of "core" inspections was being routinely accomplished. While core elements and national and local priorities are considered in the formulation of the inspection programme, a more structured risk assessment process could improve the overall basis for the programme. CNSNS is working in order to have an adaptation of the USNRC reactor oversight process implemented in the near future.

With regard to training for inspectors, there are general criteria in a draft Division procedure (e.g. AI-GSN-04) that state what an inspector must complete to be qualified (e.g. five core courses for Inspectors in Training, and five additional courses). There does not, however, appear to be an official certification or documentation of these activities.

CNSNS does track training hours. A review of the report from 2006 indicated twenty individuals had over 100 hours of training, with an individual who was in "license class" documenting 672 hours of training. However, over 40 individuals had less than 20 hours of training. Although the team verified that the Operational Verification Department of GSN had a list of about 16 training

opportunities available for Department staff in 2007, it was difficult to verify that there was a formal plan to ensure that inspectors were receiving training in all critical inspection areas or were receiving adequate initial and/or refresher training.

An individual training plan does not appear to exist for each employee (to ensure that individuals both achieve specialized training for certain job functions and maintain technical competence overall). For example, the team's review of an inspector acting as Resident Inspector indicated that he was uncomfortable with aspects of that position. It was the team's view that the individual should have more specialized training that would ensure effective inspection of the variety of issues faced at the site. Additionally, an individual was assigned as "qualified" to write the exam for the upcoming test of LVNPP operators, without having received special training under instruction for this task.

Separately, CNSNS has only performed one survey of its employees to self-assess staff members' perceptions on training and their abilities to inspect/enforce. This survey was performed approximately 10 years ago. CNSNS does not have a current method to evaluate their staff's perceptions on training and if they "feel free to raise safety concerns" or differing opinions as part of the regulatory body.

In summary, there are only general criteria defined for inspectors, which does not take into account the difficulties involved in certain positions. Additionally, in a few inspection areas reviewed, observations by the team indicated that CNSNS inspectors may not have been provided the proper training, or may not have gained the necessary experience to effectively perform their functions.

According to the Nuclear Law, nuclear and radioactive installations shall be subjected to checks, audits, verification and inspections by CNSNS in order to verify nuclear and radiological safety and physical security conditions and compliance with safeguards requirements.

In order to accomplish this objective the following types of inspections are performed:

- Routine inspections by resident inspectors at the Laguna Verde NPP of operations and equipment performance (the annual plan for the resident inspector's activities is included in procedure AI-DVO-13)
- Periodic inspections by the Department of Operational Verification, Division of Nuclear Safety
- Inspections of radiation safety by the Department of Evaluation, Division of Radiological Safety
- Inspections of emergency preparedness by the Department of Environmental Surveillance and Emergencies, Division of Radiological Safety
- Inspections of physical protection and safeguards by the Department of Physical Security and Safeguards, Division of Nuclear Safety

Routine inspections of the main control rooms are carried out daily; other inspections are performed according to a draft programme that describes annual and biannual inspections.

CNSNS conducts both announced and unannounced inspections at LVNPP. For announced inspections, the operator is typically notified of the general inspection subject matter or topic one week in advance. Other inspections (CNSNS indicates about 10%) are conducted with no prior notification to the licensee. A review of the 2006 and 2007 inspections indicated there were three unannounced inspections in 2006, and three in 2007. For radioactive installations, all inspections are unannounced.

For LVNPP, most inspections are typically conducted by one or two CNSNS staff over a two-four day period. Longer duration inspections are conducted during refueling outages. Inspections are

occasionally conducted during night shifts and on weekends. Guidance to this effect is contained in inspection programme documents.

Special inspections (Reactive Inspections) are initiated in response to an unexpected, unplanned or unusual situation or event at a nuclear or radioactive installation.

In case of abnormal events at nuclear installations, the resident inspector follows operator performance and the implementation of the corrective actions. The inspector is not involved in the operator's investigations and conclusions. For radioactive installations, the inspectors similarly subsequently review the operator's actions and evaluations.

For LVNPP, the team reviewed official event notification records for 2005 and 2006. Events reported each year (a total for both nuclear units), were 64 and 66, respectively. For 2007 it is estimated the total will be approximately 70.

No reactive inspections were conducted in 2006, and three were conducted in 2007. The first reactive inspection in 2007 was driven by an "Action Matrix" CNSNS uses in conjunction with its Performance Indicator Programme. Both nuclear units had a White indicator for unplanned power changes. Additionally, a common indicator was Yellow for emergency siren performance. Accordingly, a week-long reactive inspection was conducted.

A second reactive inspection was conducted in August 2007 following a high radiation alarm in the turbine building. A finding resulted from this inspection regarding weak procedure adherence that impacted both trains of the off-gas system.

A third inspection, which they considered "reactive" because it had not been planned for this year, regarded an authorization being considered by CNSNS for a low level waste storage facility at LVNPP.

Other than the use of the Action Matrix for Performance Indicators, there is no formal procedure that assists CNSNS in decision making for reactive inspections. In general, event reports are reviewed by managers, and individual decisions are made for event follow-up based on the staff's general knowledge of the event and input from the resident inspector at LVNPP. A draft procedure, AI-EVA-04, "Evaluacion de Eventos Reportables" is in use which utilizes a flow chart and checklist to evaluate events.

CNSNS requires inspectors to prepare a report of their inspection activities and findings. These activities are described in both GSR and GSN procedures. For LVNPP, the resident inspector prepares a report quarterly.

Inspections findings are tracked following inspections. In 2006, there were ten inspection findings for LVNPP Unit 1 (three of which came from the resident inspectors), and 13 for Unit 2 (three of which came from the resident inspectors)

CNSNS tracks inspection findings and issues an internal monthly report. The team reviewed the November 2007 report which showed 6 inspection findings which were "open" longer than the prescribed amount of time. That is, there are currently 13 findings "outstanding", but seven of these are awaiting the licensee's 30 day response. The six "open" findings have evaluations that are still being deliberated, and the time frame they have been in this category ranged from 1 to 140 days.

Currently all inspections findings are assessed for significance under a draft procedure and have been assigned a "green" significance (least safety significance). A final procedure or programme for determining the safety or risk significance of individual inspection findings has not been finalized or approved. Implementing an effective risk significance determination process will enable CNSNS to better monitor licensee safety performance.

Conclusions:

Although CNSNS has a procedure that discusses areas of its inspection responsibility, it was written in 2000 and provides only general guidance.

CNSNS has implemented an effective safety performance indicator programme for LVNPP.

CNSNS is managing safety well through its inspection programme. Although certain procedures are being updated, and some are in draft form, the inspectors are appropriately using inspection guidance, and tracking performance through indicators and follow-up inspections to properly gauge nuclear safety.

The implementation of the inspection programme at LVNPP is largely driven by available resources.

CNSNS conducts both announced and unannounced inspections. Special inspections (reactive inspections) are initiated in response to unexpected or unusual situations or events at nuclear or radioactive installations. Guidance exists to perform reactive inspections for certain performance indicators and events. There is no evidence that reactive inspections were conducted based on inspection findings.

Although inspection findings are summarized every six months, an assessment of each finding for risk/significance is not being completed as the finding is identified. Currently all inspection findings have been evaluated as "green" (all of the same significance). The existing process does not formally accommodate a timely review of individual findings to consider whether the inspection and enforcement process should be further utilized based on the findings identified.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 5.12 states *"Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility."*

R18 **Recommendation**: CNSNS shall better define the areas of regulatory responsibility and complete inspections in all appropriate areas.

S11 **Suggestion**: Consider making better use of all staff (e.g. Evaluators) by training more staff to conduct inspections.

(1) **BASIS**: GS-R-1 para 5.13 states *"The main purposes of regulatory inspection and enforcement are to ensure that:*

(1) facilities, equipment and work performance meet all necessary requirements;

(2) relevant documents and instructions are valid and are being complied with;

(3) persons employed by the operator (including contractors) possess the necessary competence for the effective performance of their functions;

(4) deficiencies and deviations are identified and are corrected or justified without undue delay;

(5) any lessons learned are identified and propagated to other operators and suppliers and to the regulatory body as appropriate;

(6) the operator is managing safety in a proper manner.

Regulatory inspections shall not diminish the operator's prime responsibility for safety or substitute for the control, supervision and verification activities that the operator must carry out."

G2 **Good Practice**: a) CNSNS utilizes comprehensive checklists in the preparation for inspections, and b) conducts thorough discussions with the licensee regarding

identified deficiencies or deviations. The explanations and information provided by CNSNS inspectors to the licensee at the end of inspections demonstrated good communications between CNSNS and the licensee regarding identified deficiencies or deviations.

(1) **BASIS**: GSR-1, para 5.14 states *"The regulatory body shall establish a planned and systematic inspection programme..."*

R19 **Recommendation:** A systematic and comprehensive inspection plan shall be developed to ensure that the minimum set of inspections is completed for nuclear inspections.

S12 **Suggestions**: CNSNS should further develop aspects of their documented inspection oversight programme covering corrective actions, human and organizational performance, and safety culture.

(1) **BASIS:** GSR-1, para 5.16 states *"In addition to routine inspection activities, the regulatory body shall carry out inspections at short notice if an abnormal occurrence warrants immediate investigation..."*

S13 **Suggestion**: CNSNS should finalize the event follow-up with a procedure that provides guidance on event response. Currently, other than management judgement, there is no guidance for staff and managers to use to ensure that all findings appropriate for follow-up are consistently completed. The use of risk insights, which CNSNS is continuing to improve, should be used to supplement this decision making process.

(1) **BASIS:** GS-R-1 para 5.13 states that one of the main purposes of regulatory inspection and enforcement is "*to ensure that…facilities, equipment and instructions are valid and being complied with.*

(2) **BASIS**: GS-R-1 para 5.14 states *"The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*

(3) **BASIS**: GSR-1 para 5.9 states *"A primary basis for review and assessment is the information submitted by the operator. A thorough review and assessment of the operator's technical submission shall be performed by the regulatory body…"*

G3 **Good Practice:** CNSNS has developed an effective Performance Indicator programme that effectively tracks a variety of indicators related to LVNPP.

(1) **BASIS:** GS-R-1, para 5.14 states *"The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*

(2) **BASIS**: GS-R-1, para 5.17 states *"Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process."*

G4 **Good Practice**: Inspection findings are summarized every six months in a detailed Assessment Report that is prepared for internal distribution at CNSNS. Trends are analysed in a qualitative manner. Insights on performance are included.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

S14 **Suggestion**: CNSNS should evaluate a method to 1) feed the insights from the licensee assessment reports into the inspection programme, and 2) share insights from the Assessment Report with LVNPP management.

S15 **Suggestion**: In developing the annual inspection programme, CNSNS should improve the systematic means of risk-informed decision making in determining areas of focus for the coming year.

S16 **Suggestion**: CNSNS should complete and implement the process for safety significance determination for inspection results, which they have underway. This process should include different categories for inspection results based on safety significance, and establish guidelines for inspection follow-up based on the inspection results' significance.

6.2. ENFORCEMENT AT NUCLEAR INSTALLATIONS

According to the Regulatory Law of Article 27 of the Constitution on Nuclear Matters, chapter IV Articles 34 to 40, and chapter VI Article 50 fraction XII, CNSNS is empowered to take enforcement actions. This includes the retention, securing or seizure, or depositing of sources of ionizing radiation or equipment containing them. Also orders to cancel or suspend the license of operation or individual licenses or civil penalties (monetary fines) can be applied.

Article 37 of the law allows civil penalties between 5 and 5000 times the minimum wage in effect at the time. Article 39 allows doubling the penalty if the violation recurs within a two-year timeframe.

Only two civil penalties were assessed to LVNPP over the last 12 years; one in the mid-1990's for a high radiation dose issue, and one in 2002 for a physical security violation. Additionally, on two occurrences operator licenses were terminated (e.g. one issue was due to actions which resulted in operation outside of the technical specification requirements).

However, due to the general nature of the nuclear law, enforcement actions are not routinely considered or taken for violations of the license or Technical Specifications.

A draft Enforcement Policy (July 2007) is in the process of being evaluated for implementation. This policy includes a Significance Determination Policy and four categories of violations (Level I to IV, in order of decreasing significance).

CNSNS issues letters to the operator following inspections that identify non-compliances. CNSNS relies on inspector skill to determine the safety significance of an issue (see Section 5.17).

For deviations or violations having at least minor safety significance at nuclear installations, a letter is issued requiring the operator to respond formally to CNSNS indicating actions taken to correct the deviations and prevent their recurrence. CNSNS will subsequently review the operator's actions in a later inspection.

At radioactive installations, all violations (minor or major significance) require the operator to respond formally to CNSNS indicating corrective actions.

Under the Law (Articles 34 to 39), CNSNS also has the authority to revoke the authorization of the operator. CNSNS may reinstate the revoked authorization once the challenge to safety has been remedied to the regulator's satisfaction. Additionally, CNSNS has the authority to impose economic sanctions (penalties) to the licensee. Penalties were issued on three occasions against radioactive installations licensed by CNSNS over the past several years.

According to the Regulatory Law of Article 27 of the Constitution on Nuclear Matters, chapter IV Article 34, in cases of danger or imminent risk to personnel in a nuclear or radioactive installation, or to society in general, CNSNS will order and execute, as appropriate, the retention, securing or seizure or depositing of sources of ionizing radiation or equipment containing them, as well as any contaminated property, in accordance with the respective regulations.

It may also order and execute, as a preventive measure, the temporary, partial or total closing down of nuclear and radioactive installations, as well as of contaminated real estate, establishing deadlines for correcting deficiencies or anomalies. In cases in which deficiencies or anomalies are not rectified before the established deadline, CNSNS based on the corresponding technical report, will proceed to the final closing down.

All enforcement decisions are confirmed to the operator in writing. However, for LVNPP, as noted earlier, enforcement decisions are rare.

For nuclear installations, the inspector informs headquarters and makes a proposal for regulatory action, but the final decision comes following a thorough review from higher level management. For radioactive installations, the inspectors have the ability to apply immediate enforcement regarding the retention, seizure or depositing of sources of ionizing radiation or equipment containing them if are present conditions of imminent risk or danger. A discussion with CNSNS staff state these actions are rarely used. However, for medical hospitals operations have been stopped for a period of time.

Although there are no special procedures to ensure that the transmission of information to the Regulatory Body is suited to the urgency of the situation, CNSNS staff interviewed believed that the inspectors would transmit the information to headquarters as soon as possible.

Conclusion: CNSNS has the ability and authority to impose enforcement, but due to the general nature of the law and not having an official Enforcement Policy that clearly states the regulatory basis, enforcement is rarely taken. The use of a formal policy could provide the CNSNS staff members with examples of enforcement sanctions for various levels of infractions, which when consistently applied can be a driver to further improve licensee performance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 5.12 requires that *"Regulatory inspection and enforcement activities shall cover all areas of regulatory responsibility."*

(2) **BASIS**: GS-R-1 para 5.18 requires that enforcement actions *"shall be commensurate with the seriousness of the non-compliance."*

R20 **Recommendation**: CNSNS shall develop a formal enforcement policy which includes sanctions commensurate with the safety significance.

S17 **Suggestion**: CNSNS should take actions to clarify the current interpretation of the Regulatory Law, which states that "all infringements" may be considered for enforcement; this would support enforcement actions being considered for a broader range of infractions.

6.3. INSPECTION OF APPLICATIONS OF IONIZING RADIATION AND RADIATION INSTALLATIONS

CNSNS carries out inspections of radiation facilities under its control.

The inspection programme covers all areas under CNSNS regulatory responsibility, but the review team did not find evidence that the inspection programme covers all facilities in accordance with frequency criteria established in the procedures.

Services and products suppliers for radiation facilities are authorized and subject to inspection as required. No evidence was reviewed on this subject, but at least the 27 transport licensees had not been inspected by the newly established Department of Inspection. It should to be noted that the new organization had only recently (2007) taken responsibility for carrying out inspections.

Inspectors of the Department of Inspection perform inspections according to the following written, but unapproved, unofficial procedures that include the legal requirements:

(1) PROCEDIMIENTO AI DPN-MED-1 VER.: 0, Inspections program (Programación de Diligencias). Medical area

(2) PROCEDIMIENTO AI DPN-MED-2 VER.: 0, Planning and general carrying out inspection (Planeación y Ejecución de Diligencias). Medical area

(3) PROCEDIMIENTO AI DPN-MED-3.1 VER.: 0, Carrying out of inspections to Cobalt Units (Ejecución de inspecciones a la práctica de Teleterapia con Co-60).

(4) PROCEDIMIENTO AI DPN-MED-3.2 VER.: 0, Carrying out of inspections to Remote Braquitherapy Units (Ejecución de inspecciones a la práctica de Braquiterapia Automática).

(5) PROCEDIMIENTO AI DPN-MED-4 VER.: 0, Inspections summary preparation (Elaboración de los Dictámenes de las Diligencias).

(6) PROCEDIMIENTO AI DPN-MED-5 VER.: 0, Sanctioning and its follow up (Solicitud de aplicación de sanciones y su seguimiento). Medical area

(7) PROCEDIMIENTO AI-DPN-IND-1 VER 0: Inspections program (Programación de Diligencias - Área de Aplicaciones Industriales)

(8) PROCEDIMIENTO AI-DPN-IND-2 VER 0: Planning and carrying out inspection for Industrial radiography, fixed and mobile (Planeación y Ejecución de Diligencias - Área de Aplicaciones Industriales - Radiografía Industrial Móvil y Fija).

(9) PROCEDIMIENTO AI-DPN-IND-3 VER 0: Planning and carrying out inspection for well logging (Planeación y Ejecución de Diligencias - Área de Aplicaciones Industriales - Registros Geofísicos de Pozos)

(10) PROCEDIMIENTO AI-DPN-IND-4 VER 0: Planning and carrying out inspection for irradiator pool type (Planeación y Ejecución de Diligencias - Área de Aplicaciones Industriales – Irradiadores Tipo Alberca)

(11) PROCEDIMIENTO AI-DPN-IND-5 VER 0: Planning and carrying out inspection for nuclear gauges (Planeación y Ejecución de Diligencias - Área de Aplicaciones Industriales - Medidores Industriales)

(12) PROCEDIMIENTO AI-DPN-IND-6 VER 0: Audit and inspection evaluation (Evaluación de la Auditoria e Inspección - Área de Aplicaciones Industriales)

(13) PROCEDIMIENTO AI-DPN-IND-7 VER 0: Evaluation of answer to audit. Or inspection Dictamen (Evaluación de la respuesta al dictamen de Auditoría o Inspección - Área de Aplicaciones Industriales)

CNSNS explained that the above procedures could not be formally approved until the new CNSNS structure is published in the official gazette. However, the review team was informed that the new structure had been approved by the Ministry of Finance.

According to the figures derived by the head of the inspection units responsible for industrial and medical practices, the staffing levels of the inspection force is adequate to fulfil their duties, at least in the short term. Figures including in procedure DPN-MED-1 VER.: 0 shows that the medical area has capability for 240 inspections by year, taking into account inspection frequency criteria and present inspector's workforce. They are committed to perform 240 inspections this year, but their projection is only for 214 inspections.

The legal framework in Mexico empowered CNSNS as the competent authority on quality control of therapy units, but in the inspection procedure it is established that it is not the responsibility of CNSNS to verify the output of equipment. CNSNS indicated that this standard designates both CNSNS and Ministry of Health as competent authorities for quality control of therapy units. There is a lack of adequate resources at CNSNS and probably a lack of staff under the Ministry of Health with the necessary qualifications to fulfil its responsibilities in this area. As a result, regulatory control of quality control of therapy units is not fully addressed.

According to the legal framework in Mexico, responsibility for regulating occupational exposure and public exposure involving the use of ionizing radiation generating devices for medical diagnosis is assigned to both the Ministry of Health and CNSNS. However, there is a lack of adequate resources at CNSNS and a lack of staff under the Ministry of Health with the necessary qualifications to regulate this practice. As a result, regulatory control of occupational exposure and public exposure for diagnostic radiology is not being addressed.

Relevant documents and instructions in use are thoroughly reviewed during inspection to verify compliance with the requirement.

During inspections CNSNS verifies that persons involved in operation of radiation facilities have been previously authorized and have been periodically trained.

Deficiencies and deviations identified during the inspections are communicated to the licensee after a period of ten days according to the procedures.

There are no processes to disseminate lessons learned.

Inspections to the following facilities were witnessed by reviewers of the IRRS team:

- November 27: Hospital Central Militar. The inspection was carried out by two teams to inspect a Cobalt Unit and a remote Brachytherapy Unit.
- November 28: Instituto Nacional de Enfermedades Respiratorias. Inspection of the Nuclear Medicine Department.
- November 30: IARI Ingenieros Asesores S.A. de C.V. Inspection of a gammagraphy facility.
- December 3: Sterigenics S. de R.L. de C.V. Inspection of a pool irradiator.

The observed inspections revealed that the inspectors, four for industrial applications and four for medical application, were well trained and applied the relevant unofficial procedures. Inspections assess both safety and security measures as required in RGSR, although there seems to have been limited training in the latter, but it is supposed that the Department of Security and Safeguards will take over this part of the inspections.

CNSNS is requested to establish an inspection programme. The 2007 programme takes into account the frequency established according to the risk and also to satisfy requirements from the Central Government to comply with the number of inspections goal. It is important to note that the number of inspections is the only indicator used by the Government to measure the performance of CNSNS and to not meet this goal could have negative impact on the budget of the whole CNSNS.

Inspections are programmed during the first half of the previous month and the monetary resources are delivered directly to each inspector.

Non-programmed inspections could be carried out with resources from the general budget of CNSNS.

The frequency of the inspection of radiation facilities is defined according to the category of the sources or practices established by CNSNS. The extent of the inspection is not affected by the category of the source or practice. Inspection frequency ranges from twice yearly to once every three years. The inspection frequency is not in accordance with the licensing frequency.

Due to the staffing shortages previously discussed, the implementation of the radiological source inspections has been significantly impacted. CNSNS still categorizes its sources under the "General Regulation of Radiological Security" which uses categories of "A", "B", and "C". Inspection frequencies for these categories are every 1, 3, and 5 years respectively for industrial sources and every 2, 3, and 5 years respectively for medical sources. The IRRS team requested data on completion of inspections for the highest risk sources (Category 1 according to the IAEA's categorization of radioactive sources). Of 254 medical licensees with Category 1 sources, only 19 (7.5%) were conducted in 2006, and through 11 months of 2007 an additional 74 were inspected (29.1%). These sources are to be inspected every 2 years, yet for the last 2-year period only approximately 37% of the inspections have been completed. Staff interviewed indicated that the prime reason for fewer medical inspections being completed in the recent years was the increased workload of authorizations in this area. It has to be noted that the organization was reformulated in this area and the new organization is in charge of inspection only in 2007.

Although almost all inspections are programmed in advance, most are carried out as unannounced inspections. The special case is to carry out an announced inspection.

CNSNS does not make use of external inspection agencies, experts or consultants.

Reactive inspections are initiated in response to an unexpected, unplanned or unusual situation or event at radiation facility.

Depending on the nature of the event, the response is conducted by the Department of Inspection or the Department of Evaluation.

There is no evidence that reactive inspections diminish the responsibility of the licensee to perform an immediate investigation of any such occurrence. Usually the same professionals that carry out inspections also respond to emergencies.

The inspection procedures establish the requirement to write a report (Acta) of the inspection describing the work accomplished. In these documents there is no identification of infractions or conclusions unless there was an inspector action to seal or for temporary or partial closure of installations. A copy duly signed by all the persons involved (including two witnesses) is handed to the licensee. Writing of this report takes a lot of time and represents a significant part of the inspection time (1/3 or more of the total time).

Outstanding findings are reported to the licensee after a period of 20 days.

The documents produced during the inspection are entered at the central file of the Division. Inspectors shall review the files of Department of Inspection and Department of Evaluation prior to an inspection to provide input to the check list to be used during the inspection.

Conclusions:

Inspection procedures have not been duly approved. There is inconsistency in procedures for the industrial and medical areas. Coordination is missing.

Oversight of quality control of therapy units is not completed. No verification of machine output has been performed.

The fact that occupational exposure and public exposure in diagnostic radiology practices is uncontrolled poses a potential risk to workers and the public.

Data provided indicated that a large percentage of high-risk medical inspections were not completed in the last two years. Additionally, many lower priority inspections have not been completed in a timely manner. In the radiological area, development of a comprehensive inspection plan with metrics established would enable CNSNS to monitor completion of the radiological inspection programme. Currently, inspections in this area are based more on available resources, and the governmental goal, than in the identification of the needed inspections or frequencies. Monthly tracking of inspections is accomplished on what "can" be accomplished with available resources versus what should be done by programme requirements.

The number of inspections is the unique indicator to measure CNSNS performance.

The time dedicated to write "Actas" is too long compared with the inspection itself.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 2.4(2) states *"Legislation shall be promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transport safety. This legislation…shall specify facilities, activities and materials that are included in the scope of the legislation and what is excluded from the requirements of any particular part of the legislation ."*

(2) **BASIS:** RS-G-1.5 para 3.26 states *"The Regulatory Authority should require that registrants and licensees establish a QA programme as a precondition for authorization…"*

(3) **BASIS:** RS-G-1.5 para 5.20 states *"As the development of a national protocol may not be feasible in many States, a well established and proven international or national programme may be followed…"*

R21 **Recommendation**: The Mexican Government shall clearly assign responsibility for regulatory oversight of quality control of therapy units, as well as occupational exposure and public exposure in diagnostic radiology practices. Adequate resources for its implementation shall be provided.

(1) **BASIS:** GS-R-1 para 5.14 states *"The regulatory body shall establish a planned and systematic inspection programme. The extent to which inspection is performed in the regulatory process will depend on the potential magnitude and nature of the hazard associated with the facility or activity."*

(2) **BASIS:** GS-G-1.5 para 3.53 states *"…The regulatory body's inspection programme should include as key elements: a system of prioritizing inspections based on a categorization system such as that established for sealed radioactive sources…"*

R22 **Recommendation:** A systematic and comprehensive inspection plan shall be developed to ensure that the minimum set of inspections is completed for radiological inspections (e.g. category 1 medical sources).

(1) **BASIS:** GS-R-1 para 5.17 states *"Regulatory inspectors shall be required to prepare reports of their inspection activities and findings, which shall be fed back into the regulatory process."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
S18 **Suggestion**: CNSNS should consider methods to reduce the time required to write inspection reports regarding radiation safety inspections.

6.4. ENFORCEMENT FOR APPLICATIONS OF IONIZING RADIATION AND RADIATION INSTALLATIONS

According to procedures, unresolved findings that are matter of sanctions are informed to the Department of Legal and International Affairs proposing sanctions. Proposed sanctions are defined according to the Manual for Applying Sanctions. This manual was reviewed by the legal unit, but has not been officially adopted or approved.

CNSNS has applied fines on three occasions against licensed radiation facilities over the past several years.

Ten days after the inspection, CNSNS sends a report (Dictamen) detailing the status on conformances and requesting corrective actions from the licensee and establishing deadlines for their correction.

According to the Nuclear Law, Articles 34 to 37, the enforcement actions could be:

- Retention, securing or seizure, or depositing of sources of ionizing radiation or equipment containing them,
- Orders to cancel or suspend the license of operation or individual licenses.
- Civil penalties (monetary fines).

The implementation of corrective/preventive actions is re-evaluated by the Department of Inspection but not through inspections.

A discussion with CNSNS staff state these actions are rarely used, for medical hospitals. However operations have been stopped for a period of time in industrial facilities.

The Dictamen specifies corrective actions to be taken by the licensee and establishes deadlines for correction of all situations regardless of its safety significance. For all violations (minor or major significance) CNSNS requires the operator to respond formally indicating corrective actions.

Inspectors are empowered to stop operations and to request the necessary actions from the licensee to restore an adequate level of safety. This power is documented in a letter that inspectors provide to the users at the beginning of the inspection.

In the event of continual, persistent or extremely serious non-compliance, or a significant release of radioactive material to the environment due to serious malfunctions or damage to a facility, CNSNS can take legal action to suspend or revoke the authorizations. Inspectors are empowered to stop operations and to request the necessary actions to restore an adequate level of safety.

Notification of enforcement actions to the licensee is requested in the procedures.

The nuclear law established the enforcement actions that inspectors may take during inspections. Inspectors are empowered to apply enforcement actions on the spot through a formal communication that the inspector handles to the users at the beginning of the inspection. Inspectors are required to transmit the information to headquarters as soon as possible.

Where on-the-spot enforcement authority is not granted to individual inspectors, procedures are in place to ensure that the transmission of information to CNSNS is suited to the urgency of the situation, so that the necessary actions are taken in a timely manner.

7. DEVELOPMENT OF REGULATIONS AND GUIDES

This section considers regulations and guides for Nuclear and Radiological Safety of nuclear and radiation facilities, using the requirements of GS-R-1, listed here, as the basis. The text references GS-R-1 as applicable.

At the present Mexican legal framework, the Nuclear Law Article 50 (XI) empowers:

CNSNS to "*Propose regulations and establish criteria for interpretation relative to nuclear and radiological safety…*" Article 26, second paragraph, of the Nuclear Law anticipates the provisions of implementing regulations by stating: "*Authorizations for the construction of such (nuclear and radioactive) installations shall be effective for a specified period, and their renewal, modification, suspension and cancellation shall be regulated by the provisions contained in the respective regulations.*"

Up to now, three regulations have been promoted by CNSNS, one Safe Transport of Radioactive Materials (Reglamento para el Transporte Seguro de Material Radiactivo) developed in relation to the general Regulations for Road Transport of Hazardous Material and Wastes (entered into force on 8 April 1993), one related to Nuclear Installations (Reglamento General de Instalaciones Nucleares) and another currently in force, the General Regulation for Radiological Safety (entered into force on 23 November 1988 and currently under an updating process to be harmonized according with the IAEA-BSS-115). The Safe Transport of Radioactive Materials, which was identified during the IRRT mission of 2001 at an advanced stage of review, remains as it was. The second regulation covering nuclear safety in Nuclear Installations has been under development within CNSNS for several years.

The issue of the regulations and standards developed and proposed by the regulatory body, is performed by the Ministry of Energy, and must be approved by the President of the Mexican Republic. After its publication in the official gazette it becomes mandatory and the requirements must be followed by all operators. Consequently, when issued, the regulations and NOMs provide a framework for more detailed conditions and requirements to be incorporated into the individual authorizations.

In addition to the development of regulations, CNSNS is active in the development and promulgation of mandatory Official Mexican Standards (Normas Oficiales Mexicanas, NOMs). Those NOMs are developed by a Consultant Committee and approved by the chairman of this Committee. For NOMs related to Nuclear and Radiological Safety the chair of this Committee is the General Director of CNSNS.

Up to now, CNSNS has not elaborated an explicit policy on the development of regulations and guides, although a programme has been established to complete the development of the Mexican nuclear regulatory pyramid through regulations and standards while maintaining consistency and links to existing regulatory codes and standards that are already being used. The CNSNS approach is to develop regulations linked to one or more Articles in the Nuclear Law, i.e. where the Article specifies the need for a regulation. CNSNS has developed performance rather than prescriptive regulations that specify which standards need to be met to fulfil the regulation.

The CNSNS' order of priority for the development of the regulations has been: 1) radiological safety, 2) transport safety, 3) physical security and 4) nuclear safety. This order of priority reflects CNSNS' judgement of the situation in Mexico, where the need to develop regulations for the large number of radiation facilities is considered, on balance, to be more urgent than the need to develop regulations for the NPP, where CNSNS has required that the licensee meet the US Code of Federal Regulations. IAEA standards, meanwhile, are not specifically included inside the Nuclear Safety Regulation.

Originally, the Nuclear Safety Regulation was drafted as a replication of the US Federal Codes but, following internal review, it was reworked as a performance based regulation drawing on, as its main reference for its structure and content, the IAEA Safety Standards Series. Standards form the next tier of documentation. Thirty NOMs have been developed and brought into force since 1996. Only one is related with selection, qualification and training requirements of the personnel of NPPs (Norma Oficial Mexicana NOM-034-nucl-2000), with the rest related to Radiological Safety. Those standards are being written to develop specific 'technical requirements' identified in the Regulations. As the General Regulation on Radiological Safety was the first regulation to come into force (1988), the Standards associated with that regulation have been the first to be developed and issued (from 1994 to 1999). The second regulation, Regulations for the Safe Transport of Radioactive Materials, has not yet entered into force due to the fact that the mentioned regulation is still awaiting final approval. While the Nuclear Safety Regulation has yet to be finalized, CNSNS has chosen, as a priority, the early development of a NOM to address the requirements for Selection, Qualification and Training of NPP Personnel.

A procedure has been written for the development of regulations (AC-CNS-05,"Elaboración de Reglamentos sobre Seguridad", version 3) to control their development within CNSNS. Also for the development of NOMs, a procedure has been written (AC-CNS-12, "Elaboración de anteproyectos de normas oficiales mexicanas", version 3).

The process of regulation development is complex, requiring a long consultation process. Essential steps are as follows:

1. The CNSNS working group develops a draft through consensus review across Divisions.
2. The draft is reviewed by the legal department of CNSNS.
3. It is submitted for endorsement to the Director General of CNSNS, who has the option to request further or iterative development.
4. Once endorsed by the Director General, it is issued for comment to the main stakeholders, i.e. Department of Energy; Ministries of Labour, Health, Environmental, Interior, Economy, Communications and Transport; plus Academic and Professional bodies involved in the nuclear industry and the National Standards Body.
5. CNSNS addresses comments and revises the draft.
6. The draft is reissued to the SENER for review within each of its Departments for both a technical and legal review and for comment.
7. CNSNS addresses comments and, once accepted, each Department in the Ministry needs to endorse the draft to allow its issue to the Legal Council of the President of the Mexican Republic for a further legal review.
8. Once accepted by the Legal Council, the regulation is published and comes into force.

For NOMs the process is similar, meanwhile it must be issued for comments as a pre-project. In this case the approval is done by the chairman of the Consultant Committee, and issued in the official gazette.

In both cases, during the development process of regulation and guides, CNSNS is required to publish the proposed document officially for comments, to send it to stakeholders asking for comments, and to publish it on the web page of the Federal Regulatory Improvement Commission for comments of the public in general. It is required to provide an answer to these comments individually.

The General Administrative Law requires an additional 'regulatory impact' review by the Federal Regulatory Improvement Commission. CNSNS provides its Regulatory Impact Evaluation Report to this Consultant Committee.

As required by the Federal Law on Metrology and Standardization (Ley Federal sobre Metrología y Normalización, published on 1/07/1992 and amended on 20/05/1997, article 51) NOMS must be reviewed periodically (each five years) to remain valid. When reviewed, the experience of its application is taken into account as necessary.

Recommendations from international bodies such as the International Commission on Radiological Protection, the International Commission on Radiation Units and Measurements and the International Atomic Energy Agency, are reviewed and incorporated in standards. According to the Federal Law on Metrology and Standardization (article 41) it is required that NOMs include concordance with international standards. The recommendations from the International Atomic Energy Agency are included inside the bibliography section of each NOM.

Conclusions: CNSNS has promoted the development of several regulations, Safe Transport of Radioactive Materials (Reglamento para el Transporte Seguro de Material Radiactivo), Nuclear Installations (Reglamento General de Instalaciones Nucleares) and the General Regulation for Radiological Safety (entered into force on 23 November 1988). Only one of them is currently in force, with the other two in different states of development (specifically the Safe Transport of Radioactive Materials remains under development during more than 12 years).

CNSNS is active in the issuing of mandatory Official Mexican Standards (Normas Oficiales Mexicanas, NOMs), associated with one regulation to develop and provide more detailed conditions. As required by the Federal Law on Metrology and Standardization (Ley Federal sobre Metrología y Normalización, 19/05/1999, article 51) NOMS must be reviewed periodically every five years, to remain valid. The time-scale to promulgate the regulations is not compatible with this five year period of review for NOMs and the needs of the regulatory body to implement the regulations and associated standards.

The General Administrative Law requires an additional 'regulatory impact' review by the Federal Regulatory Improvement Commission. CNSNS provides its Regulatory Impact Evaluation Report to this Consultant Committee.

The process of regulation development is complex and requires a long consultation, receiving comments from the main stakeholders, i.e. Ministries of Energy, Labour, Health, Environmental, Interior, Economy, Communications and Transport, plus Academic and Professional bodies involved in the nuclear industry and the National Standards Body. Each Department in the Ministry needs to endorse the draft to allow its issue to the Legal Council of the President of the Mexican Republic for a further legal review and final approval of the President of Mexican Republic.

The General Administrative Law requires an additional 'regulatory impact' review by the Federal Regulatory Improvement Commission. CNSNS provides its Regulatory Impact Evaluation Report under the development of NOMs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 5.25 states *"The system of regulation and guides shall be chosen so as to suit the legal system of the State, and the nature and extent of the facilities and activities to be regulated."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(2) **BASIS:** GS-R-1 para 5.26 states *"The main purpose of regulations is to establish requirements with which all operators must comply. Such regulations shall provide a framework for more detailed conditions and requirements to be incorporated into individual authorizations."*

R23 **Recommendation:** CNSNS shall pursue the development of the necessary nuclear regulation in order to complete the regulatory framework as a high priority activity. CNSNS shall also have one explicit policy to complete the regulatory framework.

(1) **BASIS:** GS-R-1 para 5.25 states in part: "*Where regulations are not issued by the regulatory body, the legislative and governmental mechanism shall ensure that such regulations are developed and approved in accordance with appropriate time-scales.*"

R24 **Recommendation:** CNSNS shall consider whether there is an alternative process that could be used to implement regulatory actions in a timely manner.

8. MANAGEMENT SYSTEM

Introduction

The requirement for a regulatory body to have a quality management system for its regulatory responsibilities and functions is given in GS-R-1, para 4.5. The detailed requirements for management systems for operators and service providers, as well as for regulatory bodies, are covered in IAEA Safety Standard, GS-R-3, "Management System for Facilities and Activities".

CNSNS has not established and implemented appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken.

Since 2001, it has been the intent of the Director General to develop a quality management system, but the organization has failed to integrate the different efforts done by different divisions at CNSNS. The approach to fulfil the necessity to have systematic work needs to be oriented under a common policy and strategy.

The Team was informed that although a work environment survey was performed at CNSNS, the results of this study are no longer applicable because it is very old (more than 10 years) and the conditions are not the same. A good management system considers the knowledge of the work environment as part of the quality management.

CNSNS has not established an integral Management System. The efforts in different divisions should be aligned with the goals of the Regulatory Body and under a common umbrella of policies, organizational methods and procedures.

The CNSNS senior management started to establish goals, strategies, plans and objectives that are consistent with the Quality Management Policies, but they are in an incipient phase. The plan should be reviewed by an independent group created inside CNSNS to ensure that implementation is regularly reviewed against the Regulatory Body's decisions and actions and to address deviations from plans when necessary.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 4.5 states *"The regulatory body shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken."*

(2) **BASIS**: GS-R-3 para 3.1 states *"Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of the management system and shall allocate adequate resources to carry out these activities."*

(3) **BASIS**: GS-R-3 para 3.4 states *"Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the management system."*

(4) **BASIS**: GS-R-3 para 3.**7** states *"Senior management shall develop the policies of the organization. The policies shall be appropriate to the activities and facilities of the organization."*

(5) **BASIS**: GS-R-3 para 3.12 states *"Senior management shall be ultimately responsible for the management system and shall ensure that it is established, implemented, assessed and continually improved."*

(6) **BASIS**: GS-R-3 para 2.1 *states "A management system shall be established, implemented, assessed and continually improved. It shall be aligned with the goals of the organization and shall contribute to their achievement. The main aim of the management system shall be to achieve and enhance safety by:*

- *Bringing together in a coherent manner all the requirements for managing the organization;*
- *Describing the planned and systematic actions necessary to provide adequate confidence that all these requirements are satisfied;*
- *Ensuring that health, environmental, security, quality and economic requirements are not considered separately from safety requirements, to help preclude their possible negative impact on safety."*

(7) **BASIS**: GS-R-3 para 2.10 states *"The documentation of the management system shall reflect:*

- *The characteristics of the organization and its activities;*
- *The complexities of processes and their interactions."*

(8) **BASIS**: GS-R-3 para 4.3 *states "Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained."*

(9) **BASIS**: GS-R-3 para 4.4 states *"Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the consequences for safety of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organization's objectives."*

(10) **BASIS**: GS-R-3 para 1.1 states *"This Safety Requirements publication defines the requirements for establishing, implementing, assessing and continually improving a management system. A management system designed to fulfil these requirements integrates safety, health, environmental, security, quality and economic elements. Safety is the fundamental principle upon which the management system is based. These requirements must be met to ensure the protection of people and the environment and they are governed by the objectives, concepts and principles of the environment and they are governed by the objectives, concepts and principles of the IAEA Safety Fundamentals publication."*

(11) **BASIS**: GS-R-3 para 1.6 states *"The requirements established in this publication may be used by organizations in the following ways:*

- *As the basis for the management systems of organizations directly responsible for operating facilities and activities and providing services, as described in para. 1.8;*
- *As the basis for the regulation of these facilities and activities by the*

regulatory body;

- *As the basis for the management systems of the relevant regulatory bodies;*
- *By the operator, to specify to a supplier, via contractual documentation, any specific requirements of this Safety Requirements publication that must be included in the supplier's management system for the supply and delivery of products."*

R25 **Recommendation:** CNSNS shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken. The CNSNS Management System shall be in compliance with GS-R-1 and GS-R-3 requirements.

S19 **Suggestion:** Consider the evaluation of a work environment survey as part of the self assessment and as a point to start the integration of a Management System, consistent and developed to integrate all CNSNS Divisions under a common objective toward quality.

9. EMERGENCY PREPAREDNESS

9.1. LEGAL BASIS AND RESPONSIBILITIES

The responsibilities of CNSNS are clearly defined in the Nuclear Law (Article 50).

This Article assigns the attribution to CNSNS for making recommendations and providing advisory assistance in regard to measures for nuclear and radiological safety and physical security, and for safeguards, as well as administrative measures, during anomalous conditions or emergencies at nuclear and radiation installations. In addition, this Article requires that, prior to the start-up of operations, CNSNS is to review, assess and authorize the plans that should be in place for dealing with anomalous or emergency conditions in nuclear and radiation facilities.

In particular, the General Regulations on Radiological Safety (RGSR) in Article 124 requests that prior to initiating operations, all radiation facilities must consider an Emergency Plan consistent with the guidelines contained in the National System for Civil Protection and based on a survey of the radiological consequences of accidents which could occur at the facility.

For LVNPP, Emergency Preparedness is formed by both an on-site emergency plan (PEI: Procedimiento Emergencia Interio) and an off-site emergency plan (PERE: Plan de Emergencia Radiologica Externa). The utility (CFE: Federal Commission of Electricity) has the responsibility for both developing and maintaining the on-site emergency plan. On the other hand, the responsibility for coordinating all civil emergency preparedness including the nuclear and radiological emergency is assigned to the Ministry of Interior by the National General Civil Protection Law. The Ministry of Interior organizes the External Radiological Emergency Plan Committee (COPERE) that consists of the eight relevant organizations including the Ministry of Interior, the Ministry of Energy, the Ministry of Transport and Communication, the Ministry of Defense, the Ministry of the Navy, the Ministry of Health, the State Government of Veracruz and the Preventive Federal Police and supporting organizations. The off-site emergency plan (PERE) is developed and maintained by all these relevant response organizations and approved by the Ministry of Interior. There is no national response plan for nuclear and radiological emergencies in Mexico, but the responsibilities of these relevant organizations are allocated in the PERE. CNSNS has no official position in COPERE, but the role of CNSNS is to review and assess both the on-site and off-site emergency plans.

For the radiation facilities, however, although the Article 124 of RGSR requests the applicant to have an emergency plan which is reviewed, assessed and approved by CNSNS, a national emergency response plan which allocates the responsibility of all relevant organizations does not exist for radiological emergencies for radiation facilities or radiation sources.

9.2. CAPABILITIES OF EMERGENCY RESPONSE ARRANGEMENT

CNSNS has the following three regulatory activities: to review and assess the nuclear and radiological emergency response plans, to conduct inspections to verify on-site applicability of the nuclear and radiological emergency response plans, and to perform partial and full-scale exercises to test the nuclear and radiological emergency response plans. At the same time, during the occurrence of an accident, the main responsibility of CNSNS is to advise the Federal Government in the decision-making process and to give support, if necessary, to the emergency response organizations. In order to meet this responsibility, CNSNS has developed both internal Nuclear and Radiological Contingency Plans and several related procedures.. CNSNS has an Emergency Contingency Center (CECO) that comprises three dedicated rooms, a direct phone line to the utility and relevant organizations, computers, analytical tools and dose simulation codes, and links with all the centres in which the activities are taken place during the emergency. There is a real-time display information system (SIIP) in the CECO from the LVNPP for use in source term estimates and dose

simulation codes. The emergency response plans and procedures are provided with both documents and electric files.

The number of CNSNS staff involved full-time in work on emergency preparedness is very limited. For emergencies at LVNPP, however, the Nuclear Response Organization in CNSNS is installed immediately after the notification on activation of the LVNPP Emergency Plan. This Nuclear Response Organization consists of the experts within CNSNS divided into four groups that provide emergency response duty rotation for two weeks at a time. The Executive Group is composed of the Director General and three Division Directors. This group is responsible for activating the emergency response plan. The Operative Group, which is composed of the reactor safety team, the protective actions team and on-site support team, is responsible for monitoring reactor status, assessing accident progression and source terms and dose to the public in order to monitor the actions taken by the utility according to the on-site emergency plan and advise on their appropriateness. Recently, the Radiological Response Organization has been organized to respond to radiological emergencies for industrial and medical applications.

The positions in the internal response organizations are based on the expert's professional discipline but there are no specific programmes for training the staff members for emergency preparedness. The internal exercise for the CNSNS Nuclear Response Organization is performed about once a year as well as individual and group exercises. However, CNSNS has no plans for partial or full-scale emergency exercises to demonstrate its responsibilities with the coordination of the relevant organizations, particularly the utility in LVNPP.

9.3. EMERGENCY EXERCISE PROGRAMME

CNSNS reviews and evaluates the on-site and off-site emergency plans for LVNPP, as well as the procedures to control and implement all the activities related to those plans. CNSNS has responsibilities for carrying out inspections and audits on the level of fulfilment of the preparations within each one of the organizations forming part of the Plan. CNSNS designs and performs partial off-site exercises with selected organizations involved several times per year, as well as full-scope exercises with all relevant organizations involved every two years. CNSNS assesses the performance of each one of the organizations involved. In 2007 CNSNS conducted the partial exercises for notification, accident assessment and dose estimates at the utility to review and assess its responsibilities.

In October 2006, a full scope exercise was conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for LVNPP were properly carried out. A total of 36 CNSNS staff participated in the exercise as the scenario development team, evaluators and controllers with eight national and local governmental organizations. The exercise lasted for about ten hours until the NPP got conditions under control. There are no indications that the exercise covered the action to be taken during both the emergency phase and the recovery phase.

At present there are discussions of radiation protection concepts for emergency exposure situations as well as the criteria for protective actions in the international organizations such as ICRP and IAEA. In the off-site emergency plan (PERE), the intervention criteria of protective actions such as sheltering, evacuation and stable iodine prophylaxis are adopted from the document of the US Environmental Protection Agency, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents (EPA 400-R-92-001, 1991)". For radiological emergencies, however, there are no written guidelines for protective action recommendations including intervention criteria for protective actions.

9.4. INTERNATIONAL ACTIVITIES

CNSNS is the official contact point under the terms of both the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or a Radiological Emergency. Under the agreement with IAEA, Mexico will host a large scale international nuclear emergency exercise, ConvEx-3 in 2008 to test the full operation of the emergency information exchange and assistance mechanisms among IAEA Member States, Parties to the Early Notification and Assistance Conventions and relevant international organizations. This exercise will be based on a national level exercise being conducted at LVNPP. In this exercise, the operation of notification of accident and assistance mechanisms with any neighbouring States will be tested through IAEA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 2.2 (8) states *"An effective system of governmental emergency response and intervention capabilities shall be established and emergency preparedness shall be ensured."*

(2) **BASIS**: GS-R-2 para 5.3 states *"All the operating organizations and local and national organizations involved in the performance of the functions specified in Section 4, or in support of their performance, shall document their own roles, functions, authorities and responsibilities in an emergency response and assent to the authorities, roles and responsibilities of other response organizations. Typically this is documented as part of the appropriate national and local emergency response plans. Conflicting roles and responsibilities shall be resolved as part of the planning process or by the national coordinating authority (see para. 3.4)."*

R26 **Recommendation**: CNSNS shall advise the Government to develop a national emergency plan for radiological emergencies for radiation facilities or radiation sources.

(1) **BASIS**: GS-R-1 para 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."*

(2) **BASIS**: GS-R-2 para 5.31 states *"The operator and the response organizations shall make arrangements for the selection of personnel and for training to ensure that the personnel have the requisite knowledge, skills, abilities, equipment, and procedures and other arrangements to perform their assigned response functions. The arrangements shall include ongoing refresher training on an appropriate schedule and arrangements for ensuring that personnel assigned to positions with responsibilities for emergency response undergo the specified training."*

R27 **Recommendation**: CNSNS shall ensure that all emergency response staff members receive emergency response training to perform their assigned response functions.

(1) **BASIS**: GS-R-1 para 6.5 states *"The arrangements of all parties shall be exercised on a periodic basis and shall, where appropriate, be witnessed by the regulatory body."*

(2) **BASIS**: GS-R-2 para 5.33 states *"Exercise programmes shall be conducted to ensure that all specified functions required to be performed for emergency response and all organizational interfaces for facilities in threat category I, II or III and the national level programmes for threat category IV or V are tested at suitable intervals. These programmes shall include the participation in some exercises of as many as possible of the organizations concerned. The exercises shall be systematically evaluated and some exercises shall be evaluated by the regulatory body. The programme shall be subject to review and updating in the light of experience gained (see paras 3.8, 3.16, 5.37 and 5.39 for further requirements in relation to exercises)."*

R28 **Recommendation**: CNSNS shall participate in emergency exercises for the internal Nuclear Response Organization including the participation of relevant organizations.

(1) **BASIS:** GS-R-1 para 6.3 states *"…These preparations shall include the actions to be taken both in and after an emergency."*

(2) **BASIS:** GS-R-2 para 4.99 states *"Arrangements shall be established for the transition from emergency phase operations to routine long term recovery operations. This process shall include: the definition of the roles and functions of organizations; methods of transferring information; methods of assessing radiological and non-radiological consequences; and methods of modifying the actions taken to mitigate the radiological and non-radiological consequences of the nuclear or radiological emergency."*

R29 **Recommendation**: CNSNS shall design a full-scale exercise that covers the action to be taken in both emergency and recovery phases.

(1) **BASIS**: GS-R-1 para 5.28 states *"In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback experience. Due account shall also be taken of internationally recognized standards and recommendations such as IAEA safety standards."*

(2) **BASIS**: BSS 115 para 3.14 states *"Optimized [national] intervention levels [for taking urgent protective actions]…shall be [established that are in accordance with international standards]…modified to take account of local and national conditions, such as..."*

(3) **BASIS**: GS-R-2, Paragraph 4.46 states *"National guidelines in accordance with international standards shall be adopted for the termination of urgent protective actions."*

S20 **Suggestion**: CNSNS should develop new national guidelines for protective action recommendations to include all radiological emergencies in accordance with IAEA standards.

10. RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING

10.1. NATIONAL WASTE MANAGEMENT POLICY AND STRATEGY

At present Mexico does not have a National Policy and Strategy on Radioactive Waste Management described or outlined in a legal document. However, the "Ley Reglamentaria del Artículo 27 Constitucional en Materia Nuclear", is in the process of being modified including to incorporate the legal support needed for the National Policy and Strategy to be presented to the Government. Under the IAEA Regional Project RLA 9/055, a draft proposal was suggested that could be the basis for the National Policy and Strategy on Radioactive Waste Management. In fact, the IAEA Safety Fundamentals (SF-1) are considered in the draft of the National Policy and Strategy. Mexico is still not part of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.

The General Rules on Radiological Safety (Reglamento General de Seguridad Radiológica) establishes in article 160(VIII) the responsibility for the operator to reduce the amount of radioactive waste generated during operations. In addition, in NOM-028-NUCL-1996 "Handling of radioactive waste in radioactive facilities that use open sources", requires that the operator establish a programme for the management of radioactive waste with the objective to minimize waste generation. NOM-008-NUCL-2003 "Control of the radioactive contamination" requires that during operations the operator should consider methods for reducing the generation of radioactive waste.

NOM-036-NUCL-2001, "Requirements for treatment facilities and conditioning of the radioactive waste", requires radioactive waste management facilities using open sources, to consider in their design, ways to minimize the generation of radioactive waste, including the radioactive waste generated during decommissioning.

NOM-018-NUCL-1995 standard "Methods to determine the activity concentration and total activity in the packages of radioactive waste" requires that generator of radioactive waste must provide information about the radioactive waste to the operator of the waste treatment and conditioning facility that will treat the waste. NOM-028-NUCL-1996 "Handling of radioactive waste in radioactive facilities that use open sources" established the conditions under which the waste generator will transfer waste to the waste treatment and condition operator. Finally, NOM-019-NUCL-1995 "Requirements for packages of radioactive waste of low level for disposal on near surface facilities", establishes the requirements for radioactive waste disposal packages.

During the authorization and licensing of a facility, the different stages of radioactive waste management are evaluated. License issuance and authorization will occur when it can be demonstrated that the facility complies with all the regulatory and safety requirements. During inspections and audits, verification of operator compliance with safety requirements and all license conditions will be determined.

The absence of a clearly defined National Policy and Strategy does not allow for clear allocation of responsibilities which is essential for ensuring safe radioactive waste management. There is a need for the establishment of a centralized organization that will oversee the management of radioactive waste at the national level.

Conclusion: At the Governmental level there is no established national policy on radioactive waste management and no corresponding strategies. There is not a clear allocation of responsibilities for the overall management of radioactive waste at the national level. There are neither sufficient resources, including human resources, nor adequate infrastructure in place for the management of radioactive waste.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 3.4 (4**)** states "*The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary:…(4) radioactive waste management (including determination of national policy)…"*

(2) **BASIS:** WS-R-2 para 3.5 states *"To facilitate effective and safe predisposal management of radioactive waste, the regulatory body shall ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations."*

(3) **BASIS:** WS-R-2 para 5.15 states *"All waste considered radioactive shall be collected. Decisions with respect to additional pretreatment (segregation, decontamination and chemical adjustment) shall be based upon appropriate consideration of the characteristics of the waste and of the requirements imposed by subsequent steps in the national programme of radioactive waste management (treatment, conditioning, transport, storage and disposal)."*

R30 **Recommendation:** The National Policy and Strategies on Radioactive Waste Management (including decommissioning) shall be developed and approved at the Governmental level in accordance with the IAEA Safety Standards.

(1) **BASIS**: WS-R-4 para 3.5 states "The government is required to provide an appropriate national legal and organizational framework within which a geological disposal facility can be sited, designed, constructed, operated and closed [17]. This shall include the definition of the steps in the facility's development and licensing, the clear allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions."

R31 **Recommendation**: Within the development of the National Policy for Radioactive Waste Management, the issue of high level waste (HLW) disposal shall be specifically addressed by the Government so that sound alternatives for final disposal of HLW are investigated and a long-term plan is developed and approved.

10.2. EXISTING LEGAL AND REGULATORY FRAMEWORK

The Nuclear Law, Article 18 para VII designates responsibility for radioactive waste disposal to the Secretary of Energy. The Secretary of Energy has delegated this responsibility to the Comisión Federal de Electricidad (CFE) (Nuclear Law, Article 18 para VIII) for the wastes generated by Laguna Verde NPP and to the ININ for all other wastes. Based on a 1999 CNSNS request to CFE, a fund was created to cover the decommissioning costs for Laguna Verde NPP. The resources are being collected and deposited in a bank account under the management of CFE. A monthly amount of 1.2 million US dollars per month is collected and deposited in the account. The fund is projected to reach 500 million US dollars by the year 2030, which is the expected operational life of the plant. However, there are no financial mechanism in place to guarantee adequate funds for the decommissioning and disposal of other major facilities such as ININ's waste treatment facility and its waste storage facility. Although ININ charges for collecting, treating and storing wastes from waste generators, the monies collected are diverted to cover the operational costs and not deposited in a dedicated account earmarked for decommissioning and disposal. This situation is contrary to

the *Polluter-Pays Principle*, since the monies collected from the waste generators to cover waste management costs are spent upfront, leaving the cost of long-term waste management to future generations.

The General Regulation on Radiation Safety (Articles 190 – 196) establishes the need for the Regulatory Body to authorize the import and export of radiation sources and to establish the specific conditions for the authorization. However, the regulatory regime for transboundary movements established in WS-R-2, DSR 353 and the Joint Convention is not considered by the provisions of this regulation.

The requirements for radioactive waste facilities are included in the General Regulation on Radiation Safety and other corresponding standards. Article 201 of the General Regulation on Radiation Safety, establishes the requirements for authorizing a storage facility for radioactive material and radioactive waste. Article 202 of the General Regulation, establishes the requirements for authorizing a disposal facility for radioactive material (radioactive waste also contemplated). Additional requirements are established through standards and their execution is verified by means of inspections.

Regulation NOM-036-NUCL-2001, *Requirements for Treatment and Conditioning Facilities of Radioactive Waste,* considers the different stages: siting, design, construction, operation and decommissioning.

Regulations NOM-022-NUCL-1996 1/2/3, *Requirements for a Low-level Waste Near-Surface Disposal Facility*, establishes the requirements for each stage of a low level radioactive waste disposal facility, including the siting, design, construction, operation, closure and institutional control.

Regulation NOM-020-NUCL-1995, *Requirements for Incineration Facilities of Radioactive Waste,* considers design, operation and decommissioning stages. It includes the development, operation, shutdown and decommissioning phases for radioactive waste management facilities. In addition many of the considerations are not in compliance with International Standards.

Article 147 of the General Regulation on Radiation Safety established the responsibility for radiation safety of any installation. In the particular case of radioactive waste treatment, storage and disposal facilities in Mexico, the Nuclear Law (Article 18) establishes that the Secretary of Energy is responsible for storage, transport and disposal of nuclear fuels and of non-nuclear radioactive waste (no matter its origin). The Secretary of Energy has delegated this responsibility (Nuclear Law, Article 18 para VIII) to CFE for waste generated by Laguna Verde NPP and to ININ for all other wastes.

The General Regulation for Radiation Safety (Article 223) includes enforcement provisions for decommissioning planning. Decommissioning issues are also discussed in more detail in the regulations for the specific installations (NOM-036-NUCL-2001, NOM-022-NUCL-1996, NOM-020-NUCL-1995). However, a complete regulatory framework for decommissioning is not in place.

The General Regulation for Radiation Safety (Article 223) has some provisions to enforce planning for decommissioning. Decommissioning issues are also treated in more details in the regulations for the specific installations (NOM-036-NUCL-2001, NOM-022-NUCL-1996, NOM-020-NUCL-1995). However, a complete regulatory framework for decommissioning is not in place. In particular there is no funding mechanism in place, except for LVNPP.

The Nuclear Law (Article 26) and the General Regulation for Radiation Safety (Article 221; Article 223) have some provisions for radioactive waste management and decommissioning, however a complete regulatory framework is not in place.

The Nuclear Law (Article 50) establishes the responsibilities of the regulatory body in a broad sense and covers part of the responsibilities necessary to implement a full regulatory framework.

The General Regulation for Radiation Safety (Article 148; Article 154) establishes the need and the responsibility for the licensee and the radiation protection supervisor for the installation to provide training to personnel who are occupationally exposed to radiation.

The General Regulation for Radiation Safety (Article 124; Article 125) establishes the need for and the development of an Emergency Plan for radioactive facilities, defining the objective and elements to be included.

The General Regulation for Radiation Safety (Article 220 and Article 221) establishes the need for and the development of a quality management programme for the application for a construction license and for the application for an operation license.

The Team was informed that presently there is no radioactive waste generation in the country without a license. All historical waste has already been transferred to CADER and is under the management of ININ.

Conclusions: The existing regulation on radiological protection is not totally consistent with the requirements established by the 'International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources' (Safety Series No. 115, 1996) concerning public exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 3.4 states *"The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary: (1) environmental protection; (2) public and occupational health…"*

(2) **BASIS**: SS 115 para 2.13 states *"Any legal person applying for an authorization shall…(c) make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source and take all necessary steps for the protection and safety of both workers and the public…"*

(3) **BASIS**: SS 115 para 2.26 states *"Except for medical exposure, the optimization of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints..."*

R32 **Recommendation**: CNSNS shall review the General Regulation on Radiation Safety to assure consistency with IAEA Safety Standards. Special attention shall be paid to the dose limits for public exposure and to the introduction and implementation of the optimization principle including the use of the dose constraints.

(1) **BASIS:** WS-R-2 para 3.6 states *"To protect human health and the environment, the regulatory body shall establish requirements and criteria pertaining to the safety of facilities, processes and operations for predisposal management of radioactive waste. These shall include requirements related to handling, transport and storage as well as known or likely requirements associated with the acceptance of waste packages for disposal."*

(2) **BASIS:** WS-R-2 para 3.7 states *"The regulatory body shall establish safety criteria for the decommissioning of nuclear facilities, including conditions on the end points of decommissioning."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

R33 **Recommendation**: In order to allow for the development of a complete regulatory framework for radioactive waste management, decommissioning and other safety areas, the Nuclear Law should be reviewed to provide formal empowerment of CNSNS as the national regulatory body for all safety issues in the nuclear field: radiation safety, nuclear safety, transport safety, physical protection and safeguards. In the review process of the Nuclear Law, radioactive waste management and decommissioning issues should be specifically addressed in order to provide the necessary enforcement or guidelines for the development of a national policy covering these fields.

10.3. RADIOACTIVE WASTE MANAGEMENT

General Safety Provisions for Radioactive Waste and Decommissioning

National dose limits for workers and the public prescribed in the General Regulation on Radiation Protection are based on ICRP 26 and are not harmonized with SS 115 standard. The review of the General Regulation for Radiation Protection already addresses the harmonization of dose with SS 115.

The concept of *dose constraint* is not established in the present version of the General Regulation of Radiation Protection. The concept is being introduced in the review of the document. For some practices the regulations in place already define a dose limit (dose constraint). Regulation NOM-022/1-NUCL-2001 establishes an annual dose limit of 0.25 mSv for the public for waste disposal facilities in the long term and NOM-036-NUCL also establishes an annual dose limit of 0.25 mSv for waste treatment and disposal facilities.

In the General Regulation for Radiation Protection, Article 7, Section II, requires "the design, planning use and application of radiation sources and practices should be carried out in such as way as to ensure that exposure will be kept as low as reasonably achievable, taking in to consideration social and economic factors". Additionally, in the standards developed for radioactive waste disposal in near surface facilities (NOM-022/1-NUCL-2001) it is required that the optimization principle be observed. However, the effective verification of compliance with these requirements is made only conceptually.

Regulations NOM-020-NUCL-1995 (Requirements for Waste Incineration Facilities), NOM-028-NUCL-1996 (Radioactive Waste Management in Radioactive Installations that use Open Sources) and NOM-036-NUCL-2001 (Requirements for Waste Treatment and Conditioning Facilities) provide recommendations for minimization of waste generation. However, a general regulation is missing.

In the Mexican regulation, the potential effects of the management of radioactive waste beyond national borders are not explicitly taken into account. However, there is an agreement in force with the US which establishes that siting of any installation using dangerous agents of any kind within 70 km from the border requires notification to the other country.

There is no provision in the Mexican regulations to specifically address the impacts to the environment for radioactive installations. Regulation NOM-022-NUCL-2001 (Requirements for a Low and Intermediate Level Radioactive Waste Disposal Facility) requires the development of an environmental impact assessment and the implementation of an environmental monitoring programme. However, this regulation does not apply to non-nuclear facilities. In the case of LVNPP, however, 10 CFR regulations are used and require an environmental impact assessment of the installation.

In general, there are no provisions in the regulations that require the operator to consider the final destination of the waste generated. In regulation NOM-028-NUCL-1996 there are some considerations in this regard. In regulation NOM-035-NUCL-2000, some requirements for clearance are established and are based on IAEA TECDOC 855.

The General Regulation for Radiation Protection has some guidance on the transport of radioactive material. However, in the General Regulation, the responsibility for transportation is not clearly attributed to the operator. As a consequence, there is no regulation in the country that complies with TS-R-1. TS-R-1 enforcement is accomplished through the regulatory and licensing processes by different divisions of CNSNS, but there is no official regulation specific to the enforcement of TS-R-1.

Since the waste management facilities are considered radioactive installations within the Mexican regulatory framework, the regulation for protection of workers is provided by the General Regulation and the NOM-028-NUCL-1996 regulation. Radiation protection criteria for workers are established within the General Regulation and requirements for the installations, classification of areas, personnel training, use of protective equipment and others are provided within NOM-028-NUCL-1996.

Basic regulation is provided by the General Regulation of Radiation Protection and NOM-028-NUCL-1996.

The waste classification scheme in the country is established by regulation NOM-004-NUCL-1994 (Classification of Radioactive Waste). Wastes are classified based on US low-level, intermediate-level, high-level, mixed waste and uranium tailing standards. Regulation NM-028-NUCL-1996 provides the classification of waste from the point of view of operation and segregation.

Basic guidance (NOM-018-NUCL-1995 and NOM-019-NUCL-1995) covers waste acceptance criteria for types, characteristics and form to be accepted by the treatment plant (PATRADER) from the operator and also covers the waste acceptance criteria for the storage facility (CADER) from PATRADER, but these standards do not completely address all elements of a comprehensive predisposal requirements system.

There are no specific regulations which outline notification requirements for inventory reporting. However ININ sends the Division of Relevant Facilities an updated inventory of CADER every year and LVNPP sends an updated inventory to the Division on Nuclear Safety every three months. Nuclear Safety Division forwards the waste inventory of LVNPP to the Division of Relevant Facilities. The only inventory that is not controlled is the one within the radioactive installations.

There is no provision or regulations in the country covering decommissioning issues. However, with regard to radiation protection the general provisions established in the General Regulation of Radiation Protection have to be observed.

Since the concept of *Safety Culture* is not addressed in the Mexican regulatory framework, to date, there is no regulation or regulatory procedure covering the concept and therefore it is not being applied to address decommissioning issues. In the draft of the new General Regulation on Radiation Safety this concept is already addressed.

The concept of waste minimization is already considered in the basic Mexican regulations (NOM-028-NUCL-1996). The concept of optimization is not yet in place, although the principle of optimization is considered in the General Regulations on Radiation Safety. The new (draft) version of General Regulation on Radiation Safety already considers the concept of optimization. There is no regulation in place addressing either of these concepts for decommissioning activities.

Regulation NOM-018-NUCL-1995 provides general guidance for the characterization of waste packages and regulation NOM-019-NUCL-1995 establishes requirements for waste packages (waste acceptance criteria for disposal in a near-surface disposal facility).

The current regulations do not ensure that facilities for predisposal management or disposal of radioactive waste, as applicable, are developed in a series of steps. This concept is clearly addressed only in standard NOM-022-NUCL-1996 (1/2/3), which comprises a series of three regulations establishing the different steps for the implementation of a low-level near-surface disposal facility (siting / design / construction / operation / closure / post-closure / institutional control).

Safety assessment requirements are only established for final disposal of radioactive waste (NOM-022-NUCL-1996). In this regulation, provisions are also made for a Quality Assurance programme to support the documentation and the records. Some provisions in this regard are also considered in the General Regulation (Articles 219, 220, 221, 223).

There is basic guidance on the development of a safety case in the present regulations (NOM-022-NUCL-1996), but there is no specific regulation to provide guidance on the development of the safety case according to present IAEA standards.

The General Regulation for Radiation Safety (Article 148; Article 154) establishes the need and responsibility for the licensee and the radiation protection supervisor of the installation to provide training for personnel occupationally exposed to radiation.

The General Regulation for Radiation Safety (Article 124; Article 125) establishes the need for the development of an Emergency Plan for radioactive facilities and defines the objective and elements to be included.

The General Regulation for Radiation Safety (Article 220; Article 221) establishes the need for the development of a quality management programme for the application for a construction license and for the application for an operation license.

Conclusion: The regulatory framework in place addresses the general safety provisions for radioactive waste management. However, it could be improved through the consideration of interdependencies among the different phases and the implementation of more recent safety concepts, such as the development of a safety assessment and safety cases and the explicit adoption of a safety culture. For decommissioning, however, the regulatory framework is almost non-existing and needs to be developed from its most basic guidelines.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** WS-R-2 para 2.6 states *"In addition to provision for protection against the normal exposures referred to in the preceding paragraphs, provisions shall be made for protection against potential exposures. A potential exposure is one that is not expected to be delivered with certainty but that may result from an incident or an accident. Requirements for protection against potential exposures are established in the BSS. They include managerial and technical measures to prevent the occurrence of incidents or accidents and provisions for mitigating their consequences should they occur."*

R34 **Recommendation**: CNSNS shall review the General Regulation for Radiation Safety in order to harmonize it with the safety requirements and dose limits for potential exposures as prescribed in the IAEA Safety Standards.

(1) **BASIS:** (1) WS-R-2 para 2.8 states *"A 'safety culture' shall be fostered and maintained in both the operating organization and the regulatory body in order to*

encourage a questioning and learning attitude to protection and safety and to discourage complacency. Such a culture is particularly important for decommissioning activities in which new radiological and non-radiological hazards may arise, for example, owing to the removal of safety systems and barriers. This includes the regular audit and review of performance."

R35 **Recommendation**: CNSNS shall review the General Regulation for Radiation Protection in order to clearly introduce the concept of safety culture as part of the national regulatory framework for radioactive waste management and decommissioning.

(1) **BASIS:** (1) GS-R-1 para 2.6 states *"The regulatory body shall have the authority: (3) to require any operator to conduct a safety assessment ...";* (2) WS-R-2 para 7.1 states *"In compliance with Principle 9 on the safety of facilities, the safety of operations involving radioactive waste and the decommissioning of nuclear facilities shall be ensured by means of safety assessment and quality assurance. Safety and environmental impact assessments before commissioning shall be performed to demonstrate that the facilities and operation will be adequately safe. A quality assurance programme shall be conducted to provide the necessary confidence throughout all stages of design, construction and operation that all relevant requirements and criteria are met."*

R36 **Recommendation**: CNSNS shall review the existing regulations and standards applying to each step in predisposal management of radioactive waste. The regulations and standards shall require the elaboration on safety cases and the appropriate safety assessments to support authorization requests and to serve as a basis for decision making.

(1) **BASIS**: WR-S-2 para 7.4 states "The extent and detail of the safety and environmental impact assessments shall be commensurate with the complexity and the hazard associated with the facility or operation."

R37 **Recommendation**: CNSNS shall review and introduce the concept of radiological impact assessment in all present and future regulations related to all phases of the predisposal management of radioactive waste.

(1) **BASIS**: (1) WS-R-2 para 3.5 states "To facilitate effective and safe predisposal management of radioactive waste, the regulatory body shall ensure that an appropriate waste classification scheme is established in accordance with national programmes and requirements and international recommendations."

S21 **Suggestion**: CNSNS should review the radioactive waste classification system for consistency with the IAEA Safety Standards to enable harmonization with international practices for disposal.

Clearance Regime for Radioactive Waste

CNSNS established the limits and criteria for clearance and exemption in both standards NOM-035-NUCL-2000 "Limits to consider a solid residue as radioactive waste" and NOM-039-NUCL-2003 "Specifications for the exemption of ionizing radiation sources and practices that use them". In the

standard NOM-035-NUCL-2000 solid radioactive waste is defined as materials which contain radioactivity which is higher than is established in this standard values for unconditioned clearance.

The Team was informed that the clearance levels reflected in Appendix A Table 1 of the NOM-035-NUCL-2000 were taken from the IAEA-TECDOC-855. It is necessary to point out that from this document it is not clear from where the values were taken, or what the bases for its calculations were. In addition the NOM-035-NUCL-2000 does not explain for which values of materials the clearance levels for unconditioned release are applicable.

A contradiction was found between two standards on the definition for radioactive waste. In the standard NOM-028-NUCL-1996 radioactive waste is any material which radioactive concentration or its measurement at the surface is higher than the environmental background. At the same time the NOM-035-NUCL-2000 establishes that radioactive waste could be any radioactive material for which no use is foreseen and the activity concentration is higher than the established clearance levels.

In the peer review of the authorization process and the inspection or monitoring of compliance with the established in the standard NOM-035NUCL-2000 clearance levels, it was noticed that the person charged with the authorization process for licensees with open sources did not know about the existence of "Direction for Evaluation and Licensing" and the need to apply standard NOM-035 NUCL-2000.

In the case of conditional clearance, the clearance levels shall be authorized on a case by case basis (NOM-035-NUCL-2000). The authorization will address compliance verification to ensure compliance with the approved clearance values. In the case of compliance for unconditional clearance, CNSNS stated that compliance should be verified through inspections. In NOM-028-NUCL-1996, provisions are established to verify compliance. Nevertheless in practice, compliance with the requirements for clearance is controlled only in the recently authorized practices.

There is no specific procedure established for the authorization of any request for clearance of radioactive materials. The clearance in the case of unconditioned clearance is authorized in the frame of the authorization process. Nevertheless in the presented evidences on this matter there was no limit, condition or control established for the licensee. Moreover CNSNS is not using the two year license renewal process to apply and enforce the new standards on clearance (NOM-035-NUCL-2000) to the licensees.

The standard NOM-28-NUCL 1996 in paras 5.5 and 6.1.5.6 requires that in case of radioactive materials with other dangerous components, they should be managed and cleared according to the regulations that applied to dangerous non-radioactive components. That might imply the authorization of this practice by the corresponding authority.

Conclusions: The limits and conditions for the removal from control of radioactive materials are established in the standards NOM-28-NUCL-1996 and NOM-035-NUCL-2000. These two standards complement each other but at the same time they are contradictory with relation to the definition of clearance and radioactive waste. Both standards are not fully in agreement with IAEA Safety Standards. In addition, the implementation of these standards is not fully controlled and enforced by CNSNS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** SS 115 para 2.19 states *"Sources, including substances, materials and objects, within notified or authorized practices may be released from further requirements of the Standards subject to complying with clearance levels approved by the Regulatory Authority."*

(2) **BASIS:** WS-R-2 para 3.8 states *"The regulatory body shall establish limits and conditions for the removal of controls from materials containing radionuclides. It shall provide guidance for the authorized use of materials and for the authorized discharge of liquids and gases containing radionuclides. The regulatory body shall also consider establishing criteria for the clearance of materials. Such limits, conditions and criteria shall ensure the protection of human health and the environment and shall take account of international recommendations."*

(3) **BASIS:** RS-G-1.7 para 2.13 states *"Clearance is defined as the removal of radioactive materials or radioactive objects within authorized practices from any further regulatory control by the regulatory body."*

(4) **BASIS:** RS-G-1.7 para 4.1 states *"This section provides the values of activity concentration that may be used, with account taken of a graded approach (see paras. 5.11–5.13), for exclusion, exemption and clearance pertaining to exposures from radionuclides of natural origin and bulk amounts of material containing radionuclides of artificial origin. The details of the calculations that yielded these values are provided in a Safety Report."*

R38 **Recommendation:** CNSNS shall review, update and harmonize criteria and clearance values established in both standards NOM-035-NUCL-2000 "Limits to consider a solid residue as radioactive waste" and NOM-028-NUCL-1996 "Radioactive waste management in radioactive facilities using open sources" in accordance with IAEA Safety Standards. The new standards shall explain in detail the rationale (e.g. scenarios, volumes, etc.) behind the established clearance levels.

(1) **BASIS:** GS-R-1 para 3.3 states *"In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body: (1) shall establish a process for dealing with applications, such as applications for the issuing of an authorization, accepting a notification or the granting of an exemption, or for removal from regulatory control..."*

(2) **BASIS:** RS-G-1.7 para 5.2 states *"If the activity concentration of the radionuclide exceeds the value of activity concentration given in Table 1, the regulatory body should decide on the extent to which the regulatory requirements set out in the BSS [1] should be applied. A graded approach as described in paras 5.11–5.13 may be applied".*

R39 **Recommendation:** CNSNS shall establish clear and unambiguous procedures on how users shall specify their intent regarding clearance of radioactive materials and methods to deal with conditioned and unconditioned clearance and on how CNSNS will manage the associated authorization, control and records.

Control of Discharges

The NOM-006-NUCL-1994 "Criteria for the implementation of annual limits of incorporation for critical groups of the public", published on 20 February 1996, establishes the concentration limits for discharges to air, adjacent bodies of water and sewer systems that should be applied for an operation license. These limits were calculated considering that the critical group will receive a dose equivalent of 1 mSv per year. The licensee must demonstrate in its safety report that it has systems

in place to demonstrate the compliance with the limits established in the standard. The limits of the standard are based on 10 CFR 20. In Mexican regulation the concept of dose constraints is not yet addressed, however the review Team was informed that this will be considered in the new version of the regulation, currently under revision. There are not regulatory forecasts to ensure the application of the optimization principle with respect to effluents discharges.

In the Regulatory Law of Article 27 of the Constitution on Nuclear Matters published on 4 February 1985, Article 50.III assigns to CNSNS the power to review, assess and authorize the basis for the discharge of radioactive materials. Article 211 of the General Regulation of Radiation Safety, published on 22 November 1988, establishes the requirements for discharge of radioactive liquids into the sewer system, requiring them to be soluble and water dispersible, and establish that the maximum activity allowed to be discharged is limited to 1 Ci per year. It must be noted that there is not evidence or reference of the rationale behind the establishment of this value. Article 206 states that the process for the discharge authorization of low and intermediate level radioactive wastes is established in Articles 210-212. In Article 212, guidelines are given to allow discharges that exceed the limits provided they are justified.

It should be noted that all the mentioned regulation and standards were developed before the publication of the IAEA SS 115. Currently, the Regulatory Law of Article 27 of the Constitution on Nuclear Matters and the General Regulation for Radiation Safety are under review. In this process, the recently published IAEA Safety Standards are been considered.

CNSNS exercises its functions in the control of radioactive discharges through establishing regulations such as NOM-006-NUCL-1994 and NOM-028-NUCL-1996. Articles 219, 220 and 221 of the General Regulation on Radiation Safety describe the requirements for obtaining authorization for operation, shutdown and decommissioning. Articles 210-212 of the same regulation establish the requirements for authorization of radioactive discharges to the environment that are complemented by corresponding technical standards.

CNSNS carries out inspection programmes on radioactive effluents (discharges) for the more important facilities such as the NPP, CADER waste treatment facility and the ININ facility. CNSNS also carries out inspection of radioactive facilities which are capable of discharging uncontained radioactive material to the environment, such as nuclear medicine or research activities. It should be noted that as for the case of clearance, the evaluation of the effectiveness of radiation protection measures for each authorized discharge together with the potential impact assessment of this discharge on humans and the environment is performed in a formal way.

Due to the location of the main nuclear facilities in the Mexican Territory it is almost impossible for discharges of radioactive substances to the environment to cause exposure to members of the public in another country. There are no regulatory forecasts to ensure the application of the optimization principle with regard to effluents discharges according the requirements of SS 115. In the regulation there are neither criteria nor consideration for the assessment of the impact of discharges beyond national borders.

In Article 119 of the General Regulation on Radiation Safety the installation of detectors to determine the effluent radioactivity concentration and suspended radioactive material in the air is required. In addition NOM-036-NUCL-2001 requires the design of facilities for treatment and conditioning of radioactive wastes to include a system for the monitoring of liquid and gaseous effluents in order to verify and control the activity concentration in the discharges in compliance with the NOM-006-NUCL-1994.

The General Regulation of Radiation Safety, published on 22 November 1988, Article 148 (XIII) requires the licensees to maintain records of the discharge of radioactive waste. In addition NOM-028-NUCL-1996 “Handling of Radioactive Wastes of Radioactive Facilities that Works with Open Radioactive Sources” requires the licensees to record the releases or discharges to the sewer system.

In the current regulation there is no requirement to report monitoring results to CNSNS: to report any significant increase in contamination that could be attributed to the radiation from radioactive discharges emitted by sources under the responsibility of the licensee. Nor are there requirements to ensure that corrective measures are undertaken in cases of unplanned or uncontrolled releases or to verify the adequacy of the assumptions made for the prior assessment of radiological consequences of the discharges.

Conclusions: Criteria for discharges are defined but they are not in compliance with IAEA Safety Standards. The discharges are authorized as part of the authorization process. For the main nuclear and radioactive waste management facilities the process of authorization and control is well established and there are required appropriate monitoring systems for the control of the releases and corrective measures are requested if needed. In the case of radioactive facilities, the authorization is rather formal and the control of the discharges is done mainly through the inspections by CNSNS due to the absence in licensee's facilities of adequate equipment for controlling the discharges. There are no regulatory forecasts to ensure the application of the optimization principle with respect to effluents discharges.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** SS 115 para 2.5. (a) states *"...public exposure delivered by effluent discharges or the disposal of radioactive waste arising from a practice involving natural sources shall be subject to the requirements for practices given here, unless the exposure is excluded or the practice or the source is exempted."*

(2) **BASIS:** WS-R-2 para 3.8 states *"The regulatory body shall establish limits and conditions for the removal of controls from materials containing radionuclides. It shall provide guidance for the authorized use of materials and for the authorized discharge of liquids and gases containing radionuclides. The regulatory body shall also consider establishing criteria for the clearance of materials. Such limits, conditions and criteria shall ensure the protection of human health and the environment and shall take account of international recommendations."*

R40 **Recommendation:** CNSNS shall review the regulations and standards in force for the assessment, authorization and control of radioactive discharges for the different type of facilities for consistency with IAEA Safety Standards. New regulations and standards shall be developed as necessary.

(1) **BASIS:** SS 115 para III.9. states *"Registrants and licensees shall ensure that radioactive substances from authorized practices and sources not be discharged to the environment unless: (a) the discharge is within the discharge limits authorized by the Regulatory Authority; (b) the discharges are controlled; (c) the public exposures committed by the discharges are limited as specified in Schedule II..."*

(2) **BASIS:** WS-R-2 para 3.8. *"The regulatory body shall establish limits and conditions for the removal of controls from materials containing radionuclides. It shall provide guidance for the authorized use of materials and for the authorized discharge of liquids and gases containing radionuclides."*

R41 **Recommendation:** The public exposure potentially resulting from radioactive discharges shall be limited and conditioned in accordance with IAEA Safety Standards.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** SS 116 para 111.3. states *"Registrants and licensees shall be responsible for ensuring that the optimization process for measures to control the discharge of radioactive substances from a source to the environment is subject to dose constraints established or approved by the Regulatory Authority, taking into account, as appropriate: (a) dose contributions from other sources and practices, including realistically assessed possible future sources and practices; (b) potential changes in any condition that could affect public exposure, such as changes in the characteristics and operation of the source, changes in exposure pathways, changes in the habits or distribution of the population, modification of critical groups, or changes in environmental dispersion conditions; (c) current good practice in the operation of similar sources or practices; and (d) any uncertainties in the assessment of exposures, especially in potential contributions to the exposures if the source and the critical group are separated in distance or time."*

(2) **BASIS:** WS-G-2.3 para 3.15 states *"The regulatory body is responsible for specifying the value of dose constraints, although registrants or licensees may additionally specify them in their internal rules. In any case, those who establish constraints should clearly describe the relevant source, and the magnitude of the constraint selected should be appropriate to the purpose in hand."*

R42 **Recommendation:** CNSNS shall consider the optimization principle for application in the review process of the regulation and standards to the discharge authorization and control and to establish dose constraints. All the criteria, scenarios, and conditions to be applied to the discharge regulation, evaluation, optimization and control shall be properly registered and recorded.

(1) **BASIS:** SS 115 para III. 10 states *"Registrants and licensees, before initiating the discharge to the environment of any solid, liquid or gaseous radioactive substance from sources under their responsibility, shall, as appropriate: (a) determine the characteristics and activity of the material to be discharged, and the potential points and methods of discharge; (b) determine by an appropriate pre-operational study all significant exposure pathways by which discharged radionuclides can deliver public exposure; (c) assess the doses to the critical groups due to the planned discharges; and (d) submit this information to the Regulatory Authority as an input to the establishment of authorized discharge limits and conditions for their implementation."*

R43 **Recommendation:** CNSNS shall develop and implement procedures for the request, review, assessment, authorization and control of radioactive discharges as part of the authorization process of practices and installations.

Predisposal Management of Radioactive Waste

The concept of predisposal is not established within Mexican regulations, although there are specific regulations for treatment, conditioning and disposal of radioactive waste and these regulations provide basic requirements to integrate the different steps in predisposal management. As to the transport of radioactive materials, there is no specific regulation covering the field and the IAEA regulation TS-R-1 is not officially enforced in the country.

Different regulations establish requirements for each step of radioactive waste management in order to provide for the interdependencies between the different phases. Regulations NOM-028-NUCL-1996 (Management of Radioactive Waste in Facilities that Use Open Sources); NOM-019-NUCL-1995 (Waste Acceptance Criteria for Disposal in a Near-surface Disposal Facility); NOM-018-NUCL-1995 (Methods for Determining of Activity Concentration and Total Concentration in Radioactive Waste Packages); NOM-022-NUCL-1996 (1/2/3). Basic requirements are also established to cover decommissioning issues.

There is no specific regulation for transport of radioactive material in the country. The IAEA regulation TS-R-1 is enforced by the different divisions of CNSNS. Regulation NOM-036-NUCL-2001 (Requirements for Radioactive Waste Treatment and Conditioning Installations) establishes the safety requirements for an installation that treats and conditions radioactive wastes.

Regulation NOM-036-NUCL-2001 contains general requirements on the design of waste treatment installations in which provisions are made in order to contribute to the safety of the installation during operation and decommissioning. These requirements cover a broad range of situations including requirements for siting of a waste treatment and conditioning installation, radiation protection requirements, consideration of natural events (seismicity, tornados, flooding) and also man-induced events.

In Mexico there are specific requirements for waste treatment, conditioning and disposal and these requirements have provisions to account for interdependencies within the steps. However, there is no regulation to cover waste storage, which characterizes a breach in the predisposal regulation as to the interdependencies between the different steps.

The country has a basic set of regulations covering most of the steps of radioactive waste management. CNSNS enforces its regulations through inspections, requirements and licenses.

The country regulations do not contemplate explicitly disposal considerations in the different steps of radioactive waste management.

Criteria for waste characterization are established through two regulations: NOM-018-NUCL-1995 (Methods for Determining Activity Concentration and Total Concentration in Radioactive Waste Packages) and NOM-019-NUCL-1995 (Waste Acceptance Criteria for Disposal in a Near-surface Disposal Facility). A new version of regulation NOM-028-NUCL-2003 establishes acceptance criteria for treatment and conditioning installations.

Acceptance criteria for treatment installations are provided in regulation NOM-028-NUCL-2003 (to be approved) and acceptance criteria for near-surface disposal facilities are established in regulation NOM-019-NUCL-1995.

Acceptance criteria for near-surface disposal facilities are established in regulation NOM-019-NUCL-1995.

Environmental impact assessments are required only for disposal facilities. Requirements are established in regulation NOM-022-NUCL-1996 (1/2/3) and are part of the licensing process.

Acco

The following regulations cover radioactive waste management issues and are part of the licensing and inspections process: NOM-028-NUCL-1996 (Radioactive Waste Management in Installations that Use Open Sources); NOM-036-NUCL-2001 (Requirements for Radioactive Waste Treatment and Conditioning Installations) and NOM-020-NUCL-1995 (Waste Acceptance Criteria for Disposal in a Near-surface Disposal Facility).

Most of these safety issues are covered in regulation NOM-036-NUCL-2001 (Requirements for Radioactive Waste Treatment and Conditioning Installations) and are enforced through the licensing process and through inspections.

Basic safety requirements are established in the regulations, and enforced through the licensing process and through inspections, but no specific measures are taken to address accidents or incidents.

Basic safety requirements for the waste package are established in regulation NOM-019-NUCL-1995 (Waste Acceptance Criteria for Disposal in a Near-surface Disposal Facility). Transport regulation is performed through compliance with IAEA TS-R-1.

Spent fuel from LVNPP is not considered radioactive waste. Spent fuel from LVNPP is stored in pools inside the reactor building with adequate features to avoid criticality and with forced convection cooling systems. All those security items have been approved in the Final Safety Analysis Report for the installation and are part of the licensing bases.

There are no regulatory provisions for ensuring that adequate financial resources are available to support the waste treatment facilities. Operating these facilities is dependent on a yearly budget by the government.

Staff, qualifications and training

The General Regulation for Radiation Safety (Article 148; Article 154) establishes the need and the responsibility of the licensee and the radiation protection supervisor for the installation for training of personnel occupationally exposed to radiation.

Emergency preparedness

The General Regulation for Radiation Safety (Article 124; Article 125) establishes the need for the development of an Emergency Plan for radioactive facilities and defines the objective and elements to be included.

Quality Management

The General Regulation for Radiation Safety (Article 220; Article 221) establishes the need for the development of a quality management programme for the application for a construction license and for the application for an operation license.

Conclusions: The integrated concept of predisposal management is not established in the Mexican regulatory framework. However, some of the components of the regulatory framework are already in place, such as the basic regulations for waste treatment, conditioning and disposal. Currently, the regulatory framework does not fully take into account the interdependencies between the different steps.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** WS-R-2 para 4.1 states *"Interdependences among all steps in the generation and management of radioactive waste shall be appropriately taken into account (Principle 8, Ref. [1]).Owing to the existing interdependences among the various steps in radioactive waste management, all activities from the generation of the waste to its disposal shall be seen as parts of a larger entity, and each component shall be selected so as to be compatible with the others."*

(2) **BASIS:** WR-S-2 para 5.15 states *"All waste considered radioactive shall be collected. Decisions with respect to additional pretreatment (segregation, decontamination and chemical adjustment) shall be based upon appropriate*

consideration of the characteristics of the waste and of the requirements imposed by subsequent steps in the national programme of radioactive waste management (treatment, conditioning, transport, storage and disposal).”

R44 **Recommendation**: CNSNS shall implement the concept of *predisposal management of radioactive waste* within the national regulatory framework and also review the regulations that apply to radioactive waste management in order to address the interdependencies and the adequacy of safety requirements in each phase of the radioactive waste management regulatory process.

(1) **BASIS:** GS-R-1 para 6.11 states *“Government shall ensure that the regulations provide for establishing an inventory of existing and anticipated radioactive waste, including its location and radionuclide content and other physical and chemical characteristics significant to the safety of its management; and for preventing and reducing the generation of radioactive waste and promoting the reuse and recycle of equipment and materials and the reuse of buildings.”*

R45 **Recommendation**: CNSNS shall review the regulations to ensure regular notification to the Regulatory Body of waste inventory, in all installations generating, treating and storing radioactive waste; and develop a national integrated inventory to support the control and planning of activities for predisposal management of radioactive waste and final disposal.

(1) **BASIS:** WS-R-2 para 5.11 para 2.7 states *“Waste shall be processed in such a way that the safety of the operations is appropriately ensured under normal conditions, that measures are taken to prevent the occurrence of incidents or accidents, and that provisions are made to mitigate the consequences should accidents occur. The processing shall be consistent with the type of waste, possible needs for storage, the disposal option, and requirements resulting from safety and environmental impact assessments”*;

(2) **BASIS:** WS-G-2.5 para 2.5 states *“A facility for the predisposal management of LILW should be designed so that as far as possible incidents will be avoided and accidents will be prevented, and if they do occur the consequences will be mitigated.”*

S22 **Suggestion**: CNSNS should review the license for the low level radioactive waste and disused radioactive sources treatment plant at the National Institute for Nuclear Research (ININ) to ensure that this licensee complies with IAEA Standards WS-G-2.5 and WS-G-2.7**.**

Storage of Radioactive Waste

The country has general provisions for storage of radioactive waste in the Nuclear Law and the General Regulation for Radiological Protection. For the facilities that use open sources, basic requirements are also established for radioactive waste storage in NOM-028-NUCL-1996. There is no specific regulatory provision (standard) to cover large storage facilities. CADER has been licensed as a radioactive installation, based on the provisions established in the General Regulation. The storage facility at LVNPP has been licensed within the reactor licensing process by the Nuclear Safety Division based on 10 CFR criteria. The Division for Relevant Facilities has taken part in the

process just to review radiation protection criteria. The inspection of LVNPP is performed by a former inspector of the Division for Relevant Facilities, who moved recently to work for the Nuclear Safety Division.

The regulation in place to date is the General Regulation for Radiation Protection which establishes some requirements for siting of radioactive installations. There is no specific regulation in the country to cover siting of storage facilities.

The General Regulation for Radiation Protection addresses the need to provide information on the impact to the environment of a radioactive facility but does not establish environmental impact assessment requirements for the licensing process, i.e. does not define the scope of the environmental impact assessment. Also in the General Regulation some provisions are made as to facility structure and components and also on the type of waste to be stored, but always with radiation protection concerns.

Requirements for safety assessments are those established in the General Regulation and, for radioactive installations using open sources, also those contained in NOM-028-NUCL-1996. There is no regulatory provision for the elaboration of safety cases, in accordance with present IAEA standards.

The enforcement of the safety requirements in place are through the regulatory licensing process and the inspections. The licenses for storage facilities are renewed every two years. No environmental monitoring programme is required within the present standards.

Basic safety procedures are in place through the General Regulation for Radiation Safety. The use of good engineering practices is enforced through the licensing and inspections process and the keeping of records is ensured through the quality assurance programme that is also enforced through the licensing and inspections process.

Basic requirements for safety operations are established for normal operations and accidents (emergency plan). Provisions to mitigate the consequences of accidents, should they occur, are not contemplated in the present regulatory framework.

Basic provisions for storage of radioactive waste are in place in the General Regulation for Radiation Safety. However, more detailed requirements (design, construction, operation, maintenance, period of storage, passive safety features, irretrievability, etc.) are not in place. .

Basic area control and physical security requirements are established in the General Regulation for Radiation Safety.

Basic provisions for emergency planning and reporting of events are made in the General Regulation for Radiation Safety. There are no acceptance criteria for waste storage in present regulations. Staff, qualifications and training

The General Regulation for Radiation Safety (Article 148; Article 154) establishes the need and the responsibility of the licensee and the radiation protection supervisor of the installation for training of personnel occupationally exposed to radiation.

Emergency preparedness

The General Regulation for Radiation Safety (Article 124; Article 125) establishes the need for the development of an Emergency Plan for radioactive facilities, defining the objective and elements to be included.

Quality Management

The General Regulation for Radiation Safety (Article 220; Article 221) establishes the need for the development of a quality management programme for the application for a construction license and for the application for an operation license.

There are no financial mechanisms in place to ensure that appropriate financial resources will be available to cover waste storage costs.

The storage facility at CADER is inspected annually by CNSNS and the license for the facility is renewed every two years.

Conclusions: Basic provisions are in place in the country for storage of radioactive waste through the General Regulation, once the waste storage facilities are classified as radioactive facilities. Despite the importance of long-term storage within the predisposal management of radioactive waste, the country does not have specific safety requirements for this kind of facility and lacks specific provision to address the interdependencies between waste storage and the other steps of predisposal waste management.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** WR-S-2 para 7.2 states *"Facilities and activities for predisposal management of radioactive waste, including decommissioning activities, shall be subject to safety and environmental impact assessments in order to demonstrate that they are adequately safe and, more specifically, that they will be in compliance with safety requirements established by the regulatory body."*

(2) **BASIS:** WS-R-2 para 5.23 states *"The radioactive waste storage facility shall be designed on the basis of the assumed conditions for its normal operation and assumed incidents or accidents. It shall be designed and constructed for the likely period of storage, preferably with passive safety features, with the potential for degradation taken into account. Provisions shall be made for regular monitoring, inspection and maintenance of the waste and the storage facility to ensure continued integrity. The adequacy of the storage capacity should be periodically reviewed, with account taken of the predicted waste arising and the expected life of the storage facility."*

R46 **Recommendation**: CNSNS shall develop a specific regulation to cover the licensing of storage facilities and shall review the existing regulations covering other phases of predisposal management of radioactive waste (022 NOM 1/2/3 – 1996 and 036 NOM – 2001) to ensure their coherence and consistency with the recently issued IAEA Safety Standard (WS-G-6.1).

Radioactive Waste Disposal

The regulatory requirements for operators are contained in the General Regulation of Radiological Security and the standards on radiation protection and radioactive waste management (NOM-022-NUCL-1996, NOM-022-NUCL-1996, NOM-022-NUCL-1996 (1/2/3) are all based on USNRC regulations (10 CFR 61)). Additional requirements are found in procedure CNSNS-00-009A and CNSNS-00-09B which are used to authorize the construction, operation and closure by license. During each of these licensing phases the license review process will allow for the verification that each facility proposal complies with requirements.

The framework which addresses the radiological safety criteria for the post-closure phase of a radioactive waste disposal facilities are found in the General Regulation of Radiological Security and the Official Standards on Radiation Protection and Radioactive Waste Management, and specifically include the following:

- NOM-022/1-NUCL-1996 describes/outlines siting requirements including such things as descriptions of the geologic, geotechnical, hydrologic, meteorological, climatologic, and biotic features of the disposal site and vicinity; present and projected population distribution and land use; and site activities and controls.
- NOM-022/2-NUCL-1996 describes/outlines the principal design features of a disposal facility and requires that the design provide long-term isolation of disposed waste, minimize the need for continued active maintenance after site closure, and improve the site's natural characteristics in order to protect public health and safety.
- The NOM-022/3-NUCL-1996 describes/outlines the institutional controls and post-closure requirements that will be implemented following site closure.

The responsibility for evaluating the non-radiological environmental impact from a radioactive waste disposal site is covered by the General Law of Ecological Equilibrium and Environment Protection. The Environmental Protection Agency (Environment, Natural Resources and Fishing Secretary) of Mexico will be required to evaluate hazards through the issuance of an environmental impact on non-radiological hazards.

NOM-022/1-NUCL-1996 (siting), NOM-022/2-NUCL-1996 (design) and NOM-022/3-NUCL-1996 (construction, operation, closure, post-closure and institutional control) outline the regulatory requirements for establishing systematic siting criteria for the investigation of the proposed region to evaluate its present and foreseeable future characteristics, the distribution of the population and the present and future uses of land and water; the determination of ambient radioactivity in the region as a baseline for future investigations; estimates of expected and potential releases of radioactive material over direct and indirect pathways; radiological exposure of the population in operational states of the facility as well as under accident conditions; and evaluation of potential effects from natural and human induced external events.

CNSNS will ensure that there is a reasonable assurance of compliance with safety criteria despite the uncertainties inherent in predicting future events concerning a waste repository by ensuring construction, operation, closure, post-closure and institutional control standards are complied with by the operator and by their environmental monitoring programme.

During the review process of the licensing safety assessment the likely and unlikely events and processes are considered.

Specific details of the safety assessment documentation and reporting criteria have not yet been developed but when a potential site operator begins the application process, the requirements as to safety assessment must be completed in order to meet the requirements of NOM-022/1-NUCL-1996. It is assumed that if conditions change a new safety assessment will be required.

Specific details have not yet been developed for estimating the system performance for all the situations selected; for evaluation of the level of confidence in the estimated performance; and for the overall assessment of compliance with safety requirements.

NOM-022/3-NUCL-1996 requires the operator to carry out a commissioning programme, prior to the routine disposal operation, to ensure that the repository and its associated installed equipment function as required by the approved design specification. Operation will not be allowed until CNSNS has verified compliance and approved the operating license. During operations CNSNS will conduct routine inspections to ensure the facilities are operated in accordance with the conditions of the license and that safety is not compromised.

Currently the relevant criteria for near-surface disposal includes NOM-022/1-NUCL-1996 (siting), NOM-022/2-NUCL-1996 (design), NOM-022/3-NUCL-1996 (construction, operation, closure, post-closure and institutional control), NOM-018-NUCL-1995 (Methods for determining the activity concentration and total activity in packages of radioactive wastes) and NOM-019-NUCL-

1995 (Requirements for packages of low level radioactive wastes for its disposal near the surface). Guidelines and other specific documents will be developed during the application process.

The operator will be required to establish a set of procedures to control operation that comply with the following:

- General Regulation on Radiation Safety
- Mexican Official Standards
- NOM-022/1-NUCL-1996
    - Basic Criteria (facility must consider during the process of site selection, design, operation, closure and institutional control).
    - Protection of the Staff (facilities have to comply with the General Regulation on Radiation Safety and legislation established by the Commission for protection of the staff).
    - Protection of the Population: The concentration of radioactive material released to the environment through groundwater, surface water, air, ground, plants or animals shall be minimized as reasonably possible (ALARA philosophy), but under no circumstances will it result in an annual equivalent dose exceeding 0.25 mSv (25 mrem) to whole body, 0.75 mSv (75 mrem) to thyroid or 0.25 mSv (25 mrem) to any other organ of any member of the public.
    - Protection Against Intrusion: The design must guarantee the protection of any individual who inadvertently enters the radioactive waste disposal site after the removal of institutional controls and limit exposures to an annual dose equivalent limit to whole body of 0.25 mSv.
    - Stability of the Site: The facility shall be located, designed, operated and closured in such a way that it assures long-term (at least 500 years) stability and minimizes the need for active maintenance after the closure.
- The regulatory requirements to comply with during operation are contained in NOM-022/3-NUCL-1996, “Requirements for a facility for the disposal of low level radioactive wastes near the surface part 3 construction, operation, closure, post-closure and institutional control.”

Conditions for the waste acceptance criteria and waste form will be specified once a site is selected and the site characteristics are known. NOM-019-NUCL-1995 includes information on package acceptance criteria. Waste packages that do not conform to waste acceptance criteria will be determined through inspections and audits by CNSNS and the facility operator

NOM-022/3-NUCL-1996 establishes requirements for operation. Section 7.1(d) states “The necessary limits and conditions (technical specifications of operation) necessary to guarantee that the facility will be operated in a safe way, both in normal operation and accident conditions have been identified and established, and forecasts have been taken in procedures to allow the surveillance of the compliment of these” and section 7.1 states “The necessary plans and procedures to allow in a timely way the actions during accident or abnormal conditions to mitigate the impact to environment and to safeguard the safety of the workers and population have been established”.

CNSNS standards NOM-022/1-NUCL-1996 (siting), NOM-022/2-NUCL-1996 (design), NOM-022/3-NUCL-1996 (construction, operation, closure, post-closure and institutional control), NOM-018-NUCL-1995 (Methods for determining the activity concentration and total activity in packages of radioactive wastes) and NOM-019-NUCL-1995 (Requirements for packages of low level radioactive wastes for disposal in near the surface) contain requirements to ensure:

- isolation of the waste for the required time

- operational requirements, closure plan, minimization of active maintenance after closure, site stability
- retrievability, if required
- monitoring arrangements
- containment of waste with its associated hazard
- compatibility with the host geological and/or surface environment
- provision of post-closure safety features that complement those afforded by the host environment
- safety during the operational period

Section 7.11 of NOM-022/3-NUCL-1996 requires procedures to prevent the entry of unauthorized personnel and unauthorized work affecting the safety of the facility.

Regulations requiring periodic safety reviews during the operational phase have not been developed.

Section 8 of NOM-022/3-NUCL-1996 establishes closure plan requirements and requires a review of the safety plan to ensure the safety is still valid.

The post-closure institutional control requirements are addressed in NOM-022/3-NUCL-1996.

CNSNS has not developed a regulatory approval process for the operators' post-closure monitoring programme which addresses (1) radiological and other monitoring of the facility and its surrounding area in order to verify the absence of unacceptable radiological impacts, and to confirm, as far as possible, the assumptions made in the safety assessment; and (2) other measurements of system parameters to confirm that the performance of the isolation system is as expected. However NOM-022/3-NUCL-1996 requires the development of such a programme.

NOM-022/3-NUCL-1996 requires that records be kept and section 7.13 states "…shall have a record system to allow the knowledge in every moment of the location and radiological and non-radiological features of every package of radioactive waste, the inventory of radioactive material placed in containers, modules and disposal units, including the date of production and every necessary information that allows to carry out mitigation activities", and shall be delivered both to CNSNS and the organization who will conduct the Institutional Control.

The interaction between CNSNS and the operator to ensure the designation of organizations involved in and responsible, technically, financially and legally, for each implementation phase of the near surface disposal system, and in particular of organizations that will be responsible for post-closure control of the repository if such control is needed, have not been addressed yet.

CNSNS still needs to develop an appropriate level of supervision to be applied in order to protect and preserve the passive safety barriers, financial provisions to be made in order to enable the appropriate institutional controls, and monitoring arrangements and basis and periodicity of this demonstration.

CNSNS has not developed requirements to ensure the timely reporting of:

- incidents and accidents;
- information that calls into question any aspect of safety;
- non-compliance with acceptance criteria; or
- actions taken or proposed to rectify the situation

CNSNS has not developed requirements for the safety of the waste repository, established the procedures for meeting the requirements for the various stages of the licensing process and has not set detailed conditions for the development, operation and closure of the waste repository.

NOM-022/2-NUCL-1996 (design) requires the operators to site, design, construct, operate and close the disposal facility in such a way that safety is ensured by passive means to the extent possible and the need for actions to be taken after the closure of the facility is minimized.

NOM-022/2-NUCL-1996 (design) requires the operator of a disposal facility to develop an adequate understanding of the facility and its host environment and the factors that influence its post-closure safety over suitably long time periods, so that a sufficient level of confidence in safety is achieved.

NOM-022/2-NUCL-1996 (design) requires that the selection of the host environment and the design of the engineered components of the facility ensure that post-closure safety is provided by means of multiple safety functions.

NOM-019-NUCL-1996 and NOM-022/2-NUCL-1996 requires the engineered barriers, including the waste form and packaging, are designed, and the host environment selected, to provide containment of the waste during the period when radioactive decay has not yet significantly reduced the hazard posed by the waste and in the case of heat generating waste when the waste produces heat energy in amounts that could adversely affect the containment.

Safeguards will not be required at the low level radioactive wastes facility because of waste type criteria.

NOM-022/3-NUCL-1996 requires, for the construction and operation stages, the establishment of a qualified and capacitated organization, according to each one of the stages. Additionally, the General Regulation on Radiation Safety requires the Radiation Safety Supervisor in charge of the radioactive facilities to train and qualify the radiation workers on the correct application of the standards and procedures of physical and radiological safety. For the authorization of a Radiation Safety Supervisor specific training and certification are required.

Emergency preparedness

The General Regulation on Radiation Safety requires the persons in charge of licensed radioactive facilities to establish an Emergency Plan in according with the guidelines of the civil protection system and based on radiological consequences of the accidents that may occur in the facilities and includes personnel training. Additionally there is a requirement to notify CNSNS of any accident and within 24 hours to submit a report about the accident and submit a detailed report within 15 working days.

Quality Management

The General Regulation on Radiation Safety requires a construction permit, an operations license and a quality assurance programme. Standards NOM-022/1-NUCL-1996, NOM-022/2-NUCL-1996 and NOM-022/3-NUCL-1996 all require a Quality Assurance Program.

Conclusions: Although the regulatory requirements in the General Regulation on Radiological Safety and the standards on radiation protection and radioactive waste management (NOM-022-NUCL-1996 (1/2/3) address basic requirements for waste acceptance criteria, siting, design, construction, operation, closure, and post closure, there is no national policy and strategy for developing a disposal facility in the near term.

Currently there are no low-level or high-level waste disposal sites identified by CNSNS in Mexico. However, the Centro de Almacenamiento de Desechos Radiactivos (CADER) facility was once operated as a low level radioactive waste disposal facility, before being reclassified as an interim

storage facility. This reclassification was necessary because it was determined that it did not meet design and siting safety criteria.

Another reason to address the waste disposal issue now is the fact that LVNPP continues to generate radioactive waste and the waste storage facilities on site are projected to be full within the next two years. Additionally the non-nuclear radioactive waste collected from across the country ends up at the CADER site which failed as a disposal facility. Continued delays in the siting and licensing of a disposal facility put an undue burden on LVNPP, CADER, non-nuclear waste generators and future generations.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 para 6.10 states *"Government shall ensure that adequate arrangements are made for the safe storage and disposal of radioactive waste. Responsibilities shall be delineated and assigned to ensure that any transfer of responsibility for waste is adequately managed."*

(2) **BASIS:** WS-R-2 states *"The operator shall identify an acceptable destination for the radioactive waste and shall ensure that radioactive waste is transported safely and in accordance with transport requirements"*

R47 **Recommendation:** The Government shall make a decision to establish a national disposal facility for low level radioactive waste to ensure there is a safe disposal option for radioactive waste in the country.

(1) **BASIS:** GS-R-1 para 6.7 states *"Radioactive waste generated in nuclear facilities and activities may necessitate special considerations, particularly in view of the long time-scales and different organizations which may be involved from its generation through to its final disposal and the closure of a repository. Continuity of responsibility between the organizations involved shall be ensured. Consequently, national policies and implementation strategies for the safe management of radioactive waste shall be developed, in accordance with the objectives and principles set out in the IAEA Safety Fundamentals publication on The Principles of Radioactive Waste Management [4]. These strategies shall take into account the diversity between types of radioactive waste and shall be commensurate with the radiological characteristics of the waste. The regulatory body shall ensure that an appropriate waste classification scheme is established accordingly."*

R48 **Recommendation:** CNSNS shall review, update and harmonize radioactive waste disposal criteria and requirements in NOM-022-NUCL-1996 (1/2/3) to comply with IAEA Safety Standards.

(1) **BASIS**: WS-R-4 para 3.5 states *"The government is required to provide an appropriate national legal and organizational framework within which a geological disposal facility can be sited, designed, constructed, operated and closed [17]. This shall include the definition of the steps in the facility's development and licensing, the clear allocation of responsibilities, the securing of financial and other resources, and the provision of independent regulatory functions."*

(2) **BASIS**: WS-R-4 para 3.8 states "The regulatory body shall establish the regulatory requirements for the development of geological disposal facilities and shall set out the procedures for meeting the requirements for the various stages of the licensing

process. It shall also set conditions for the development, operation and closure of a geological disposal facility and shall carry out such activities as are necessary to ensure that the conditions are met."

R49 **Recommendation**: CNSNS shall plan for the development of a regulatory framework for HLW disposal.

(1) **BASIS**: WS-R-1 para 7.1 states "The repository shall be designed to provide adequate isolation of disposed waste for the required period of time, with account taken of the waste characteristics, the characteristics of the site and the safety requirements applicable to the repository."

(1) **BASIS**: WS-R-2 para 5.22 states "Radioactive waste may be stored in solid, liquid or gaseous form or as raw, pretreated, treated or conditioned waste. The intention of storage is that the waste will be retrieved for authorized discharge, authorized use or clearance or for processing and/or disposal at a later time. The criteria for acceptance of waste packages in a storage facility shall therefore take account of the known or likely requirements for subsequent radioactive waste disposal. Safety requirements for the protection of human health and the environment shall be met by appropriate design, construction, operation and maintenance of the respective facilities, including provision for the eventual retrieval of the waste."

S23 **Suggestion**: CNSNS should redefine the status of the CADER facility and, in accordance with this decision, review the license for the CADER low level radioactive waste storage/disposal facility, to ensure that this license complies with IAEA Standards.

10.4. DECOMMISSIONING

Although the regulatory framework covers all aspects of decommissioning it lacks specific details for nuclear and non-nuclear facilities. The following information was provided in support of the nuclear decommissioning requirements:

The Mexican Regulatory Framework for Shut-Down and Decommissioning of Nuclear Installations is based on the Regulatory Law of Article 27 of the Constitution on Nuclear Matters. Other Nuclear Matters are covered in general terms in the following articles:

Article 26: The siting, design, construction, operation, modification, end of operations, final closing down and decommissioning of nuclear and radioactive installations require authorization from the Secretariat of Energy.

Article 28: Authorization for the construction and operation of a nuclear installation shall be issued only when it can be demonstrated, by presenting pertinent information that safety objectives can be attained and the specific procedures and methods that will be used during the siting, design, construction, operation, modification, final closing down and decommissioning stages are available. In addition, the radiation emergency plan shall be submitted and approved. All such information should meet terms and forms stipulated in the regulatory provisions of this Law.

Furthermore, any request for authorization shall contain the necessary information on the environmental impact from the installation and be submitted to National Commission on Nuclear Safety and Safeguards for evaluation.

Article 50: The National Commission on Nuclear Safety and Safeguards is a semi-autonomous body under the Secretariat of Energy, Mines, with the following responsibilities:

III.- Review, assess and authorize the siting, design, construction, operation, modification, final closing and decommissioning of nuclear and radioactive installations, as well as all aspects of the manufacture, use, handling, storage, reprocessing and transportation of nuclear materials and fuels, radioactive materials and equipment. It also covers the processing, conditioning, storage and disposal of radioactive wastes.

IV.- Issues opinion prior to any authorization granted by the Secretary of Energy, in connection with the siting, design, construction, operation, modification, final closure and decommissioning of nuclear installations.

Conditions of licenses for la Central Nucleoeléctrica de Laguna Verde Unit 1 and 2 establish that the Comision Federal de Electricidad (CFE) must assure that adequate funds will be available for decommissioning and the end of final shut-down; and that the design, construction and operation follow IAEA guidance on Nuclear Safety, Radiological Protection and Physical Protection. It also states that the regulations of the designer country, in this case the United States (USNRC) must be followed for decommissioning and must follow the regulatory framework as established by:

Regulatory Guide 1.86 Termination of Operating Licenses for Nuclear Reactors

10 CFR part 20, subpart E. Criteria for Decommissioning

50.33 Contents of applications; general information

51.53 Post construction Environmental Reports

50.54 Conditions of Licenses

50.75 Reporting and Recordkeeping for Decommissioning Planning

50.82 Termination of License

License conditions for the Reactor Triga Mark III (RTMIII) establish that the ININ must have a plan that assures funding for final closure within five years of closure. The plan must include a cost estimate that must be approved by CNSNS. The fund will be paid by the Secretariat of Energy to fulfil the financial requirements established in 10 CFR 50.53 and NUREG-1537.

No other written responses were submitted for this section of the questionnaire. During the programme review no additional information was provided except that USNRC regulations and regulatory guides would be followed. There are two separate programmes, one for nuclear and one for non-nuclear radiation users. It appears the non-nuclear programme has no regulations in place for decommissioning and the nuclear side depends on USNRC regulations and guidance documents.

CNSNS has not addressed possible restrictions for future use of a site but would use USNRC regulations to determine restrictions.

CNSNS has not addressed requirements that:

- the operator implements planning for decommissioning and carries out the decommissioning activities in compliance with the national safety standards and requirements.
- the operator is also responsible for all aspects of safety and environmental protection during the decommissioning activities.
- the operator provides financial assurances and resources to cover the costs associated with safe decommissioning, including management of resulting radioactive waste.

CNSNS has not addressed the requirement that the responsibilities of the operator include:

- establishing a decommissioning strategy and preparing and maintaining a decommissioning plan throughout the life of the facility;
- managing the decommissioning project and performing the decommissioning activities;
- identifying an acceptable destination for all waste arising from decommissioning;
- performing safety and environmental impact assessments related to decommissioning;
- performing appropriate radiological surveys in support of decommissioning;
- assuring that end state criteria have been met by performing a final survey;
- keeping records and submitting reports as required by the regulatory body;
- establishing a quality management programme.

CNSNS has not addressed a national decommissioning strategy. CNSNS has not addressed the requirement that the strategy is consistent with national decommissioning and waste management policy.

CNSNS has not addressed that requirements for the facility shall remain in place unless CNSNS has agreed to their reduction on the basis of a reduction of the hazards.

CNSNS has not addressed the requirement that provisions are included in the decommissioning strategy to ensure that, if final shutdown occurs before a final decommissioning plan is prepared, adequate arrangements are provided to ensure the safety of the facility until a satisfactory decommissioning plan can be prepared and implemented.

CNSNS has not addressed the requirement that in case of a sudden shutdown of a facility (e.g. as a consequence of a severe accident), it is established that the facility shall be brought to a safe configuration before an approved decommissioning plan is implemented

CNSNS has not addressed the requirement that disposal is the preferred option for waste that is generated during decommissioning activities.

CNSNS has not addressed the sites that consist of more than one facility and has not required that a site decommissioning programme be developed so that interdependencies are taken into account in the planning for individual facilities.

CNSNS has not required the applicant to develop and maintain a decommissioning plan throughout the life of the facility, unless otherwise approved by the regulatory body, in order to show that the decommissioning can be accomplished safely to meet the defined end state.

CNSNS has not addressed the requirement that assessments address the occupational exposures and potential releases of radioactive substances with resulting exposure of the public.

CNSNS has not addressed the requirement that a graded approach is applied to the development of the decommissioning plan.

CNSNS has not addressed the requirement that operators consider eventual decommissioning activities in the design of the facility, including features to facilitate decommissioning, the maintenance of records of the facility, and consideration of physical and procedural methods to prevent the spread of contamination.

CNSNS has not addressed the requirement for preparing a decommissioning plan.

CNSNS has not addressed the requirement that the operator prepares and submits an initial decommissioning plan together with the application for authorization to operate the facility, in order to assure that sufficient funds will be available for decommissioning, to facilitate early planning for

minimization of contamination, and to provide for early acquisition and maintenance of records important for decommissioning.

CNSNS has not required the licensee to:

- review and periodically update the decommissioning plans at least every five years or as prescribed by the regulatory body, or when specific circumstances warrant, such as if changes in an operational process lead to significant changes to the plan;
- revise or amend the plans as necessary in the light of operational experience, revised safety requirements or technological developments;
- review decommissioning plans as soon as possible and modified as necessary if an incident or accident occurs.

CNSNS has not required that a baseline survey of the site, including obtaining information on radiological conditions, is performed prior to construction and updated prior to commissioning of a new facility.

CNSNS has not required that, as far as possible, key staff is retained and institutional knowledge about the facility is maintained and is accessible.

CNSNS has not required a final decommissioning plan is prepared and submitted to CNSNS for approval prior to the implementation phase of decommissioning.

CNSNS has not addressed the requirement that the extent and type of radioactive material (irradiated and contaminated structures and components) at the facility are determined by means of a detailed characterization survey and on the basis of records collected during the operational period.

When deferred dismantling strategy has been selected, CNSNS has not required that the decommissioning plan demonstrates that such an option will be implemented safely and will require minimum active safety systems, radiological monitoring and human intervention and that future requirements for information, technology and funds have been taken into consideration.

CNSNS has not required that the operator states in the decommissioning plan the methodology and criteria used for demonstrating that the proposed end state has been achieved.

CNSNS has not addressed the requirement that interested parties are provided with an opportunity to review the decommissioning plan and to provide comments on the plan to the regulatory body prior to its approval.

CNSNS has not addressed the requirement that adequate financial resources are available when needed, even in the event of premature shutdown of the facility, to cover the costs associated with safe decommissioning, including the management of the resulting waste.

CNSNS has not addressed the requirement for financial assurance prior to license renewal or extension.

CNSNS has not addressed the requirement that the financial assurance, adequate to ensure that all necessary controls remain effective, is obtained before authorization is terminated.

CNSNS has not addressed the requirement that regulatory provisions are in place in respect of the organization and management for the implementation of decommissioning.

CNSNS has not addressed the requirement that ultimate responsibility for safety during decommissioning belongs with the operator.

CNSNS has not required that:

- all individuals have the responsibility and authority to bring any safety concerns to the decommissioning management;
- decommissioning management ensures that appropriate authority for stopping work is provided.

CNSNS has not addressed the requirement that:

- decommissioning tasks are controlled through the use of written procedures;
- these procedures are subject to review and approval by the appropriate operator organizations responsible for ensuring safety and practicability;
- that a methodology for issuing, modifying and terminating work procedures has been established.

CNSNS has not addressed the requirement that relevant documents and records, prepared by the operator, are kept for an agreed time and maintained to a specified quality by appropriate parties before, during and after decommissioning.

CNSNS has not addressed the requirement that the operator informs the regulatory body prior to shutting down the facility permanently.

CNSNS has not addressed the requirement that an adequate maintenance and surveillance programme, approved by CNSNS, is developed to ensure safety during the period of deferment.

CNSNS has not addressed the requirement that the operator performs safety assessments and environmental impact assessments; and prepares and implements appropriate safety procedures.

CNSNS has not addressed the requirement that prior to using any new or untried methods for decommissioning, it is demonstrated that the use of such methods are justified and are addressed within the optimization analysis supporting the decommissioning plan. CNSNS has not addressed the requirement that:

- a proper waste management path is established for all waste streams arising from decommissioning activities;
- the operator has arrangements for the safe storage of that waste for which a final decision on disposal has not been made until its final disposition; and
- if operational waste or nuclear fuel remains at the site after permanent shutdown of a facility, it is ensured that material is removed and transported to an authorized facility in compliance with applicable regulations.

CNSNS has not addressed the requirement that the end state criteria, as defined in the decommissioning plan and any additional regulatory requirements, have been met.

CNSNS has not addressed the requirement that a final report that documents the decommissioning activities must be prepared.

CNSNS has not addressed the requirement that a revised or new, separate authorization, including requirements for decommissioning, is issued for the facility following changes.

CNSNS has not addressed the requirement that:

- appropriate controls are maintained to ensure the protection of human health and the environment;
- these controls are specified and are subject to approval by the regulatory body;
- clear responsibility is assigned for implementing and maintaining these controls.

Conclusions: There is no national strategy for decommissioning of nuclear and non-nuclear facilities. Decommissioning is addressed in a broad concept in some of the present CNSNS

regulations and is not in compliance with IAEA Safety Standards. According to CFE information, a decommissioning cost assessment has been prepared by a US consultancy firm for LVNPP and, based on that cost estimate, resources are being collected in a fund to cover decommissioning costs. There is no clear allocation of responsibility for evaluating the adequacy of a decommissioning proposal or verifying cost estimates submitted with a proposal. There are still insufficient resources, including human resources, to address the decommissioning issue.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: WS-R-5 para 3.5 states *"The regulatory body is responsible for the regulation of all phases of decommissioning, from initial planning to termination of the practice or final release of the facility from regulatory control. The regulatory body shall establish the safety standards and requirements for decommissioning, including management of the resulting radioactive waste, and shall carry out activities to ensure that the regulatory requirements are met."*

R50 **Recommendation:** CNSNS shall establish a full set of regulatory standards to cover safety requirements on decommissioning, taking into account IAEA Safety Standards.

(1) **BASIS:** GS-R-1 para 5.10 states *"The regulatory body shall prepare its own programme of review and assessment of the facilities and activities under scrutiny. The regulatory body shall follow the development of a facility or activity, as applicable, from initial selection of the site, through design, construction, commissioning and operation, to decommissioning, closure or closeout."*

S24 **Suggestion:** CNSNS should consider establishing a formal group within the organization with the responsibility to plan, implement and control decommissioning regulatory activities.

11. PUBLIC EXPOSURE, CHRONIC EXPOSURE AND REMEDIATION

11.1. PUBLIC EXPOSURE

The General Regulation on Radiation Safety, published on 22 November 1988, establishes some requirements on public exposure control. The effective equivalent dose limit for the members of the public is 5 mSv per year (Article 37). In cases of prolonged exposure this limit must be reduced to 1 mSv per year (Article 38). In addition the Radiation Protection Officers of the facilities have the responsibility for applying the principle of optimization everywhere that is possible. The Team was informed that this regulation is under review to consider international safety standards and national experience in the application of this regulation.

Conclusions: The existing regulation on radiological protection is not totally consistent with the requirements established by the 'International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources' (Safety Series No. 115, 1996) concerning public exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: GS-R-1 para 3.4. states *"The regulatory body shall co-operate with other relevant authorities, advise them and provide them with information on safety matters in the following areas, as necessary: (1) environmental protection; (2) public and occupational health…"*

(2) **BASIS**: SS 115 para 2.13 states *"Any legal person applying for an authorization shall…(c) make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source and take all necessary steps for the protection and safety of both workers and the public..."*

(3) **BASIS**: SS 115 para 2.26 states *"Except for medical exposure, the optimization of the protection and safety measures associated with any particular source within a practice shall be subject to dose constraints."*

R51 **Recommendation**: CNSNS shall review the General Regulation on Radiation Safety to assure consistency with IAEA Safety Standards. Special attention shall be paid to the dose limits for public exposure and to the introduction and implementation of the optimization principle including the use of dose constraints.

11.2. CONTROL OF RADIOACTIVITY IN MATERIALS FOR RECYCLING

CNSNS follows its Nuclear Exemption Standard Article 39 (NOM-035-NUCL-2000) to evaluate and determine if radioactive material can be released and disposed of at a sanitary landfill or sent to recycling facilities like a scrap iron facility. Unconditional release tables in NOM-035-NUCL-2000 are not consistent RS-G-1.7 table 2. Although CNSNS limits are higher, it was determined that CNSNS has a national system in place for the control of radioactive substances/orphan sources going to metal recyclers. The standard is used to make technical decisions on the final disposition of materials when alarms are set off.

CNSNS does not have regulations that require metal recyclers to install radiation detection systems but many recyclers have installed detection systems for their own protection. CNSNS has a training programme for metal recyclers that encourages them to install detection systems. The training programme has been very effective in building trust between industry and CNSNS. Many of the

recyclers now feel more comfortable reporting that alarms have been activated and to ask for assistance. CNSNS also has a toll free 24 hour emergency number that is used by licensees to report incidents. Available incident reports for 2007 were reviewed and found to be handled in a timely way. Depending on the physical size of the radioactive material and activity the material is either secured at the incident site until ININ can pick it up for possible treatment and storage at CADER or the item is taken to CNSNS for safe storage until ININ picks it up. Metal recycling incidents are considered emergencies, and the response to them is under the authority of the Ministry of Interior. The CNSNS role is one of advisor, however, in the interest of safety CNSNS responds to these incidents using their more senior well-trained staff. Because emergency response is under the Ministry of Interior there is no funding allocated to CNSNS for such activities.

Conclusions: There is a national system in place that is technically capable of making evaluations for controlling the presence of significant amounts of radioactive substances in materials going for recycling. However the standards used to determine release options are not consistent with IAEA RS-G-1.7.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** RS-G-1.7 para 5.9 states *"Confirmation that the activity concentration values given in Tables 1 and 2 are not exceeded should be obtained at the first point of entry into trade. This does not imply the need for systematic monitoring of materials, but authorities in exporting States should ensure that systems are in place to prevent unrestricted trade in material with higher activity concentrations. In general, it should not be necessary for each importing State to set up its own routine measurement programme solely for the purpose of monitoring commodities, particularly if there is confidence in the controls exercised by the exporting State."*

S25 **Suggestion**: CNSNS should review, update and harmonize Nuclear Exemption Standard (NOM-035-NUCL-2000) so that it is consistent with IAEA RS-G-1.7.

G4 **Good practice:** The CNSNS training programme for metal recyclers is building trust and cooperation between industry and the Regulatory Body.

11.3. ENVIRONMENTAL MONITORING ASSOCIATED WITH AUTHORIZED PRACTICES FOR PUBLIC RADIATION PROTECTION PURPOSES

There are no specific national regulations covering environmental monitoring associated with authorized practices for public radiation protection. However, CNSNS does use license conditions and agreements with the operator that require the operator to follow USNRC regulations (10 CFR) and USNRC regulatory guides to ensure that adequate monitoring programmes are in place.

Specific license conditions, operating procedures, USNRC regulations (10 CFR) and USNRC regulatory guides for LVNPP and the Instituto Nacional de Investigaciones (ININ) research reactor were reviewed during the mission and found to address environmental requirements for public exposure and assessment criteria.

LVNPP has specified technical requirements in their Technical Specifications of Operation (ETO) document which are based on the following USNRC regulations and regulatory guides:

- 10 CFR 50.34a, Design objectives for equipment to control releases of radioactive material in effluents – nuclear power reactors.
- 10 CFR 50.36a, Technical specifications on effluents from nuclear power reactors.
- 10 CFR Part 20, Standards for Protection against Radiation.

- 10 CFR 50.72, immediate notification requirements for operating nuclear power reactors.
- 10 CFR 50.73, Licensee event report system.
- 10 CFR 50.75(g), Reporting and recordkeeping for decommissioning planning.
- 10 CFR Part 50, Appendix I, Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low As Is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents. (40 FR 19437 as an effective rule on May 5, 1975)
- 10 CFR Part 50, Appendix A; Design Criteria 60, Control of Releases of Radioactive Materials to the Environment.
- 10 CFR Part 50, Appendix A; Design Criteria 61, Fuel storage and handling and radioactivity control.
- 10 CFR Part 50, Appendix A; Design Criteria 64, Monitoring Radioactivity Releases.
- Regulatory Guide 4.1, Programs for Monitoring Radioactivity in the Environs of Nuclear Power Plants. (1/73)
- C Regulatory Guide 4.2, Preparation of Environmental Reports for Nuclear Power Stations. (Rev. 2, 7/76)
- C Regulatory Guide 4.8, Environmental Technical Specifications for Nuclear Power Plants. (12/75)
- Branch Technical Position (Rev. 1, 11/79; specific to environmental monitoring program).

The ETO covers topics such as source characteristics (Table 3.12-2), significance of each possible exposure pathway (Table 3.12-1) and magnitude of the expected doses to individuals. Dose limits for the public are based on USNRC guidance and are set at 25 mrem for whole body and 75 mrem to any organ except thyroid.

Requirements for the research reactor at ININ are based on specific license conditions 15 and 16 and the following USNRC regulations:

- 10 CFR Part 20, "Standards for Protection Against Radiation".
- 10 CFR Part 50, "Domestic Licensing of Production and Utilization".
- R.G. 8.10, "Operating Philosophy for Maintaining Operational Exposures As Low As Is Reasonably Achievable".
- R.G. 8.37, "ALARA Levels for Effluents from Materials Facilities".
- R.G. 1.109, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents", 1977.

ININ has also adopted the same environmental programme at the Salazar Centre (Mexico State) waste treatment facility and at the Centro de Almacenamiento de Desechos Radiactivos (CADER) waste storage facility in Maquixco (Mexico State). ININ is also revising its current environmental monitoring programme procedures to bring them into compliance with international standards. CNSNS's environmental monitoring programme supports this work and will likely approve the changes when they are submitted for license amendment approval.

CNSNS's environmental monitoring programme staff has also developed a draft license application guide "Guide for the Design and Application of Environmental Radiological Surveillance for Radiological Facilities in Normal Operations" which covers international standards, but the

guidance has not been accepted or used by the license application review section when license application packets are sent to interested parties.

There also appears to be a lack of coordination between the license review section and the environmental section. As a result, licenses are issued without the opportunity for review and comment by the environmental section. This lack of coordination has resulted in the issuance of licenses that do not meet the environmental monitoring requirements.

There are no specific regulations requiring pre-operational environmental monitoring programmes investigations during or after operation. There are no specific regulations that address reporting requirements when there is a significant increase in environmental radiation fields or contamination. However LVNPP, ININ, the waste treatment facilities and storage facilities are all following USNRC regulations and guidance documents to comply with pre-operational investigations such as environmental monitoring during and after operation, dose limits criteria and reporting requirements.

CNSNS environmental monitoring programme collects samples on a regular basis at LVNPP and ININ facilities in order to verify compliance with the license conditions and to assess/compare data results. Sample locations are based on population densities. Annual environmental reports are prepared by CNSNS, LVNPP and ININ.

During CNSNS inspections, facility operators are required to provide evidence that proper environmental monitoring technical requirements are being followed and that sample collection techniques are satisfactory. Environmental monitoring data is also validated by comparing CNSNS data with the operator's data. Environmental data can be accessed by the public by formally submitting a request to Federal Institute of Access to Information (IFAI).

CNSNS does not delegate environmental monitoring activities to other agencies.

There are no regulations that establish the standard content and periodicity of environmental monitoring reports or the summarizing of the monitoring results sent to CNSNS. However environmental monitoring requirements are specified through the use of the following documents:

- Regulatory Guide 4.1, Programs for Monitoring Radioactivity in the Environs of Nuclear Power Plants. (1/73)
- Regulatory Guide 4.2, Preparation of Environmental Reports for Nuclear Power Stations. (Rev. 2, 7/76)
- Regulatory Guide 4.8, Environmental Technical Specifications for Nuclear Power Plants (12/75) and Branch Technical Position (Rev. 1, 11/79; specific to environmental monitoring program).

These documents require submittal of the following:

- periodic reports to determine and verify compliance with the limits on discharges authorized by CNSNS;
- reporting data that meets the objectives of the monitoring programme as specified by CNSNS;
- summary reports including requirements to ensure that sampling data results meet the objective established at the beginning of the year and help establish objectives for the next year.

The first semester (6 month) data in the "Report of Effluent Release for 2007" for LVNPP was reviewed and found to contain no significant items for reporting to CNSNS.

There are no regulations that require the registrants/licensees to report promptly to CNSNS any significant increase in environmental radiation fields or contamination that could be attributable to the operator. However there are operating procedures that require them to report increases in environmental radioactivity. These requirements are based on USNRC regulatory guides and are located in ETO.

There are no regulations that require the registrants/licensees to keep monitoring programme results records. However, environmental monitoring is specified in registrants/licensees procedures such as the ETO.

CNSNS inspections include reviews of the monitoring programmes following USNRC regulations (10 CFR 50.59) to identify changes.

The public can get information on environmental monitoring programmes and results (including an explanation of their significance) by making formal requests to the Federal Institute of Access to Information (IFAI). The IFAI has ten days to reply.

There are no regulations that establish the need for verifying the adequacy of the assumptions made for the prior assessment of radiological consequences of exposures to the public associated with authorized registrants' and licensees' practices. However during the licensing process, assumption verification is accomplished through the evaluation of the safety report submittal.

CNSNS uses license conditions and operator procedures to set the standards for technical skills, qualifications and experience necessary for all personnel performing safety related duties involving public protection, environmental monitoring of practices and control of foodstuffs and/or selected commodities. CNSNS uses license conditions and operator procedures to ensure adequate provisions are in place for the selection of suitable qualified personnel and also uses them for establishing the necessary training, retraining and instruction to enable staff to perform their duties correctly.

During the license review process, license submittals are reviewed to ensure environmental monitoring programmes address emergency preparedness and response, public protection, environmental monitoring of practices and control of foodstuffs and/or selected commodities are addressed correctly.

Quality assurance plans are based on 10 CFR 50 Appendix B.

Conclusions: There are neither specific national regulations nor standards covering the following environmental monitoring topics:

- pre-operational investigations;
- environmental monitoring programmes during and after operation;
- requirements for facility operators to report any significant increase in environmental radiation fields or contamination;
- addressing technical requirements for monitoring;
- establishing the standard content and periodicity of reports;
- requiring the summarization of monitoring results;
- environmental reporting requirements;
- establishing the need for verification of the adequacy of the assumptions made for prior assessment of radiological consequences of exposures to the public associated with authorized registrants' and licensees' practices.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** RS-G-1.8 para 2.9 states *"The type of monitoring programme, as well as its scale and extent, should be commensurate with the source characteristics at the expected or current discharge rates, the radionuclide composition, the comparative significance of different exposure pathways, and the magnitudes of expected and potential doses to individuals. Some practices and sources (e.g. hospitals or research institutes using short lived radionuclides) may not require a monitoring programme for the environment; some (e.g. small nuclear installations or nuclear medicine departments using radionuclides for diagnostic purposes) may require routine monitoring at the source but only occasional checks on environmental levels; and others (e.g. most nuclear installations, large nuclear medicine departments) require continuous and comprehensive monitoring of both source and environment. Every facility should be prepared to conduct emergency monitoring at an appropriate level."*

(2) **BASIS:** RS-G-1.8 para 3.5 states *"With regard to specific responsibilities in the area of monitoring, the regulatory body: (a) Should establish technical requirements for monitoring arrangements, including arrangements for emergency monitoring and quality assurance, and should regularly review them; (b) Should check the monitoring data provided by operators; (c) Should provide evidence that can satisfy the public that authorized sources of exposure are being suitably monitored and controlled."*

(3) **BASIS:** RS-G-1.8 para 10.2 states *"The recording of monitoring results and related information should be such as to satisfy the objectives of the monitoring programme, which include the requirement to carry out a comparison of measured values with appropriate derived levels and, where appropriate, to calculate the annual dose to the average individual of the critical group and the collective dose."*

S26 **Suggestion**: CNSNS shall as soon as practicable update the General Regulation for Radiation Safety and include specific comprehensive environmental monitoring requirements to ensure that it appropriately addresses environmental monitoring programmes.

S27 **Suggestion:** CNSNS should enforce environmental monitoring issues through licensing conditions until the General Regulation is updated.

G5 **Good Practice:** CNSNS officially supports the ININ effort to modify and develop its environmental monitoring programme in accordance with IAEA International Standards.

11.4. CONTROL OF CHRONIC EXPOSURES (RADON, NORM AND PAST PRACTICES)

At the moment there are no well defined national responsibilities between CNSNS and national or local intervening organizations or persons identified for chronic exposure control. Nevertheless there is some work ongoing with the civil defence at the regional level. The metallurgic industry is interested in this issue due to the amount of potentially contaminated NORM pipelines material coming from the oil industry.

The regulatory framework does not characterize the national situation with respect to existing radiation levels and environmental radionuclide concentrations. Nevertheless, CNSNS has a

programme that evaluates and characterizes radon in homes at the national level. The investigation information showed there are some areas with anomalies but no intervention or remedial actions are required.

Studies were carried out to determine radon concentrations in homes across the country. In addition, a national project for the control of minerals in drinking water was developed. Only one location was identified as presenting chronic exposure due to the concentration of NORM in the drinking water. Measures were recommended to reduce the concentrations of NORM in the drinking water at this location. Several other projects were performed to characterize the environment.

There are no criteria established by CNSNS to determine when remedial actions should be mandatory and when they should be advisory in nature. Only in the case cited above was the criteria in NORM-SSA1-126-1994 (Ministry of Health) applied as a recommendation to address the elevated levels of NORM found. Requirements have not been established on the capabilities of the operators to evaluate chronic exposure scenarios and to then make recommendations to CNSNS regarding corrective suggestions.

Conclusion: The issue of chronic exposure has not been developed in the regulations, however it has been included in the new, proposed version of the General Regulation on Radiation Safety, which is under revision and considers the requirements of the SS-115. There is not a complete characterization of chronic exposure scenarios occurring in the country. However, appropriate actions have been taken in those situations in which the established action levels were exceeded.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** SS 115, App VI.1 states *"It is presumed that the State will have determined the allocation of responsibilities for the management of interventions in chronic exposure situations between the Regulatory Authority, national and local Intervening Organizations and registrants or licensees."*

R52 **Recommendation**: CNSNS shall elaborate on and establish, according to the IAEA Safety Standards, the regulatory framework needed, and supported by appropriate guidance material, to establish the safety requirements to protect the public from chronic exposure.

11.5. REMEDIATION

At present CNSNS does not have any regulation addressing the internationally recommended criteria and requirements for remediation. CNSNS has not identified all the potential areas that have been contaminated by past practices or intervention situations. They have not evaluated whether assessments of these areas addressed all relevant situations, including those with enhanced levels of natural radioactivity. They also have not determined that an adequate programme for the safe management and remediation of the affected areas is in place or being planned in compliance with the regulatory requirements. Nevertheless CNSNS is dealing with remediation situations from past practices as illustrated by their actions at the CADER site.

Conclusion: There is neither a national strategy for the identification of potential contaminated areas by past practices or chronic exposure nor a necessary regulatory framework for the planning and implementation of remedial actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** WS-R-3 para 4.1 states *"A national strategy shall be formulated to specify, prioritize and manage remediation situations and to ensure that an adequate legal and regulatory framework, supported where necessary by appropriate guidance material, is in place so that workers, the public and the environment are protected when remediation programmes are undertaken."*

(2) **BASIS:** GS-R-1 para 2.2(6) states *"Adequate infrastructural arrangements shall be made for decommissioning, close-out or closure, site rehabilitation, and the safe management of spent fuel and radioactive waste."*

(3) **BASIS:** GS-R-1 para 2.3 states *"The operator shall have the responsibility for ensuring safety in the siting, design, construction, commissioning, operation, decommissioning, close-out or closure of its facilities, including, as appropriate, rehabilitation of contaminated area..."*

R53 **Recommendation**: CNSNS shall elaborate on and establish a regulatory framework, supported where necessary by appropriate guidance material, to guarantee that workers, the public and the environment are protected when remediation programmes are undertaken.

(1) **BASIS:** WS-R-3 para 4.3 states *"The legal framework shall be established such that it specifies the situations that are included in its scope, sets objectives and principles for remedial measures, and assigns responsibilities."*

(2) **BASIS:** WS-R-3 para 4.9 states *"The regulatory body shall establish safety criteria for the remediation of contaminated areas, including conditions on the end points of remediation. The responsibilities of the regulatory body shall include, among other things, the following: (a) To investigate potentially contaminated areas and to designate as contaminated areas those areas requiring remediation…"*

(3) **BASIS:** WS-R-3 para 4.1 states *"A national strategy shall be formulated to specify, prioritize and manage remediation situations and to ensure that an adequate legal and regulatory framework, supported where necessary by appropriate guidance material, is in place so that workers, the public and the environment are protected when remediation programmes are undertaken."*

R54 **Recommendation**: CNSNS together with other interested parties shall elaborate and implement a national strategy to investigate and identify potential areas requiring remedial actions.

12. TRANSPORT OF RADIOACTIVE MATERIAL

The legal requirements applicable to the transport of radioactive materials are the following:

- Article 50 bullet 3 of the Regulatory Law designated CNSNS as the competent authority for transport of radioactive materials.
- Article 199 of RGSR empowers to CNSNS to propose the regulations for transport of radioactive materials.
- Article 198 of RGSR establishes the requirements for issuing transport authorizations.

Mexico does not have regulations on transport of radioactive materials, only the few requirements in the regulations for transport of dangerous goods.

There is a project of regulations based on ST-1, revised 1996, in the approval process. These regulations contain mainly the administrative requirements of ST-1, and most of the technical requirements will be in the form of standards. This approach could help to update the regulations with fewer problems and probably it will be possible to incorporate many of the modifications to that version of the regulations. These standards are in preparation.

Compliance with TS-R-1 is required as a licensing condition. CNSNS is empowered to include license conditions by article 148, bullet 4, of the Regulatory Law.

There are not specific training courses on transport of radioactive material for operators.

Licensees are not required to have persons specialized in transport of radioactive materials.

CNSNS does not have written procedures for issuing packages or expeditions certificates, although they have issued some certificates.

Although CNSNS has issued 27 transport authorizations, no inspections of this licensee have been carried out.

CNSNS has not defined specific responsibilities within its organization to handle transport of radioactive material subjects.

CNSNS is not carrying out periodic assessments of the radiation doses to persons involved in transport of radioactive material.

CONCLUSIONS:

- There are no regulations on transport of radioactive material.
- CNSNS has no procedures to deal with transport of radioactive material matters.
- CNSNS has not designated persons to address transport of radioactive material.
- CNSNS does not have enough persons trained in transport of radioactive material.
- There are no requirements regarding persons performing transport of radioactive material.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: TS-R-1 para 307 states "*Competent authority is responsible for assuring compliance with these Regulations. Means to discharge this responsibility include the establishment and execution of a programme for monitoring the design, manufacture, testing, inspection and maintenance of packaging, special form radioactive material and low dispersible radioactive material, and the preparation, documentation, handling and stowage of packages by consignors and carriers, to provide evidence that the provisions of these Regulations are being met in practice.*"

(2) **BASIS:** WS-R-2 para 3.15 states *"The operator shall identify an acceptable destination for the radioactive waste and shall ensure that radioactive waste is transported safely and in accordance with transport requirements."*

R55 **Recommendation**: CNSNS shall elaborate on specific regulations to enforce compliance with IAEA Safety Standard TS-R-1, including recent revisions, on transport of all radioactive material in the country.

R56 **Recommendation**: CNSNS shall establish a programme to assure compliance with requirements related to transport of radioactive material, establish procedures to carry out its regulatory activities on transport of radioactive materials, and assign staff to fulfil the responsibility for conducting regulatory activities related to transport of radioactive material.

(1) **BASIS**: TS-R-1 para 308 states "*The relevant competent authority shall arrange for periodic assessments of the radiation doses to persons due to the transport of radioactive material, to ensure that the system of protection and safety complies with the Basic Safety Standards [2].*"

R57 **Recommendation**: CNSNS shall establish requirements and procedures to periodically assess radiation doses to persons due to the transport of radioactive material.

13. SAFETY AND SECURITY OF RADIOACTIVE SOURCES

Code of Conduct on the Safety and Security of Radioactive Sources

The Nuclear Law gives power to the National Commission on Nuclear Safety and Safeguards to regulate and ensure compliance with regulations on security (Article 18, paragraph III).

The Radiological Safety General Regulations, Article 126, requires security measures for storage of radioactive materials. Articles 192 part VI and 198 Part VI establish the need of a security plan for import and transport of radioactive material.

A new Regulation specifically on security is now being prepared.

CNSNS does not have procedures designating different levels of safety based on the IAEA system of source categorization.

A document regarding guidance for security has been drafted: "Seguridad fisica de Fuentes radiactivas para el licenciamiento de instalaciones radiactivas con fuentes categoria 1 y 2".

CNSNS promotes actions with the scrap metal dealers to have appropriate monitoring devices to detect radioactive sources but there is no CNSNS formal programme to ensure the proper functioning of the detectors.

CNSNS made some visits to radiation facilities (i.e. radiotherapy, brachytherapy, waste, irradiator) to identify important aspects related to security. In 2007, 20 inspections were conducted.

CNSNS has not implemented procedures to track movement of high-risk sources in cooperation with other relevant competent authorities. However, the team was informed that the Customs authorities have instruments to detect any movement of sources.

Conclusions: CNSNS has taken significant steps to increase the awareness of scrap metal dealers regarding the hazards and detection of radioactive sources. Further efforts in this regard, including ensuring the proper functioning of detectors, would aid in minimizing risks to the public.

Although CNSNS has initiated some activities with respect to the security of radioactive sources, it lacks the necessary regulatory framework to implement a comprehensive programme to address security.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS**: Code of Conduct on the Safety and Security of Radioactive Sources para 18 states *"Every State should have in place legislation and regulations that: (a) prescribe and assign governmental responsibilities to assure the safety and security of radioactive sources... (d) specify the requirements for the safety and security of radioactive sources and of the devices in which sources are incorporated."*

R58 **Recommendation**: CNSNS shall take measures to address the security of radioactive sources pending a comprehensive review of the Regulatory Law.

14. RADIATION SAFETY AND SOURCE SECURITY INFORMATION MANAGEMENT

CNSNS has had initiatives to disseminate relevant information to interested parties such as using the website of CNSNS and electronic communications with managers of radiation sources and service providers, participating actively with professional societies, and taking part in courses, seminars, or meetings, etc.

CNSNS has not disseminated information to the public because this is done through the Office of Public Relations at the Department of Energy.

CNSNS has not had a relationship with any environmental action groups.

CNSNS uses a channel of communication with all the agencies belonging to intelligence and military for matters related to security programmes.

CNSNS has procedures to prevent unauthorized access or use of electronic material (e.g. source register) that is protected through an installed firewall. Only CNSNS personnel can use the written material; no other people are allowed to use CNSNS' files. CNSNS has the following computer databases: SCOR, SCOST, TRAMITES, IMPORT/EXPORT.

CNSNS has not yet implemented procedures to ensure security against theft of computers and removable media that hold sensitive information (e.g. source register).

CNSNS has not implemented procedures for the controlled disposal of obsolete or replacement computer hardware (including removable media). The CNSNS Informatics Department deletes all information before the computers are disposed.

CNSNS has not established and implemented procedures for the rapid dissemination of information in the event of an actual or potential safety or security incident. In the past, CNSNS used different media to communicate with the public about an event regarding the loss of sources and the precautions needed to handle such an event.

Conclusion: There is no developed policy ensuring that sensitive radiation safety and security information is held in a secure manner and protected to prevent misuse. In addition, CNSNS has not yet established approved written procedures to prevent unauthorized access to its records (written and electronic), including access to the source register and facility drawings, or to prevent theft of computers and removable media that hold sensitive information.

APPENDIX I – LIST OF PARTICIPANTS

INTERNATIONAL EXPERTS:		
1. Marta **ŽIAKOVÁ**	Nuclear Regulatory Authority of the Slovak Republic	marta.ziakova@ujd.gov.sk
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8. Gary **ROBERTSON**	Department of Health	gary.robertson@doh.wa.gov
9. Marcelo **TOSTES**	National Nuclear Energy Commission (CNEN)	mallat@cnen.gov.br
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IAEA STAFF MEMBERS		
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OFFICIAL CNSNS LIAISON OFFICER:		
1. Jaime **AGUIRRE**	CNSNS	jaguirre@cnsns.gob.mx

APPENDIX II – MISSION PROGRAMME

MISSION PROGRAMME		
Sunday, 25 November 2007		
14: 00 – 17:00	**IRRS Initial Team Meeting at the Hotel in Mexico City**	
Monday, 26 November 2007		
09:30 – 10:30	**Entrance Meeting at CNSNS Headquarters** • *Welcome and introduction* • *Opening remarks* • *IRRS remarks* • *IAEA experts introduction*	*Mr. J. Eibenschutz* *Ms. M. Ziakova*
10:30 – 13:00	**CNSNS Presentations** • *Working and logistical arrangements* • *Review areas* • *Self-assessment executive summary*	*Mr. J. Aguirre* *CNSNS Staff*
14:00 – 17:00	**Experts and counterparts open discussion** • *Identifying emerging issues* • *Interview sessions*	*Counterparts & IRRS Review Team*
17:00 – 18:00	Introductory Social	*All*
Tuesday, 27 November 2007		
09:00 – 12:00	**Reviewer visit to Hospital Centrale**	*Mr. Basaez* *Mr. Da Silva*
09:00 – 15:00	**Reviewer visit to Radioactive Waste interim storage center (CADER)**	*Mr. Jova Sed* *Mr. Tostes* *Mr. Robertson*
09:00 – 10:00	**Policy Issues Discussion**	*All available*
10:00 - 1300	**Interviews at CNSNS Headquarters**	*IRRS Review Team*
14:00-16:30	**Interviews at CNSNS Headquarters**	*All*
16:30 – 18:00	**Team Meeting**	*All*
18:00 -	**Report writing**	*IRRS Review Team*
Wednesday, 28 November 2007		
09:00 – 10:00	**Policy Issues Discussion**	*All available*
09:00 – 12:00	**Reviewer visit to Radioactive Waste Treatment Plant at ININ (PATRADER)**	*Mr. Jova Sed* *Mr. Tostes* *Mr. Robertson*
10:00 – 13:00	**Interviews at CNSNS Headquarters**	*All*
09:00 – 12:00	**Reviewer visit to Instituto Nacional de Emfermedades (INER)**	*Mr. Basaez* *Mr. da Silva*
09:00 – 16:00	**Reviewer visit to Research Reactor at ININ**	*Mr. Munuero* *Mr. Waldman*
16:30 –18:00	**Team Meeting**	*All*
18:00 -	**Report Writing**	*IRRS Review Team*
Thursday, 29 November 2007		
09:00 – 10:00	**Policy Issues Discussion**	**All available**
09:00 – 12:00	**Reviewer Visit to Ingenieros Asesores En Radiografia Industrial**	*Mr. Basaez* *Mr. da Silva*
09:00 – 12:00	**Meeting with Ministry of Energy (Rad Waste Specific)**	*Mr. Jova-Sed*
10:00 – 13:00	**Interviews at CNSNS Headquarters**	*All*
14:00 – 16:30	**Interviews at CNSNS Headquarters**	*All*

MISSION PROGRAMME		
16:30 – 18:00	**Team Meeting**	*All*
18:00 -	**Report Writing**	*IRRS Review Team*
16:00	**Departure to Vera Cruz to observe inspections at Laguna Verde**	*Mr. Calpena* *Mr. Holian* *Mr. Robertson* *Mr. Tostes*
Friday, 30 November 2007		
09:00 – 13:00	**Interviews at CNSNS Headquarters**	*All*
09:00 – 16:00	**Onsite reviews at Laguna Verde (Rad Waste and NPP)**	*Messers. Calpena, Holian, Robertson, and Tostes*
14:00 – 16:30	**Interviews at CNSNS Headquarters**	*All*
16:30 – 18:00	**Team Meeting**	*All*
18:00 -	**Report writing**	*IRRS Review Team*
21:00	**Laguna Verde reviewers return to Mexico City**	*Mr. Calpena* *Mr. Holian* *Mr. Robertson* *Mr. Tostes*
Saturday, 1 December 2007:		
09:00 – 12:00	***Team Meeting at Hotel***	
12:00 – 17:00	***Reviewers continue drafting report***	
Sunday, 2 December 2007		
09:00 – 16:00	**Cultural Event- Reviewers continue drafting report as needed**	*IRRS Team*
Monday, 3 December 2007:		
09:00 – 12:00	**Reviewer visit to Hospital de Especialidades del Centro Medico Siglo XXI**	*Mr. Jova Sed* *Mr. Tostes*
09:00 – 16:00	**Reviewer visit to Industrial Irradiator - Sterigenics S de R.L. de C.V.**	*Mr. Basaez* *Mr. da Silva*
09:00 – 13:00	**Interviews at CNSNS Headquarters**	*All*
14:00 – 16:30	**Interviews at CNSNS Headquarters**	*All*
16:30 – 18:00	**Team Meeting**	*All*
Tuesday, 4 December 2007:		
08:30 – 09:00	**Depart Hotel to CNSNS Headquarters**	*All*
09:00 – 13:00	**Discussions to finalize draft report/Resolution of report issues**	*All*
14:00 – 18:00	**Discussions to finalize draft report/Resolution of report issues**	*All*
Wednesday, 5 December 2007		
09:00 – 13:00	**Finalize Draft Report**	*All*
14:00 – 16:00	**Exit meeting**	*IRRS Team*

APPENDIX III – SITE VISITS

1.	Hospital Central
2.	Radioactive Waste interim storage center (CADER)
3.	Radioactive Waste Treatment Plant at ININ (PATRADER)
4.	Instituto Nacional de Emfermedades (INER)
5.	Research Reactor at ININ
6.	Ingenieros Asesores En Radiografia Industrial (IARI) S.A. DE C.V.
7.	Ministry of Energy (RAD Specific)
8.	Laguna Verde x(Rad Waste and NPP)
9.	Hospital de Especialidades del Centro Medico Siglo XXI
10.	Industrial Irradiator – Sterigenics S de R.L. de C.V.

APPENDIX IV – MISSION COUNTERPARTS

item	Subject Area	IRRS Experts	Lead Counterparts
I	LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES	• Ms. Marta Ziakova • Ms. Cynthia Heinberg • Mr. Lucian Biro	• Mr. Jose Luis Delgado Guardado • Mr. Viktor Manuel Mercardo Gonzalez • Mr. Sergio Waller Mejia
II	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	• Ms. Marta Ziakova • Ms. Cynthia Heinberg • Mr. Lucian Biro	• Mr. Jose Luis Delgado Guardado • Mr. Viktor Manuel Mercardo Gonzalez • Mr. Sergio Waller Mejia
III	ORGANIZATION OF THE REGULATORY BODY	• Ms. Marta Ziakova • Ms. Cynthia Heinberg • Mr. Lucian Biro	• Mr. Jose Luis Delgado Guardado • Mr. Viktor Manuel Mercardo Gonzalez • Mr. Sergio Waller Mejia
IV	AUTHORIZATION	• Mr. Ricardo Waldman • Mr. Stephane Calpena	• Mr. Hermenegildu Maldonado Mercado • Mr. Ricardo Perez Perez
V	REVIEW AND ASSESSMENT	• Mr. Ricardo Waldman • Mr. Stephane Calpena	• Mr. Hermenegildu Maldonado Mercado • Mr. Ricardo Perez Perez
VI	INSPECTION AND ENFORCEMENT	• Mr. Brian Holian • Mr. Antonio Munuera	• Mr. Mardonio Jimenez Rojas • Mr. Luis Miguel Gutierrez • Mr. Mario Ivan Pinto Cunille
VII	REGULATIONS AND GUIDES	• Mr. Brian Holian • Mr. Antonio Munuera	• Mr. Jesus Basurto Cazares
VIII	MANAGEMENT SYSTEM FOR REGULATORY BODY	• Ms. Marta Ziakova • Mr. Lucian Biro	• Mr. Jose Luis Delgado Guardado • Mr. Viktor Manuel Mercardo Gonzalez • Mr. Sergio Waller Mejia
	EMERGENCY PREPAREDNESS AND RESPONSE	• Mr. Toshimitsu Homma	• Mr. Jaime Aguirre Gomez • Mr. Alejandro Cortes Carmona

item	Subject Area	IRRS Experts	Lead Counterparts
	MEDICAL APPLICATIONS, INDUSTRIAL APPLICATIONS, TRANSPORT, SAFETY AND SECURITY OF SOURCES	• Mr. Hector Basaez • Mr. Francisco Da Silva	• Mr. Mardonio Jimenez Rojas • Mr. Mario Arturo Reyes • Mr. Emilio Ordonez • Mr. Ruben Ramirez Guerrero
	DECOMMISSIONING, REMEDIATION, RAD WASTE: REGULATORY FRAMEWORK, GENERAL SAFETY REQUIREMENTS, NATIONAL POLICY AND STRATEGY	• Mr. Gary Robertson • Mr. Marcelo Tostes • Mr. Luis Jova Sed	• Mr. Jaime Aguirre Gomez • Mr. Maria Mejia Lopez • Mr. Roberto Fabian Ortega • Mr. Alejandro Cortes Carmona
	PREDISPOSAL MANAGEMENT OF RAD WASTE: PUBLIC EXPOSURE; DISCHARGES; ENVIRONMENTAL MONITORING; CHRONIC EXPOSURE; CLEARANCE; DISPOSAL AND STORAGE	• Mr. Marcelo Tostes	• Mr. Jaime Aguirre Gomez • Mr. Mario Mejia Lopez • Mr. Luciano Sanchez Herrera • Mr. Slejandro Cortes Carmona

APPENDIX V – RECOMMENDATIONS/SUGGESTIONS/GOOD PRACTICES FROM THE IRRS MISSION

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
I	**LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES**	R1	**Recommendation**: The existing legislation shall be reviewed and revised as necessary to establish a regulatory body effectively independent of organizations or bodies charged with the promotion of nuclear technologies or responsible for facilities or activities.
		R2	**Recommendation**: Regulations based on provisions of Regulatory Law shall be issued to create a legal framework for the discharge of regulatory responsibilities by CNSNS.
		R3	**Recommendation**: The Regulatory Body should be exempted from the provisions of the Decision issued by Federal Commission for Regulations and published in Official Gazette, Primary Section on May 12, 2004 and entered into force on April 29, 2005.
II	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**	R4	**Recommendation**: CNSNS shall be empowered to inform the public on any safety issues as appropriate.
III	**ORGANIZATION OF THE REGULATORY BODY**	R5	**Recommendation:** CNSNS shall hire to fill current vacancies and ensure staffing levels are adequate to be able to discharge its responsibilities in all appropriate areas.
		S1	**Suggestion:** CNSNS should consider methods to improve retention, hiring, motivation of current staff, and career planning where appropriate.
		R6	**Recommendation:** Funding shall be made available to allow CNSNS to hire external contractors as necessary.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R7	**Recommendation:** To review the organization of the different activities of CNSNS in the area of radioactive waste management and its control in order to harmonize the criteria, the procedures and to enhance the coordination and the performance of the control in this area.
		R8	**Recommendation:** CNSNS shall establish competencies and training requirements for each position. Staff shall complete required training before being assigned to conduct specific tasks without supervision.
		S2	**Suggestion**: The possibility to create advisory bodies, on a permanent or ad hoc basis, should be allowed by legislation to provide CNSNS independent opinions of experts on technical or non-technical issues.
IV	**AUTHORIZATION**	S3	**Suggestion**: CNSNS should ensure that there is coordination between review and assessment activities and inspection activities, as appropriate. Safety Evaluators should be provided the opportunity to make site visits as necessary to assess any relevant safety issues at nuclear installations and to participate in inspections and technical meetings with inspectors as appropriate.
		R9	**Recommendation**: Adequate staffing and financial resources shall be provided to CNSNS to ensure it can discharge its assigned responsibilities and especially to review and assess submissions on safety from the operators both prior to authorization and during operation as it deems necessary.
		G1	**Good practice**: CNSNS staff responsible for licensing of NPP operators receives the same training as licensed operators.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R10	**Recommendation**: Regarding sub-critical assemblies, CNSNS shall ensure that radiation safety, nuclear safety and operator competence are adequate.
		R11	**Recommendation**: Governmental mechanisms shall be established to ensure that RGSR is reviewed and revised and any other necessary regulations are developed, which are then approved in accordance
		S4	**Suggestion**: CNSNS should encourage the licensee to analyse the risks associated with LVNPP zero power state as well as external hazards.
		R12	**Recommendation**: Guidance and criteria to release nuclear sites from regulatory control shall be established. Such criteria shall ensure that adequate systems are in place to properly manage this release.
		S5	**Suggestion**: CNSNS should introduce hold-points for Research Reactors during the 10-year period of the operating licence especially after significant maintenance activities so that CNSNS could review, assess and authorize safe operations to continue.
		S6	**Suggestion**: Regulations or guidance should be established to deal with the legal situation of a nuclear installation when its licence has expired without a licence renewal or when its licence has been suspended or revoked.
		R13	**Recommendation**: The authorization system for applications of ionizing radiation shall be reviewed to ensure that it includes all controlled activities.
		R14	**Recommendation**: The authorization process for radiation facilities/installations shall be modified to include notification.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S7	**Suggestion**: CNSNS should consider modifying the authorization system to include the use of a graded approach to take into account risk (e.g. registration as a type of authorization).
		S8	**Suggestion**: CNSNS should review the authorization system to take into account the IAEA categorization of radioactive sources.
		R15	**Recommendation**: Written guidelines and evaluation procedures for all practices and activities for radiation facilities shall be prepared and formally approved.
		S9	**Suggestion**: Publishing of application forms and guidance documents should be extended to all practices. This would help to speed the process for submitting the application.
		R16	**Recommendation**: Written procedures for dealing with any subsequent amendment, renewal, suspension or revocation of an authorization shall be prepared and formally approved.
V	**REVIEW AND ASSESSMENT**	R17	**Recommendation:** CNSNS shall establish and implement arrangements for a systematic approach and should therefore write and approve internal procedures dealing with the CNSNS review and assessment process. Written procedures for all practices and activities shall be prepared and formally approved.
		S10	**Suggestion**: CSNSN should make efforts to issue the authorization before its expiry.
VI	**INSPECTION AND ENFORCEMENT**	R18	**Recommendation**: CNSNS shall better define the areas of regulatory responsibility and complete inspections in all appropriate areas.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S11	**Suggestion**: Consider making better use of all staff (e.g. Evaluators) by training more staff to conduct inspections.
		G2	**Good Practice**: a) CNSNS utilizes comprehensive checklists in the preparation for inspections, and b) conducts thorough discussions with the licensee regarding identified deficiencies or deviations. The explanations and information provided by CNSNS inspectors to the licensee at the end of inspections demonstrated good communications between CNSNS and the licensee regarding identified deficiencies or deviations.
		R19	**Recommendation:** A systematic and comprehensive inspection plan shall be developed to ensure that the minimum set of inspections is completed for nuclear inspections.
		S12	**Suggestions**: CNSNS should further develop aspects of their documented inspection oversight programme covering corrective actions, human and organizational performance, and safety culture.
		S13	**Suggestion**: CNSNS should finalize the event follow-up with a procedure that provides guidance on event response. Currently, other than management judgement, there is no guidance for staff and managers to use to ensure that all findings appropriate for follow-up are consistently completed. The use of risk insights, which CNSNS is continuing to improve, should be used to supplement this decision making process.
		G3	**Good Practice:** CNSNS has developed an effective Performance Indicator programme that effectively tracks a variety of indicators related to LVNPP.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		G4	**Good Practice**: Inspection findings are summarized every six months in a detailed Assessment Report that is prepared for internal distribution at CNSNS. Trends are analysed in a qualitative manner. Insights on performance are included.
		S14	**Suggestion**: CNSNS should evaluate a method to 1) feed the insights from the licensee assessment reports into the inspection programme, and 2) share insights from the Assessment Report with LVNPP management.
		S15	**Suggestion**: In developing the annual inspection programme, CNSNS should improve the systematic means of risk-informed decision making in determining areas of focus for the coming year.
		S16	**Suggestion**: CNSNS should complete and implement the process for safety significance determination for inspection results, which they have underway. This process should include different categories for inspection results based on safety significance, and establish guidelines for inspection follow-up based on the inspection results' significance.
		R20	**Recommendation**: CNSNS shall develop a formal enforcement policy which includes sanctions commensurate with the safety significance.
		S17	**Suggestion**: CNSNS should take actions to clarify the current interpretation of the Regulatory Law, which states that "all infringements" may be considered for enforcement; this would support enforcement actions being considered for a broader range of infractions.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R21	**Recommendation**: The Mexican Government shall clearly assign responsibility for regulatory oversight of quality control of therapy units, as well as occupational exposure and public exposure in diagnostic radiology practices. Adequate resources for its implementation shall be provided.
		R22	**Recommendation:** A systematic and comprehensive inspection plan shall be developed to ensure that the minimum set of inspections is completed for radiological inspections (e.g. category 1 medical sources).
		S18	**Suggestion**: CNSNS should consider methods to reduce the time required to write inspection reports regarding radiation safety inspections.
VII	**DEVELOPMENT OF REGULATIONS AND GUIDES**	R23	**Recommendation:** CNSNS shall pursue the development of the necessary nuclear regulation in order to complete the regulatory framework as a high priority activity. CNSNS shall also have one explicit policy to complete the regulatory framework.
		R24	**Recommendation:** CNSNS shall consider whether there is an alternative process that could be used to implement regulatory actions in a timely manner.
VIII	**MANAGEMENT SYSTEM**	R25	**Recommendation:** CNSNS shall establish and implement appropriate arrangements for a systematic approach to quality management which extend throughout the range of responsibilities and functions undertaken. The CNSNS Management System shall be in compliance with GS-R-1 and GS-R-3 requirements.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S19	**Suggestion:** Consider the evaluation of a work environment survey as part of the self assessment and as a point to start the integration of a Management System, consistent and developed to integrate all CNSNS Divisions under a common objective toward quality.
	EMERGENCY PREPAREDNESS	R26	**Recommendation**: CNSNS shall advise the Government to develop a national emergency plan for radiological emergencies for radiation facilities or radiation sources.
		R27	**Recommendation**: CNSNS shall ensure that all emergency response staff members receive emergency response training to perform their assigned response functions.
		R28	**Recommendation**: CNSNS shall participate in emergency exercises for the internal Nuclear Response Organization including the participation of relevant organizations.
		R29	**Recommendation**: CNSNS shall design a full-scale exercise that covers the action to be taken in both emergency and recovery phases.
		S20	**Suggestion**: CNSNS should develop new national guidelines for protective action recommendations to include all radiological emergencies in accordance with IAEA standards.
	RADIOACTIVE WASTE MANAGEMENT AND DECOMMISSIONING	R30	**Recommendation:** The National Policy and Strategies on Radioactive Waste Management (including decommissioning) shall be developed and approved at the Governmental level in accordance with the IAEA Safety Standards.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R31	**Recommendation**: Within the development of the National Policy for Radioactive Waste Management, the issue of high level waste (HLW) disposal shall be specifically addressed by the Government so that sound alternatives for final disposal of HLW are investigated and a long-term plan is developed and approved.
		R32	**Recommendation**: CNSNS shall review the General Regulation on Radiation Safety to assure consistency with IAEA Safety Standards. Special attention shall be paid to the dose limits for public exposure and to the introduction and implementation of the optimization principle including the use of the dose constraints.
		R33	**Recommendation**: In order to allow for the development of a complete regulatory framework for radioactive waste management, decommissioning and other safety areas, the Nuclear Law should be reviewed to provide formal empowerment of CNSNS as the national regulatory body for all safety issues in the nuclear field: radiation safety, nuclear safety, transport safety, physical protection and safeguards. In the review process of the Nuclear Law, radioactive waste management and decommissioning issues should be specifically addressed in order to provide the necessary enforcement or guidelines for the development of a national policy covering these fields.
		R34	**Recommendation**: CNSNS shall review the General Regulation for Radiation Safety in order to harmonize it with the safety requirements and dose limits for potential exposures as prescribed in the IAEA Safety Standards.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R35	**Recommendation**: CNSNS shall review the General Regulation for Radiation Protection in order to clearly introduce the concept of safety culture as part of the national regulatory framework for radioactive waste management and decommissioning.
		R36	**Recommendation**: CNSNS shall review the existing regulations and standards applying to each step in predisposal management of radioactive waste. The regulations and standards shall require the elaboration on safety cases and the appropriate safety assessments to support authorization requests and to serve as a basis for decision making.
		R37	**Recommendation**: CNSNS shall review and introduce the concept of radiological impact assessment in all present and future regulations related to all phases of the predisposal management of radioactive waste.
		S21	**Suggestion**: CNSNS should review the radioactive waste classification system for consistency with the IAEA Safety Standards to enable harmonization with international practices for disposal.
		R38	**Recommendation:** CNSNS shall review, update and harmonize criteria and clearance values established in both standards NOM-035-NUCL-2000 “Limits to consider a solid residue as radioactive waste” and NOM-028-NUCL-1996 “Radioactive waste management in radioactive facilities using open sources” in accordance with IAEA Safety Standards. The new standards shall explain in detail the rationale (e.g. scenarios, volumes, etc.) behind the established clearance levels.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R39	**Recommendation:** CNSNS shall establish clear and unambiguous procedures on how users shall specify their intent regarding clearance of radioactive materials and methods to deal with conditioned and unconditioned clearance and on how CNSNS will manage the associated authorization, control and records.
		R40	**Recommendation:** CNSNS shall review the regulations and standards in force for the assessment, authorization and control of radioactive discharges for the different type of facilities for consistency with IAEA Safety Standards. New regulations and standards shall be developed as necessary.
		R41	**Recommendation:** The public exposure potentially resulting from radioactive discharges shall be limited and conditioned in accordance with IAEA Safety Standards.
		R42	**Recommendation:** CNSNS shall consider the optimization principle for application in the review process of the regulation and standards to the discharge authorization and control and to establish dose constraints. All the criteria, scenarios, and conditions to be applied to the discharge regulation, evaluation, optimization and control shall be properly registered and recorded.
		R43	**Recommendation:** CNSNS shall develop and implement procedures for the request, review, assessment, authorization and control of radioactive discharges as part of the authorization process of practices and installations.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R44	**Recommendation**: CNSNS shall implement the concept of *predisposal management of radioactive waste* within the national regulatory framework and also review the regulations that apply to radioactive waste management in order to address the interdependencies and the adequacy of safety requirements in each phase of the radioactive waste management regulatory process.
		R45	**Recommendation**: CNSNS shall review the regulations to ensure regular notification to the Regulatory Body of waste inventory, in all installations generating, treating and storing radioactive waste; and develop a national integrated inventory to support the control and planning of activities for predisposal management of radioactive waste and final disposal.
		S22	**Suggestion**: CNSNS should review the license for the low level radioactive waste and disused radioactive sources treatment plant at the National Institute for Nuclear Research (ININ) to ensure that this licensee complies with IAEA Standards WS-G-2.5 and WS-G-2.7**.**
		R46	**Recommendation**: CNSNS shall develop a specific regulation to cover the licensing of storage facilities and shall review the existing regulations covering other phases of predisposal management of radioactive waste (022 NOM 1/2/3 – 1996 and 036 NOM – 2001) to ensure their coherence and consistency with the recently issued IAEA Safety Standard (WS-G-6.1).

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R47	**Recommendation:** The Government shall make a decision to establish a national disposal facility for low level radioactive waste to ensure there is a safe disposal option for radioactive waste in the country.
		R48	**Recommendation:** CNSNS shall review, update and harmonize radioactive waste disposal criteria and requirements in NOM-022-NUCL-1996 (1/2/3) to comply with IAEA Safety Standards.
		R49	**Recommendation**: CNSNS shall plan for the development of a regulatory framework for HLW disposal.
		S23	**Suggestion**: CNSNS should redefine the status of the CADER facility and, in accordance with this decision, review the license for the CADER low level radioactive waste storage/disposal facility, to ensure that this license complies with IAEA Standards.
		R50	**Recommendation:** CNSNS shall establish a full set of regulatory standards to cover safety requirements on decommissioning, taking into account IAEA Safety Standards.
		S24	**Suggestion:** CNSNS should consider establishing a formal group within the organization with the responsibility to plan, implement and control decommissioning regulatory activities.
	PUBLIC EXPOSURE, CHRONIC EXPOSURE AND REMEDIATION	R51	**Recommendation**: CNSNS shall review the General Regulation on Radiation Safety to assure consistency with IAEA Safety Standards. Special attention shall be paid to the dose limits for public exposure and to the introduction and implementation of the optimization principle including the use of dose constraints.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		S25	**Suggestion**: CNSNS should review, update and harmonize Nuclear Exemption Standard (NOM-035-NUCL-2000) so that it is consistent with IAEA RS-G-1.7.
		G4	**Good practice:** The CNSNS training programme for metal recyclers is building trust and cooperation between industry and the Regulatory Body.
		S26	**Suggestion**: CNSNS shall as soon as practicable update the General Regulation for Radiation Safety and include specific comprehensive environmental monitoring requirements to ensure that it appropriately addresses environmental monitoring programmes.
		S27	**Suggestion:** CNSNS should enforce environmental monitoring issues through licensing conditions until the General Regulation is updated.
		G5	**Good Practice:** CNSNS officially supports the ININ effort to modify and develop its environmental monitoring programme in accordance with IAEA International Standards.
		R52	**Recommendation**: CNSNS shall elaborate on and establish, according to the IAEA Safety Standards, the regulatory framework needed, and supported by appropriate guidance material, to establish the safety requirements to protect the public from chronic exposure.
		R53	**Recommendation**: CNSNS shall elaborate on and establish a regulatory framework, supported where necessary by appropriate guidance material, to guarantee that workers, the public and the environment are protected when remediation programmes are undertaken.

	Areas	IAEA Comment No R: Recommendations, S: Suggestions, G: Good practices	Recommendations, Suggestions or Good Practices
		R54	**Recommendation**: CNSNS together with other interested parties shall elaborate and implement a national strategy to investigate and identify potential areas requiring remedial actions.
	TRANSPORT OF RADIOACTIVE MATERIAL	R55	**Recommendation**: CNSNS shall elaborate on specific regulations to enforce compliance with IAEA Safety Standard TS-R-1, including recent revisions, on transport of all radioactive material in the country.
		R56	**Recommendation**: CNSNS shall establish a programme to assure compliance with requirements related to transport of radioactive material, establish procedures to carry out its regulatory activities on transport of radioactive materials, and assign staff to fulfil the responsibility for conducting regulatory activities related to transport of radioactive material.
		R57	**Recommendation**: CNSNS shall establish requirements and procedures to periodically assess radiation doses to persons due to the transport of radioactive material.
	SAFETY AND SECURITY OF RADIOACTIVE SOURCES	R58	**Recommendation**: CNSNS shall take measures to address the security of radioactive sources pending a comprehensive review of the Regulatory Law.

APPENDIX VI – REFERENCE MATERIAL PROVIDED BY CNSNS

CLAVE	LIST OF CSN PROCEDURES	AÑO
AI DIR 20	Programa de diligencias	
AI DIR 21	Planeación y ejecución de diligencias	
AI VRA-01	Recolección de muestras ambientales en instalaciones nucleares y radiactivas	2002
AI VRA-02	Recepción y registro de muestras en el departamento de vigilancia radiológica ambiental	2002
AI VRA-03	Preparación de muestras en el departamento de vigilancia radiológica ambiental	2002
AI VRA-04	Determinación de i-131 en leche	2002
AI VRA-05	Determinación de sr-89 y sr-90 en leche	2004
AI VRA-06	Determinación de tritio en leche por centelleo liquido	2003
AI VRA-07	Toma de muestras para pruebas de fuga	1998
AI VRA-08	Determinación de la concentración de actividad alfa y beta total en agua	2004
AI VRA-09	Determinación de sr-89 y 90 en cenizas de alimentos y otras muestras ambientales	2004
AI VRA-10	Determinación de sr-90 en agua de mar	2004
AI VRA-11	Evaluación de los informes de liberación de efluentes radiactivos en la central laguna verde	2007
AI VRA-12	Evaluación del informe radiológica ambiental de la clv	2007
AI VRA-13	Determinación de ra-226 en agua por centelleo líquido	2004
AI VRA-14	Determinación de tritio en agua por centelleo liquido	2003
AI VRA-15	Determinación de tritio en humedad de aire por centelleo líquido	2004
AI VRA-17	Determinación de la concentración de actividad alfa y beta total en agua de lluvia y en depositos secos	2004
AI VRA-20	Determinación de la concentración de actividad de radionuclidos en muestras ambientales y de alimentos por espectrometria gamma	2005
AI VRA-21	Determinación de la concentración de actividad beta total en filtros de aire	2007
AI VRA-24	Manejo de soluciones radiactivas (fuentes abiertas)	2003
AI VRA-31	Condiciones de operación del contador de centelleo líquido beckman ls 5801	2002
AI VRA-33	Calibración del detector termoluminiscente (tl)	1998
AI VRA-34	Calibración de dosímetros termoluminiscentes (tl)	2005
AI VRA-35	Preparación de dosímetros para trabajo de campo	2005
AI VRA-36	Preparación de dosímetros ambientales (dt-amb), para trabajo de campo	1998
AI VRA-37	Calibración de las balanzas analíticas	2002
AI VRA-38	Programa permanente de supervisión de los servicios de dosimetría	2000
AI VRA-39	Verificación de monitores portátiles de radiación	2005
AI VRA-41	Ejecución de inspeccion del departamento de vigilancia radiológica ambiental	1999

AI VRA-52	Control estadístico de calidad del equipo de conteo para mediciones de rutina	2003
AI VRA-53	Limpieza y descontaminación de material de laboratorio	2002

CLAVE	ORGANIZACIÓN DE CONTINGENCIAS NUCLEARES
PRE-100	Entrenamiento y conservación continua de la capacidad de respuesta a emergencias.
PRE-101	Verificación y mantenimiento de instalaciones y equipos.
PRE-102	Conformación preventiva de la oc.
PRE-103	Revisión y actualización del plan de contingencias nucleares y su manual de procedimientos.
PRE-200	Activación inicial de la respuesta.
PRE-201	Primer persona en arribar al ceco.
PRE-202	Manejo de las comunicaciones durante una emergencia.
PRE-203	Análisis de seguridad nuclear (operación).
PRE-204	Análisis de seguridad nuclear (sistemas).
PRE-205	Análisis de secuencias de accidentes.
PRE-206	Pronostico de dosis.
PRE-207	Seguimiento de la respuesta externa y análisis de consecuencias radiológicas.
PRE-208	Seguimiento de la respuesta en el sitio.
PRE-209	Manejo y disponibilidad del equipo de computo y telecomunicaciones
PRE-210	Manejo de la información y la comunicación social durante una emergencia.
PRE-211	Información a otros países y al organismo internacional de energía atómica (oiea).
PRE-300	Organización y análisis de documentos.
PRE-301	Actividad reguladora posterior a un accidente.

CLAVE	GERENCIA DE SEGURIDAD NUCLEAR PROCEDIMIENTO
AI DVO-01	Programación de inspecciones
AI DVO-02	Elaboración y uso de listas de verificación
AI DVO-03	Elaboración y trámite de informes de inspección
AI DVO-04	Elaboración y trámites de agendas de inspección
AI DVO-05	Ejecución de inspecciones
AI DVO-06	Controles administrativos para el licenciamiento de operadores y supervisores del reactor de instalaciones nucleares
AI DVO-07	Examen escrito para licenciar operadores y supervisores de reactores nucleares de investigación y desarrollo
AI EVA-05	Evaluación de asuntos de seguridad

CLAVE	GERENCIA DE TECNOLOGÍA REGLAMENTACIÓN Y SERVICIOS PROCEDIMIENTO	ANO

AC CNS-01	Elaboración y modificación de procedimientos	2007
AC CNS 05	Elaboración de reglamentación sobre seguridad	2007
AC CNS 12	Elaboración de anteproyectos de normas oficiales mexicanas	2007

LIST OF STANDARDS	
001-NOM-NUCL-1994	Factores para el cálculo del equivalente de dosis.
002-NOM-NUCL-1994	Pruebas de fuga y hermeticidad de fuentes selladas
003-NOM-NUCL-1994	Clasificación de instalaciones o laboratorios que utilizan fuentes abiertas.
004-NOM-NUCL-1994	Clasificación de los desechos radiactivos.
005-NOM-NUCL-1994	Límites anuales de incorporación (LAI) y concentraciones derivadas en aire(CDA) de radionúclidos para el personal ocupacionalmente expuesto
006-NOM-NUCL-1994	Criterios para la aplicación de los límites anuales de incorporación para grupos críticos del público.
007-NOM-NUCL-1994	Requerimientos de seguridad radiológica que deben ser observados en los implantes permanentes de material radiactivo con fines terapéuticos a seres humanos.
008-NOM-NUCL-2003	Límites de contaminación superficial con material radiactivo.
01209-NOM-NUCL-	Índice de transporte para el material radiactivo
012-NOM-NUCL-2002	Requerimientos y calibración de monitores de radiación ionizante
013 –NOM-NUCL-1995	Requerimientos de seguridad radiológica para egresar a pacientes a quienes se les ha administrado material radiactivo
018-NOM-NUCL-1995	Métodos para determinar la concentración de actividad y actividad total en los bultos de desechos radiactivos
019-NOM-NUCL-1995	Requerimientos para bultos de desechos radiactivos de nivel bajo para su almacenamiento definitivo cerca de la superficie.
020-NOM-NUCL-1995	Requerimientos para instalaciones de incineración de desechos radiactivos.
021-NOM-NUCL-1996	Pruebas de lixiviación para especimenes de desechos radiactivos solidificados
22-1-NOM-NUCL-1996	Requerimientos para una instalación para el almacenamiento definitivo de desechos radiactivos de nivel bajo cerca de la superficie. . parte 1 sitio.
22-2-NOM-NUCL-1996	Requerimientos para una instalación para el almacenamiento definitivo de desechos radiactivos de nivel bajo cerca de la superficie. parte 2 diseño.
22-3 -NOM-NUCL-1996	Requerimientos para una instalación para el almacenamiento definitivo de desechos radiactivos de nivel bajo cerca de la superficie. parte 3. Operación y clausura
24-NOM-NUCL-1995	Requerimientos y calibración de dosímetros de lectura directa.
25-1-NOM-NUCL-2000	Requisitos para equipo de radiografía industrial. parte 1: requisitos generales
25-2-NOM-NUCL-1996	Requisitos para equipo de radiografía industrial. parte 2 operación.
26-NOM-NUCL-1999	Vigilancia médica del personal ocupacionalmente expuesto a radiaciones ionizantes
27 -NOM-NUCL-1996	Especificaciones para el diseño de instalaciones radiactivas tipo II clases a, b y c.
28-NOM-NUCL-1996	Manejo de desechos radiactivos en instalaciones radiactivas que utilizan fuentes abiertas.

031-NOM-NUCL-1999 Requerimientos para la calificación y entrenamiento del personal ocupacionalmente expuesto a radiaciones ionizantes
032-NOM-NUCL-1997 Especificaciones técnicas para la operación de unidades de teleterapia que utilizan material radiactivo
033-NOM-NUCL-1999 Especificaciones técnicas para la operación de unidades de teleterapia: aceleradores lineales
034-NOM-NUCL-2000 Requerimientos de selección, calificación y entrenamiento del personal de centrales núcleoeléctricas
035-NOM-NUCL-2000 Límites para considerar un residuo sólido como desecho radiactivo
036-NOM-NUCL-2001 Requerimientos para instalaciones de tratamiento y acondicionamiento de desechos radiactivos
039--NOM-NUCL-2003 Especificaciones para la exención de fuentes de radiación ionizante y de prácticas que las utilicen
088-NOM- SSA1-1994 Contaminación por radionúclidos en alimentos de consumo masivo importados. LMP
002-NOM-SSA2-1993 Organización, funcionamiento e ingeniería sanitaria del servicio de radioterapia.
NOM-012-STPS-1999 Condiciones de seguridad e higiene en los centros de trabajo donde se produzcan, usen manejen, almacenen transporten fuentes de radiación ionizante.
NOM-127-SSA1-1994 Salud ambiental. Agua para uso y consumo humano. Límites permisibles de calidad y tratamientos a que debe someterse el agua para su potabilización.
LIST OF LAWS
Mexican Constitution
Nuclear Materials Law
Professional Service of Career Law
Administrative Responsibilities of Public SERVANTS Federal Law
Administrative Procedure Federal Law
Metrology and Standardization Federal Law
Transparency and Access to the Governmental Public Information Federal Law
Health General Law
Civil Protection General Law
Nuclear Law
Ecological Equilibrium and Environmental Protection General Law

APPENDIX VII – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

[1.] **IAEA SAFETY STANDARDS SERIES GS-R-1 -** *Legislative and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*

[2.] **IAEA SAFETY STANDARDS SERIES GS-G-1.1 -** *Organization and Staffing of the Regulatory Body for Nuclear Facilities*

[3.] **IAEA SAFETY STANDARDS SERIES GS-G-1.2 -** *Review and Assessment of Nuclear Facilities by the Regulatory Body*

[4.] **IAEA SAFETY STANDARDS SERIES GS-G-1.3 -** *Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body*

[5.] **IAEA SAFETY STANDARDS SERIES GS-G-1.4 -** *Documentation for use in Regulation of Nuclear Facilities*

[6.] **IAEA SAFETY STANDARDS SERIES GS-G-1.5 -** *Regulatory Control of Radiation Sources*

[7.] **IAEA SAFETY STANDARDS SERIES GS-R-2 -** *Preparedness and Response for a Nuclear or Radiological Emergency Safety Requirements*

[8.] **IAEA SAFETY STANDARDS SERIES GS-R-3 -** *Management System for Facilities and Activities*

[9.] **IAEA SAFETY STANDARDS SERIES NS-R-1 -** *Safety of Nuclear Power Plants: Design Safety Requirements*

[10.] **IAEA SAFETY STANDARDS SERIES NS-R-2 -** *Safety of Nuclear Power Plants: Operation Safety Requirements*

[11.] **IAEA SAFETY STANDARDS SERIES NS-R-4 -** *Safety of Research Reactors*

[12.] **IAEA SAFETY STANDARDS SERIES NS-G-4.1 -** *Commissioning of Research Reactors*

[13.] **IAEA SAFETY STANDARDS SERIES SS115 -** *International Basic Safety standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*

[14.] **IAEA SAFETY STANDARDS SERIES TS-R-1 -** *Regulations for the Safe Transport of Radioactive Material*

[15.] **IAEA SAFETY STANDARDS SERIES WS-G-2.1 -** *Decommissioning of Nuclear Power Plants and Research Reactors*

[16.] **IAEA SAFETY STANDARDS SERIES WS-G-2.2 -** *Decommissioning of Medical, Industrial and Research Reactors*

[17.] **IAEA SAFETY STANDARDS SERIES WS-R-1 -** *Near Surface Disposal of Radioactive Waste*

[18.] **IAEA SAFETY STANDARDS SERIES WS-R-2 -** *Predisposal Management of Radioactive Waste including Decommissioning*

[19.] **IAEA SAFETY STANDARDS SERIES WS-G-2.3 -** *Regulatory Control of Radioactive Discharges to the Environment*

[20.] **IAEA SAFETY STANDARDS SERIES WS-G-2.4 -** *Decommission of Nuclear Fuel Cycle Facilities*

[21.] **IAEA SAFETY STANDARDS SERIES WS-G-2.5 -** *Predisposal Management of Low and Intermediate Level Radioactive Waste*

[22.] **IAEA SAFETY STANDARDS SERIES WS-G-2.6 -** *Predisposal Management of High Level Radioactive Waste*

[23.] **IAEA SAFETY STANDARDS SERIES WS-G-2.7 -** *Management of Waste from the use of Radioactive Material in Medicine, Industry, Agriculture, Research and Education*

[24.] **IAEA SAFETY STANDARDS SERIES WS-R-3 -** *Remediation of areas contaminated by past activities and accidents*

[25.] **IAEA SAFETY STANDARDS SERIES WS-R-5 -** *Decommissioning of facilities using Radioactive Material*

[26.] **IAEA SAFETY STANDARDS SERIES WS-G-6.1 -** *Storage of Radioactive Waste*

[27.] **IAEA SAFETY STANDARDS SERIES RS-G-1.7 -** *Application of the Concepts of Exclusion, Exemption and Clearance*

[28.] **IAEA SAFETY STANDARDS SERIES RS-G-1.8 -** *Environmental and Source monitoring for Purpose of Radiation Protection*

[29.] **IAEA SAFETY STANDARDS SERIES RS-G-1.9 –** *Categorization of Radioactive Sources,*

[30.] **IAEA CODE OF CONDUCT** *on the Safety and Security of Radioactive Sources*

[31.] **IAEA CODE OF CONDUCT** *on the Safety of Research Reactors*

[32.] **IAEA GUIDANCE** *on the Import and Export of Radioactive Sources*

[33.] **IAEA SAFETY SERIES NO. 111-G-1.1** - *Classification of Radioactive Waste*

[34.] **SAFETY SERIES NO. 35 – G2 -** *Safety in the Utilization and Modification of Research Reactors*

[35.] **IAEA TECDOC 1388 -** *Strengthening control over radioactive sources in authorized use and regaining control over orphan source national strategies*

[36.] **INSAG SERIES NO. 17 -** *Independence in Regulatory Decision Making*

[37.] **INSAG SERIES NO. 20 -** *Stakeholder Involvement in Nuclear Issues*

[38.] **INSAG SERIES NO. 21 -** *Strengthening the Global Nuclear Safety Regime*

[39.] **IAEA LEGAL SERIES NO.14** - *Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident or Radiological Emergency Adopted on 26 September 1986 at the 18th 1986 plenary meeting*

APPENDIX VIII – CNSNS ORGANIZATIONAL CHART