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**INTEGRATED
REGULATORY
REVIEW SERVICE
(IRRS)
TO
CANADA**

Ottawa, Canada

31 May to 12 June 2009

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

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

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

REPORT
INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
THE GOVERNMENT OF CANADA

Ottawa, Canada
31 May to 12 June 2009



REPORT
INTERNATIONAL REGULATORY REVIEW SERVICE (IRRS)
REPORT TO
THE GOVERNMENT OF CANADA
Ottawa, Canada

Mission date: 31 May to 12 June 2009

Regulatory body: Canadian Nuclear Safety Commission (CNSC)

Location: CNSC Headquarters, Ottawa, Canada

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, uranium mines and milling.

Organized by: IAEA

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FOREWORD

by Mohamed ElBaradei
Director General

The General Conference Resolution of September 2006 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, and consider availing themselves of the Secretariat’s new Integrated Regulatory Review Service (IRRS) and notes with satisfaction the increased interest of the Member States in the IRRS.”

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

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

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EXECUTIVE SUMMARY

At the request of the Government of Canada, an international team of twenty one experts in nuclear, radiation and radioactive waste safety visited the Canadian Nuclear Safety Commission (CNSC) from 31 May to 12 June 2009 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the CNSC regulatory framework and its effectiveness.

The purpose of this IRRS mission was to review the application of the CNSC regulatory framework and regulatory activities to all regulated sources, facilities and activities, to review the effectiveness of the CNSC and to exchange information and experience in the areas covered by IRRS. The review was carried out by comparison against IAEA safety standards and the relevant Codes of Conduct as the international benchmark for safety.

It is expected that the IRRS mission will facilitate regulatory improvements in Canada and throughout the world from the knowledge gained and experiences shared by CNSC and the IRRS reviewers and through the evaluation of the effectiveness of the CNSC regulatory framework and its good practices.

The IRRS Review Team consisted of 15 senior regulatory experts from 13 Member States, one observer, four staff members from the IAEA and an IAEA administrative assistant. The IRRS team carried out the review of the CNSC in all relevant areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities of the regulatory body, including the authorization process, review and assessment, inspection and enforcement, the development of regulations and guides, the Management System and communication and consultation with interested parties.

The IRRS review addressed facilities and activities regulated by CNSC, including the operation of nuclear power plants, research reactors, waste management facilities, uranium mines and mills and other fuel cycle facilities; refurbishment of nuclear power plants; licensing of new nuclear power plants; and industrial, medical and research facilities and activities. The review also addressed radiation protection programs, waste safety and environmental protection programmes, implementation of the Code of Conduct on Safety and Security of Radioactive Sources and the transport of radioactive material. Emergency preparedness was not included in the IRRS scope.

In addition, policy issues were addressed, including “Research for Safety and Regulatory Purposes”, “Roles and Responsibilities of Technical Services in Support of Regulatory Decision Makers” and “New Builds: Regulatory Transition from Pre-Operational to Operational Phases”.

The mission included observations of regulatory activities and a series of interviews and discussions with key CNSC personnel and the staff of other organizations to help assess the effectiveness of the system. These involved the Ministry of Natural Resources (NRCan); Health Canada; Chalk River Laboratories (CRL) including the NRU research reactor; several fuel cycle facilities (Cameco-Zircatec, Port Hope and GE-Hitachi, Peterborough); McArthur River Uranium Mine and Key Lake Uranium Mill; OPG Western Waste Management Facility (Bruce Site); Darlington (OPG) and Bruce (Bruce Power) nuclear power plants; Calgary (Radiation Devices); Laval Irradiation Facility (MDS Canada Inc) and the Ottawa Hospital.

CNSC provided the IRRS Review Team with substantial documentation as advance reference material and a well prepared self-assessment, including an assessment of the strengths of CNSC and proposed actions to improve its regulatory effectiveness. The IRRS Review Team was impressed by the extensive preparation at all CNSC staff levels. Throughout the review,

the team was extended full cooperation in technical regulatory and policy discussions with CNSC management and staff. The IRRS Review Team identified a number of good practices and made recommendations and suggestions that indicate where improvements are necessary or desirable to continue improving the effectiveness of regulatory controls.

These recommendations and suggestions are made to an organization that is seeking to improve its performance and many of them are related to areas in which CNSC has already or is in the process of implementing a programme for change.

Subsequent to the unplanned shutdown in December 2007 of Atomic Energy of Canada Limited's (AECL) National Research Universal (NRU) reactor, CNSC's authorization and verification processes were reviewed by an independent team from Talisman International, LLC. The "Talisman report" provides a concise overview of key findings and recommended improvements to the authorization and verification processes. The implementation status of these recommendations was reviewed by the IRRS team, which concluded that the recommendations made by the Talisman report on NRU have been adequately addressed by the CNSC. The action plans for many of the issues are currently included in the "Harmonized Plan for Improvement Initiatives".

Particular strengths of CNSC, its policy, its legal and regulatory framework as well as its regulatory activities identified by the IRRS team were:

- The Canadian legislative and regulatory framework is comprehensive, with an appropriate range of instruments allowing for an effective application of the legal regime.
- The consistent Harmonized Plan that considers the results of all recent audits and assessments brings together all improvement initiatives under one plan and prioritizes them to optimize use of resources to deliver further improvements in key areas.
- The recruiting process is facilitated by optimized employment conditions provided by CNSC.
- CNSC has done extensive and commendable work over the last years to develop the Management System in order to make the organization more process-based.
- CNSC provides for a comprehensive and robust authorization/licensing system for all facilities and activities.
- CNSC processes and strategies for third party engagement and in particular for public involvement are comprehensive, open and transparent.
- Targeted use of inspections to focus limited regulatory resources on poor performance is a good example of optimization of regulatory resources to encourage licensees to improve their regulatory performance.
- A robust inspection programme along with good quality documentation and databases allow for a good level of feedback in the regulatory process.
- Where appropriate the CNSC adopts or adapts international standards when developing regulatory requirements.
- The CNSC's on-line sealed source tracking system provides an excellent model for other Member States.

The IRRS Review Team identified some priority issues and believes that consideration of these items should enhance the overall performance of the regulatory system:

- CNSC should initiate a periodic strategic planning programme to define both short-term and long-term research activities with a view to supporting regulatory decisions.
- Sufficient resources for research activities should be allocated to support the outcome of the strategic planning programme.
- The activities and processes identified within the Harmonized Plan for authorizations in relation to preparation of a comprehensive set of procedures, criteria and review guides should continue to be developed and should be fully implemented.
- CNSC should ensure that non-safety significant changes to licences for nuclear installations and uranium mines and mills do not generate disproportionate regulatory work.
- In order to fully implement its Management System, CNSC should invest the necessary efforts to finalize the remaining activities, to develop some new activities and to transfer them to the decided format, as defined within the Harmonized Plan.
- CNSC should develop a methodology and implement Management System reviews at planned intervals by internal or/and external resources. CNSC should also supplement the internal audit programme by implementing a mechanism to identify opportunities for improvement, and should monitor improvement actions and check the effectiveness of the improvements.
- CNSC should consider updating the 1998 Memorandum of Understanding with Health Canada in order to define the roles and responsibilities of the Federal Provincial Territorial Radiation Protection Committee and to ensure comprehensive and consistent safety regulation and oversight.
- CNSC should ensure that its operational and technical support branches work together in a more harmonized manner to assure security measures not compromise safety and vice versa.
- CNSC should refine existing plans for new-build and confirm the organizational readiness to support the transition from the project planning phase to the technical review of new design applications, inspection of construction activities and oversight of the start-up and operations.

The IRRS Review Team findings are summarized in Appendix V.

A press release was issued at the end of the mission. The CNSC's own press release featured the IAEA press release.

I. INTRODUCTION

At the request of the Government of Canada, an international team of twenty one experts in Nuclear, Radiation and Radioactive Waste Safety visited the Canadian Nuclear Safety Commission (CNSC) from 31 May to 12 June 2009 to conduct an Integrated Regulatory Review Service (IRRS) mission to review the CNSC regulatory framework and its effectiveness. In October 2008, a preparatory meeting had been carried out in Ottawa to discuss the objective and purpose of the review as well as its scope in connection with all aspects of the work of CNSC.

The IRRS Review Team consisted of 15 senior regulatory experts from 13 Member States, one observer, four staff members from the IAEA and an IAEA administrative assistant. The IRRS team carried out the review of the CNSC in all relevant areas: legislative and governmental responsibilities; responsibilities and functions of the regulatory body; organization of the regulatory body; activities of the regulatory body, including the authorization process, review and assessment, inspection and enforcement, the development of regulations and guides, the Management System and communication and consultation with interested parties.

The IRRS review addressed facilities and activities regulated by CNSC, including the operation of nuclear power plants, research reactors, waste management facilities, uranium mines and mills and other fuel cycle facilities; refurbishment of nuclear power plants; licensing of new nuclear power plants; and industrial, medical and research facilities and activities. The review also addressed radiation protection programs, environmental protection programmes, implementation of the Code of Conduct on Safety and Security of Radioactive Sources, and the transport of radioactive material. Emergency preparedness was not included in the IRRS scope.

In addition, policy issues were addressed, including: “Research for Safety and Regulatory Purposes”, “Roles and Responsibilities of Technical Services in Support of Regulatory Decision Makers” and “New Builds: Regulatory Transition from Pre-Operational to Operational Phases”.

CNSC prepared substantial documentation as advance reference material and a well prepared self-assessment, including an evolution of the strengths of, and proposed actions to improve, the regulatory effectiveness of CNSC. During the mission the team performed a systematic review of all topics using the advance reference material, interviews with CNSC staff, other involved organizations and direct observation of their working practices during inspections carried out by CNSC.

The mission included observations of regulatory activities and a series of interviews and discussions with key CNSC personnel and the staff of other organizations to help assess the effectiveness of the system. These involved Ministry of Natural Resources (NRCan); Health Canada; Chalk River Laboratories (CRL) including the NRU research reactor; Fuel Cycle Facilities (Cameco-Zircatec, Port Hope and GE-Hitachi, Peterborough); McArthur River Uranium Mine and Key Lake Uranium Mill; OPG Western Waste Management Facility (Bruce Site); Darlington (OPG) and Bruce (Bruce Power) NPPs; Calgary (Radiation Devices); Laval Irradiation Facility (MDS Canada Inc) and the Ottawa Hospital.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to conduct a review of the CNSC regulatory framework and regulatory activities as applied to all regulated sources, facilities and activities, to review its regulatory effectiveness and to exchange information and experience in the areas covered by IRRS. The review was carried out by comparison against IAEA safety standards and the relevant Codes of Conduct as the international benchmark for safety. It is expected that the IRRS mission will facilitate regulatory improvements in Canada and throughout the world from the knowledge gained and experiences shared by CNSC and the IRRS reviewers and through the evaluation of the effectiveness of the CNSC regulatory framework and its good practices.

Subsequent to the unplanned shutdown in December 2007 of Atomic Energy of Canada Limited's (AECL) National Research Universal (NRU), CNSC's authorization and verification processes were reviewed by an independent team from Talisman International, LLC. The "Talisman report" provides a concise overview of key findings and recommended improvements to the authorization and verification processes. The implementation status of these recommendations was also reviewed by the IRRS team.

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

- ✓ Providing CNSC, through completion of the IRRS questionnaire, with an opportunity for self-assessment of its activities against international safety standards.
- ✓ Providing Canada (CNSC and governmental authorities) with a review of their regulatory programmes and policy issues relating to nuclear and radiation safety;
- ✓ Providing Canada (CNSC and governmental authorities) with an objective evaluation of their nuclear and radiation safety regulatory activities with respect to international safety standards;
- ✓ Contributing to the harmonization of regulatory approaches among Member States;
- ✓ Promoting the sharing of experience and exchange of lessons learned;
- ✓ Providing reviewers from member States and the IAEA staff with opportunities to broaden their experience and knowledge of their own field;
- ✓ Providing key staff with an opportunity to discuss their practices with reviewers who have experience of other practices in the same field;
- ✓ Providing Canada (CNSC and governmental authorities) with recommendations and suggestions for improvement;
- ✓ Providing other States with information regarding good practices identified in the course of the review;

III. BASIS FOR THE REVIEW

A) PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Canadian government authorities, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 6 to 8 October 2008. The preparatory work for the mission was carried out by the appointed Team Leader Mr. Shojiro Matsuura President, Nuclear Safety Research Association, Japan, the appointed Deputy Team Leader Mr. Martin Virgilio Deputy Executive Director, Materials, Research, State, Tribal and Compliance Programmes, US Nuclear Regulatory Commission, the IRRS IAEA Team Coordinator Mr. Gustavo Caruso, and the IRRS IAEA Deputy Team Coordinator Mr. John Wheatley,.

The team had extensive discussions regarding regulatory programs and policy issues with the senior management of CNSC represented by the newly appointed CNSC President, Mr. Michael Binder, Mr. Ramzi Jammal, CNSC Executive Vice-President and Chief Regulatory Operations Officer, Mr. Barclay Howden, Director General, Directorate of Regulatory Improvement and Major Projects Management, Mr. Greg Rzentkowski, Director General, Directorate of Power Reactor Regulation, Mr Peter Elder, Director General, Directorate of Nuclear Cycle and Facilities Regulation and Mr. André Régimbald, Director General, Directorate of Nuclear Substance Regulation. The Liaison Officer for the IRRS mission was Mr. Jean LeClair, Director, Internal Quality Management Division. The discussions resulted in the following areas to be covered by the IRRS mission:

- Nuclear Power Plants;
- Research Reactors;
- Processing Facilities;
- Fuel Cycle Facilities;
- Uranium mines, mills, refining, conversion and fuel fabrication;
- Nuclear Substances and Radiation Devices;
- Waste Management, Transportation and Radiation Protection;
- Selected policy issues.

In addition, it was decided that the Code of Conduct for radioactive sources would be included

Mr Binder and Mr Jammal made a comprehensive presentation on the CNSC organization, main responsibilities and its current activities and current regulatory challenges. Mr. Howden provided an overview of the CNSC Authorization Process, Review and Assessment, Inspection, Enforcement and development of Regulations and Guides for all regulated Facilities and Activities. Mr Al Omar presented the self assessments made by the CNSC. Finally, Mr. LeClair presented the CNSC Management System. This was followed by a discussion on the documentation to be submitted by the CNSC to the IAEA.

The team composition (senior regulators from Member States to be involved in the review) was discussed and the size of the team was confirmed. Logistics including meeting and work space, counterpart identification, lodging and transportation to accommodate site visits and observations were also addressed.

B) REFERENCE FOR THE REVIEW

The most relevant IAEA safety standards used as review criteria are: GS-R-1, Safety Requirements on Legal and Governmental Infrastructure; the revision of GS-R-1 (DS415, Draft Safety Requirements Governmental, Legal and Regulatory Framework for Safety); GS-R-3, Safety Requirements on The Management System for Facilities and Activities; the

International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (the BSS); and the Code of Conduct for Safety and Security of Radioactive Sources.

C) CONDUCT OF THE REVIEW

An opening team meeting was conducted on Sunday, 31st May 2009 in Ottawa by the IRRS Team Leader, the IRRS Deputy Team Leader, the IRRS IAEA Team Coordinator and the IRRS IAEA Deputy Team Coordinator to discuss the specifics of the mission, to clarify the basis for the review and the background, context and objectives of the IRRS and to agree on the methodology for the review and the evaluation among all reviewers.

The opening remarks were given by Mr. Ramzi Jammal. The Liaison Officer, Mr. Jean LeClair, was present at the opening team meeting, in accordance with the IRRS guidelines. The reviewers also reported their first impressions of the advance reference material.

The IRRS entrance meeting was held on Monday, 1st June 2009, with the participation of CNSC senior management. Opening remarks were made by Dr. Michael Binder, CNSC President, the IRRS Team Leader and the IRRS Deputy Team Leader.

During the mission, a systematic review was conducted for all the review areas with the objective of providing CNSC with recommendations and suggestions as well as identifying good practices. The review was conducted through meetings, interviews and discussions, visits to relevant organizations and direct observations regarding the national practices and activities.

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

The IRRS exit meeting was held on Friday, 12th June 2009. The opening remarks of the exit meeting were presented by Mr. Ramzi Jammal. The results of the IRRS mission were presented by Mr. Matsuura and Mr. Virgilio. The closing remarks were made by Mr. Tomihiro Taniguchi, Deputy Director General of IAEA and Head of the Department of Nuclear Safety and Security and Dr. Michael Binder, CNSC President.

NOTE: The scope of the mission was focused on CNSC as the nuclear regulator. There are other regulatory bodies for some aspects for industrial and medical activities i.e. Health Canada and the provinces/territories. The report refers only to CNSC as 'the Regulatory Body'.

1. LEGISLATIVE AND GOVERNMENTAL RESPONSIBILITIES

1.1 STATE ORGANIZATION FOR SAFETY

Legislative and statutory framework

Works and undertakings for the production, use and application of nuclear energy and the related research are considered as works for the general advantage of Canada and therefore subject to federal legislative control.

At the top level of Canada's nuclear regulatory framework is the *Nuclear Safety and Control Act*. It came into force on May 31, 2000 and provides the Canadian Nuclear Safety Commission (CNSC) with its regulatory authority. Under the Act, the Commission's mandate is to regulate:

- the development, production and use of nuclear energy;
- the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to prevent unreasonable risk to the environment, to the health and safety of persons and to national security; and
- to achieve conformity with Canada's international commitments regarding nuclear non-proliferation, safeguards and security.

Equally, the Commission is charged with providing objective scientific, technical and regulatory information to the public. The CNSC also

- administers the *Nuclear Liability Act*; and
- conducts environmental assessments under the *Canadian Environmental Assessment Act* concerning the effects of the nuclear industries on health, safety and the environment.

The following other legislation enacted by Parliament also applies to the nuclear industry in Canada:

- the *Nuclear Energy Act*;
- the *Nuclear Fuel Waste Act*;
- the *Emergencies Act*;
- the *Emergency Management Act*;
- the *Canadian Environmental Protection Act*; and
- the *Canada Labour Code*.

The Canadian Government applies the provisions of international conventions and has ratified the following international conventions affecting radiation protection and nuclear safety such as:

- the Convention on Nuclear Safety;

- the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management;
- the Non-Proliferation Treaty;
- the Convention on Physical Protection of Nuclear Materials;
- the Convention on Early Notification; and
- the Convention on Assistance in Case of a Nuclear Emergency.

Below the level of the laws and the conventions, there are **Regulations** concerning nuclear safety and radiation protection and related subjects. The following regulations are issued under the NSCA:

- General Nuclear Safety and Control Regulations;
- Radiation Protection Regulations;
- Class I Nuclear Facilities Regulations;
- Class II Nuclear Facilities and Prescribed Equipment Regulations;
- Nuclear Substances and Radiation Devices Regulations;
- Packaging and Transport of Nuclear Substances Regulations;
- Uranium Mines and Mills Regulations; and
- Nuclear Security Regulations;
- Nuclear Non-proliferation Import and Export Control Regulations;
- Canadian Nuclear Safety Commission Cost Recovery Fees Regulations;
- Canadian Nuclear Safety Commission Rules of Procedure; and
- Canadian Nuclear Safety Commission Bylaws.

These regulations are legally binding and generally non prescriptive. They are established by the CNSC and are subject to governmental approval.

The Commission's legal framework includes, in addition to legally enforceable instruments such as acts, regulations, licences and orders, non-binding regulatory documents that may be used to support and provide further information and guidance to the regulated community on these instruments. Regulatory documents can be a means of informing applicants of the Commission's regulatory expectations.

The IRRS team assessed this legislative and regulatory framework as being comprehensive, with an appropriate range of instruments allowing for an effective legal regime. It certainly meets the requirements of GS-R-1 2.2(1).

Establishment of an effectively independent regulatory body

The original legislation in Canada governing nuclear safety, the *Atomic Energy Control Act* of 1946, encompassed both regulatory and developmental aspects of nuclear activities. With the new NSCA these two functions are separated in law. The NSCA (section 8) denominates the CNSC as the regulatory body in Canada. It clearly distinguishes its regulatory role from that of the federal research, development and marketing organization known as Atomic Energy of Canada Limited (AECL). No other authorities than the CNSC are involved in the licensing and the regulation of the safety aspects of nuclear activities.

The Commission is a quasi judicial tribunal. CNSC has the legal status of a departmental corporation. The Commissioners of the CNSC are, according to section 10 of the NSCA, appointed by the Governor in Council (representative of the Queen in Canada acting on advice of the Cabinet). The Governor in Council may, according to section 19 of NSCA issue to the Commission directives of general application on broad policy matters with respect to the objects of the Commission. Such orders are binding upon the Commission and must be presented to Parliament.

CNSC reports to the Parliament of Canada through the Minister of Natural Resources Canada (NRCan). It also requires the involvement and support of the Minister for special initiatives such as amendments to regulations.

NRCan formulates the Government of Canada's policy regarding nuclear energy and natural resources; it is also a licensee for the cleanup of certain low-level radioactive wastes on behalf of the Government of Canada and consequently is subject to CNSC policies and licensing matters. Moreover NRCan is the appropriate ministry of AECL and is the administrative channel for the reporting of AECL.

While NRCan has important responsibilities relating to nuclear energy, the decision to invest in electricity generation rests with the provinces. It is up to the provinces, in concert with the relevant provincial energy organizations/power utilities, to determine whether or not new nuclear power plants should be built.

Because of NRCan's role as appropriate ministry for both the CNSC and AECL, as well as a licensee of CNSC, the IRRS Team closely inquired into the *de jure* and *de facto* independence of the CNSC from NRCan. On the basis of the CNSC self assessment and interviews with CNSC and NRCan, the team noted:

- NRCan acts as the administrative channel for the Commission. The CNSC submits its Reports through the Minister of NRCan to Parliament.
- NRCan has limited executive powers on the CNSC e.g. it can request reporting on issues concerning the general administration and management of the affairs of the Commission (NSCA section 12(4))
- All significant decisions like the appointment of commissioners, the issuing of directives and the approval of regulation are taken by the Cabinet as whole and enacted by the Governor in Council.
- A member of the Commission may only be removed from its function by the Governor in Council for misconduct.

The IRRS Team agrees that the Canadian arrangements meet the requirements of 2.2(2) of GS-R-1. Nevertheless it has to be pointed to the fact that the aspects of promotion in respect to nuclear energy are represented by the ministry that CNSC reports through.

Regulatory body - assigned authority and resources

The Commission has the authority to regulate a broad scope of activities involving the development, production and use of nuclear energy in Canada.

The objects of the Commission are (NSCA, section 9):

- the regulation of the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information in order to prevent unreasonable risk to the environment and to the health and safety of persons, to national security and to achieve conformity with measures of control and international obligations to which Canada has agreed,

- the dissemination of objective scientific, technical and regulatory information to the public concerning the activities of the Commission and the effects on the environment and on the health and safety of persons.

The Nuclear Safety and Control Act (NSCA) assigns responsibility to CNSC for:

- authorization;
- regulatory review and assessment;
- inspection and enforcement;
- establishing safety principles, criteria, regulations and guides; and
- communication and public information.

NSCA (section 20) makes the Commission a court of record which has all the powers necessary to carry out its duties. In particular, any decision or order of the Commission may, for the purposes of enforcement, be made a rule, order or decree of the Federal Court or of a superior court of a province and be enforced accordingly.

According to Section 16 of the NSCA, CNSC has the status of a separate employer. CNSC can employ the professional, scientific, technical and other staff it needs to carry out its responsibilities. It sets their conditions of employment on its own classification scheme and, in consultation with Treasury Board, sets salary levels. The Commission has the statutory authority to prescribe and charge cost recovery fees for its regulatory activities concerning applicants and licensees. Some activities not directly related to licensees, and the activities for licensees that are fee-exempt, are financed by parliamentary appropriations.

Legal and governmental mechanisms are in place to ensure that no other responsibilities are assigned to the CNSC which might jeopardize, or conflict with, its responsibility for regulating safety. The Commission's mandate is limited to safety aspects of nuclear activities. Developmental aspects of nuclear energy or political or economic objectives are not part of CNSC mandate.

The team considered the question whether the directive issued by the Governor in Council on 10 December 2007 clarifying that "in regulating the production, possession and use of nuclear substances in order to prevent unreasonable risk to the health of persons, the Canadian Nuclear Safety Commission shall take into account the health of Canadians who, for medical purposes, depend on nuclear substances produced by nuclear reactors" would be an exception and came to the following conclusions:

- The directive – as written – is limited to production, possession and use of nuclear substances for medical purposes.
- The consideration for the health of the Canadians was already part of operational procedures in the CNSC but was not sufficiently documented. The CNSC documented their approach to integrate the medical health aspects into their regulatory decision making. For example measures are in place to reduce the response time for licensing processes associated with the use of medical isotopes.
- The application of the directive can not lead to a conflict with the regulation on nuclear safety

CNSC is fully involved in the system of governmental emergency response and intervention capability in Canada. It cooperates with other bodies that share responsibility for emergency preparedness through provisions of Memoranda of Understanding, the Federal Nuclear Emergency Plan, regular meetings and single-points-of-contact with key organizations and groups, and joint emergency exercises. In addition, the CNSC has trained first responders to

support emergency response when and as needed. The mission did not review the details of the emergency preparedness organization since it was outside the scope of this mission.

With the approval of the Governor in Council, the CNSC may make legally binding regulations. The matters over which the Commission can make regulations are set out in Subsection 44(1) of the NSCA. In addition the Commission is authorized to release non-binding regulatory documents that may be used to support and provide further information and guidance to the regulated community on these instruments.

The requirement to conduct a safety assessment results from the licensing procedure. The CNSC only grants a licence for Class I nuclear facilities, if an acceptable safety analysis report has been submitted by the applicant. There is no requirement of a formal periodic safety review, but CNSC requires that Class I and II nuclear facilities regularly update their facility description and their safety analyses. In addition, a safety assessment is submitted in support of licence renewal. Furthermore, power reactor operators have to perform an integrated safety assessment comparable with an IAEA Periodic Safety Review as part of any refurbishment activity for the purposes of life extension.

The legislation gives the CNSC the authority:

- to require an operator to provide any necessary information, including information from its suppliers, even if this information is proprietary (Based on NSCA Section 32(g) an inspector may examine any information related to nuclear safety).
- to issue, amend, suspend or revoke authorizations and to set conditions (Subsection 24(2) of the NSCA)
- to enter a site or facility at any time to carry out an inspection (NSCA Section 30) empowers an inspector to inspect nuclear facilities at any reasonable time. In situations deemed as bearing unreasonable risk to the health or safety of persons or to the environment or in case of suspecting a contamination, the inspections can be carried out at any time).
- to enforce regulatory requirements. (see NSCA Section 35. Depending on the level of risk of the condition observed, CNSC enforces by recommendations, action notices, directives or orders to take corrective actions. The Commission may also amend or revoke the licence or issue an emergency order.)
- to communicate directly with governmental authorities at higher levels when it is considered necessary for exercising effectively the functions of the Regulatory Body (CNSC communicates frequently with NRCAN and other governmental organizations. With respect to matters related to general administration and management the President of the Commission has the status of a deputy minister).
- to liaise and co-ordinate with other governmental or non-governmental bodies having competence in such areas as health and safety, environmental protection, security, and transport of dangerous goods (CNSC cooperates with other governmental bodies at the federal and provincial level and can enter into arrangements with them; see NSCA paragraph 21(1)(a)).

The IRRS Team comes to the conclusion that the requirements of GS-R-1, paragraph 2.6 are met and has no specific recommendations or suggestions with respect to the authority of CNSC.

Advisory Bodies, Technical Support and Research Organizations

Paragraph 21(1)(c) of the NSCA provides that the Commission may, in order to attain its objects, establish and fix the terms of reference of advisory, standing and other committees.

The Commission has, however, chosen not to establish any such technical advisory committees (see also section 3.3).

On the governmental level the Natural Sciences and Engineering Research Council and National Research Council promote and support research in the natural sciences and engineering, except the medical sciences, and advise the minister on aspects of such research, on request.

Paragraph 21(1)(b) of the NSCA provides that the Commission may, to attain its objects, establish and maintain programmes to provide the Commission with scientific, technical and other advice and information.

1.2. LEGISLATIVE AND REGULATORY ASPECTS

Legislative requirements

Adequate legal and governmental mechanisms are in place to ensure adequate regulation of all phases of nuclear facilities and activities, up to and including decommissioning,, site rehabilitation, and activities such as the safe management of radioactive waste and the safe transport of radioactive material.

Legislation has been promulgated in Canada that provides for effective control of nuclear, radiation radioactive waste and transport safety.

The legislation sets out in NSCA Section 3 effective objectives for protecting individuals, society and the environment from radiation hazards. This is reflected and specified in the objectives set to the CNSC in Section 9. The mandate to prevent unreasonable risk to the environment and to the health and safety of persons is by its nature focused on the individual, on society and the environment, both in the present and the future.

The legislation specifies facilities, activities and materials that are included in its scope, and provides for some exemptions. See Sections 4-7 of the NSCA.

The legislation establishes authorization and other processes (such as notification), which take account of the potential magnitude and nature of the hazard associated with the facility or activity, and specifies the steps of the processes. Sections 24 and 25 of NSCA define the authorization process and take into account the potential magnitude and nature of the associated hazards. Regulations made by CNSC under Section 44 of the NSCA (Class I Nuclear Facilities Regulations, Uranium Mines and Mills Regulations, and Class II Nuclear Facilities and Prescribed Equipment Regulations) define the facilities that are included and in itself take into account the magnitude and nature of the hazards. Section 26 of the NSCA prohibits any use without holding a licence.

Legislation (Section 26 NSCA) specifies the process (licensing) for removal of nuclear facilities from regulatory control.

The Commission is the first appeal instance for its own regulatory decisions. The NSCA provides mechanisms for the redetermination of decisions, on application (Subsection 43(2)), and appeals against a decision made by a Designated Officer (DO). A final decision of the Commission can be subjected to judicial review by the Federal Court of Canada.

An independent review of the Chalk River NRU reactor event (the Talisman report; see appendix to Chapter 3) recommended that CNSC strengthen its enforcement capabilities by seeking authority to issue civil penalties without referral to the justice department. Implementing this recommendation would require a change to the NSCA. This recommendation has been comprehensively reviewed by CNSC in particular the implications of introducing administrative fines into a generally non prescriptive legal framework and the

establishment of a corresponding appeal mechanism. A decision on further actions has not yet been taken.

Newly established legally binding requirements are enacted through the development and implementation of new/revised regulations or regulatory documents which are made binding in connection with licence amendments.

Operator responsibility

The *Nuclear Liability Act* provides for compensation on a no-fault basis to third parties who have suffered injuries or damages as a result of a nuclear incident. Although Canada is not a party to any of the international conventions on nuclear third party liability, the *Nuclear Liability Act* is largely based on the principles laid down in the Paris and Brussels Conventions on Third Party Indemnity in the event of an accident from a nuclear installation. The *Nuclear Liability Act* is in the process of being amended. The proposed amendments have been approved by the government and discussion in parliament is underway.

The operator's prime responsibility for nuclear and radiation safety follows from the licensing principles of the NSCA and the General Nuclear Safety and Control Regulations (Subsection 12(1)). The direct assignment of responsibility to the operator is contained in CNSC's Regulatory Fundamentals (P-299), which is a policy statement of CNSC.

Legal requirements governing continuity of responsibility when activities are carried out by several successive operators are defined in Subsection 24(8) of the NSCA, which requires a new licence for the facility in case of change of operators.

The CNSC can impose a licence condition (Subsection 24(5) of the NSCA) requesting the applicant to provide a financial guarantee in a form that is acceptable to the Commission. The Commission has made use of its authority to require financial guarantees in order to ensure funds are available in the event of decommissioning and for safe radioactive waste management.

2. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

2.1. GENERAL

Regulatory body - fulfilling statutory obligations

In addition to the legally binding regulations, the CNSC has defined a comprehensive range of non-binding **regulatory documents** which describe “the philosophy, principles or fundamental factors which underlie the CNSC’s approach to its regulatory mission”. The CNSC policy is to use the IAEA standard as far as possible. These are further described in chapter 7 on development of regulations and guides and Chapter 8 on the Management System.

The CNSC has established a detailed and comprehensive process for review and assessment of submissions from operators prior to initially granting a licence or on the occasion of licence renewals. The processes for review and assessment are considered in Chapter 5. The introduction of Periodic Safety Reviews is being considered. See Chapter 4.

The licences issued by CNSC specify:

- the facilities, activities or inventories of sources authorized in the licence;
- the licence conditions specifying the obligations of the operator in respect of its facility, equipment, radiation source(s) and personnel.
- dose and discharge limits
- conditioning criteria for radioactive waste processing in the appendices of the licences of waste management facilities
- any additional separate authorizations that the operator is required to obtain from the regulatory body;

Licences are usually issued for a period of 2 to 5 years.

The requirements for incident reporting, the reports that the operator is required to make, the records that the operator is required to retain and the emergency preparedness arrangements are prescribed in various regulations made by the Commission and in the licences.

Licences for Class I facilities and uranium mines and mills are issued by the Commission. In order to reduce the processing time of licensing decisions, the amendment of licences can be delegated to panels of the Commission. The Commission has the right (Section 37 of the NSCA) to designate persons as Designated Officers (DO) who have delegated authority for certain activities. For example Designated Officers have been authorized by the Commission to issue licences for Class II facilities, nuclear substances and radiation devices. They have to report significant activities to the Commission and have to refer any order to the Commission for review. The DO does not have the power to correct or overturn a decision by the Commission.

In the event of serious safety concerns DOs have the authority to issue orders without prior involvement of the Commission.

CNSC carries out regulatory inspections. There is a detailed inspection planning process taking into account risk and performance aspects. There is a graded range of enforcement powers, ranging from verbal request to prosecution. The issues of inspection and enforcement are discussed in chapter 6.

Regulatory body – discharging its main responsibilities

The main responsibilities that are discharged by the CNSC include licensing, review and assessment, inspection, enforcement, and communication.

The CNSC is establishing procedures in the Management System for dealing with all licence applications within its area of responsibility. An amendment of a licence is possible either on application by the licensee or on the Commission's own initiative under prescribed conditions.

Information with respect to the licensing process for new facilities, such as NPPs, has recently been clarified in guidance documents.

Further efforts are taken to describe the assessment activities in review guides, to map them in the Management System and to harmonize and standardize the licences of all facilities in order to make them clearer and to remove potential sources of misunderstanding.

The CNSC currently requires major licensees to perform an integrated safety assessment comparable with an IAEA Periodic Safety Review as part of any refurbishment activity for the purposes of life extension. In addition, the CNSC is considering moving towards formal periodic safety review every 10 years.

The CNSC Information Security Directive provides specific guidance on corporate procedures for identifying and managing sensitive information. Training and advice is available to assist staff.

For all licence applications, the Commission Rules of Procedure Section 15(1)(d) requires that a record be made of any final decision, including reasons.

CNSC operates on the principle of openness and transparency and liaises with many other governmental and international bodies. One of its objects is "to disseminate objective scientific, technical and regulatory information to the public". CNSC provides an annual report to Parliament that contains a description of its activities with respect to facilities and activities and an overall report on whether licensees have met requirements and provides extensive information on its Web site.

Each licensee, of class I nuclear facilities and Uranium mines and mills, monitors internal events and events at other similar facilities. Corrective actions and improvements are implemented. Dissemination of the lessons learned occurs within the frame of facility owner organizations like WANO or COG.

For significant events, the CNSC does require licensees to conduct a full root cause analysis.

There are legal requirements for records relating to the safety of facilities and activities to be retained and retrievable (Section 27 of the NSCA). Any additional requirements related to record-keeping that might be required may be imposed through licence condition under Subsection 24(5) of the NSCA.

As a principle national and international standards have to be applied to the development, production and use of nuclear energy in Canada. The regulations made by the Commission follow this principle and are subjected to extensive internal reviews and consultation with stakeholders.

The CNSC promotes strong safety culture amongst all its licensees. For example, the CNSC recommends power reactor licensees to institute a safety management system to foster safety culture.

Regulatory body – cooperation with other relevant authorities

There is cooperation with several government and provincial agencies regarding

1. Environmental Protection;
2. Public and Occupational Health;
3. Emergency Planning and Preparedness;
4. Radioactive waste management (including determination of national policy);
5. Public liability (including implementation of national regulations and international conventions concerning third party liability);
6. Water use and consumption of food;
7. Land use and planning; and
8. Safety in the transport of dangerous goods.

In some cases the cooperation has been supplemented with Memoranda of Understanding (MoU). Two particular MoUs of interest were studied in some detail by the review team.

The CNSC is responsible for package approval and the transportation of class 7 radioactive material. CNSC staff performs audits and inspections of licensees and carriers. Transport Canada and CNSC share responsibility for regulations of dangerous goods. In 2007, Transport Canada and CNSC entered into a particularly comprehensive MoU formalizing their authority and assurance of regulatory oversight in transportation of radioactive material.

Atomic Energy Control Board (now the CNSC) and Health Canada's 1998 MoU requires coordination and cooperation with each other on regulatory issues and establishing and identifying authorization for each participant. The establishment of the specific regulatory authority, the National Dose Registry, the development on quality assurance standards and a mechanism for cooperation with investigation are a few of the conditions. Since 1998, significant technological changes have occurred which may have resulted in omission or duplication of regulatory effort, particularly in medical applications. The memorandum does not authorize the two parties to establish any frequency of coordination or establish any committee to support effective communication. CNSC participates in the Federal Provincial Territorial Radiation Protection Committee (FPTRPC) created in 1993, but the FPTRPC is not referenced in the memorandum. FPTRPC's mandate is to develop and harmonize the practices and standards for radiation protection by providing a national focus on government radiation protection agencies, emerging issues in radiation protection and providing a communication forum for all radiation regulators. Consideration should be given to incorporating the FPTRPC in the memorandum and reaffirming the regulatory responsibilities of each agency to ensure effective protection for patients and workers in medical applications.

Protecting the environment is an important part of the CNSC's mandate. In accordance with the Canadian Environmental Assessment Act and its regulations, CNSC conducts environmental assessments (EAs) in cooperation with the Canadian Environmental Assessment Agency. EAs provide opportunities for public participation in activities undertaken by potential licensees and/or CNSC, including Aboriginal consultations.

The CNSC co-operates and obtains input from other regulatory authorities through multiple processes. For example, in relation to EAs, the CNSC cooperates with federal and provincial authorities who have an interest to provide input to the review processes. In relation to compliance with licence requirements, the CNSC has established cooperative arrangements such as 'Joint Regulatory Groups' whereby relevant authorities have the opportunity to provide input into licensing decisions, and participate in inspections. The CNSC is the authority for regulation of radioactive waste management. Defining the 'national policy' on radioactive waste management is the role of NRCAN. The CNSC provides input into policies under consideration when requested.

In the other areas related to nuclear safety like emergency planning and preparedness, public liability, water use and consumption of food and land use and planning, the CNSC has no leading role. It cooperates with the national and provincial authorities in charge with these responsibilities, advises them and provides information, as necessary.

Regulatory body – additional functions

The CNSC conducts additional activities such as radiological monitoring of some licensed facilities and activities as part of its compliance programme, licensing of dosimetry services for monitoring radiation workers and it oversees some areas of conventional safety directly related to nuclear safety like pressure retaining components and fire protection.

The CNSC provides calibration services for its own radiation monitors. Other additional functions such as providing dosimetry services, conducting medical examinations, independent testing or quality control measurements are provided as services to the CNSC, and therefore CNSC does not have conflicts of interests that might arise from such activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 4.2 states that *“If the regulatory body consists of more than one authority, effective arrangements shall be made to ensure that regulatory responsibilities and functions are clearly defined and co-ordinate, in order to avoid any omissions or unnecessary duplication and to prevent conflicting requirements being placed on the operator.”*
- S1 **Suggestion:** Consideration should be given to updating the 1998 Memorandum of Understanding with Health Canada. This update should also define the roles and responsibilities of the Federal Provincial Territorial Radiation Protection Committee to ensure that there is a comprehensive and consistent safety regulation and oversight.
- G1 **Good Practice:** The Memorandum of Understanding with Transport Canada is particularly comprehensive and could be considered as a model for similar applications.

3. ORGANIZATION OF THE REGULATORY BODY

3.1. GENERAL ORGANIZATION

Organizational structure

The CNSC is the nuclear regulatory body in Canada, established by the NSCA. The Commission, a quasi-judicial administrative tribunal comprises a maximum of seven members. Members are appointed by the Governor in Council (Cabinet). One member of the Commission is designated as both the President of the Commission and the Chief Executive Officer of the CNSC as an organization. The CNSC is divided into five major groups:

- Regulatory Operations Branch (ROB), responsible for regulating the development, production and use of nuclear energy, for regulating the nuclear fuel cycle as well as the production, possession, transport and use of nuclear substances and radiation devices;
- Technical Support Branch (TSB), responsible for the detailed technical analyses in direct support to ROB
- Regulatory Affairs Branch (RAB), providing strategic direction and implementation of the CNSC's regulatory policy, planning and communications areas;
- Corporate Services Branch (CSB), ensures general services necessary for the functioning of CNSC; and
- Legal Services to ensure stable, consistent and informed legal advice.

In addition, the Secretariat ensures that the seven-member Commission has the administrative and technical support it needs to function efficiently and effectively. Other groups in the CNSC organizational structure that support the President include the Quality Council and the Office of Audit, Evaluation and Ethics.

The organization was modified in 2007 with the creation of ROB and TSB, providing better alignment with the three key processes as defined in the CNSC's Management System.

Both safety and security are regulated by CNSC. A special division within the Technical Support Branch (TSB) is responsible for reviewing and assessing physical security aspects.

ROB and the security specialists from TSB work together to ensure that safety is not compromised by any security arrangements, although joint safety/security inspections are not performed and only a limited number of safety inspectors are allowed to see the licensees' security plan. It should be noted however that generally security was outside the scope of the IRRS mission although it has been considered within the mission regarding the IAEA Code of Conduct on Safety and Security of Radioactive Sources.

In line 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

The CNSC receives its funding from two sources:

- Fees paid by applicants, licensees and other special project sponsors: The CNSC can, in accordance with its Cost Recovery Fees Regulations, charge cost covering fees for the services, products and information that it provides under the NSCA. The settings

of fees is based on the actual resource used by CNSC for the particular licensee. Public hospitals and other exempt licensees are not subject to licensing fees.

- **Parliamentary Appropriation:** Activities related to international obligations, public relations, regulatory framework, emergency preparedness and licensees that are fee-exempt are financed by parliamentary funds.

CNSC has been given the Revenue Spending Authority (RSA). This allows CNSC to directly invoice the licensees and use the fees without following the parliamentary budget process. The introduction of the RSA system provides additional flexibility by allowing the CNSC to grow to meet new or pressing demands (such as unanticipated applications or events) and to directly recover the costs for that growth through its cost recovery structure. For the regulation of radioactive materials, CNSC is enhancing the existing compliance coefficient for cost recovery based on the regulatory effort in managing the licence. This project will allow the CNSC to recover the costs for licensees who require additional inspections or multiple administrative changes to the licence.

Since 2009 (the year of the implementation of the RSA) fees paid directly by the licensees to the CNSC are the primary funding source for the CNSC. The application of such a funding system tool seems to have considerable merit.

It is noted that about 30% of CNSC budget is still subject to parliamentary appropriation and that this part of the budget is subject to the same limitations as other Canadian administrations. Some of the activities that are paid by public money like the development of regulation and emergency preparedness are closely related to nuclear safety. Although these activities can not be assigned to a single licensee they build a requisite foundation for regulatory decisions. Opportunities should be sought to further recover these costs from licensees as appropriate.

In contrast from some other government agencies CNSC prepares its budget completely on its own and deals directly with the Treasury Board Secretariat. There is no approval necessary by NRCan nor is there directive power outside of general and administrative issues.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 2.2 (4) states that *“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-G 1.1§ 2.15 states that *“If a State has an established nuclear power programme, the costs of the regulatory body could be recovered in whole or in part through fees. The costs of the preparation of a licence, review and assessment, inspection, and the development of regulations and guides could be recovered through fees, whereas certain other activities of the regulatory body, such as participation in international activities, could be funded by other means.”*
- S2 **Suggestion:** CNSC should review its arrangements to ensure that it can adequately recover its regulatory costs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** Safety Fundamentals § 1.10. states that “*Safety measures and security measures have in common the aim of protecting human life and health and the environment. The safety principles concern the security of facilities and activities to the extent that they apply to measures that contribute to both safety and security, such as:*

—*Appropriate provisions in the design and construction of nuclear installations and other facilities;*

—*Controls on access to nuclear installations and other facilities to prevent the loss of, and the unauthorized removal, possession, transfer and use of, radioactive material;*

—*Arrangements for mitigating the consequences of accidents and failures, which also facilitate measures for dealing with breaches in security that give rise to radiation risks;*

—*Measures for the security of the management of radioactive sources and radioactive material.*

Safety measures and security measures must be designed and implemented in an integrated manner so that security measures do not compromise safety and safety measures do not compromise security”.

- S3 **Suggestion:** Staff from the ROB and TSB branches of CNSC may wish to review how they could work together in a more harmonized manner to ensure that security measures do not compromise safety and vice versa and to ensure continued compliance with security requirements as reviewed.

3.2. STAFFING AND TRAINING

Staffing

CNSC currently has a staff of approximately 800 people including highly educated and experienced professionals involved in all technical aspects of licensing and compliance verification and enforcement. For professional occupations, this generally includes University educated scientists, engineers, lawyers and administrators, often at a Masters or PhD level.

The CNSC has been successful in obtaining financial and human resources (staff and contractors) to fulfil its functions and responsibilities, however, rapid growth and evolution of the nuclear industry is an ongoing challenge. To meet this challenge, the CNSC is improving the efficiency of its processes and has also sought and obtained its Revenue Spending Authority that will assist in securing resources to meet rapidly changing or unanticipated demands as they emerge.

Recruitment and retention of staff has been a key strategic objective of the CNSC for several years. It has developed a recruitment strategy that is built on five pillars:

- internal assessment;
- general recruitment;
- international recruitment;
- university partnerships; and
- employee retention.

By applying this strategy the CNSC has been successful in recruiting new staff. In the last four years CNSC has managed to increase the number of employees from 550 to 800 and is now ready to meet current regulatory challenges.

The recruiting process is facilitated by the fact the CNSC is an independent employer and can optimize its employment conditions with respect to the recruitment market (within the framework of the government standards).

The annual staffing planning process takes into account current vacancies, current and projected operational pressures, staff demographics and other factors. Decisions considering the allocation of staff to the organizational units are taken by the CNSC senior management.

Training

As part of the general human resource plan, all CNSC managers maintain Individual Learning Plans for each of their staff in order to develop and maintain internal competencies.

Often sources of training can be identified through the industry or private sector institutions. In addition the CNSC is developing its own training programmes. One of these programmes is the Training & Qualification programme for inspectors. It is part of the Harmonized Plan initiative to standardize the training of the inspectors. The T&Q process covers all the steps from the first day of a newly employed inspector candidate to certification. The training programme includes core training and service-line specific training as well as mentoring and job-shadowing. Other specially designed programmes will be designed for Leadership Development.

As the experienced personnel retire there is a need to transfer their knowledge to less experienced staff. The CNSC targets a mix of experienced and junior staff in its hiring. Junior recruits are teamed up with experienced staff and, in some cases, are rotated through different parts of the organization to help them gain the necessary experience and knowledge. Furthermore an alumni programme has been started that allows retired CNSC staff to be consulted and thus transmit their knowledge to younger staff. The ongoing creation of review guides and the implementation of the Management System are also means to transmit knowledge. Similar to other regulators CNSC will be faced with the need to formalize their knowledge management system.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 2.2 (4) states that *“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”*
- G2 **Good Practice:** The authority of CNSC to independently define its own employment conditions is considered to be a good practice.

3.3. ADVISORY BODIES AND RESEARCH ORGANIZATIONS

Technical support organization (TSO)

The CNSC has minimized its dependency on external consultants and the experts employed by the licensees by developing and maintaining, over time, a large, highly-qualified and multi-disciplinary staff of subject matter experts. It can however when required make use of external experts.

Research

Research on nuclear energy in Canada is mainly fed from 3 different sources:

- Federal Programmes: The Programme of Energy Research and Development (PERD) is an interdepartmental programme operated by NRCan. PERD funds research and development designed to ensure a sustainable energy future for Canada in the best interests of both economy and environment.
- Industry Programmes: The research effort made by the Canadian industry, particularly by AECL and the CANDU owners' group focus on: safety; software performance; physics and fuel; fuel channels; components and systems; hydrogen and heavy water; environmental emissions and health physics; and control and information.
- Regulatory safety research: The CNSC funds a mission-oriented research and support programme (RSP) through which staff can access advice and assistance from consultants as needed to discharge its responsibilities.

Although CNSC is involved in the definition of the PERD, monitors the industry's research activities and can request the industry to perform research on licensing and safety-related issues, CNSC's own RSP is an important source of advice, expertise, and experience.

The RSP is reviewed and evaluated on an annual basis in order to identify the need for research and support in the following year. The annual budget of the RSP is approximately \$3 million and supports about 50 projects, via contracts, grants and contributions placed with the private sector as well as other agencies and organizations in Canada and internationally.

The team noted that:

- the Canadian research programmes are only loosely coordinated and distributed over many different organizations;
- the RSP supports a wide range of projects with relatively small financial contributions and does not show clear priorities;
- many of the RSP projects are reviews by external experts (i.e., "support") rather than research projects;
- the CNSC budget for independent regulatory research is low compared to the budgets of regulators of other countries; and
- there is very limited CNSC-led research on new builds and independent computer codes.

The strategic planning programme should take into account Canada's special responsibility for CANDU reactors and the need of a strong effort by CNSC as the regulator to secure support for resolving safety issues specific to CANDU reactors.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 4.3 states that *"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."*
- (2) **BASIS:** GS-R-1 § 2.4.(10) states that *"Legislation shall be promulgated to provide for the effective control of nuclear, radiation, radioactive waste and transport safety. This legislation:
(10) shall set up a means whereby research and development work is undertaken in important areas of safety; ..."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (3) **BASIS:** GS-R-1 § 6.13 states that “Government shall ensure that appropriate research and development programmes for radioactive waste disposal are implemented, in particular for long term safety.”
- (4) **BASIS:** GS-G-1.1 § 3.33 states that “The regulatory body should encourage facility operators to carry out the research and development necessary to produce an adequate body of knowledge about safety. However, there may be situations in which the operator’s research and development are insufficient or in which the regulatory body requires independent research and development to confirm specific important findings. The regulatory body may need to conduct or commission research and development work in support of its regulatory functions in such areas as inspection techniques and analytical methods or in developing new regulations and guides.”
- (5) **BASIS:** GS-G-1.1 § 3.34 states that “The organizational structure of the regulatory body should reflect these needs for research and development, either by the establishment of a research unit or by recruiting staff who can define research and development needs, initiate, co-ordinate and monitor the necessary work, and evaluate the results. Regardless of how the research is carried out, the regulatory body should ensure that it is focused on regulatory needs, whether in the short or long term, and that the results are disseminated to the appropriate organizational units.”
- R1 **Recommendation:** CNSC should initiate a periodic strategic planning programme to define both short term and longer term research activities needed to support pending and potential regulatory decisions.
- R2 **Recommendation:** Sufficient resources for research activities should be allocated to support the outcome of the strategic planning programme.

Advisory Bodies

CNSC has the authority to establish Technical Advisory Bodies. It has, however, chosen not to establish any such technical advisory committees, neither regarding the safety of nuclear installations nor regarding radiation protection issues or waste management issues..

The Commission being an independent quasi-judicial administrative tribunal makes independent decisions. For this purpose it seeks and receives the views and advice from its own staff and variety of interested parties. If needed, the Commission can call in external experts.

The CNSC staff provides extensive technical expertise in various scientific fields and safety areas to the commission. For added advice, an independent opinion of a senior expert panel could be advantageous in the case of regulatory decisions involving either new, complex technologies (e.g., emerging medical applications) or issues of high public interest. It is common practice for many regulatory organizations to have a technical advisory group to enhance technical decision making. This group is typically composed of independent technical subject matter experts.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 4.3 states that “*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.*”

Suggestion: Change the BASIS for 4.9

- S4 **Suggestion:** The CNSC should consider the use of issue-specific advisory bodies to support regulatory decisions where there are either new, complex technologies (e.g. emerging medical applications) or issues of high public interest.

3.4. INTERFACES AND LIAISON WITH LICENSEE'S AND OTHER ORGANIZATIONS

Relations with Operator

The CNSC promotes an open, frank and appropriately formal and professional relationship with the regulated industry. Some of its staff is permanently located at the major facilities. They keep the licensee informed of the regulatory activities that are taking place and solicit the assistance and cooperation of the licensee staff in carrying them out. In addition to professional regulatory contacts, CNSC encourages the open dialogue and discussion between its subject matter experts and the licensee.

There are a number of formal arrangements for communication with the licensees including regular management meetings at various management levels, Commission Tribunal hearings and the formal correspondence via a Single Point of Contact. Both licensees and CNSC emphasize that the communication has been improved as a result of the NRU Lessons Learned initiatives. Both parties agreed that the frequency and extent of the communication measures are now adequate. The licensees appreciate the "no surprise approach" and the more structured way of doing business of CNSC.

In cases where the Commission tribunal has made licensing decisions, minor issues may have to be brought before the tribunal. This is a concern for some licensees. There is also a concern about the absence of application of the graded (risk-informed) approach in some cases.

CNSC has established formal mechanisms for certain groups of licensees to consult with CNSC staff; for example, the Industrial Radiography Working Group was directed by CNSC to work towards improving the radiation protection and inspection compliance of industrial radiography.

3.5. INTERNATIONAL CO-OPERATION

CNSC participates on a regular basis in the activities of the International Atomic Energy Agency (IAEA) and the OECD/NEA. It also has participated actively in the meetings of the Convention on Nuclear Safety, the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and the Codes of Conduct on the Safety and Security of Radioactive Sources and on the Safety of Research Reactors.

CNSC also participates in regulatory associations such as International Nuclear Regulators Association and has concluded MoUs, Administrative Arrangements and Protocols for the exchange of information in nuclear regulatory matters with a number of foreign regulators including, but not limited to, other CANDU regulators.

The CNSC maintains regulatory cooperation arrangements with Argentina, Australia, France, Indonesia, the Republic of Korea, the Russian Federation, the United Kingdom and the

United States; the Commission is working on a series of new arrangements that would expand this list, including arrangements focusing on cooperation in the context of new nuclear power plant projects. In addition, the CNSC establishes and maintains administrative arrangements to implement the non-proliferation provisions.

CNSC and the United States have entered into an agreement on the approval process of Type B(U) and fissile material transportation packages to allow for easy import and exportation across their borders.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 § 3.3(6) states that “*In order to discharge its main responsibilities, as outlined in para. 3.2, the regulatory body.....*

(6) shall communicate with, and provide information to, other competent governmental bodies, international organizations and the public;.....”

G3 **Good Practice:** The arrangement between CNSC and agencies in the United States of America on the approval process of fissile material transport packages facilitates the easy import and export across their borders, and could act as a model for other countries.

It should be noted that Canada has a special for CANDU reactors. Therefore, under the global safety regime, CNSC, as the regulator, has the responsibility to support the resolution of CANDU specific safety issues and to share the relevant information with other CANDU owners’ countries.

POLICY DISCUSSION ON RESEARCH FOR SAFETY AND REGULATORY PURPOSES

Introductory statements

Budgets for safety research are decreasing all around the world. In Canada, the NSCA assigns the CNSC with responsibility to conduct research for enhancing safety knowledge and disseminating information to the general public.

It was noted that safety research has two main objectives which should be clearly differentiated:

- research aiming at supporting safety assessment of the regulatory body and resolve some regulatory issues; this “support research” is more of a reactive nature;
- research for long-term safety issues, which can also be shared with the industry; this “pure research” is of a more proactive nature.

Benchmark with other countries’ practices

This policy discussion was a good opportunity for the CNSC to learn about the practices of the peer reviewers’ countries in terms of regulatory research, such as the part of the regulatory body’s budget for research, the involvement of the regulatory body in the definition of research activities, the planning and coordination of research activities, etc.

Discussion

The CNSC has a Technical Support Branch (TSB) embedded in its organization which supports assessment for the Regulatory Operations Branch (ROB). However, additional research is necessary to anticipate or to support these current assessment processes.

The CNSC’s current research programme is very modest compared with other countries (3 million Canadian dollars) and mainly focuses on the ageing CANDU fleet.

An important component of the national research is the research effort made by the industry (particularly by the CANDU owners' group, COG), which represents up to 100 million dollars. This research is performed by the industry, but on licensing and safety-related issues which are raised and identified by the CNSC. Approximately 20 million dollars have been devoted to close molten fuel/moderator interaction issues. Compared with the research programme of the industry, the effort made by the CNSC is fairly small in terms of financial resources.

Addressing the issue of the "independence" of research, the team agreed that a regulatory body does not necessarily have to duplicate all the research effort made by the industry but it should ensure and satisfy itself that this is done properly.

In accordance with the regulatory document S-99, major licensees have to regularly report about their research activities. The regulator can then incorporate the findings or the outcome of this research in its regulatory perspectives.

The team also investigated the question on how much "in advance" a regulatory body should conduct research. It appeared that CNSC's research programme is primarily reactive and includes limited proactive components which would enable it to anticipate some of the safety issues.

This issue is particularly relevant when it comes to the new build projects in Canada since CNSC has limited knowledge on PWR technologies. As a first step, the CNSC has started gathering information through networks (NEA/MDEP...) or cooperation activities with foreign regulatory bodies

Globally, the team came to a consensus that CNSC's research effort is very strongly reactive and responsive, and that CNSC should devote more effort and resources to strategy planning as well as to proactive research on long term issues.

The team noted that, to achieve a better coordination among key players, sufficient human resources are necessary. Some examples were given which highlighted the necessity to establish close links between the researchers and the users of this research so as to avoid 'isolation' of the research. Consideration might also be given to implementing an advisory committee for the oversight of research activities; this issue is further discussed in the following "policy discussion".

Recommendations arising from the Policy discussion:

The CNSC should initiate a periodic strategic planning programme to define both short term and longer term research activities needed to support pending and potential regulatory decisions.

Strategic planning should specifically consider the research programmes needed to support regulatory decisions for new power reactor applications.

Sufficient resources for research activities should be allocated to support the outcome of the strategic planning programme.

POLICY DISCUSSION ON THE ROLES AND RESPONSIBILITIES OF TECHNICAL SERVICES IN SUPPORT OF REGULATORY DECISION MAKERS

Responsibility of the regulatory decision makers

The team agreed on the fact that, to make an informed decision, a regulatory body needs to have competence not only for regulations but also for technical matters. The regulatory decision maker should not dilute its responsibilities by giving part of its decision to its technical support staff. Although the Regulatory Operations Branch has to give due

consideration to all the expert advice provided by its technical support, it is its responsibility to make “well informed” decisions. The advice from technical supports does not “close” an issue, it rather documents and informs it, but the final decision of the regulatory body might take into account a broader range of factors (consideration of social aspects...).

Some team members noted that, when making contracts for external technical support, it is important to identify specific and well defined issues. It is then essential to be an “intelligent customer”, by establishing hold points, performance indicators, close monitoring processes, etc. It should also be reminded that the outcome of the contract is the technical basis for the decision, not the decision itself. Again, one should not outsource the decision-making responsibility.

The CNSC has a Technical Support Branch (TSB) embedded in its organization which supports assessment for the Regulatory Operations Branch (ROB).

CNSC’s situation regarding Advisory bodies

Although the NSCA allows the CNSC to implement an advisory committee, the Commission has not created one. The team discussed whether and to what extent such an advisory committee could be beneficial to the CNSC in its decision making process.

First, it was noted that advisory committees can be useful in providing high-level advice on issues where the regulatory body has limited in-house competence. In the Canadian case, this could be particularly relevant in the context of new build projects since the CNSC has no regulatory experience with PWR technologies.

The independent advice provided by an advisory committee would constitute an additional input for the Commission to make decisions and would thus enable it to be better informed in this process, taking into account a greater number of views in its final decisions.

In this respect, the team also highlighted that the use of advisory committees may be beneficial for transparency and thus for public acceptance, and various instructive examples were given. The CNSC informed the team that in 2006 it had resorted to an international peer review of a technical assessment, which the team considered a good initiative.

Although the team came to a consensus that the CNSC should consider the use to advisory bodies, it also agreed that this should be done carefully.

Some team members noted that the nomination of Advisory body’s members should be carried out with due diligence, keeping in mind that political considerations might jeopardize the objectivity, impartiality and independence of the advice.

Moreover, the issues on which such Advisory bodies are consulted should be precise, well defined and chosen in accordance with the specific needs of the regulatory body (“new build” was again mentioned as an example).

Suggestion arising from the Policy discussion:

The CNSC should consider the use of issue-specific advisory bodies to support regulatory decisions where there are either new, complex technologies (e.g., emerging medical applications) or high public interest.

APPENDIX TO SECTION 3

The NRU Lessons Learned Report

During 2007–08 the Chalk River NRU reactor was temporarily shut down to address safety issues regarding safety system upgrades. The situation triggered concern about domestic and worldwide supplies of radioisotopes – resulting in the issuing by Parliament of emergency legislation authorizing the restart of the NRU reactor and its operation for 120 days (counter to the position of the CNSC).

CNSC initiated a review of lessons learned, conducted by an independent consulting firm (Talisman International LLC). The review provided a concise overview of key findings and recommended improvements aiming to prevent a recurrence of a similar situation.

The IRRS team assessed the way CNSC addressed the implementation of the mentioned improvements. Findings:

- In addition to NRU specific improvement initiatives that were specifically addressed, broader recommendations of the NRU review formed the basis of several generic improvement initiatives, which were incorporated into the Harmonized Plan (the CNSC’s plan for improvement across the agency).
- The implementation process is very structured and is based on clear priorities.
- The implementation process receives high attention from senior management.
- Although the long-term work is not yet completed AECL and CNSC agree on the priorities and see progress in their regulatory relationship.

The following issues were part of the Talisman recommendations and were reviewed by the IRRS team:

- CNSC should improve the clarity of future NRU operating licence conditions,
- CNSC should strengthen its enforcement capability by requesting the authority to issue civil penalties (fines) without referral to the Justice Department
- CNSC and AECL should develop a formal process to promptly determine whether, and under what conditions, continued NRU reactor operation may be justified during off-normal conditions.
- CNSC senior management should provide training for all CNSC staff that conducts inspections.
- CNSC should adopt the concept of “timely renewal” of licences and should require from licensees licence renewal applications within a reasonable timescale.
- CNSC and AECL should strengthen the quality and timeliness of internal and external communications.
- CNSC should shift to a more process-based system where regulatory requirements and expectations are specified in writing and in guidance documents.
- CNSC should install a tracking system for corrective actions and licensees commitments.

The IRRS Peer Review Team has come to the conclusion that the recommendations made by the Talisman report specific to NRU have been adequately addressed by the CNSC. Broader

improvement initiatives beyond NRU are being managed under the CNSC's Harmonized Plan (see chapter 8 for details)

4. AUTHORIZATION

All activities in Canada involving the development, production and use of nuclear energy and the production, possession and use of nuclear substances, prescribed equipment and prescribed information may only be carried out under an authorization (i.e., licence) granted by the Commission, or Designated Officer (DO), as the case may be, except where expressly exempted by regulations.

All applicants are required to submit a detailed demonstration of safety that is appropriate to the facility, activity or practice sought, before the Commission or DO considers granting the applicable authorization.

To specify what information an applicant must submit to the CNSC to demonstrate the adequacy of its qualifications and the ability to make adequate provisions, the Commission has made a number of binding regulations.

General licence application requirements (i.e., those that apply generally to all types of nuclear facilities and activities) are set out in regulations such as the General Nuclear Safety and Control Regulations, Radiation Protection Regulations, and Nuclear Security Regulations. In addition further requirements for licence and certification applications are set out by the Commission in the more activity-specific Regulations. The Commission has established the requirements for each licensing stage in the life-cycle of a nuclear facility, including, for example, site preparation, construction, operation, decommissioning, and abandonment.

Regulatory requirements are aimed at ensuring applicants for licences and certificates demonstrate in their applications that they are qualified to carry out the activity and that they will make adequate provisions for health, safety, environmental protection, and security.

These requirements are part of the *Licensing Basis* for a regulated facility or activity. In general, the Licensing Basis consists of

- (i) the applicable legislative and regulatory requirements;
- (ii) the facility's or activity's licence and the documents and conditions cited in that licence; and
- (iii) the licence application and the documents submitted in support of that licence application.

The licensing basis for any particular facility or activity is being updated periodically, at every licence renewal, taking into account the recent revision of relevant codes and standards.

The CNSC has launched a licence reform project, now included in the Harmonized Plan, to introduce consistency in licences and to streamline the processes for licence issue and renewal across Class I nuclear facilities and uranium mines and mills.

Historically, operating licences were generally issued for a renewable period of two years. In 2002, the CNSC introduced flexible licence periods to enable it to regulate in a more risk-informed manner, through the adjustment of the licence period to the licensee's performance and findings of compliance-verification activities. This means that a shorter licence period may be an option where focused improvement is required.

To assist CNSC staff in making recommendations on licence periods for Class I nuclear facilities and uranium mines and mills, a set of factors was compiled in CNSC Commission Member Document 02-M12, "New Staff Approach to Recommending Licence Periods."

These factors include facility-related hazards; the presence and effective implementation of the licensee's quality management programmes; the implementation of an effective compliance programme on the part of both the licensee and the CNSC; compliance history; the extent of the licensee's experience; demonstrated acceptable licensee performance; the requirements of the CNSC Cost Recovery Fees Regulations; and the facility's planning cycle.

For the issue of all other licences by the CNSC, the Commission has delegated authority to Designated Officers, as outlined in Section 2 of this report. Designated Officers consider the same factors, as provided in CMD 02-M12, but utilize a less formal process to arrive at regulatory decisions. In addition, Designated Officers consider the quality of the licensing submission in arriving at a licence period.

For a licence renewal, regulations allow licensees to refer to previously submitted documents in support of a licence application.

CNSC is currently developing guidelines for licence applications for new nuclear power plants and for new uranium mines and mills. Plans are being developed to produce similar guidelines for waste facilities. All of these guidelines are being developed in accordance with IAEA safety standards. Application guidelines for other activities and facilities regulated by the CNSC have also been prepared and identify information to be submitted to address the applicable regulations.

CNSC staff provides written and documented recommendations to the Commission or the Designated Officers, as the case may be. All decision documents are stored in corporate records, and are available to the public. Furthermore, there is a project under the Harmonized Plan for documenting clear and standardized procedures to prepare Commission Member Documents (CMDs) across the organization.

The Canadian regulatory framework provides for a comprehensive and robust authorization system, and processes are in place for authorizing/licensing all facilities and activities.

The CNSC employs a risk-informed approach to define the scope of the assessments in its authorization process. Further refinement, formalization and documentation of the common licensing authorization process and criteria are continuing as part of a number of initiatives being coordinated under the Harmonized Plan.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** **GS-R-1** § 5.3. states that *“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.”*
- R3 **Recommendation:** The activities and processes identified within the Harmonized Plan for authorizations in relation to preparation of a comprehensive set of procedures, criteria and review guides should continue to be developed and should be fully implemented.
- (1) **BASIS:** **GS-R-1** § 5.5. states that *“The regulatory review and assessment will lead to a series of regulatory decisions. At a certain stage in the authorization process, the regulatory body shall take formal actions which will result in either:*
- (1) the granting of an authorization which, if appropriate, imposes conditions or*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

limitations on the operator's subsequent activities; or

(2) the refusal of such an authorization.

The regulatory body shall formally record the basis for these decisions.”

- G4 **Good Practice:** The Canadian regulatory framework provides for a comprehensive and robust authorization system, and processes are in place for authorizing/licensing for all facilities and activities. There are clearly documented authorities and responsibilities either through the commission or delegated to appropriate CNSC staff, e.g. designated officers.

4.1. NUCLEAR INSTALLATIONS: NUCLEAR POWER PLANTS (NPPs), RESEARCH REACTORS (RRs) AND FUEL CYCLE FACILITIES (FCFs)

For some Class I nuclear facilities, the current licences are very detailed and restrictive. This could lead to potentially disproportionate effort being applied to make non-safety significant changes to reference documents which may change over the timeframe of the licence. In addition, the licences are of limited duration which has the potential to increase the administrative burden on the CNSC and licensees.

However, as part of the licence reform project, the CNSC is in the process of establishing a consistent approach to defining the licensing basis for all nuclear facilities and establishing a licence that reflects the appropriate level of control.

The licence reform activity should lead to further work including refining the facility-specific safe operating envelope and limiting conditions for operation (LCOs), and the licensee's management process for tracking of unavailability of key safety systems.

As part of licence renewal, licensees are required to systematically review key safety areas. However, these licence renewal reviews do not include all the elements set out in the IAEA guide NS-G-2.10 "Periodic Safety Review of Nuclear Power Plants Safety Guide". In particular, no fully integrated review is undertaken against all modern standards.

For some nuclear facilities undertaking life extension reviews such as Bruce and NRU, CNSC required that the licensees perform an Integrated Safety Review (ISR). The CNSC approach to ISRs is described in CNSC regulatory document RD-360 "Life Extension of Nuclear Power Plants", which reflects IAEA Guide NS-G-2.10. For example, it suggests that they should use the elements set out in the above guide, i.e.:

- (1) Plant design;
- (2) Actual condition of SSCs;
- (3) Equipment qualification;
- (4) Ageing;
- (5) Deterministic safety analysis;
- (6) Probabilistic safety analysis;
- (7) Hazard analysis;
- (8) Safety performance;

- (9) Use of experience from other plants and research findings;
- (10) Organization and administration;
- (11) Procedures;
- (12) The human factor;
- (13) Emergency planning; and
- (14) Radiological impact on the environment.

Such safety reviews have not been, and are not, undertaken on licensed facilities in Canada on a routine basis.

Requirements in Class I Nuclear Facilities Regulations state that an application for licence to operate a Class I nuclear facility shall contain a Final Safety Analysis Report (FSAR) demonstrating the adequacy of the design of the nuclear facility. Once the licence is renewed any changes to documents included in the licensing basis are subject to prior approval of the Commission or a person authorised by the Commission.

It was acknowledged that the current regulatory activities were based on CANDU philosophy, close cooperation and trust between the CNSC and the licensee.

For example, Operating Policies & Principles may not provide enough specific parameters. Some parameters do exist within the licensee's documentation but are spread apart in different cascades of documents including:

- Abnormal Instruction Manual (AIM) which includes abnormal operating instructions and safety parameters;
- Operating Safety Requirements.

However, these documents are not under direct control of the CNSC because there is not always a link in the cascade of licensee's operating documents. The CNSC's Safe Operating Envelope project should consider gathering all necessary parameters, limits and conditions, including system defect management, to help the CNSC perform its compliance inspections.

Certification of licensee personnel

In order to confirm the competence of personnel responsible for the safe operation of the facility or activity, the CNSC delivers and renews certifications of licensee personnel.

According to the Class I Nuclear Facilities Regulations, the certification, delivered by the Commission or a designated officer, insures that the certified person:

- meets the applicable qualification requirements referred to in the certificate;
- has successfully completed the applicable training programme and examination referred to in the licence; and
- is capable, in the opinion of the licensee, of performing the duties of the position.

For Nuclear Power Plants, a regulatory document "RD-204. Certification of Persons Working at Nuclear Power Plants" defines requirements aiming to ensure that certified persons are qualified to carry out their duties.

There is no such requirement for other Class I facilities. Nevertheless, similar certifications may be required in the licence of certain facilities (NRU research reactor for instance).

Recently, the requirements for certification of the power reactor operators have been amended to place the responsibility for confirmation on the licensee with the regulatory body checking and verifying the licensees' processes and supporting documentation of the completed activity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.6 and 5.3 states that ... *“for amendment and renewal the associated regulatory review and assessment shall be consistent with... the potential magnitude and nature of the hazard presented”*
- R4 **Recommendation:** CNSC should complete its licence reform project and should document processes and arrangements for Class I nuclear facilities, waste facilities, uranium mines and mills, to ensure that any change or amendment to a licence including the licensing basis does not generate disproportionate amounts of work that would not be commensurate with the potential hazard of the change being proposed.
- S5 **Suggestion:** As part of the licence reform project CNSC should consider if alternative approaches with longer term licences and greater use of delegated powers would improve efficiency and effectiveness.
- (1) **BASIS:** GS-R-1 § 3.3 (10) states that *“in order to discharge its main responsibilities the regulatory bodyshall establish and inform the operator of any requirements for systematic safety reassessment or periodic safety review....”*
- (2) **BASIS:** NS-G-2.10 § 2.3. states that *“PSRs are considered an effective way to obtain an overall view of actual plant safety, to determine reasonable and practical modifications that should be made in order to maintain a high level of safety and to improve the safety of older nuclear power plants to a level approaching that of modern plants. In this connection, it is useful to identify any lifetime limiting features of the plant in order to help evaluate whether a proposed modification is worthwhile.”*
- R5 **Recommendation:** CNSC should consider how to introduce effective arrangements for undertaking periodic safety reviews (PSRs) for these Class-1 facilities. Such PSRs should be proportionate and commensurate to the hazards to be controlled.
- S6 **Suggestion:** Such PSRs should follow all of the elements set out in IAEA guides including the adoption of PSA (probabilistic safety analysis) for nuclear power plants (IAEA NS-G-2.10 or other appropriate safety guidance).
- (1) **BASIS GS-R-1 § 5.3.** states that *“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.”*
- S7 **Suggestion:** The CNSC should complete the project for Safe Operating Envelope (SOE) and consider including its results into the licence limiting conditions for operation (LCOs) as an extension to OP&Ps for nuclear power plants.
- (1) **BASIS:** GS-R-1 § 3.3. states that *“... the regulatory body: ... shall confirm the competence of personnel responsible for the safe operation of the facility or activity ...”*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- S8 **Suggestion:** CNSC should review and continue adopting a consistent process for confirming competence of operators of facilities commensurate with the risks / hazards posed by the facilities.

4.2. NEW BUILD

Applications for new reactor build in Canada have been received. These applications are for multiple technologies. For new NPPs, the CNSC initiates an Environmental Assessment (EA) when an applicant requests a licence under the NSCA to prepare the site and submits a complete Project description and application. Before any licensing decision can be made the EA must be completed and accepted by the federal Government. EAs examine the five Canadian phases in the lifecycle of a nuclear power plant: siting, construction, operation, decommissioning and abandonment. The EA and the “*licence to prepare a site*” have overlapping but distinct information requirements.

Processes, such as the “Integrated Document Assessment Process” used by the Directorate of Power Reactor Regulation and divisions in the Technical Support Branch, are used to help plan, coordinate and schedule the review and assessment of major, complex power reactor licensing submissions. Recently, and in preparation for the receipt of several applications for new major reactor build, CNSC staff has been preparing internal Assessment Plans and Staff Review Guides which are capturing many of the relevant assessment criteria to be used in assessing the merits and acceptability of the related Environmental Assessments (EAs) and licence applications.

The Assessment Plans and Staff Review Guides provide the means to manage work-flow for these complex technical reviews.

Licence application guidelines are being developed in accordance with IAEA GS-G-4.1, “Format and Content of Safety Analysis Reports”.

There are four pre-project designs which are currently being considered in Canada:

- ACR-1000 (AECL)
- Enhanced CANDU 6 reactors (AECL)
- EPR (AREVA)
- AP-1000 (WESTINGHOUSE)

In order to lead this complex and long (more than 9 years) assessment of New NPP licences with efficiency, CNSC has established a new major facility licensing management division.

Specialized topic area lead reviewers coordinate multidisciplinary review and consolidate the review in review reports. The integration of different contributions, delivered by many contributors including external ones, is validated through a steering committee composed by executive members of Directorates of both the Regulatory Operations Branch and the Technical Support Branch.

An assessment plan is performed for each stage of the licensing process. Utilizing such a tool allows CNSC to match and control resources required to lead the project taking into account the technology chosen by the applicant (light water or heavy water reactor).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.3 states that “*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.*”
- (2) **BASIS:** GS-R-1 § 5.4 states that “*The regulatory body shall issue guidance on the format and content of documents to be submitted by the operator in support of applications for authorization.*”
- R6 **Recommendation:** CNSC should continue and complete its preparation of relevant documentation to support the authorization process (licensing process) for new build.
- S9 **Suggestion:** The CNSC should refine existing plans and confirm its organizational readiness (e.g. structure, staffing, skills) to support the transition from the project planning phase to the technical review of new design applications, inspection of construction activities and oversight of the start-up and operations.

POLICY DISCUSSION ON NEW BUILDS: REGULATORY TRANSITION FROM PRE-OPERATIONAL TO OPERATIONAL PHASES

The CNSC is facing a complex situation since, at the same time and on a same site, it may have to regulate operating units, units under refurbishment and units in construction. This complexity induces managerial challenges for the CNSC in terms of planning, organization, competencies and resources.

The team members discussed different approaches for new build (such as design certifications) and identified some differences to be considered by the CNSC. For instance, in some countries, technical review teams are clearly separate from inspector teams and no staff exchange is allowed; unlike other countries where it is encouraged to follow the regulatory process throughout the various steps of the regulatory process (technical review, licensing, inspection, etc.) to gain experience on a specific technology.

During the policy discussion, the team dealt with regulatory approaches for the manufacturing and construction phases. It was recognized that, to conduct comprehensive regulatory oversight during those phases, a significant number of inspectors is necessary. To tackle this challenge, the regulatory body has to decide to what extent it should rely on the licensee to monitor the vendor and its cascade of contractors. The regulatory body has to define the depth and the breadth of its oversight (sampling in the field, sampling of the documentation, review of management systems, etc.).

Suggestions arising from the Policy discussion:

The CNSC should refine existing plans and confirm its organizational readiness (e.g., structure, staff, skills) to support the transition from the project planning phase to the technical review of new design applications, inspection of construction activities and oversight of the start-up and operations.

The CNSC should consider (as part of the licence reform project) if alternative approaches with longer term licences and greater use of delegated powers would improve efficiency and effectiveness.

4.3. INDUSTRIAL, MEDICAL AND RESEARCH ACTIVITIES

In addition to the General Nuclear Safety and Control Regulations the regulatory provisions that apply to industrial, medical and research uses of nuclear substances are specified in the Class II Nuclear Facilities and Prescribed Equipment Regulations and Nuclear Substances and Radiation Devices Regulations.

Included in the Class II Nuclear Facilities regulations are provisions for:

- An application, to construct, operate, and decommission;
- Licence to service;
- Authorization of activities;
- Certification of equipment requirements; and
- Appeal process regarding certification.

In addition, for some licensing activities, specific facility construction, shielding and safety equipment and procedures are required. There are specific requirements for irradiators, brachytherapy remote afterloaders and sealed source installations.

Nuclear Substances and Radiation Device Regulations are prescriptive and require licensees to provide documentation on specific provisions for:

- Procedures;
- Monitoring;
- Contamination control plan;
- Action levels;
- Location of activity;
- Training;
- Records retention;
- Survey meter and calibration requirements;
- Leak tests;
- Record retention; and
- Emergency response.

The regulations allow for the CNSC to issue licences using a graded approach dependent on risk of the material used by the licensee. There does not appear to be any “unnecessary” regulatory authority or duplication of effort with the regulations themselves. This series of regulations provide adequate authority for regulating Class II nuclear facilities and prescribed equipment and nuclear substances and radiation devices in Canada. Newer applications (e.g. cyclotrons) have not been codified in rules. The current authority granted by the NSCA provides general oversight, yet allows through licence conditions the necessary regulations for safe use.

4.4. AUTHORIZATION OF DOSIMETRY SERVICES

Under the Radiation Protection Regulations, CNSC is empowered to issue licences for both internal and external dosimetry services.

There are currently 3 approved services for external dosimetry and 9 approved services for internal dosimetry serving about 77,000 exposed workers annually. Licensing of these services and requirements for notification of overexposure can be found in the Radiation Protection Regulations. Licensee’s requirements to measure and comply with monitoring occupational dose are found in the General Nuclear Safety and Control Regulations. These

include the notification of occupational dose to the National Dose Registry maintained by the Radiation Protection Bureau of Health Canada. As a condition of licensing, both external and internal occupational dose is reported to the National Dose Registry.

4.5. TRANSPORTATION

The IRRS team reviewed transportation as applicable to the GS-R-1 framework, as the review of Transportation against TS-R-1 was not included in the scope of the mission.

CNSC regulations require the issuance of licences for the transport of Category I, II and III nuclear material. Licences have very prescriptive requirements for information related to the transport. The regulations provide exemptions from licensing requirements for most transport carriers.

Certificates are issued for package design, special form or low dispersal radioactive material. The certificate appears to comply with the current IAEA Standards Regulations for the Safe Transport of Radioactive Material, but an audit of compliance was not part of the mission.

4.6. WASTE FACILITIES, URANIUM MINES AND MILLS

In common with other Class I facilities, radioactive waste facilities and, uranium mines and mills are authorized using similar authorization processes and arrangements.

CNSC regulates a considerable number of waste management facilities and activities. In addition it has recently received an application for a deep geologic repository for radioactive waste.

The Canadian regulatory approach to the safety of spent fuel and radioactive waste management is based on three principles:

- lifecycle responsibility and licensing,
- in-depth defense, and
- multiple barriers.

The Uranium Mines and Mills Licences are structured similar to Class I facilities with the primary reference document being the Mining Facility Licensing Manual. This document, which is submitted by the licensee, provides basic description of the facilities and activities, the limits and condition of operation and an overview of the programs that govern operations.

Applicants applying for a licence to operate a uranium mine or mill must demonstrate that they have adequate safety management systems. In addition to complying with the relevant requirements of the NSCA, plans and programmes for safe and secure operation of uranium mines and mills must also comply with the appropriate requirements of the Uranium Mines and Mills Regulations. The Uranium Mines and Mills Regulations contain additional specific application information required for each licensing stage of uranium mining and milling facilities.

There are currently five active uranium mine and mill sites in Canada all of which are located in the province of Saskatchewan.

Under subsection 2(2) of the Uranium Mines and Mills Regulations, exploration is exempt from the requirements of the regulation and is not a licensed activity.

The CNSC strives for a consistent regulatory approach for the uranium mining industry. CNSC is the principle regulator, although the federal departments of Environment, Fisheries

and Oceans, Indian and Northern Affairs, Health Canada and Transport Canada may also be involved. Local, provincial and territorial requirements may also apply. A joint regulatory approach built on strong communications provides for an efficient multi-jurisdictional perspective to regulatory decisions.

5. REVIEW AND ASSESSMENT

Review and assessment principles and the associated criteria are defined by the CNSC legislative and regulatory framework and provide the basis for all regulatory requirements and decisions. This framework includes regulatory documents that provide clarification and additional details to the regulatory requirements set out in the NSCA and its related regulations. Although staff review guides have been completed for the regulation of nuclear substances and Class II nuclear facilities and for the review of environmental assessments and site preparation applications for new NPPs, other staff review guides have not been fully developed for other facilities and activities. Staff review guides define how to apply pre-determined acceptance criteria to review and assess applications. The guides are available to licensees to help them better understand the principles and criteria used when making licensing decisions.

Any proposed changes to the authorized activities or to an approved design must be submitted for review and assessment and approval prior to implementation. The proposed safety modifications need to be justified in submissions by the licensees. Such submissions are subject to review and assessment by the CNSC staff based on safety requirements and safety goals. Review and assessment of the applicants' submissions are performed in detail by the CNSC staff according to the information and type of application submitted. The depth of the assessment is related to the significance and hazard associated with the proposed modification.

The CNSC promotes understanding of its regulatory basis for review and assessment activities. In addition, the CNSC lists those documents that must be submitted by a licensee with an application in specific licence application guides.

Review and assessment of submissions is performed according to the information and type of information submitted. Should a detailed review and assessment of a specific technical area of the application be required, subject matter experts for the specific technical area are consulted for their review and recommendations.

A unique feature of the CNSC assessment program is a requirement (via licence condition or the regulations) for the submittal of an annual or quarterly report to the CNSC. This report could be described as a self-audit of licensed activities and provides information by the licensee on licensed activities that were carried out during the reporting period. This may include operational information, nuclear substance inventory, transfers of nuclear substances and radiation devices, dosimetry results for workers and environmental monitoring. CNSC reviews the information submitted by the licensee to ensure that all licensed activities remain within the limits identified in the licence and to identify potential licensing and compliance actions.

For some facilities, CNSC uses the Facility Assessment and Compliance Teams (FACTeam) concept. FACTeams are comprised of inspectors and technical specialists who are responsible for planning and executing, as a team, all licensing and compliance activities for some Class I facilities and uranium mines and mills. This approach promotes cross-specialist collaboration and leads to a well executed risk-informed compliance program. Analyses and reviews may be integrated by groups of specialists (as part of the FACTeam) and they are reported in the evaluation cycle by a formal report of the assessment. This concept is applied in a similar fashion across all service lines.

Integration of data gathered from performance indicators, inspection findings, compliance reports, surveillance, responsiveness of licensees, as well as event reports may trigger a focused review to determine if additional regulatory intervention is required.

CNSC promotes licensee understanding of its regulatory basis for review and assessment activities by:

- Issuance of relevant guidance documents;
- Describing information that must be submitted by a licensee;
- Ensuring applicants understand their requirements and expectations;
- Maintaining the CNSC Web site which contains useful regulatory information and guidance to licensees, applicants and stakeholders; and
- Using external outreach and industry specific conferences.

CNSC's authorization review and assessment process is very open and transparent with applicants, licensees and other interested parties.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.10 states that *“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. Additional requirements for the review and assessment of a nuclear power plant are given in the Appendix.”*
- G5 **Good Practice:** The use of Facility Assessment Compliance Teams provides an integrated multi-disciplinary approach to the assessment of licensing actions.

5.1. NUCLEAR INSTALLATIONS: NPPS, RRS AND FCFS

The CNSC reviewers and assessors may also perform plant walk-throughs occasionally, or request CNSC site staff, as appropriate, to verify assessment findings and relevant information provided. For certain facilities, the assessment process may include a pre-licensing or pre-authorization inspection of the site.

The CNSC Regulatory document S-99 requires licensees of NPPs (and NRU) to update the Facility Safety Analysis Report every three years. As such, any new analyses, such as those supporting modifications or new findings of R&D, are incorporated into the Safety Analysis Report. Those parts of the Safety Analysis Report that are updated are reviewed and assessed. However, in the absence of sufficient control, this arrangement would be in conflict with the context of licensing basis of which any modification shall be subject to prior approval of CNSC.

PSA and Risk-Informed Decision Making Process

For NPPs the application of CNSC's risk-informed decision making (RIDM) process involves considering, weighting, and integrating, complex inputs and insights from

deterministic analyses, probabilistic analyses, operational experiences, cost-benefit considerations, and other pertinent consideration such as time at risk. CNSC staff have used the RIDM process in several applications in the regulatory programme such as resolution of CANDU generic safety issues, issues pertaining to NRU, and a regulatory decision regarding trip coverage adequacy. Based upon these applications, a more refined and enhanced RIDM process was developed and presented in the “Risk-Informed Approach for the CNSC Power Reactor Regulatory Programme.”

This process has been used to determine the risk profile of NPP licensees, which are derived using eight CNSC-identified safety areas: operating performance, performance assurance, design and analysis, equipment fitness for service, emergency preparedness, environmental performance, radiation protection, and safeguards.

Risk profiles are also developed for research reactors and fuel cycle facilities (as well as waste management facilities) using similar risk/safety areas. Risk rankings, which combine a description of the potential negative impacts of the facility and the associated probability, are considered for each area in conjunction with the operating performance of the licensees. The resulting risk profiles are used to determine the allocation of resources for regulatory programs and details such as the nature and frequencies of inspections and reporting.

The key element, for the RIDM process to be successful, is to have an appropriate number of persons to lead its application. In this regard, the CNSC have trained team leaders, and inspectors on the application of the RIDM for NPPs over the past 2 years.

In April 2005, CNSC issued a regulatory document, S-294, “Probabilistic Safety Analysis (PSA) for Nuclear Power Plants” to put PSA requirements in a legally enforceable instrument. To comply with this document, the licensee will have to carry out Level 2 PSA taking into account external events and shutdown state, although the external events may be excluded with the agreement of the Commission. This requirement is being implemented on a staged basis with NPP licence renewals.

The PSA focuses on evaluating the risk arising from various events to confirm that safety goals are met whereas the deterministic safety analysis focuses on evaluating the consequence of various events to confirm that the dose acceptance criteria are met. CNSC is currently developing a guide “Guidance on the Use of Deterministic and Probabilistic Criteria in Decision-making for Class I Nuclear Facilities (RD-152)”.

For NPPs, CNSC staff maintains some capability to replicate PSAs and perform reactor physics and system thermal-hydraulic code calculations. This is usually limited to performing sensitivity calculations using the licensee’s computer codes. Where PSA results are available, these are used within CNSC’s risk informed decision making process.

Reporting requirement and Operating Experiences for operating NPPs

At all licensing stages, the application incorporates new or previously submitted information in accordance with legislated requirements and the best judgment of the applicant. An application that is submitted at one licensing stage can become a building block for the next stage.

Once the operating licence is issued, reporting in accordance with the regulatory standard, “Reporting Requirements for Operating Nuclear Plants (S-99), issued in March 2003, becomes mandatory for NPP licensees (and also NRU).

- This standard specifies requirements for both scheduled and unscheduled reporting. In the requirements for unscheduled reporting, two types of situations and events are

applied: situations and events that require both preliminary and detailed reports, situations and events that require notification or report. The former requirements include all the anticipated operational occurrences and the latter are for the reaching of an action level in terms of radiation protection regulation, employment situation of certified person by CNSC, and problems identified by research finding or revised analyses. In case of event report, a preliminary report is an initial report, made or filed at an immediate or very early stage following the occurrence of a precipitating situation or event. The detailed report will be completed, for the intended purposes, within a time period specified. The scheduled reporting requirements provide the basis of licensee's self-reporting system upon which the regulators rely as the main 'live' information resource. The scheduled reporting is carried out on a periodic basis.

A performance indicator report is prepared as one of the scheduled reports. This includes very extensive operational data for NPPs. The performance indicators review is conducted to determine if further monitoring of licensee operation is required in specific areas or programmes, and it allows the CNSC to focus their resources on the high risk issues. The performance indicators cover crosscutting areas, so they are reviewed by all divisions.

The particular requirement for a report on "progress of research and development", per Clause 6.4.6 of S-99, is a unique example of self-reporting by licensees. This aids the resolution of safety issues and enables the CNSC to monitor the maintenance and enhancement of licensees' technical capability.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.11 states that *any modification to safety related aspects of a facility or activity shall be subject to review and assessment, with the potential magnitude and nature of the associated hazard being taken into account.*
- S10 **Suggestion:** CNSC should review regulatory documents to resolve conflicts associated with updating the final safety analysis report and maintaining the licensing basis. (*see recommendation R4*)
- G6 **Good Practice:** The development and use by CNSC of processes and tools for risk informed decision making.
- G7 **Good Practice:** CNSC's expectations for scheduled reporting of research and development activities.

5.2. INDUSTRIAL, MEDICAL AND RESEARCH ACTIVITIES

CNSC has a very impressive licence assessment process for Class II facilities and nuclear substances and prescribed equipment following an integrated risk-informed approach.

The objective of the licence assessment is to verify, through licensing documentation, agreement with the applicable regulations and the establishment of an adequate safety and protection level. The assessment of the technical documentation attached to the authorization applications is commensurate with the nature and potential magnitude of the associated radiological hazards. The regulated activities are divided into two groups: Class II nuclear facilities and prescribed equipment; and nuclear substances and radiation devices.

The Class II nuclear facilities consist of medical and industrial applications such as teletherapy, brachytherapy, irradiators and accelerators. Nuclear substances and radiation

devices encompasses medical, academic and industrial applications for uses such as industrial radiography, fixed and portable gages, diagnostic and therapeutic nuclear medicine, biomedical research using unsealed sources of radioactive materials, oil and gas exploration and production. For some authorized activities, the CNSC issues amalgamated licences that combine all facility activities under one authority. The CNSC also certifies radiation devices and Class II prescribed equipment.

The applicant/licensee provides information to the CNSC through an application –for new licence or certificate and amendment or renewal of an existing licence or certificate.

Once an application is received the Project Officer (Class II) or Licensing Specialist becomes the point of contact for the applicant. The expectations are clearly defined to the applicant. The Licensing Specialist or the Project Officer uses detailed worksheets that identify the regulation, the expectation from the applicant and a risk value that demonstrate the importance of the regulations and activity. For evaluations of new Class II applications or device certifications where there are no regulations, CNSC refers to industry or national standards to assist in the review of the application. CNSC has technical staff to assist with the assessment of licensing and certification activities.

Once the project officer or licensing specialist has completed the process, another project officer or licensing specialist repeats the project. This peer review process assures consistency in interpreting the regulations and assuring that all regulatory concerns have been adequately addressed by the applicant. This also assures a thorough review of the application and supporting documents, this improves consistency between evaluators and can be used as a training opportunity through mentoring. Upon completion of the two reviews of the application, the draft licences are referred to the Designated Officer for consideration of authorization.

CNSC maintains an extensive assessment, licensing and compliance database and processing tracking system (LOUIS). The licensing system incorporates all applications, corresponding documentation, licence, inspection and annual reports for at least 10 years in an electronic form. Access to the historical information can assist the project officer or licensing specialist in documenting changes in activity or compliance. CNSC has implemented this comprehensive data base for licensee profile, tracking licensing and certification activities, compliance and inspection, and financial aspects. This system is also used to determine the expiration date of licences. The database for Class II and nuclear substances enhances the ability to perform detailed individual licensing activities that can assist in evaluating potential compliance and need for additional or more frequent regulatory oversight.

The current workload for renewing nuclear substances and radiation devices licences is distributed unevenly. Many licences will need to be renewed later this year (2009). In an attempt to evenly distribute the review over the terms of the licence, the CNSC is considering varying the renewal date for medium risk licences with a good compliance history. As the renewal is submitted to CNSC, the compliance history and a modified renewal assessment will be performed. The comprehensive renewal review will be completed prior to the new expiration date. This levelling of resources will improve the efficiency of the renewal process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.3 states that “*prior to granting of an authorization the applicant shall be required to submit a detailed demonstration of safety, which shall reviewed and assessed by the regulatory body.*”
- G8 **Good Practice:** The review process for authorization of a licence for medical, industrial, and research activities is based on well established comprehensive guidelines and transparent procedures. The formalized assessment process includes an initial review, peer review and review prior to the Designated Officer issuing the licence.
- (1) **BASIS:** GS-R-1 § 5.8 states that “*In connection with its review and assessment activities, the regulatory body shall define and make available to the operator the principles and associated criteria on which its judgements and decisions are based*”.
- G9 **Good Practice:** CNSC regulatory guidance, including draft or proposed regulatory guidance is available to the applicant and licensees for medical, industrial, and research activities. This information provides the licensee with a very clear and transparent overview of their responsibilities. Licensees reported that CNSC staff were very approachable and attentive to their needs.
- (1) **BASIS:** GS-R-1 § 5.7 states that “*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.*”
- G10 **Good Practice:** CNSC has an impressive evaluation process for supporting the issuance of a licence for medical, industrial, and research activities. The evaluation takes account of expectations of the licensee and is based on detailed and transparent assessment of the hazard associated with the activity

5.3. ASSESSMENT OF DOSIMETRY SERVICES

Review and assessment of dosimetry services is carried out by CNSC using the regulatory standard ‘Technical and Quality Assurance Requirements for Dosimetry Services’ and numerous regulatory guides.

Primarily, the ‘Technical and Quality Assurance Requirements for Dosimetry Services’ is used to review applications to confirm that the dosimetry service provider can accurately and reliably measure the radiation exposures of persons using its service. During the assessment, the CNSC also determines if the dosimetry service provider can comply with the requirements to submit the radiation worker doses to the national dose registry. The review process is assigned to a radiation protection specialist, who is responsible for both the assessment of the licence and verification of compliance. Licences are issued with an expiration date not to exceed 5 years.

5.4. WASTE FACILITIES, URANIUM MINES AND MILLS

Wastes can present a variety of radiological, physical and biological hazards. These hazards must be taken into account in the design and operation of facilities that generate, handle,

transport and manage radioactive wastes. Hazard assessments of radioactive wastes are undertaken beginning with waste generation and for each subsequent step where the waste's properties could be altered. The level of detail required in the review and assessment is commensurate with the potential hazard and quantity of the waste.

In the case of long-term storage and disposal facilities, many of which are undergoing preliminary assessment and review currently, the CNSC bases its assessments upon engineering standards and design, best practices (both domestic and international), critical review of licensee's predictive modelling (including performing independent confirmatory calculations) and potential for interaction with persons and the environment.

To cover the very long-term storage and disposal of radioactive waste, CNSC staff continues to participate in leading-edge research projects as well as in international initiatives. Examples include DECOVALEX (Development of Coupled models and their Validation against Experiments), OECD/NEA Radioactive Waste Management Committee (RWMC) and subcommittees Regulators Forum (RF), Integration Group for the Safety Case (IGSC) and Forum for Stakeholder Confidence (FSC).

Specific safety programme areas which are particularly important for review and assessment of the licensee programmes and implementation for uranium mine or mills include:

- Mine and Mill Operations
- Ventilation
- Waste Management, particularly waste rock and tailings management, and effluent treatment
- Environmental Protection
- Transport and Packaging

In particular, Uranium Mines and Mills Regulations require an environmental management program (as do Class Nuclear I Facilities Regulations). This program contains the documented policies, programs and procedures necessary to meet all of the environmental protection requirements set out in regulations.

An important issue for uranium mines and mills regarding environmental protection is the treatment of effluents. Historically, effluent has been regulated through the Metal Mining Liquid Effluent Regulation (MMLER 1977), recently upgraded to the Metal Mining Effluent Regulations (MMER), and similar provincial mining effluent regulations. The MMER effluent limits identify the minimal level of effluent treatment required of all metal mines in Canada, including uranium mines. Since the MMER and provincial regulatory limits do not cover all possible types of effluents, CNSC has adopted Environmental Risk Assessment (ERA) methodologies, directly linked with site-specific receiving monitoring, to address these limitations and ensure that licensees have taken all reasonable precautions to control releases.

6. INSPECTION AND ENFORCEMENT

The regulatory framework for inspections is defined in the *Nuclear Safety and Control Act* (NSCA), Sections 29 to 36, CNSC Regulations and the Policy P-211 “Compliance”.

NSCA clearly states the licensee is responsible for safety, control, supervision and verification compliance.

The NSCA gives the authority to the CNSC for carrying out functions to determine licence compliance and the powers of the inspector are clearly described (Sections 30 to 35 of the NSCA). All authorized CNSC inspectors are issued with an Inspector Card which is valid for a period of five years and lists any restrictions imposed on the ability of the inspector to conduct inspections. In order to obtain an Inspector Card, the CNSC staff member must have requisite knowledge, have completed required training, thus demonstrating to the Designated Officer they are qualified to perform such inspections. The Inspector’s Card must be surrendered when the inspector no longer carries out such inspections or the inspector leaves the employment of the CNSC.

The inspections of regulated facilities and activities are carried out by inspectors located at CNSC headquarters, site offices and regional offices. Inspectors can be accompanied by any other persons who can assist in the inspections.

The compliance model of the CNSC is based on activities to assure that regulatory requirements are met. These are:

Promotion

Promotion is designed to encourage voluntary adherence to regulatory requirements. This includes holding meetings with the licensees and exchanging information about events or requests for information about regulatory requirements.

Verification

Verification includes inspections as well as other regulatory functions of oversight. This includes verifying that a licensee's activities are properly conducted to ensure safe operations in accordance with CNSC's regulations through:

- Type-I Inspection (audits, such as of a licensee program or on a specific issue, with experts on the subject matter present; it is based on ISO-19011 and usually takes longer than one day);
- Type-II Inspection (routine inspection providing a quick impression on the degree of compliance by the licensee, the implementation or performance of a program, etc.);
- Desktop review consists of assessing information submitted by the licensee to demonstrate compliance with the regulatory requirements. For example, reviewing results of environmental monitoring programmes.

Type I and Type II inspections are described in procedures. Many relevant documents related to inspection activities are still being developed within the various service lines.

The CNSC conducts announced and unannounced inspections for a variety of purposes:

- Pre-licensing inspections performed on a case by case basis and planned in advance in accordance with licensing activities to verify the adequacy of the documentation and the commitments made by the licensee in support of its application

- Baseline, routine inspections performed according to a given list of topics
- Reactive inspections, event investigations and associated corrective action-oriented inspections; the criteria for triggering such an inspection are based on the assessment of the event relevance
- Supplementary inspections (the so-called “focused” inspections) based on the observation of some safety performance degradation in the specified safety areas which are subjected to periodic regulatory oversight

These are the main means of detection and collection of real time information about the performance of licensees, and possible emergent issues

Enforcement

Enforcement is designed to compel the licensees to cease non-compliant activities. This includes issuing sanctions to licensees who contravene the NSCA, the regulations or licence. A risk-informed graded approach is used to select appropriate enforcement tools which may include:

- Recommendations;
- Action Notices;
- Directives;
- Formal requests;
- Orders;
- Licensing actions; and
- Prosecution.

Inspectors are empowered to cease unsafe operations and may conduct investigations as appropriate.

To achieve consistency and improve the competency and quality of the inspector’s knowledge and between the various programmes, CNSC has established a comprehensive inspector training programme. The IRRS team accompanied CNSC inspectors on a Type II inspection and found the results of the training programme very evident.

CNSC has developed a number of IT tools for the tracking of corrective actions and licensees’ commitments (e.g., LOUIS; CERTS; ATT; etc.). The Action Tracking Tool (ATT) has been developed in response to one of the Talisman report’s recommendations (see appendix to Section 3). As part of the Harmonized Plan, CNSC is further developing these IT tools to ensure full integration in a modern IT framework.

The process to establish the inspection programme begins during the annual planning cycle (approximately six months prior to next fiscal year). CNSC utilizes several electronic planning tools which produce regulatory activity plans that contain scheduled tasks for staff and the calculated costs for human resources.

Factors such as licensee past performance, risk of the licensed activity, length of time from previous inspection and new activities will determine the frequency of inspections and the scope of the regulatory activity plan. To judge past performance CNSC utilizes information from its licensing and inspection results. This process allows the CNSC to target poor performing licensees. Poor performers will shoulder a larger percentage of the overall regulatory programme effort as they are inspected more frequently; this requires the licensee to devote additional resources to resolving the identified issues, thus providing an incentive for improved compliance.

In order to address safety concerns raised by licensees, workers or members of the public, the CNSC investigates all situations reported in this regard. However, the CNSC does not have formal procedures to conduct such investigations.

Restrictions to move to licensee organization for CNSC staff are only in force for senior management. Other staff are required to notify the CNSC of their intention and to sign specific agreements.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.14 states that *“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.”*
- G11 **Good Practice:** The targeted use of inspections to focus limited regulatory resources on poor performance is an excellent example of optimization of regulatory resources to encourage licensees to improve their regulatory performance.
- (1) **BASIS:** DS415, DRAFT Version § 4.45 states that *“For an integrated safety assessment, the regulatory body first has to organise the results obtained in a systematic manner. It then has to try to identify trends and consequences from inspections and from reviews and assessments*
- S11 **Suggestion:** CNSC should maintain progress in further developing IT tools for action tracking under the Harmonized Plan.

6.1. NUCLEAR INSTALLATIONS: NPPS, RRS AND FCFS

For Nuclear Power Plants there is a move to have more Type II inspections (relative to the number of Type I inspections) to allow the inspectors be more focused on actual plant activities

Inspectors training and recruiting

Most of CNSC Nuclear Power Plant inspectors do not undertake a simulator specific course to enhance their knowledge about systems interactions, performance criteria and plant response to important events.

Baseline inspection plan

The baseline inspection plan is mainly deterministic (covers all aspects with inspections at preset frequencies) with the intention to introduce a more risk-informed approach.

Many guides explaining the scope and conduct of baseline inspections are still to be written and approved. In these cases, inspectors conduct the inspection based on their expertise and historical check lists.

For fire protection and boiler and pressure vessel code related inspections CNSC uses some contractors to undertake inspections in these areas (i.e., inspections related to large fire exercises, involving offsite resources and the verification of Non-destructive Testing and In-service Inspections of ASME Code components).

For Nuclear Power Plant operations, very few inspections are included in the Baseline Inspection Plan to verify safety systems availability. This situation is exacerbated by the fact

that the safety systems operability requirements are not clearly defined (licensee's Operating Policies and Principles document). However, the detailed operability requirements are established in licensee documents, out of the scope of CNSC's direct control. CNSC has initiated, jointly with the industry, the Safe Operating Envelope project to address this gap. As part of the licence reform project this work should be streamlined and actively prioritized.

The baseline inspection programme for Nuclear Power Plants includes close follow-up, by the site inspectors, of the licensee Corrective Action Programme and associated issues related to the problem identification and resolution area.

Reactive inspections for event investigations

CNSC S-99 Standard details the reporting requirements by NPP and NRU licensees to CNSC should an event take place. Additionally, CNSC has procedures to respond to reported events. Follow-up activities for NPPs are documented in a very thorough and useful database about incident assessment and verification by the inspectors (CERTS), which is available for information and other purposes to CNSC staff.

Licensee safety performance assessment

The recently developed RIDM process is used to assess the safety significance of inspection findings with the objective of incorporating risk insights in the assessment of NPP licensees' safety performance. The significance determination is based on a qualitative risk assessment in several predefined risk categories.

Other inputs to this process include information on events and desktop reviews of licensees' submissions, including assessments of safety Performance Indicators. The performance indicators set out in S99 address a number of important safety areas, such as: operational events, safety systems' unavailability and assessment of test results, emergency preparedness relevant data, radiation protection data and incidents, plant chemistry, etc. These constitute a thorough and comprehensive set of indicators for effective safety performance oversight. Nevertheless, it should be pointed out that no thresholds for regulatory action have been defined for those indicators.

An annual assessment of the licensee safety performance is undertaken by combining the inputs previously mentioned. Recently the results of such assessment have been included in documents submitted to the Commission and presented in public hearings.

CNSC Site Offices

The site visits which were organized for the IRRS Team, showed that the observed inspections were efficiently conducted.

The inspectors have free access to any site location, to any internal meetings of the licensee and also to all its documents and databases, with limited restrictions regarding protection of personal data.

The relationship between the licensee and the site inspectors appeared to be very open, communicative and cooperative. The communications paths have been shown to be effective at resolving issues.

There are inconsistencies in the approach to and conduct of inspections (in Class I Facilities and Uranium Mines and Mills) between and within the service lines.

There is no apparent strategy for maintaining consistent and ongoing regulatory oversight of some Class I facilities following changes in the assignments of the CNSC on-site inspectors or project officers.

There are no limits established by the CNSC regarding the stay period of resident on-site inspectors at NPPs and Chalk River site. Excessive time of close daily contact with the licensee could be detrimental to the preservation of inspectors' objectivity. There are examples of long stays for some site inspectors. Furthermore, this issue could be of a concern where inspectors previously worked for the licensee. The CNSC should therefore define adequate means to preserve inspector "de facto" independence and objectivity.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 §5.12 states that *“Regulatory inspection and enforcement activities shall cover all the areas of regulatory responsibility. The regulatory body shall conduct inspections to satisfy itself that the operator is in compliance with conditions set out, for example, in the authorization or regulations....”*
- (2) **BASIS:** GS-R-1 § 5.13 states that *“ 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; and*
 - (6) *the operator is managing safety in a proper manner.”*
- R7 **Recommendation:** CNSC should include in the baseline inspection plan how the licensee executes the supervision of safety system operability status as defined in the Licensing Basis.
- R8 **Recommendation:** CNSC should review and establish coherent and consistent arrangements for the conduct of inspections in Class I Facilities between and within the service lines.
- R9 **Recommendation:** CNSC should establish a process for maintaining continuity of actions and consistency of priorities following changes to the CNSC staff.
 - (1) **BASIS:** DS415, DRAFT Version § 4.45 states that *“For an integrated safety assessment, the regulatory body first has to organise the results obtained in a systematic manner. It then has to try to identify trends and consequences from inspections and from reviews and assessments....”*
- G12 **Good practice:** The CERTS application developed for event inspection, assessment and corrective action tracking constitutes an efficient tool for event tracking, related inspections and corrective actions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-G-1.1 § 3.22 states that “*to assist inspectors in maintaining objectivity and independence, consideration should be given to changing the facility to which they are assigned from time to time or giving them general duties at headquarters. Where resident inspectors are employed, consideration should be given to locating more than one at a particular site for mutual support. There should be adequate communication between resident inspectors and headquarters in order to maintain their regulatory effectiveness.*”
- S12 **Suggestion:** Strategies, processes and methods should be established to ensure the objectivity and independence of the site inspector. Consideration should be given to changing the site to which they are assigned from time to time or giving them general duties at headquarters.

6.2. INDUSTRIAL, MEDICAL AND RESEARCH ACTIVITIES

Inspection

In the last reporting period (2008/09) CNSC performed 1512 inspections, of these 28 were Type I and 1476 were Type II. Type I inspections are audits that require at least two inspectors who conduct a thorough and comprehensive review of all licensed activities. The inspection team reviews the licence, annual reports, and reports on equipment malfunctions or overexposures. These are announced inspections and the CNSC provides the licensee with information on the scope of the inspection. For Class II Nuclear Facilities the licence project coordinator participates as a team member.

Type II inspections are less detailed, may be announced or unannounced and are commonly described by CNSC staff as “snapshot” reviews of activities. Type II inspections may take an inspector several hours to complete, depending on the identification of issues during the inspection.

Inspectors use worksheets to ensure consistency and that all relevant issues are addressed. Licensee documentation, radiation protection results and records retention reviews are part of the scope of the CNSC inspection. Security specialists assess compliance with the enhanced physical security requirements for IAEA Category 1 and 2 sources. The CNSC has established a planned and systematic inspection programme for high-risk and medium-risk licensees, based on risk, with many licensees having annual inspections. The goal is for all high-risk and medium-risk licensees to be inspected at least once every two years. In case of limited resources, other frequencies may be allowed. The inspection programme covers all aspects of CNSC regulatory requirements.

Inspections were reviewed during the IRRS mission and it was observed that they are carried out in a very detailed and planned manner. Consolidated worksheets are currently being used by CNSC inspectors which ensure the implementation of a highly consistent and harmonized inspection programme.

The description of the activities to be carried out during an inspection is available to the licensees prior to the inspection as guidance, which contributes to good communication between CNSC and the licensee and better implementation of the regulation requirements. Any non-compliance is immediately brought to the attention of the licensee and subsequently communicated in writing to the licensee. All the inspection results are documented and

entered into LOUIS, and this information is used in the assessment of the applicant in the licensing process.

Enforcement

The CNSC has assessed each licensed activity, using a high, medium and low-risk rating scale. This risk rating scale has been incorporated into the inspection guidance. The inspector uses discretion in determining the appropriate enforcement action commensurate with the violation. The inspector has the authority to issue orders, and request correction of noncompliant issues. CNSC does not have the authority to levy financial sanctions for non-compliance, except as provided following a prosecution and imposed by the courts. As with inspectors, designated officers and the Commission itself also have the authority to issue orders to correct non-compliance issues.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GR-S-1 § 5.17 states that “*Regulatory inspectors shall be required to prepare reports of their inspection activities and finds, which shall be fed back in to regulatory process.*”
- G13 **Good practice:** The implementation of a robust and detailed inspection programme for radiation facilities (medical, industrial, and research) associated with high quality consistent documentation and a database carried out by CNSC allow a high level of feedback into the regulatory process.

6.3. INSPECTION DOSIMETRY SERVICES

CNSC performs radiation protection audits of all facilities (15 audits last year). Audits for Class I Nuclear Facilities are conducted based on licence conditions and international standards, however, the team noted different radiation protection standards for different facilities. Occupational doses are reviewed during these audits, along with reports of accidents and other type of reportable events.

Dosimetry service providers are also audited by CNSC to verify compliance with the requirements for dosimetry service providers.

CNSC conducts radiation protection assessments based on internal regulation guides and international standards.

For overexposures, the dosimetry service notifies the licensee and National Dose Registry. The National Dose Registry and, as required by regulation, the licensee notifies the CNSC, who may undertake a dose reconstruction in the event of a potential overexposure. In case of exceeding an individual regulatory dose limit, the licensee is required to remove the referred worker from activities which involve occupational exposure. The return to these activities will occur only after the investigation and authorization of CNSC. If it is verified by CNSC that the registered dose is invalid, the modification of the referred dose in the National Dose Registry is the responsibility of the licensee following the regulatory standard, “Making Changes to Dose-Related Information Filed with the National Dose Registry.”

6.4. WASTE FACILITIES, URANIUM MINES AND MILLS

The inspection and enforcement program applicable to waste facilities and uranium and milling follows the same general approach applied to all Class I facilities. This includes baseline Type 1 and 2 inspections and reactive inspections based on events and overall licensee performance.

Inspection of waste facilities relies on expert knowledge supported by checklists.

Topics of particular importance are:

- classification of wastes,
- waste characterization and waste acceptance criteria,
- handling and storage,
- packaging and transport, and
- security and environmental monitoring.

Inspection of uranium mines and mills is conducted in a graded approach following specific worksheets and evaluation criteria. Some of these criteria cover:

- geotechnical aspects,
- mine-specific construction and engineering (e.g. ventilation),
- yellow-cake handling and packaging,
- stability of tailings,
- status of containment ponds,
- radon and dust monitoring in mines and mills, and
- radioactive and hazardous effluents and emissions.

For uranium mines, there is also on-going monitoring and control by provincial or territorial departments.

A Licensing and Inspection Mapping System allows CNSC staff to track action items for uranium mines and mills. CNSC staff records and reports the violation, ensures that the licensee has the same understanding of the nature of the non-compliance, and ensures that the licensee closes the non-compliance with adequate measures. The equivalent of a written warning is issued. CNSC verifies that the action(s) taken by the licensee have been adequate to correct the identified non-compliance or deficiency. Open items identified from previous inspections are reviewed and confirmed to be addressed. These items are then documented and considered closed.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-1 § 5.18 states that *“Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action shall be commensurate with the seriousness of the non-compliance. Thus there are different enforcement actions, from written warnings to penalties and, ultimately, withdrawal of an authorization. In all cases the operator shall be required to remedy the non-compliance, to perform a thorough investigation in accordance with an agreed time-scale, and to take all necessary measures to prevent recurrence. The*

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regulatory body shall ensure that the operator has effectively implemented any remedial actions.”

- G14 **Good Practice**: The use of a Licensing and Inspection Mapping System is an excellent method for tracking compliance and maintaining continuity from inspection to inspection. It is also valuable tool for knowledge transfer as the history of a licensee’s performance is recorded in the database.
- R10 **Recommendation**: The Licensing and Inspection Mapping System should be integrated into the CNSC action tracking tool to assist planning and compliance monitoring activities.

7. DEVELOPMENT OF REGULATIONS AND GUIDES

The Canadian nuclear regulator as well as the regulatory framework was founded over 60 years ago, in 1946. A major restructuring took place in the year 2000 when the new *Nuclear Safety and Control Act* was published and the Canadian Nuclear Safety Commission was formed. Since then, several steps in developing the regulatory framework including regulations and guides have been taken. Now CNSC develops mandatory regulations pursuant to the regulation-making powers set out in the *Nuclear Safety and Control Act* Section 44 and in accordance with the regulatory policy objectives set out in the Government of Canada's *Cabinet Directive on Streamlining Regulation*. Section 9 of the *Nuclear Safety and Control Act* obligates CNSC to disseminate objective scientific, technical and regulatory information. The CNSC meets this objective partly through the development of non-binding regulatory documents and review guides, which provide guidance to licensees on CNSC's regulatory programme and how to meet CNSC's regulatory expectations. Only documents referenced in a licence condition or in an order issued by CNSC become legally binding.

The present CNSC regulatory framework includes a comprehensive set of regulations and guidelines that cover the extent of the facilities and activities and practices regulated by the CNSC. All three categories of regulatory documents as specified in para 2.3. IAEA Safety Guide GS-G-1.4 are in place in the Canadian regulatory framework. *Nuclear Safety and Control Act* forms the key legislative part of the document hierarchy. The second mandatory level is divided in two parts: regulations form one level, licences and other mandatory instruments are the other. The lowest level is the non-mandatory guidance.

Currently, there are 11 mandatory regulations under the *Nuclear Safety and Control Act* formulated in line with the regulation-making power set in the *Act*. These regulations came into force at the same time as the *Act*. Since then, most of them have been amended, but the number of regulations has not changed. In the present annual plan, in addition to the existing 11 mandatory regulations, there are two new ones proposed for consideration. These two new regulations regard Safeguards and Environmental Protection. Two further safety areas for which the IRRS team did not find any dedicated regulation are Waste Management and Emergency Preparedness, although some requirements for these are found in other regulations.

There is a large number of guidance documents. During the years, the names of the lowest level regulatory guidance documents have changed. Since September 2007, the non-mandatory guides are categorized as Regulatory Documents (RD, different than the wording used in the IAEA documents). The documents published in the earlier years were categorized into Policies (P), Standards (S), Guides (G) and Requirements (R) and contain some regulatory requirements. The CNSC noted that, when these documents are revised, consideration will be given to transferring requirements into regulations or incorporating them into licence conditions and only guidance material will remain in Regulatory Documents. Some guidance documents are old (from 1970's). Many have remained as draft documents and have not been finalized. The coverage of the guidance is difficult to estimate. In addition to the RD, P, S, G and R documents there are information documents (INFO).

In spring 2009, the CNSC confirmed an earlier decision to distinguish between two classes of documents. The higher level documents will contain clear requirements, and will be written in mandatory language. This will allow them to be more readily incorporated into licence conditions, as part of the licensing basis. The preparation of the higher level documents will

follow an extensive internal and external review process, and go to the Commission for approval. Lower level guides will provide guidance, to be approved by CNSC management.

A strategic analysis of the whole guidance field is to be conducted by the CNSC staff by the end of 2009. A matrix form result of the analysis will indicate which guides need to be revised, which can remain as they are, which may be withdrawn and which new guides are needed. The effort also addresses all the older guides, independent of whether they are draft or final. The Regulatory Policy Analysis Division, which was founded last year, will lead this comprehensive task. There are two plans for the preparation of the guides: a three year general plan and a one year priority plan. The strategic drivers of the process are: new major facilities, refurbishment, environment, research reactors, regulatory regime modernization, and licence reform. The first year work programme contains 37 documents and the three-year programme contains 69 documents.

Outside the regulation and guidance directed to the licensee, there is guidance to the regulatory body's own personnel. (According to para 2.27 of IAEA Safety Guide GS-G-1.4, the regulatory body should establish its own set of internal guidance documents which describe its functions and the methods of performing them.). Review guides are primarily intended for staff responsible for reviewing licence applications. They are shared with licensees on request to provide insight into what CNSC staff will be considering in their review. Staff review guides have been completed for the regulation of nuclear substances and Class II nuclear facilities. The preparation of staff review guides for purposes of licensing new build power reactors was started last year. The CNSC recognizes that this approach has other benefits (e.g. as a method to capture the knowledge otherwise possibly lost when senior experts retire) and could be applied more broadly across all major facilities.

CNSC's practice of sharing the review guides and assessment plans with the licensees is to be considered strength of the CNSC regulatory process.

An updated list of guidance documents has recently been established on the CNSC Web site to provide guidance according to a certain topic or a service line.

The development of regulations and regulatory documents is subject to both internal review and external consultation.

To develop regulations, CNSC has in place a well documented Regulation Making Process that assures transparency and balanced consultation. CNSC proactively communicates with licensees, interested stakeholders, and other bodies and parties who may be interested in commenting on the proposed regulations. These other parties include independent bodies (such as non-governmental organizations and local communities) where appropriate, operators, and other stakeholders, such as other government departments. CNSC regulations, as with all federal regulations, are subject to the *Statutory Instruments Act*, which calls for pre-publication of draft regulations in the *Canada Gazette, Part I*, to ensure that all Canadians have the opportunity to comment on the draft regulations. Following the comment period, stakeholder submissions are posted on the CNSC's external Internet site with an invitation to respond to comments. All input is then reviewed by CNSC staff and the draft regulation revised, if necessary, reissued for further comment, withdrawn, or finalized and published.

The regulation preparation process with several consultation and publication steps has been effectively formalized. The openness and transparency of the process is notable. CNSC proactively communicates with licensees, interested stakeholders, and other bodies who may be interested in commenting on the proposed regulations. The group of interested parties is consulted on the basis of a discussion paper before any drafting starts to determine whether

regulation is the best solution to address the problem. The Regulation Making Process was first documented in 2004 and updated in 2007 since publication of the *Cabinet Directive on Streamlining Regulation*. The newest regulations have been prepared along this consistent, robust and consultative process. Of the 11 regulations all but two have been amended after publication of the *Cabinet Directive on Streamlining Regulation*.

According to the *Cabinet Directive on Streamlining Regulation* a cost-benefit analysis has to be carried out when determining the need to issue a new regulation that may have a significant impact on industry or Canadians. The full-scale procedure is not mandatory. For screening the need for a full analysis, a questionnaire with 13 questions regarding the financial impact has been formulated by the Canadian Treasury Board. The categories to each question are: low, medium, high. If the answer to all items is “low”, no analysis is needed. If even one of the answers is “medium” pre-consultation is needed and if even one answer is “high” the whole analysis has to be carried out. The expertise for execution of the cost-benefit analysis effort is available on the federal level.

Regulations require the approval of both the Commission tribunal and the government before becoming law. According to experience the timeframe for the whole preparation process of a regulation varies from six months to five years depending on the complexity and the immediacy of the need for the regulation.

Risk should be considered in determining the need to issue new regulations or regulatory documents. This effort is aligned with the Canadian Standard CAN/CSA-Q850-97 (R2002) “Risk management: Guideline for Decision Makers”. Several key risk areas have to be considered such as health and safety risk, environmental risk, legal risk, security risk, policy and commitment, public perception as well as effectiveness and efficiency. In practice the risk related to the preparation of regulation is difficult to quantify and other factors may decide the start of the preparation process. The risk-informed decision making in determining need of a regulation is clearer when dealing with the low-risk non-power facilities. There, the lengthy regulation making process may not be the most effective tool. A review guide issued through a substantially less tedious process and shared to the applicants/licensees may be sufficient.

According to paragraph 3.28 of IAEA Safety Guide GS-G-1.4 the regulatory body should ensure that regulations and guides are kept up to date, and procedures should be established for their periodic review. At present there is no fixed CNSC rule on the interval to revisit existing regulations. In fact, all the 11 existing regulations were put into force in year 2000. In practical terms the CNSC staff foresees that five years will become the interval for revisiting the regulations and guides.

The preparation process for the guidance documents (regulatory documents) is simplified from that for mandatory regulations. Regulatory documents are drafted by cross-functional teams that build on existing knowledge, feedback, and experience from existing documents. Initial drafts are reviewed by selected CNSC specialists and then by Legal Services before being submitted to the Regulatory Policy Committee for approval to proceed to the Commission for approval to post the draft document for external stakeholder consultation. Following consultation, final approval is also provided by the Commission.

The regulatory control by CNSC is not hindered by lack of regulation as the needed legally binding requirements can always be incorporated into the licence conditions. The regulations and guidance documents clarifying the regulator expectations are prepared to cover issues common for classes of licensees. The preparation of regulations and guides is planned with a three-year horizon, at the moment up to March 2012. Preparation of regulations and guides is a

rather lengthy process. The most rapid tool to address all the licensees is a regulatory order, (e.g.: an order was applied to introduce enhanced physical security requirements after 9/11.)

CNSC participates in the standard-setting activities of the IAEA and of accredited standard-setting bodies such as the Canadian Standards Association (CSA). In addition to setting out good industry practice, such standards may be incorporated by reference into regulations or licence conditions. In practice the CNSC takes into account internationally recognized safety standards and recommendations and adopts or adapts them in the extent possible. CNSC is required to follow the *Cabinet Directive on Streamlining Regulation* which also promotes the use of international standards, guidelines and recommendations as a basis for technical regulations, and recommends limiting the number of specific Canadian regulatory requirements or approaches. As an example, the CNSC regulatory document RD-337, “Design of New Nuclear Power Plants”, adopted the principles set forth by the IAEA in NS-R-1, Safety of Nuclear Plants: Design, regarding design, the interfaces between NPP design and other topics, such as environmental protection, radiation protection, ageing, human factors, security, safeguards, transportation, and accident and emergency response planning. Another example is the limit for radiation exposure to the public (1 mSv/a).

The principle to use internationally recognized standards in the largest possible extent is a positive sign of the Canadians striving to international harmonization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** **GS-G-1.4 § 2.3** states that: *The regulatory body should specify the purposes of the various regulatory documents necessary for it to perform its functions. The documents may be categorized as comprising: legislation; regulations, licences and other mandatory documents; guides and other advisory documents.*
- S13 **Suggestion:** CNSC should review and adopt a consistent terminology for its regulatory guides.
- (1) **BASIS:** **GS-G-1.4 § 3.28** states that *“The regulatory body should ensure that regulations and guides are kept up to date, and procedures should be established for their periodic review.”*
- S14 **Suggestion:** CNSC should systematically carry out regular periodic review of the published regulations and guides. Then the need for revision of the all regulation and guidance material should be evaluated and on the basis of the evaluation the defined revision steps should be taken.
- (1) **BASIS:** **GS-R-1 § 5.28** states that *“In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards”*
- G15 **Good practice:** Where appropriate the CNSC adopts or adapts national and international standards when developing regulatory requirements. The Canadian government promotes participation in standard setting activities of the IAEA and to the Canadian Standards Association.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-G-1.4 § 2.27 states that “*The regulatory body should establish its own set of internal guidance documents which describe its functions and the methods performing them.*”
- S15 **Suggestion:** To support knowledge management the CNSC should extend the concept of its internal staff review guides to cover all key areas of its function.
- (1) **BASIS:** GS-R-1 § 5.28 states that “*In developing regulations and guides, the regulatory body shall take into consideration comments from interested parties and the feedback of experience. Due account shall also be taken of internationally recognized standards and recommendations, such as IAEA safety standards*”
- G16 **Good Practice:** The Regulation Making Process is very open and transparent with extensive pre-consultations built into the process. Interested parties are consulted already before starting to draft the regulation.

7.1. NUCLEAR INSTALLATIONS: NPPS, RRS AND FCFS

There are no specific findings.

7.2. NEW BUILD

Two regulatory guides for new build reactors have been published so far, related to siting and design. These documents are technologically neutral, as they can be applied also to reactor types other than CANDU. Other proposed regulatory documents related to new build will follow the same approach.

At present the CNSC is developing the Application Guideline Documents to provide guidance to applicants planning to submit applications for licences under the *Nuclear Safety and Control Act*. Three new documents are being written to provide guidelines for applicants for licences to prepare site, to construct and to operate the power reactor. Deadlines for publishing these documents are considered by CNSC to be in 2009 and 2010.

Pre-project design reviews are taking place without a finalized review guide.

Staff Review guides are being developed by the CNSC for the internal use by staff in reviewing applications associated with new nuclear power plants. These staff review guides, currently addresses site preparation and environmental assessment. Further staff review guide to cover the construction licensing stage are being developed. While the CNSC does not consult on their development and/or modifications, these guides are provided to applicants upon request. The CNSC welcomes feedback on the staff review guides. As knowledge evolves, staff review guides can be rapidly revised using an auditable controlled document change process.

7.3. INDUSTRIAL, MEDICAL AND RESEARCH ACTIVITIES

CNSC issues a comprehensive set of regulations and regulatory documents covering Class II facilities and prescribed equipment and nuclear substance and radiation devices. Issued documents include standards, application guides, other regulatory guides and requirements and provide more detailed and specific information on the requirements established by Canadian legislation and associated regulations. There are also a set of draft regulatory documents under revision; these documents are available for consultation and include

requirements such as for the import and export of radioactive sources, radioactive source security as well as the specific requirements verified during the inspections carried out by CNSC.

7.4. WASTE FACILITIES, MINES AND MILLS

Requirements for the regulation of waste management facilities are captured in the General Nuclear Safety and Control Regulations, and further elaborated in facility and activity specific regulations, such as the Class I Nuclear Facilities Regulations. These are supported in a number of regulatory guides and CSA Standards including for example, CSA N292.3-08 Management of low and intermediate level radioactive waste.

In March 2008, the Canadian Standards Association (CSA) developed – in collaboration with industry, government and the regulatory body – a standard that includes a radioactive waste-classification system. The development of the radioactive waste classification system took into account both the International Atomic Energy Agency (IAEA) standards and the needs of the Canadian industry.

Currently, CNSC recognizes that its set of regulatory documents needs to be expanded expeditiously to ensure that radioactive waste is managed in a consistent manner.

Uranium Mines and Mills are governed by the Uranium Mines and Mills Regulations and associated regulations. CNSC has prepared several standards and draft regulatory guides to support licence application submittals and regulatory reviews. For example CNSC has completed or drafted the following regulatory guides:

- Emergency Planning at Class I Nuclear Facilities and Uranium Mines and Mills (G-225)
- A Guide to Ventilation Requirements for Uranium Mines and Mills
- Measuring Airborne Radon Progeny at Uranium Mines and Mills (G-4)
- Environmental Monitoring Programs at Class I Nuclear Facilities and Uranium Mines and Mills (G-224)), currently in draft form
- Developing Environmental Procedures at Class I Facilities and Uranium Mines and Mills (G-296)

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

(1) **BASIS:** GS-R-1 § 5.25 states that *“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:** CNSC should improve its regulatory framework including regulatory documents and guides with respect to radioactive waste management to ensure that radioactive waste is managed in a consistent manner.

8. MANAGEMENT SYSTEM

Introduction

The IAEA Safety Requirements publication GS-R-3, issued 2006, defines the requirements for establishing, implementing, assessing and continually improving a Management System that integrates safety, health, environmental, security, quality and economic elements. This integration aims to ensure that safety is properly taken into account in all the activities of an organization in order to ensure the protection of people and the environment. The requirements are applicable on Management Systems for industrial nuclear facilities and activities as well as for regulation of such facilities and activities. GS-R-3 with its integrative approach, emphasis on safety culture promotion and strong focus on continuous improvement can be seen as an evolution of the earlier concept of Quality Management.

Background

The first effort by CNSC to formalize its Management System in 2004 had limited success. A new start was made in 2005 with more clear top management commitment and organizational resources to develop a comprehensive system meeting the requirements and guidance of GS-R-1 and accompanying guides (GS-R-3 was issued in 2006). The IRRS self-assessment review, conducted in 2006 by five consultants and two CNSC staff members, noted that a clear plan and priorities had been missing for the Management System development. Other concerns had to do with internal decision making practices, internal communication, safety culture promotion, performance management, identification and handling of corrective actions and management of change. The improvement programme driven by the NRU Lessons Learned and previous audits has addressed all these issues but work remains and some time commitments are unclear.

Well developed elements of the CNSC Management System

Coverage and documentation

The Management System Manual (latest update in May 2009) presents an integrated approach to the performance of mandated functions across the organization. It is clearly pointed out that a combination of factors related to processes, people and resources are needed to deliver results. The Manual is well structured. Commitments to the Management System by the President and the Management Committee are signed on the introductory pages. Descriptions are provided of policy, culture and regulatory philosophy, the main processes and closing with descriptions of evaluating and improving performance and the organizational authorities and responsibilities. The Management System documentation is ordered in a hierarchy from the Manual at the top (level 1), over key policy and process documents at level 2, process documents at level 3, standards, working instructions, templates at level 4, and records. All processes have been identified. The overall process map includes three groups of processes needed to deliver the outcomes of the organization. These are:

- Core Processes; manage the regulatory framework, manage licensing and certification and assure compliance (3 key processes)
- Management Processes; direct and manage the organization, manage communications and stakeholders engagement, evaluate and improve performance, manage processes (4 key processes)
- Enabling Processes; human resources management, occupational health and safety services, learning and development, information management, information

technology, finance, internal security, legal services, physical resources, procurement and contracting (10 key processes)

In addition to the 17 key processes, the whole system contains about 40 subprocesses.

The process to manage processes is a key document in the development of the Management System. It defines how processes are to be developed, implemented and maintained. Level 4 documents further describe how processes are to be documented and templates are provided as well as requirements for IT-tools. The process to manage processes assures a standardized approach to the development, implementation and maintenance of the Management System, including standardized process maps, across the organization.

The processes of the Management System reflect the graded approach with regard to complexity and risk significance. A well elaborated concept exists for risk-informed decision making based on the Canadian standard CAN/CSA-Q850-97. Facilities and activities are graded according to risk which determines the regulatory priorities. The concept uses a combination of qualitative and quantitative analyses.

All Management System documents are available on the Intranet. A new document management system E-Access has been implemented. This system enables an easy navigation among the Management System documents as well as a strict version control over documents. Several documents can be opened directly from the process maps. All process documents are provided with a symbol showing their place in the document hierarchy.

Management commitment, responsibilities and activity planning

Development and improvement of the Management System and other strategic initiatives are controlled by the Harmonized Plan for Improvement Initiatives. This plan has a clearly defined governance structure allowing for full engagement and participation of CNSC senior management and allocation of resources. The commitment to the Harmonized Plan is further strengthened by its inclusion in the performance management contract of all managers. The governance structure with specified responsibilities and authorities include the Management Committee, the Executive Authority, the Programme Authority, the Project Manager for specific initiatives, Champions for key initiatives and temporary Tiger Teams which are focussed teams of dedicated persons.

The Harmonized Plan contains items in three priority groups allocated to different processes of the Management System with specified deliverables and time commitments for the most important items. Currently most of the items were identified by the NRU Lessons Learned. However, the plan is meant to be an “evergreen” plan evolving as new information becomes available and priorities change. For this purpose, the plan is followed up and updated on a quarterly basis. In order to make the plan visible in the organization a communications strategy has been developed with a dedicated Intranet site (BORIS) where information on the current status of the plan and other related information and messages are easily accessible for all staff.

In general, management commitment, responsibilities and authorities for all CNSC activities are well defined within the Management System. The Commission is ultimately responsible for matters under the NSCA (*Nuclear Safety and Control Act*). The President is responsible for the strategic leadership of CNSC. The four Vice-Presidents are responsible for all management matters within their respective areas and reporting to the President. Further descriptions are given in the Manual of other functions reporting directly to the President. In

addition, general management responsibilities are described as well as general employee responsibilities.

The roles and responsibilities of process owners for the key processes are also defined and described.

The mandate of CNSC, mission, vision and organizational values are described. A large number of staff has been involved in discussing the organizational values. The finally established values are quality, integrity, competence, dedication and respect for others.

Management processes exist for strategic and annual planning. This planning is to a great extent controlled by Government of Canada requirements. The basic document is a five-year strategic rolling plan based on an environmental scan of possible regulatory challenges. This plan provides the basis for the annual “Plans and Priorities” sent to Parliament through the Ministry of Natural Resources. This plan is developed using a Programme Activity Architecture that aligns with the Management System key processes. The plan contains planned spending and full time equivalents for the different programme activity areas. Expected results are specified as well as performance indicators and targets, and description of benefits to Canadians. Annual planning includes the development of Regulatory Activity Plans which are the basis for cost recovery fee estimates that are sent to the licensees. Within CNSC, this resource planning is coordinated by planners in each directorate in a combination of top down, bottom up approach. Based on this annual plan, each division (technical area) knows how many working hours that are planned to be spent on defined projects. Individual planning is done on that basis by the division head in communication with the staff members. Reserve time is kept for unforeseen events.

The planning has developed from a very detailed task planning to a more flexible overall planning.

A midyear follow-up of the annual plan, mainly on the use of financial resources (all resources are translated to financial equivalents), is conducted and fee invoices for licensees are adjusted accordingly. The follow-up is focused on integrating performance management information with the information of the use of financial resources. A quarterly follow-up is planned. At the end of the year, an official Departmental Performance Report (DPR) is prepared for Parliament on achievements and outcomes as well as the financial records. The DPR is laid out in the standard Programme Activity Architecture. In addition, as required by the NSCA, an Annual Report is prepared for the minister of NRCan. This report is aimed at the Canadian public and is published in an attractive and more informative format.

The internal follow-up of substantial tasks follows another workstream based on standard project management approaches. Project Managers are assigned primary responsibility for the planning and follow-up of project activities. Currently, the CNSC is standardizing its project management tools and supporting infrastructure. Management oversight includes the regular monitoring of progress through a combination of progress reports, performance dashboards and scheduled discussions in management committees. All major projects receive senior management oversight. Organizational priorities and associated resource allocation are reviewed, adjusted and shared with staff. Work remains in fully integrating the many projects across the organization (projects that are both underway and planned).

The CNSC has the ambition to better integrate the planning, monitoring and reporting of ongoing regulatory activities with that for projects. This initiative is included in the Harmonized Plan.

Management of information and knowledge of CNSC as a resource

Information and knowledge management such as making necessary technical information available and maintaining and developing the knowledge base are covered by management procedures. Competence profiles exist for all positions or groups of similar positions. Each employee has an individual learning plan where planned training courses are specified. All managers have special contracts for their professional development and performance criteria to meet.

A systematic approach to training is being implemented starting with inspector training. A mandatory training programme has been developed in order to receive the inspector card which is an authorization to act on behalf of CNSC towards the licensees. A systematic orientation programme exists for all new employees.

The CNSC is free to decide on staffing and employment conditions. Contractors (except former CNSC staff) are used to a very limited extent. Staffing plans are made by each directorate and coordinated by the Human Resources Directorate. A proactive approach is used to predict retirements and other changes. Several means to retain necessary competency are used such as alumni programmes where retired staff is contracted to transmit their knowledge to younger staff.

CNSC has an Intranet-based information management system to support the management processes and to facilitate access to information and records. The system is under further development. It holds all relevant records in digital format; several associated databases provide reference information, such as safety assessments and operational documentation from the facilities. This system is used by the head office as well as by the regional offices.

Although further improvements are still required, the document management system can support consistent and timely regulatory decision-making by providing staff with prompt access on the Intranet to previous regulatory decisions and the technical assessments underpinning them, enabling rapid comparison of information submitted by operators with previous CNSC reviews, assessments and decisions.

Control of documents and records

In principle all documents are handled by the electronic documentation system which makes non-security classified documents available to staff. All documents are well controlled. Incoming documents are allocated directly to the responsible officer who makes a first review and if needed sets a response time. Many licensing and compliance activities are documented in databases that automatically provide for monitoring of deadlines. Key records of the Commission are available on the Intranet as well as the Internet.

External communication

In line with the *Nuclear Safety and Control Act* and the *Access to Information Act*, CNSC has a policy of openness towards the stakeholders and the general public. The most obvious exponent of this is the public hearings conducted by the Commission. Decisions and other matters of interest are posted on the Web site if not protected for individual integrity or security reasons. Inspection reports are not published; however they will be released to the public if asked for.

Opportunities for further improvement of the CNSC Management System

It is clear to the mission that CNSC has done a large and commendable work over the last years to develop the Management System in order to make the organization more process-based.

As mentioned, all processes and subprocesses have been identified but a number of the processes, especially at level 3 and working documents at level 4, remain to be developed or to be transferred to the decided format. The system is therefore not fully implemented. However, work is underway with clear priorities but less clear time-frame. Major steps are included in the Harmonized Plan for Improvement Initiatives that assures allocation of resources for the higher priorities. CNSC estimates that the remaining work to complete the system will require about two years. This is not reflected in the Harmonized Plan since there is no time commitment for the lower priorities. The remaining efforts to complete the Management System in line with GS-R-3 could therefore be more clearly enveloped and time framed.

In relation to GS-R-3, the following improvement areas could be more clearly addressed:

Promotion and support of a strong safety culture

The Management System Manual describes features of the CNSC regulatory and organizational culture. For a regulatory body, it might be more appropriate to talk about a regulatory culture than a safety culture. How to apply the concept of safety culture on a regulatory body is elaborated to some extent in INSAG-4 and INSAG-15. Currently, there is no systematic mechanism in place at CNSC to promote or assess the regulatory culture. This is an item in the Harmonized Plan with longer term priorities. Taking into account the lessons learned from the NRU event, the programming of regulatory culture promotion could receive a higher priority and be further developed in the Manual.

Consideration of stakeholders' expectations

CNSC has many interfaces with institutional parties as well as international organizations, industry stakeholders, environmental organizations and the interested public. Several procedures in the Management System explain how to interact with these parties but there is no description in the Management System how to investigate stakeholders' expectations and criteria for follow-up on the results.

Human resources

Until now CNSC has had no systematic approach to training based on organizational needs (SAT). The new system developed for inspectors will provide management with a much better tool for assessing and follow-up of individual staff competence belonging to this category based on organizational needs. It is included in the Harmonized Plan to develop SAT-based training for operational staff as a short-term priority but without time commitment. The strategic objectives on this issue are not clear—for instance, whether a systematic analysis of organizational competence needs and the implementation of resulting training programmes are planned for other key categories of staff such as the technical experts of the Technical Support Branch.

Management of organizational change

CNSC is a stable organization with few changes. However, changes have been made over the last years to better deal with the organizational needs. For instance the operational and technical support branches have been separated and a new directorate to prepare, among other tasks, for licensing of new build has been created. Procedures for change management are foreseen in the Harmonized Plan as a longer-term priority but without time commitment.

Organizational change is not easy to assess with objective criteria. For this, the organizational design basis needs to be defined as well as a methodology to assess organizational change. CNSC could solicit international experience on these issues.

Management self-assessment

Although there are general requirements that CNSC managers follow-up on the status of planned activities, there are no systematic approaches to management self-assessments. Level 3 and 4 processes documents, dashboards and reporting tools for defining, tracking and reporting on performance are included in the Harmonized Plan to be developed in the short term but with no time commitment. GS-R-3 requires management at all levels in the organization to carry out self-assessments to evaluate the performance of work and the improvement of safety culture. CNSC could develop general tools for such self-assessments and encourage management to develop and use performance indicators for their areas of responsibility. Performance indicators could also be attached to each level 2 and 3 process in order to support the process owners.

Independent assessments on behalf of senior management

CNSC recently established a high level Audit Committee according to the internal audit policy of the Government of Canada composed of three external members and the CNSC President and the Commission Secretary. The Committee has a general supervisory function of the overall performance of the organization and provides direction to the CNSC Office of Audit Evaluation and Ethics. This office performs internal audits with a dedicated staff of four persons according to an audit plan. How these audits are performed is not described in the Management System Manual but it seems that they have been done primarily to satisfy governmental requirements on administrative efficiency and effectiveness and not necessarily to provide feedback for CNSC's own purposes. GS-R-3 is clear about independent assessments to be conducted regularly on behalf of senior management: an organizational unit provided with the necessary authority shall be assigned the responsibility to manage these assessments. The practice in many regulatory bodies is to select and train a group of auditors from different parts of the organization and to compose audit teams from this pool, depending on the function to be audited. Auditors shall not assess their own work. A common practice is also to develop an audit programme to ensure that all Management System processes are audited within a certain time period, often 3-4 years depending on the scope of activities. CNSC could consider a similar practice tailored to support the further development and implementation of its Management System.

Management system review

GS-R-3 requires a comprehensive Management System review to be carried out at planned intervals to ensure the continuing suitability and effectiveness of the system and its ability to enable the objectives of the organization to be accomplished. There are plans to assess the Management System on a biannual basis. However, CNSC has no methodology and programme in place to conduct these reviews. A methodology needs to be developed and a mechanism established for handling of the results. For CNSC, with a relatively large number of Management System documents, it seems well motivated to carry out these reviews to make sure that the Management System provides consistency as well as the necessary flexibility in the regulatory activities to achieve the organizational objectives. Not least to make sure that the application of the graded approach is adequate for all types of regulated facilities and activities.

Systematic approach for handling of non-conformances and potential non-conformances

There is currently no process or procedure in place to handle non-conformances with regard to management processes and products of the CNSC. A procedure to manage corrective actions is identified in The Harmonized Plan as a longer term priority with no time commitment. This is a matter closely connected with an internal audit programme. Regarding potential non-conformances, there are regular contacts between CNSC and regulatory bodies abroad to exchange views on regulatory and management matters in order to identify potential non-conformances and opportunities for improvement. Meetings within IAEA, OECD/NEA, INRA, the safety Conventions as well as the IRRS mission are instruments for this. However, no regular feedback programme from other organizations is defined within the Management System.

Identification and monitoring of improvement actions

In addition to handling of non-conformances, GS-R-3 calls for a general procedure or mechanism to identify opportunities for improvement of the Management System as well as to monitor improvement actions and assess the effectiveness of the improvements. Such a mechanism could be built into each process and be managed by the process owners. For instance each process could have a mailbox on the intranet for comments and suggestions from the staff.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** GS-R-3 § 2.1 states that *“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.”*
 - (2) **BASIS:** GS-R-3 § 2.4 states that *“The organization shall be able to demonstrate the effective fulfilment of its management system requirements.”*
- R12 **Recommendation:** CNSC should more clearly envelope and timeframe the remaining efforts to complete the Management System according to GS-R-3 and for that purpose update the Harmonized Plan.
- (1) **BASIS:** GS-R-3 § 6.7 *“A management system review shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the management system and its ability to enable the objectives set for the organization to be accomplished.”*
 - (2) **BASIS:** GS-R-3 § 6.10 *“The review shall identify whether there is a need to make changes to or improvements in policies, goals, strategies, plans, objectives and processes.”*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- R13 **Recommendation:** CNSC should develop a methodology and implement Management System reviews to be conducted at planned intervals by internal or/and external resources. This programme should ensure the continuing suitability and effectiveness of the Management System as a whole and its ability to enable the objectives of the organization to be met. One important factor to be reviewed in this perspective is the application of the graded (risk-informed) approach to the regulation of facilities and activities
- (1) **BASIS:** GS-R-3 § 3.9 “Senior management shall develop the goals, strategies, plans and objectives of the organization in the integrated manner so that their collective impact on safety is understood and managed”
 - (2) **BASIS:** GS-R-3 § 3.10 “Senior management shall ensure that measurable objectives for implementing the goals, strategies and plans are established through appropriate processes at various levels in the organization”
- S16 **Suggestion:** CNSC should continue integration of its strategic and annual planning processes as well as its in year control and monitoring processes for better invoices to licensees and to ensure alignment and reallocation of resources according to corporate priorities. For this purpose CNSC should consider the integrated use of performance indicators for each programme activity and related processes.
- (1) **BASIS:** GS-R-3 § 6.3 “Independent assessments shall be conducted regularly on behalf of senior management:
 - To evaluate the effectiveness of processes in meeting and fulfilling goals, strategies, plans and objectives;
 - To determine the adequacy of work performance and leadership;
 - To evaluate the organization’s safety culture;
 - To monitor product quality;
 - To identify opportunities for improvement.”
 - (2) **BASIS:** GS-R-3 § 6.6 “Senior management shall evaluate the results of the independent assessments, shall take any necessary actions, and shall record and communicate their decisions and the reasons for them.”
 - (3) **BASIS:** GS-R-3 § 6.11 “The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence.”
 - (4) **BASIS:** GS-R-3 § 6.14 “Corrective actions for eliminating non-conformances shall be determined and implemented. Preventive actions to eliminate the causes of potential nonconformances shall be determined and taken.”
 - (5) **BASIS:** GS-R-3 § 6.15 “The status and effectiveness of all corrective and preventive actions shall be monitored and reported to management at an appropriate level in the organization.”
 - (6) **BASIS:** GS-R-3 § 6.16 “Potential non-conformances that could detract from the organization’s performance shall be identified. This shall be done: by using feedback from other organizations, both internal and external; through the use of

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

technical advances and research; through the sharing of knowledge and experience; and through the use of techniques that identify best practices.”

- S17 **Suggestion:** CNSC should supplement the internal audit programme in order to provide feedback to senior management on the development and implementation and output of the Management System processes. To support this programme, a number of internal auditors representing different parts of the organization could be used. In connection with the audit programme, a systematic approach to the management of non-conformances and potential non-conformances of processes and products should be developed and formalized
- (1) **BASIS:** GS-R-3 § 6.17 *“Opportunities for the improvement of the management system shall be identified and actions to improve the processes shall be selected, planned and recorded.”*
- R14 **Recommendation:** CNSC should implement a mechanism to regularly identify opportunities for improvement of the Management System and should evaluate the effectiveness of the improvement actions.
- G17 **Good Practice:** The Harmonized Plan developed by CNSC is an excellent tool for driving improvement initiatives across the organization with clear management commitment and allocation of resources and is supported by a communications strategy.

9. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

9.1 TRANSPARENCY AND OPENNESS OF CNSC

Communication and consultation with interested parties plays a central role in the Canadian regulatory framework. The dissemination of objective scientific, technical and regulatory information to the public concerning the activities of the Commission and the effects on the environment and on the health and safety of persons is one of the two legislative objectives of the CNSC (NSCA, Section 9). As a federal institution, the CNSC follows the principles of the government of Canada's policy on communication to openly inform the public. Furthermore the Access to Information Act (ATI Act) sets forth the principle that every person in Canada has a right, on request, to be given access to records under the control of CNSC unless it is restricted.

CNSC communicates actively with many external stakeholders including:

- other federal departments and agencies,
- the public (individuals, community groups, and public interest groups) and the media,
- First Nations and other aboriginal groups,
- non-Governmental Organizations,
- professional and scientific associations, and
- municipal, provincial and foreign governments and agencies.

The obligation to disseminate objective information and to involve the stakeholders in the regulatory processes is prominently reflected as one of the organizational foundations in CNSC's Management System. Management of Communications and Stakeholder Engagement is part of CNSC's management processes.

Promotion of regulations and guides to interested parties

The information about the principles and criteria for safety is mainly based on the development of regulatory documents, review guides, which provide guidance to licensees on CNSC's regulatory programme and how to meet CNSC's regulatory expectations. Review guides are primarily intended for staff responsible for reviewing licence applications, and are shared with licensees on request to provide insight into what CNSC staff will be considering in their review.

The legally binding Regulations made by the Commission are made in accordance with the requirements of the *Statutory Instruments Act*. Consultation with stakeholders is a fundamental part of this process. Normally, this means pre-consultation with affected stakeholders to determine whether regulation is the best solution to address the problem. In addition, CNSC regulations, as with all federal regulations, are subject to the pre-publication in the *Canada Gazette* to ensure that all Canadians have the opportunity to comment on the draft regulations. When pre-publishing regulations, the CNSC proactively communicates with licensees, interested stakeholders, and other bodies who may be interested in commenting on the proposed regulations. As a result of the pre-consultation process a Pre-Consultation Report is generated, which includes a Summary of Disposition of Comments.

Within the structure of developing non-legally binding regulatory documents, the CNSC uses a comprehensive internal review and external consultation process for developing application

guides and regulatory documents. CNSC staff also participates and provides guidance to licensees and applicants during external outreach activities and industry specific conferences.

Communication and consultation with interested parties

Canada fosters broad involvement of the public in the regulatory process. It has a well-developed programme for communicating information about its activities to the public. Communications plans and products are drafted for all significant programme and regulatory activities and the organization engages in public outreach activities in host communities that are open to all interested parties. The CNSC uses the Internet extensively as a communications vehicle, maintaining a Web site that is updated regularly as a source of information on the fulfilment of its mandate and discussion of current events and activities.

The public's primary opportunity to participate in the procedures for rendering major licensing decisions is in the Commission public hearings. Approximately 30 public hearings related to such decisions are held each year. They are a highly visible component of the work of the Commission. The Rules of Procedure, which set out the process for Commission hearings, include the opportunity for interested persons to intervene in the hearings and make presentations or challenge the evidence. Notices of hearings are posted on the Commission's website and in national and local newspapers, in sufficient time for the public to be apprised of the materials and to seek intervener status.

The Commission also holds public meetings to consider a wide range of topics related to the nuclear regulatory process and, in certain cases, to make legislative, policy or administrative decisions on matters of particular or general application.

The CNSC enters into memorandum of understanding with other government bodies. It communicates with other federal departments including Health Canada, Environment Canada, Transportation Canada and the Department of Foreign Affairs and International Trade.

The CNSC also oversees a Non Governmental Organization Regulatory Affairs Committee (NGO RAC), which is intended to serve as a mechanism for the CNSC to communicate and consult with NGOs on regulatory and policy matters that are within the mandate of the CNSC. The NGO RAC is a forum for exchanging and clarifying information to ensure a common understanding of issues, thus allowing the CNSC to better respond to the information needs of the NGOs.

CNSC may inform other governmental, national and international organizations and foreign governments or international agencies about incidents and the possible radiation risks associated with facilities and activities. The communication procedures are formalized for emergency situations; other cases are covered as necessary. On the international level, Canada contributes to the IAEA Incident Reporting System and has special notification arrangements with the United States Nuclear Regulatory Commission (USNRC).

Incidents of public interest are published on CNSC's Web site. Information on incidents and abnormal events is also communicated regularly through the Commission's proceedings and meetings, which are generally open to the public, through a variety of reports which are on the public record as Commission Member Documents. During a nuclear emergency CNSC has the approach to communicate quickly and openly to the public.

The CNSC ensures that the Government and Parliament are advised of matters related to the safety of facilities and activities through its annual report and other more frequent communications from the President and senior staff of CNSC. For example, CNSC staff gives evidence at Parliamentary committee meetings and makes recommendations to Government.

9.2 Transparency and Openness of Licensees

An information programme on the nature of a facility's operations and effects on the environment has to be submitted as part of a licence application. The general guidance with respect to such programmes is provided in G-217 Licensee Public Information Programmes. Major licensees can be subject to licence conditions requiring public information.

All major licensees have comprehensive Web sites and inform the public about the possible radiation risks associated with the facilities. In addition, for more significant events, they regularly inform the public with press releases.

10. CODE OF CONDUCT ON SAFETY AND SECURITY OF RADIOACTIVE SOURCES

10.1. GENERAL

CNSC played a significant role in participating in the international meetings to develop the Code of Conduct on the Safety and Security of Radioactive Sources (the ‘Code’), the Code’s supplementary Guidance on Import and Export of Radioactive Sources (the ‘Guidance’) and the IAEA categorization system for radioactive sources. Canada was among the first G8 countries to make a political commitment to follow the principles of the Code and to implement the Guidance in a harmonized manner. Canada has provided financial support to IAEA to enable representatives from developing countries to participate in meetings on the Code.

This section is devoted to the following areas related to the Code where information was provided to the IRRS team in advance of the mission:

- Regulation of sealed sources;
- National registry and tracking of radioactive sources;
- National strategy of gaining and regaining control over orphan sources; and
- Import and export of category 1 and 2 radioactive sources under the Code.

Additional information related to the authorization, inspection and enforcement of radioactive sources is provided in Sections 4 and 6. Although a review of ‘security’ was outside the scope of the mission, the interface between staff of the Directorate of Nuclear Substances and that of the Nuclear Security Division was briefly discussed during the interviews.

The fore-runner to CNSC, the Atomic Energy Control Board, regulated radioactive sealed sources and radiation devices in Canada through a comprehensive licensing and compliance programme. In 2000, the *Nuclear Safety and Control Act* (NSCA) came into force and the Canadian Nuclear Safety Commission was created to replace the Atomic Energy Control Board.

10.2. REGULATION OF SEALED SOURCES AND RADIATION DEVICES

The CNSC regulates the use of radioactive sealed sources and radiation devices starting from the principle that the licensee has the prime responsibility for safety, while the role of the CNSC is to verify that licensees properly carry out this responsibility. The regulatory process, in general, consists of setting regulatory requirements, applying them through licensing, and then conducting reviews, inspections and enforcement activities to ensure that regulatory requirements are being followed. Radioactive sealed sources and radiation devices are regulated under several sets of regulations made under the NSCA. In addition to the General Nuclear Safety and Control Regulations, radioactive sources and devices are regulated mainly through the Class II Nuclear Facilities and Prescribed Equipment Regulations and the Nuclear Substances and Radiation Devices Regulations.

According to the NSCA, no person, company or organization may possess, use, import or export (in accordance with the Nuclear Non-Proliferation Import and Export Control Regulations) radioactive sealed sources or radiation devices unless authorized by licence from the CNSC. All applicants for a licence must be legitimate entities with valid reasons to

possess the source, and they must demonstrate that they are qualified to carry on their licensed activity, and will make adequate provision for the protection of the environment, the health and safety of persons, and national security, and the maintenance of measures required by any pertinent international obligations to which Canada has agreed.

Each licence is specific to the radioactive substance being used, its quantity, and the make and model of the radiation device. Very small quantities of radioactive substances may be exempted from the requirement for a licence (Nuclear Substances and Radiation Devices Regulations).

As required under the NSCA, the regulations, or their licence, licensees must implement all of the programs, precautions and measures which were demonstrated in their licence application to CNSC. The CNSC conducts compliance inspections, to verify that the radiation safety program of the licensee is functioning properly, and that the NSCA, regulations and licence conditions are respected. For high-risk activities, the CNSC also conducts compliance audits. Most licences are issued for a period of five years, and licensees must apply again to renew the licence before expiration.

In 2002, the CNSC launched a project to develop and document a risk-informed approach to the regulation of nuclear substances and radiation devices. During the first phase, CNSC staff assigned a risk ranking to every regulatory requirement. In addition, every type of use pertaining to radioactive substances and radiation devices was classified according to risk, as high, medium or low. The project team then developed a customized approach to the assessment of licence applications and to the performance of compliance inspections for each of the types of uses. The CNSC announced this risk-informed approach to inspections on its Web site, in the form of inspection checklists, with clearly described compliance expectations.

The CNSC risk-informed regulatory program resulted in clearer requirements and expectations being established for some licensees, and changed inspection frequencies and other compliance monitoring methods for most licensees. A practical outcome of the risk-informed regulatory program is that high-risk uses are inspected more frequently, whereas low-risk sources and devices are no longer regularly inspected. Instead, licensees having low-risk sources are only required to report to the CNSC annually, to confirm that the sources and devices are still in their possession, and that they are safely used and stored.

The CNSC follows a “cradle-to-grave” approach in regulating radioactive sealed sources and radiation devices, recognizing that every stage in the life cycle of radioactive sources has its own unique needs for regulatory control and security. The safety and security measures recommended in the IAEA Code of Conduct are specifically applied at each step in the life cycle of the source.

- CNSC regulates the facilities that produce the radioactive substances, and regulates their packaging and transport to the source manufacturing facilities, and beyond, to other stages of the life-cycle of sealed sources.
- CNSC regulates manufacturers of radioactive sealed sources, and certifies radiation devices.
- CNSC regulates the users of sealed sources and radiation devices, and, for as long as the source or device is licensed, the CNSC conducts regular inspections to verify the compliance of the licensee with the NSCA, the regulations and the licence conditions.

Non-compliance results in corrective actions and enforcement measures are applied on a risk-informed basis.

- CNSC also assesses the security risk associated with the use and storage of radioactive sealed sources and radiation devices, and, if necessary, requires licensees to enhance physical protection measures, in order to reduce that risk. At the end of their useful lives, disused sources are commonly stored for a varying period of time, prior to their recycling or disposal. Sources must be stored securely, leak-tested and inventoried regularly, and they continue to be inspected by the CNSC.
- CNSC also regulates the disposal facilities for radioactive sources and radiation devices.
- CNSC authorizes the suppliers and manufacturers to take back disused sources, including sources from outside Canada, for either disposal or recycling. Licensees may return disused sources to the manufacturer, or send them to a licensed waste facility with a CNSC operating licence that authorizes the receipt of disused sources.

10.3. NATIONAL SEALED SOURCE REGISTRY AND THE SEALED SOURCE TRACKING SYSTEM

During the development of the Code of Conduct and the Guidance, the CNSC identified a need for two major improvements to its regulatory programs. These were the need for a sealed source tracking system and for enhanced import and export controls on category 1 and 2 sources. In 2004, the CNSC formed a project team to develop the National Sealed Source Registry (NSSR) and the Sealed Source Tracking System (SSTS). The SSTS is a secure information management program used to populate the NSSR for Category 1 and 2 sources, and allows licensees to report on-line source transactions. The NSSR enables the CNSC to build an accurate and secure inventory of all sealed sources in Canada. The information is as current as the reporting timeframes required by the licence (e.g., for Category 1 and 2 sealed sources, reporting within two days of receipt and seven days in advance of any transfer). On January 1, 2006, the CNSC fully implemented the SSTS and the NSSR. The NSSR is designed to hold information about the radioactive sources in every category, for all licensees (see below). The SSTS is targeted exclusively at category 1 and category 2 radioactive sources inline with the Code. It has been designed to enable the reporting of receipts and transfers, imports and exports, within time limits. Each import, export, receipt and transfer is termed a “transaction” for SSTS purposes. The SSTS tracks each radioactive source in the system throughout its complete life cycle. During the first year of operation, the CNSC conducted extensive outreach activities to provide licensees with information about the regulatory changes relating to source tracking. The CNSC also prepared demonstration CDs with “how-to” guides about the source tracking system. An information package (which consisted of a letter, a demonstration CD, and individual security authorization codes) was sent to every CNSC licensee whose licences were amended. For the first half of 2006, all SSTS transactions were reported by mail, fax or by e-mail. Canada was the first G8 country to implement on-line reporting of SSTS transactions. This was done in July 2006, when the CNSC successfully launched a secure Web-based application which provided licensees a means of reporting SSTS transactions on-line, using the Government of Canada’s “e-Pass” technology. In 2008, the Web-based application was significantly improved by having a more user-friendly interface through the availability of drop-down listings of information, improved reference tools, and the incorporation of CNSC’s new Web page design. By the end of 2006, the SSTS had logged more than 30,194 transactions for Category 1 and 2 source imports,

exports, transfers and receipts. The majority of these transactions represented bulk shipments by a single large Canadian source manufacturer. In December of 2006, the CNSC was tracking 1,638 Category 1 sources and 3,920 Category 2 sources in Canada.

Throughout 2007 and 2008, the NSSR continued to be populated with data on category 1 and 2 sources as licensees reported their transactions. Gradually, the NSSR is also receiving information about category 3, 4 and 5 (medium to low-risk) sources in Canada. This information about medium and low-risk sources is added to the NSSR as licensees annually submit details of their current source inventories. By the end of December 2008, the NSSR had information regarding 19,847 radioactive sealed sources of all categories in Canada. For 2008, the SSTS was tracking 2,410 sources of category 1 and 12,881 sources of category 2. The other 4,556 sources in the NSSR were category 3, 4 and 5 (medium and low-risk), which are not subject to mandatory tracking but reported by licensees as an integral part of their overall inventory. In 2009, inventories for category 3, 4 and 5 sources will continue to be added to the NSSR as part of the second phase of the NSSR/SSTS program. The SSTS registered more than 36,000 transactions of all types throughout the year (2008).

The SSTS was built on the CNSC's regulatory information database used for nuclear substances and radiation devices. The SSTS and NSSR are components of the CNSC's overall nuclear substances and radiation devices licensing and compliance database. Building the SSTS and NSSR in this manner enables sources and devices to be associated with specific licensees at particular locations. The SSTS is used to populate the NSSR, and it allows the CNSC to have an accurate inventory of high-risk sealed sources (Category 1 and 2). Each transaction in the SSTS is paired: each transfer has a corresponding receipt, and each transaction represents a separate report to the CNSC. The SSTS automatically looks for unpaired transactions, to alert the CNSC about late reporting or potentially diverted sources.

In order to gauge the effectiveness of the SSTS program and the accuracy of the data in the system, the CNSC designed and implemented in 2007 a project to establish performance measures. This involves conducting inspections to physically verify licensees' inventories, source movement and locations against the information in the NSSR and SSTS. As part of this project, random checks of data entries from licensees using the SSTS for Category 1 and 2 sources against actual licensee inventories were done to verify that real inventories matched the data entered in the SSTS. The results demonstrated that all sources in inventory for the licensees tested were accounted for in the system. The CNSC is planning to incorporate SSTS/NSSR field verifications into the procedures for routine inspections. Currently, performance measures are being developed allowing the CNSC to monitor the effectiveness and efficiency of the NSSR and SSTS. CNSC inspection staff has already conducted sample comparisons of licensee source and device inventories, using NSSR data. This will become a regular part of routine compliance inspections. The SSTS secure Web interface has been improved in June 2008 to make it more user-friendly. Licensees are better able to track their radiation devices containing sealed sources, and several features - such as an on-line radioactivity calculator has been added to the list of functionality of the Web interface.

The IRRS team was informed that some licensees are voluntarily fitting GPS tracking systems to vehicles during transport of industrial radiography radioactive sources.

Import and Export of Category 1 and 2 radioactive sources.

As with the Code itself, CNSC staff participated in the drafting of the Guidance, and Canada committed to implement an export and import control program as outlined in the Guidance. Canada is a major exporter of category 1 and 2 radioactive sources for use in medical,

scientific and industrial applications, and therefore has a strong interest in the establishment and maintenance of an effective, efficient and harmonized international regime for ensuring the security and safety of such sources.

CNSC is responsible for controlling the export and import of radioactive sources in Canada, and its existing export and import control processes for radioactive sources were modified and enhanced to be fully consistent with the provisions of the Code of Conduct and the Guidance. The enhanced export and import control program for category 1 and 2 radioactive sources was implemented on April 1, 2007. Through this program, the CNSC contributes to national and international safety and security, by ensuring that only authorized persons are recipients of category 1 and 2 radioactive sealed sources. On a case-by-case basis, the CNSC ensures that importers and exporters comply with the requirements from the Code. This encompasses full export control, notifications and consent as required under the Code and its Guidance. The key elements of the export and import control program include a licensing process for the export of category 1 and 2 sources; a control process for the import of such sources; and the implementation of bilateral administrative procedures with foreign regulatory counterparts.

10.4. NATIONAL STRATEGY OF GAINING AND REGAINING CONTROL OVER ORPHAN SOURCES

CNSC regulation requires that licensees must immediately report missing sources to the CNSC, accompanied by documents describing the circumstances and any action the licensee has taken or proposes to take to recover the source. For high and moderate-risk sources, the loss or theft will require the licensee to work with local police and other authorities, to inform the public and to obtain necessary additional resources to assist with a search. According to the CNSC risk-informed model, regulatory concern with the loss or theft is not considered closed until the CNSC is satisfied that appropriate corrective action has been taken to minimize any likelihood of further losses or thefts.

In 2002, while seeking a way to deal more effectively with these reports, the CNSC enhanced its processes for reporting and recording such unusual events, involving all radioactive substances, sealed sources and radiation devices. The CNSC revised its procedures and designed standard reporting forms, which were made accessible to licensees. Information about these events for the aforementioned sources is captured in a database from which reports are routinely produced. In recent years, the predominant types of unusual events are unrecovered Category 3, 4 and 5 sources. These strengthened event reporting processes are logical extensions of the provisions of the Code of Conduct, which call for the states to take measures to minimize the loss of control of sources and devices, and to require prompt reporting of unusual events. The CNSC's own program for recording and tracking unusual events involving radioactive sealed sources and radiation devices enables it to collect data about the most common types of events and improve its regulatory oversight.

CNSC has distributed leaflets to scrap metal dealers to show them what radioactive sources and devices may typically look like. It was reported that the majority of large scrap yards, municipal landfill sites and private hazardous waste sites in Canada have installed portal radiation detectors. If a source is found the scrap dealers know to contact CNSC. If the former owner of the source can be traced (e.g.; by using the above mentioned SSTS and LOUIS), that owner has to pay for disposal of the source. If not, then the scrap dealer may have to pay, although in most cases to date, the CNSC has taken possession of these sources.

Although ‘security’ was outside the scope of the mission the team was informed that CNSC has security officers who make security assessments, and that ‘safety inspectors’ also check some aspects of security that affect safety.

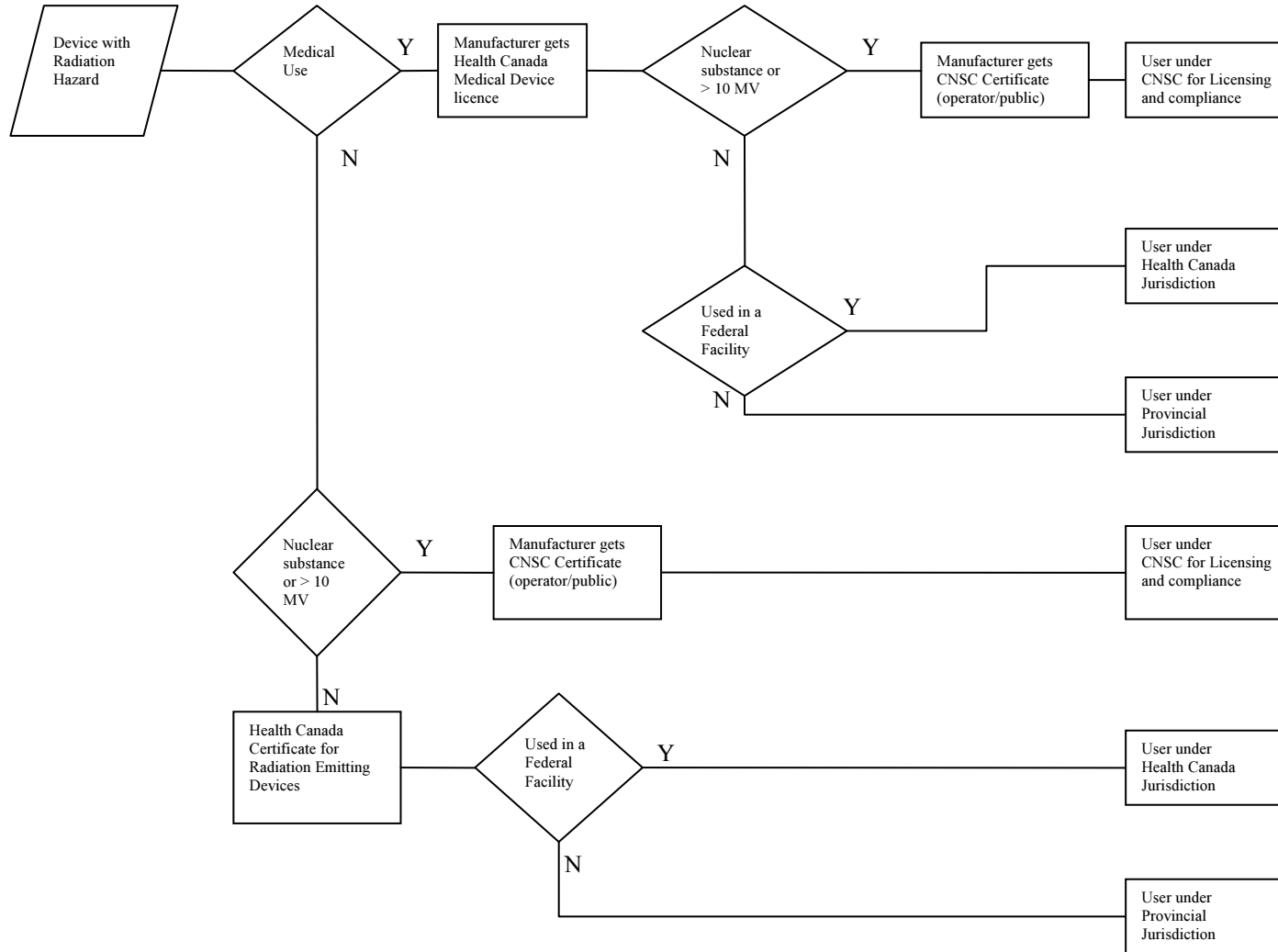
The IAEA Code of Conduct on the Safety and Security of Radioactive Sources has provided the CNSC with an opportunity to develop and strengthen its regulatory programs for radioactive sealed sources and radiation devices. The major challenges to the CNSC, while adopting the provisions of the Code of Conduct, were the development of programs for sealed source tracking and a national sealed source registry, and for enhanced import and export controls. Canada’s commitment to work toward full implementation of the Code of Conduct and Guidance does not fundamentally change the CNSC’s regulatory framework or practices. Instead, it offers an occasion to review them, to reassess priorities and to strengthen programs where appropriate. The CNSC has been successful in implementing every major new program, and is working on strengthening its existing programs to fully meet all of the Code of Conduct provisions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

- (1) **BASIS:** Paragraph 22 (g) of the Code of Conduct for safety and security of radioactive sources states: *“Every State should ensure that its regulatory body establishes systems for ensuring that, where practicable, radioactive sources are identifiable and **traceable**, or where this is not practicable, ensures that alternative processes for identifying and tracing those sources are in place;”*
- G18 **Good practice:** The CNSC’s on-line sealed source tracking system is outstanding, and provides an excellent model for others to follow.
- (1) **BASIS:** Code of Conduct for safety and security states that *“13 (b). Every State should: ...encourage bodies and persons likely to encounter orphan sources during the course of their operations (such as scrap metal recyclers and customs posts) to implement appropriate monitoring programmes to detect such sources....*
- 17. Every State should ensure that its regulatory body:*
- ...(m) is prepared, or has established provisions, to recover orphan sources and to deal with radiological emergencies and has established appropriate response plans and measures*
- S18 **Suggestion:** In order to encourage bodies and persons likely to encounter an orphan source to promptly report it, CNSC could consider offering a cost-free recovery service to ensure that found sources are not re-orphaned, recognizing that this would require additional funds so as not to impose a financial burden on CNSC.
- (1) **BASIS:** Para 22. *“In the interests of international safety and security, the cooperation of all States in following the recommendations in the Guidance would be welcome.”*
- G19 **Good practice:** The implementation of bilateral agreements is an important initiative in order to fully implement the provisions of the Code of Conduct concerning import and export of radioactive sources.

CNSC, Health Canada and Provincial Jurisdictions in the regulation of radiation equipment in Canada

Note: The 10MV threshold is based on the (n, γ) threshold for photonuclear reactions. This threshold is taken as 10 MV for machines used in radiation therapy, based on the dose rate of the units and actual neutron flux. In theory, if the dose rates are very high, the (n, γ) threshold is lower, at 8MV.



11. NATIONAL SAFETY RECORDS

CNSC posts annual reports, reports on plans and priorities, auditor general reports, and department performance reports on its Web site. CNSC has maintained records relating to assessment of safety of facilities, decommissioning, releases to the environment and accidents for over 30 years.

For IAEA Category 1 and 2 sources, CNSC maintains an inventory and a tracking system for the movement of sources from one location to another. CNSC plans to include all sources in this system within the next year. The level of tracking will be commensurate with the radiation risk of the activity of each source.

Occupational dose records are managed by the National Dose Registry maintained by Health Canada. A copy of their annual report is available on their Web site.

Licensees are required by regulation or licence conditions to maintain radiation protection records such as radiation surveys, inventories, and shielding assessments. The regulations identify the retention dates for each type of record.

CNSC has established a system for obtaining and maintaining safety records and has generally made them publicly available on their Web site or upon request.



APPENDIX I – LIST OF PARTICIPANTS

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APPENDIX II – MISSION PROGRAMME

	Sunday May 31	Monday June 1	Tuesday June 2	Wednesday June 3	Thursday June 4	Friday June 5	Saturday June 6
8:00			Daily Mtg Jammal, Matsuura, Virgilio	Daily Mtg Jammal, Matsuura, Virgilio	Daily Mtg Jammal, Matsuura, Virgilio	Daily Mtg Jammal, Matsuura, Virgilio	Travel from remote sites for some team members
8:30							
9:00		Entrance Meeting Introduction Modules 1, 2, 3 Module 8 Module 7	Interviews & discussions with Counterparts for Modules 1, 2, 3 Module 4 Module 6 Module 7	Follow-up interviews & discussions with Counterparts for all Modules	Possible NRCAN meeting with Matsuura, Virgilio, Caruso	Possible NRCAN meeting with Matsuura, Virgilio, Caruso	
9:30							
10:00							
10:30							
11:00							
11:30					Site visits all day	Site visits all day	
12:00		Lunch					
12:30							
1:00		Entrance Meeting (cont'd)	Interviews & discussions with Counterparts for Module 5 Module 6 (cont'd) Module 7 (cont'd) Module 8	Interviews & discussions with Subject Matter Experts for all Thematic Areas			
1:30		Module 4					
2:00	Peer review team orientation	Module 5					
2:30		Module 6					
3:00							
3:30							
4:00		Thematic Areas (breakout sessions)					
4:30							
5:00		Common Thematic Areas & Closure					
5:30							
6:00			Peer review team meeting	Peer review team meeting (tele-conf)	Peer review team meeting (tele-conf)	Peer review team meeting (tele-conf)	Report writing
6:30		Peer review team meeting					
7:00							
7:30							
8:00				Travel to remote sites for some team members			
8:30							
9:00							

	Sunday June 7	Monday June 8	Tuesday June 9	Wednesday June 10	Thursday June 11	Friday June 12			
8:00		Daily Mtg Jammal, Matsuura, Virgilio	Daily Mtg Jammal, Matsuura, Virgilio	Daily Mtg Jammal, Matsuura, Virgilio	Daily Mtg Jammal, Matsuura, Virgilio	Daily Mtg Jammal, Matsuura, Virgilio			
8:30									
9:00	Report writing	Follow-up with SMEs	Mtg of peer review team & counterparts to review findings	Commission Hearing Introduction of Matsuura, Virgilio at beginning	Finalizing Report	Finalize Press Release			
9:30									
10:00									
10:30									
11:00				Status mtg: Binder, Matsuura, Virgilio, Jammal			Follow-up with SMEs (as required)	Finalizing Report	Finalizing Report
11:30									
12:00		Return from Laval irradiation facility	Preparations for Press Release (IAEA press secretary and CNSC communications)	Preparations for Press Release (IAEA press secretary and CNSC communications)		Exit Meeting			
12:30									
1:00		Policy Issues Discussion							
1:30									
2:00									
2:30									
3:00									
3:30		Finalize Report	Finalize Report	Preparations for Press Release (IAEA press secretary and CNSC communications)		Preparations for Press Release (IAEA press secretary and CNSC communications)	Exit Meeting		
4:00									
4:30									
5:00									
5:30									
6:00									
6:30			Peer review team meeting	Peer review team meeting	Peer review team meeting				
7:00	Travel to Laval irradiation facility	Special Dinner to Recognize Peer Review Team							
7:30									
8:00									
8:30									
9:00									

APENDIX III – SITE VISITS

SITE VISITS IRRS CANADA		
1.	Nuclear Power Plants	Mr. De la Vega Mr. Park Mr. Calpena
2.	Research Reactor	Mr. Olivier Mr. Jende
3.	Mines and Mills	Mr. Robertson Mr. Edge
4.	Waste	Mr. Selling
5.	UF6 (FcF)	Mr. Gray
6.	Medical	Ms. Gilley
7.	Radiology and Industrial	Mr. Gutterres

APPENDIX IV – RECOMMENDATIONS/SUGGESTIONS/GOOD PRACTICES FROM THE IRRS MISSION

	AREAS	<i>R: Recommendations, S: Suggestions, G: Good Practices</i>	<i>RECOMMENDATIONS, SUGGESTIONS OR GOOD PRACTICES ARISED FROM THE FOLLOW UP MISSION</i>
1.			<i>No recommendations or suggestions where mad</i>
2.	RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	S1	Suggestion: Consideration should be given to updating the 1998 Memorandum of Understanding with Health Canada. This update should also define the roles and responsibilities of the Federal Provincial Territorial Radiation Protection Committee to ensure that there is a comprehensive and consistent safety regulation and oversight.
		G1	Good Practice: The Memorandum of Understanding with Transport Canada is particularly comprehensive and could be considered as a model for similar applications.
3.	ORGANIZATION OF THE REGULATORY BODY	S2	Suggestion: CNSC should review its arrangements to ensure that it can adequately recover its regulatory costs.
		S3	Suggestion: Staff from the ROB and TSB branches of CNSC may wish to review how they could work together in a more harmonized manner to ensure that security measures do not compromise safety and vice versa and to ensure continued compliance with security requirements as reviewed.
		G2	Good Practice: The authority of CNSC to independently define its own employment conditions is considered to be a good practice.
		R1	Recommendation: CNSC should initiate a periodic strategic planning programme to define both short term and longer term research activities needed to support pending and potential regulatory decisions.

		R2	Recommendation: Sufficient resources for research activities should be allocated to support the outcome of the strategic planning programme.
		S4	Suggestion: The CNSC should consider the use of issue-specific advisory bodies to support regulatory decisions where there are either new, complex technologies (e.g. emerging medical applications) or issues of high public interest.
		G3	Good Practice: The arrangement between CNSC and agencies in the United States of America on the approval process of fissile material transport packages facilitates the easy import and export across their borders, and could act as a model for other countries.
4.	AUTHORIZATION	R3	Recommendation: The activities and processes identified within the Harmonized Plan for authorizations in relation to preparation of a comprehensive set of procedures, criteria and review guides should continue to be developed and should be fully implemented.
		G4	Good Practice: The Canadian regulatory framework provides for a comprehensive and robust authorization system, and processes are in place for authorizing/licensing for all facilities and activities. There are clearly documented authorities and responsibilities either through the commission or delegated to appropriate CNSC staff, e.g. designated officers.
		R4	Recommendation: CNSC should complete its licence reform project and should document processes and arrangements for Class I nuclear facilities, waste facilities, uranium mines and mills, to ensure that any change or amendment to a licence including the licensing basis does not generate disproportionate amounts of work that would not be commensurate with the potential hazard of the change being proposed.

	S5	Suggestion: As part of the licence reform project CNSC should consider if alternative approaches with longer term licences and greater use of delegated powers would improve efficiency and effectiveness.
	R5	Recommendation: CNSC should consider how to introduce effective arrangements for undertaking periodic safety reviews (PSRs) for these Class-1 facilities. Such PSRs should be proportionate and commensurate to the hazards to be controlled.
	S6	Suggestion: Such PSRs should follow all of the elements set out in IAEA guides including the adoption of PSA (probabilistic safety analysis) for nuclear power plants (IAEA NS-G-2.10 or other appropriate safety guidance).
	S7	Suggestion: The CNSC should complete the project for Safe Operating Envelope (SOE) and consider including its results into the licence limiting conditions for operation (LCOs) as an extension to OP&Ps for nuclear power plants.
	S8	Suggestion: CNSC should review and continue adopting a consistent process for confirming competence of operators of facilities commensurate with the risks / hazards posed by the facilities.
	R6	Recommendation: CNSC should continue and complete its preparation of relevant documentation to support the authorization process (licensing process) for new build.
	S9	Suggestion: The CNSC should refine existing plans and confirm its organizational readiness (e.g. structure, staffing, skills) to support the transition from the project planning phase to the technical review of new design applications, inspection of construction activities and oversight of the start-up and operations.

5. REVIEW AND ASSESSMENT	G5	Good Practice: The use of Facility Assessment Compliance Teams provides an integrated multi-disciplinary approach to the assessment of licensing actions.
	S10	Suggestion: CNSC should review regulatory documents to resolve conflicts associated with updating the final safety analysis report and maintaining the licensing basis. (<i>see recommendation R4</i>)
	G6	Good Practice: The development and use by CNSC of processes and tools for risk informed decision making.
	G7	Good Practice: CNSC's expectations for scheduled reporting of research and development activities.
	G8	Good Practice: The review process for authorization of a licence for medical, industrial, and research activities is based on well established comprehensive guidelines and transparent procedures. The formalized assessment process includes an initial review, peer review and review prior to the Designated Officer issuing the licence.
	G9	Good Practice: CNSC regulatory guidance, including draft or proposed regulatory guidance is available to the applicant and licensees for medical, industrial, and research activities. This information provides the licensee with a very clear and transparent overview of their responsibilities. Licensees reported that CNSC staff were very approachable and attentive to their needs.
	G10	Good Practice: CNSC has an impressive evaluation process for supporting the issuance of a licence for medical, industrial, and research activities. The evaluation takes account of expectations of the licensee and is based on detailed and transparent assessment of the hazard associated with the activity

6. INSPECTION AND ENFORCEMENT	G11	Good Practice: The targeted use of inspections to focus limited regulatory resources on poor performance is an excellent example of optimization of regulatory resources to encourage licensees to improve their regulatory performance.
	S11	Suggestion: CNSC should maintain progress in further developing IT tools for action tracking under the Harmonized Plan.
	R7	Recommendation: CNSC should include in the baseline inspection plan how the licensee executes the supervision of safety system operability status as defined in the Licensing Basis.
	R8	Recommendation: CNSC should review and establish coherent and consistent arrangements for the conduct of inspections in Class I Facilities between and within the service lines.
	R9	Recommendation: CNSC should establish a process for maintaining continuity of actions and consistency of priorities following changes to the CNSC staff.
	G12	Good practice: The CERTS application developed for event inspection, assessment and corrective action tracking constitutes an efficient tool for event tracking, related inspections and corrective actions.
	S12	Suggestion: Strategies, processes and methods should be established to ensure the objectivity and independence of the site inspector. Consideration should be given to changing the site to which they are assigned from time to time or giving them general duties at headquarters.
	G13	Good practice: The implementation of a robust and detailed inspection programme for radiation facilities (medical, industrial, and research) associated with high quality consistent documentation and a database carried out by CNSC allow a high level of feedback into the regulatory process.

		G14	Good Practice: The use of a Licensing and Inspection Mapping System is an excellent method for tracking compliance and maintaining continuity from inspection to inspection. It is also valuable tool for knowledge transfer as the history of a licensee's performance is recorded in the database.
		R10	Recommendation: The Licensing and Inspection Mapping System should be integrated into the CNSC action tracking tool to assist planning and compliance monitoring activities.
7.	DEVELOPMENT OF REGULATIONS AND GUIDES	S13	Suggestion: CNSC should review and adopt a consistent terminology for its regulatory guides.
		S14	Suggestion: CNSC should systematically carry out regular periodic review of the published regulations and guides. Then the need for revision of the all regulation and guidance material should be evaluated and on the basis of the evaluation the defined revision steps should be taken.
		G15	Good practice: Where appropriate the CNSC adopts or adapts national and international standards when developing regulatory requirements. The Canadian government promotes participation in standard setting activities of the IAEA and to the Canadian Standards Association.
		S15	Suggestion: To support knowledge management the CNSC should extend the concept of its internal staff review guides to cover all key areas of its function.
		G16	Good Practice: The Regulation Making Process is very open and transparent with extensive pre-consultations built into the process. Interested parties are consulted already before starting to draft the regulation.

		R11	<u>Recommendation:</u> CNSC should improve its regulatory framework including regulatory documents and guides with respect to radioactive waste management to ensure that radioactive waste is managed in a consistent manner.
8.	MANAGEMENT SYSTEM	R12	<u>Recommendation:</u> CNSC should more clearly envelope and timeframe the remaining efforts to complete the Management System according to GS-R-3 and for that purpose update the Harmonized Plan.
		R13	<u>Recommendation:</u> CNSC should develop a methodology and implement Management System reviews to be conducted at planned intervals by internal or/and external resources. This programme should ensure the continuing suitability and effectiveness of the Management System as a whole and its ability to enable the objectives of the organization to be met. One important factor to be reviewed in this perspective is the application of the graded (risk-informed) approach to the regulation of facilities and activities
		S16	<u>Suggestion:</u> CNSC should continue integration of its strategic and annual planning processes as well as its in year control and monitoring processes for better invoices to licensees and to ensure alignment and reallocation of resources according to corporate priorities. For this purpose CNSC should consider the integrated use of performance indicators for each programme activity and related processes.
		S17	<u>Suggestion:</u> CNSC should supplement the internal audit programme in order to provide feedback to senior management on the development and implementation and output of the Management System processes. To support this programme, a number of internal auditors representing different parts of the organization could be used. In connection with the audit programme, a systematic approach to the management of non-conformances and potential non-conformances of processes and products should be developed and formalized

		R14	Recommendation: CNSC should implement a mechanism to regularly identify opportunities for improvement of the Management System and should evaluate the effectiveness of the improvement actions.
		G17	Good Practice: The Harmonized Plan developed by CNSC is an excellent tool for driving improvement initiatives across the organization with clear management commitment and allocation of resources and is supported by a communications strategy.
9.0	COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES	<u>No Recommendations or suggestions where made in this section</u>	
10.	CODE OF CONDUCT ON SAFETY AND SECURITY OF RADIOACTIVE SOURCES	G18	Good practice: The CNSC's on-line sealed source tracking system is outstanding, and provides an excellent model for others to follow.
		S18	Suggestion: In order to encourage bodies and persons likely to encounter an orphan source to promptly report it, CNSC could consider offering a cost-free recovery service to ensure that found sources are not re-orphaned, recognizing that this would require additional funds so as not to impose a financial burden on CNSC.
		G19	Good practice: The implementation of bilateral agreements is an important initiative in order to fully implement the provisions of the Code of Conduct concerning import and export of radioactive sources.
11.	NATIONAL SAFETY RECORDS	<u>No recommendations or suggestions where made in this section</u>	

APPENDIX V – CNSC REFERENCE MATERIAL USED FOR THE REVIEW

Overview of Nuclear Regulation in Canada

Legal and Regulatory Framework
Foundations of the Canadian Nuclear Safety Commission
Regulatory Philosophy
Organizational Structure of the CNSC

History of Self-assessment and Corrective Action

Self-Assessment (SART—2006)
Integrated Improvement Initiatives Program (I3P)
Complementary Self-Assessment (CSAR—2008)
Harmonized Plan

Questionnaire

Module 1: Legislative and governmental responsibilities
Module 2: Responsibilities and functions of the regulatory body
Module 3: Organisation of the regulatory body
Module 4: Authorization by the regulatory body
Module 5: Review and assessment
Module 6: Inspection and enforcement
Module 7: Development of regulations and guides
Module 8: Management system

Thematic Areas

Radiation Protection Programs
Environmental Protection Programs
Code of Conduct on the Safety and Security of Radioactive Sources
Code of Conduct on the Safety of Research Reactors
Regulation of Operating Nuclear Power Reactors
Approach for Life Extension of Nuclear Power Reactors
Licensing New Nuclear Power Reactors
Regulation of Uranium Mines

Self-Assessment Results

Brief Report on Module I – Legislative and Governmental Responsibilities
Brief Report on Module II – Responsibilities and Functions of the Regulatory Body
Brief Report on Module III – Organization of the Regulatory Body
Brief Report on Module IV – Authorization
Brief Report on Module V – Review and Assessment
Brief Summary of Module VI – Inspection and Enforcement
Brief Report on Module VII – Regulations and Guides
Brief Report on Module VIII – Management System
Summary of CNSC Action Plan

APPENDIX VI – IAEA REFERENCE MATERIAL USED FOR THE REVIEW

- [1] *No. GS-R-1 – Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety*
- [2] *No. GS-R-2 – Preparedness and Response for a Nuclear or Radiological Emergency*
- [3] *No. GS-R-3 – The Management System for Facilities and Activities*
- [4] *No. GS-G-1.1 – Organization and Staffing of the Regulatory Body for Nuclear Facilities*
- [5] *No. GS-G-1.2 – Review and Assessment of Nuclear Facilities by the Regulatory Body*
- [6] *No. GS-G-1.4 – Documentation for Use in Regulatory Nuclear Facility*
- [7] *No. GS-R-2 – Preparedness and Response for Nuclear and Radiological Emergencies Requirements*
- [8] *No. WS-R-1 – Review and Assessment of Nuclear Facilities by the Regulatory Body*
- [9] *No. WS-R-2 – Predisposal Management of Radioactive Waste, including Decommissioning;*
- [10] *No. WS-R-3 – Remediation of Areas Contaminated by Past Activities and Accidents;*
- [11] *No. WS-R-4 – Geological Disposal of Radioactive Waste;*
- [12] *No. TS-R-1 – Regulations for the Safe Transport of Radioactive Material TS-R-1*
- [13] *No. Safety Series 115 – International Basic Safety Standards*
- [14] *No. NS-R-1/2 – Safety Requirements of Nuclear Power Plants: Operation and Design*
- [15] *No. NS-R-3 – Safety Requirements of Research Reactors*
- [16] *No. NS-R-4 – Safety Requirements of and Fuel Cycle Facilities*

APPENDIX VII – CNSC ORGANIZATIONAL CHART

