Canada's Nuclear Regulator

Evaluation of the Directorate of Nuclear Substance Regulation's Compliance Verification Program

Final Evaluation Report

Recommended by the Evaluation Committee on 6 June 2014 for approval by the President

Approved by the President on 6 June 2014

Canadian Nuclear Safety Commission
Commission canadienne de sûreté nucléaire
Canada

Evaluation of the Directorate of Nuclear Substances Regulation's Compliance Verification Program Final Evaluation Report

PWGSC catalogue number CC172-117/2014E-PDF
ISBN number: 978-1-100-25188-2

Également publié en français sous le titre : Évaluation du Programme de vérification de la conformité de la Direction de la réglementation des substances nucléaires – Rapport d'évaluation final

Document availability

This document can be viewed on the CNSC website at nuclearsafety.gc.ca. To request a copy of the document in English or French, please contact:

Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
Ottawa, Ontario K1P 5S9
CANADA

Tel.: 613-995-5894 or 1-800-668-5284 (in Canada only)
Facsimile: 613-995-5086
Email: info@cnsc-ccsn.gc.ca
Website: nuclearsafety.gc.ca
Facebook: facebook.com/CanadianNuclearSafetyCommission
YouTube: youtube.com/cnscccsn

Table of Contents

List of Acronyms

ACFD	Accelerators and Class II Facilities Division
ACR	Annual compliance report
AECB	Atomic Energy Control Board
BRC	Bureau of Radiation Control (Florida)
CFIA	Canadian Food Inspection Agency
CNSC	Canadian Nuclear Safety Commission
CPMRS	Corporate Planning and Management Reporting System
DEC	Departmental Evaluation Committee
DNSR	Directorate of Nuclear Substance Regulation
EAC	Evaluation Advisory Committee
EWG	Evaluation Working Group
FTE	Full-time equivalent
HSE	Health and Safety Executive
IRWG	Industrial Radiography Working Group
IT	Information Technology
LOUIS	Licensing Operations & User Integrated System
NRC	Nuclear Regulatory Commission
NSC	Nuclear Substances and Control
NSCA	*Nuclear Safety and Control Act*
NSRD	Nuclear Substances and Radiation Devices
NSRDLD	Nuclear Substances and Radiation Devices Licensing Division
OID	Operations Inspection Division
OMC	Operations Management Committee
RIB/BIR	Regulatory Information Bank
RSO	Radiation Safety Officer
SSTS	Sealed Source Tracking System
TLSSD	Transport and Licensing and Strategic Support Division
TSPS	Task and Solutions Professional Services

Executive Summary

This report presents the findings, conclusions and recommendations of an evaluation of the Directorate of Nuclear Substance Regulation's Compliance Verification Program. The evaluation examined the program's relevance, effectiveness, efficiency and design/delivery for continuous improvement during the period March 31, 2007 to March 31, 2014. The conduct of this evaluation was undertaken between October 2012 and March 2014.

Program context

Compliance verification has been an integral part of Canada's nuclear regulatory regime since the overseeing organization – currently known as the Canadian Nuclear Safety Commission (CNSC) – first came into existence as the Atomic Energy Control Board (AECB) in 1946. The function of the program was strengthened through the modern legislative framework, under the authority of the *Nuclear Safety and Control Act* (NSCA) in 2000.

The Directorate of Nuclear Substance Regulation (DNSR) at the CNSC is responsible for regulating the production, possession, packaging, transport and use of nuclear substances, radiation devices, Class II nuclear facilities, and prescribed equipment.

Compliance verification is essential to ensuring that the possession, transport and use of nuclear substances, prescribed equipment and radiation devices are carried out in a safe manner to protect the health and safety of workers and the public, as well as to maintain security and protect the environment. Compliance verification consists of:

- identifying and planning high-priority, risk-informed verification activities
- identifying non-compliance without undue delay and according to risk level
- conducting inspections in a timely, transparent and risk-informed manner
- promoting awareness of regulations and scientific, technical guidance
- sharing best practices and lessons learned with stakeholders (licensees, industry and the public)

Methodology

The CNSC is designated a "small department or agency"[1] under the Treasury Board Policy on Evaluation (April 1, 2009) and is not required to assess the DNSR Compliance Verification Program according to the five core issue areas.[2] Nevertheless, the CNSC views the five core issue areas as a best practice and has adopted this structure when performing assessments of its programs and initiatives. This evaluation addresses the following issues: continued need for the program, achievement of expected outcomes, efficiency, and design/delivery for continuous improvement.

[1] The CNSC is designated as a small department or agency 42.1, which requires the evaluation of all ongoing grants and contributions using the assessment and reporting requirements established in the Treasury Board Policy on Evaluation, April 1, 2009.

[2] The five core issue areas include the following: continued need for program, alignment with government priorities, alignment with federal roles and responsibilities, achievement of expected outcomes, and demonstration of efficiency and economy. See the Treasury Board's Directive on the Evaluation Function, *Annex A – Core Issues to be Addressed in Evaluations*, April 1, 2009, http://www.tbs-sct.gc.ca /pol/doc-eng.aspx?id=15681&section=text#appA.

The evaluation includes the use of qualitative and quantitative complementary research methods as a means to ensure the reliability of the information and data collected. The evaluation employed five main lines of inquiry:

- document and program data review
- interviews with key CNSC staff and management
- Web-based survey of Nuclear Substances and Radiation Devices (NSRD) and Class II licensees[3]
- financial review
- domestic and international comparison studies

Relevance

The DNSR Compliance Verification Program's long-term objectives are clearly understood by all stakeholders: to ensure compliance and to ensure the health and safety of persons and the protection of the environment. There is a need for the program to identify and implement short-term objectives that would serve to align activities to the longer-term objectives.

The DNSR Compliance Verification Program is the only Canadian program verifying that holders of nuclear substances, devices and prescribed equipment adhere to regulatory requirements in order to protect the health and safety of workers and the public, maintain security, and protect the environment to ensure safety of workers and the public. The usefulness and impact of the program is established in activities to ensure compliance and ensure safety of workers and the public. Surveyed DNSR licensees stated that the sharing of expertise and knowledge between DNSR project officers/inspectors and licensees directly impacts the ability of the licensee to ensure the safe use and handling of substances/devices.

DNSR staff and management and NSRD and Class II licensees offered suggestions where potential improvements could be made. The involved parties offered no clear consensus on which areas were the most important, but suggested improvements were to:

- periodically review the DNSR regulatory model so as to ensure that inspection frequencies and types of inspections are based upon an up-to-date licensee risk profile
- review the inspection approach among all divisions in the DNSR (includes the licensing–inspection functions)
- review the role of inspections in the Operations Inspection Division, or OID (the extent of field inspection work and balancing the facilitator and enforcer roles[4])

[3] Government of Canada, *Class II Nuclear Facilities and Prescribed Equipment Regulations*, S.C. 1997, c.9. Class II facility refers to a facility that includes Class II prescribed equipment – i.e., an irradiator that uses more than 10^{15} Bq of nuclear substance; an irradiator that requires shielding that is not part of the irradiator and that is designed to deliver a dose of radiation at a rate exceeding 1cGy/min at a distance of 1 m; a radioactive source teletherapy machine; a particle accelerator that is capable of producing nuclear energy and has a beam of less than 50 MeV for beams of particles with a mass equal to or less than 4 atomic mass units; a particle accelerator that is capable of producing nuclear energy and has a beam energy of no more than 15 MeV per atomic mass unit for beams of particles with a mass greater than 4 atomic mass units; or a brachytherapy remote afterloader.

[4] Interview participants described two, sometimes competing, roles that an inspector can undertake during an inspection. An inspector can act as a facilitator to educate the licensee in areas of non-compliance or potential non-compliance. On the other hand, an inspector can act as an enforcer to require the licensee to take corrective action in areas of non-compliance.

Effectiveness

The DNSR Compliance Verification Program is mature and relatively stable. The risk-informed model, designed in 2004, has largely been implemented as designed and resources allocated and used by the program have remained relatively constant. Licensees have exhibited a high rate of compliance over the five-year time frame of 2007–2008 to 2011–2012.

The DNSR Compliance Verification Program has fully demonstrated the impact of three immediate outcomes that are expected by the program. Internal and external stakeholders are aware of regulations and scientific and technical guidance; inspections are conducted in a transparent and risk-informed manner; and best practices and lessons learned are shared with internal and external stakeholders. The program has partially demonstrated impact of its outcome to identify and plan high-priority and risk-informed verification activities, and has demonstrated limited impact in identifying/correcting/justifying non-compliance issues without undue delay.

The DNSR Compliance Verification Program has implemented successful mechanisms to increase awareness of regulations; scientific and technical guidance are reaching intended internal and external stakeholders. The mechanisms, ranging from one-on-one correspondence to formalized stakeholder working groups, are attributable to fostering a culture of safety.

The DNSR has established a variety of process and procedural documents to standardize the way in which Type I and Type II inspections are carried out. Among surveyed DNSR licensees, there is a high degree of transparency felt that inspections are conducted in a consistent manner. The development and implementation of inspection processes and procedures is a key element of effective regulation, and DNSR is consistent in this area when compared to other regulators outlined in the comparative study.

The DNSR has implemented a variety of mechanisms to share best practices and lessons learned with internal and external stakeholders. Internal to the DNSR, modes of engagement include operational meetings, technical review meetings, annual DNSR meetings, and major event summaries where staff and management actively engage in sharing and learning about best practices and lessons learned to date. Externally, the DNSR shares best practices and lessons learned with licensees and the broader radiation safety community through presentations and poster sessions at national venues, participates in the Federal/Provincial/Territorial Radiation Protection Committee, delivers annual national outreach activities for licensees, and organizes the Industrial Radiography Working Group.

There is potential for the DNSR to further refine its risk-informed model. The last major re-examination of DNSR's risk-informed regulatory model occurred eight years ago (2004) and was built upon known characteristics of various licensed activities. These characteristics were used to create usetypes and associated static inspection frequencies for each type. In order for the model to be applied effectively, however, there is a need to accommodate more dynamic factors such as positive and negative risks associated with new technologies, changing industrial/commercial trends, and licensee compliance history.

An analysis of all inspection data located in the Licensing Operations & User Integrated System (LOUIS) during the five-year time period 2007–08 to 2011–12 concluded that licensees are in compliance with regulatory requirements, on average, 85 percent of the time. Non-compliance issues arise, on average, during 15 percent of inspections and, in most cases, correspond to a "C" compliance rate, which denotes that performance is deteriorating or falling below expectations. Overall, there is a relatively low rate of licensee non-compliance, as established by DNSR compliance verification activities. The DNSR did not, however, track the timeliness of non-compliance issues that have been identified, corrected or justified in an aggregate, or summary, fashion. Instead, timeliness is managed by inspectors on a case-by-case basis.

Provided that the OID and the Accelerators and Class II Facilities Division (ACFD) together manage the regulatory compliance of thousands of licences every year, a case-by-case examination of inspection reports would be inefficient to assess for the purposes of this evaluation. A selected sample was constructed for the purpose of testing timeliness to assess all inspection reports; the sample was selected from two usetypes during the five-year period. The selected sample yielded data revealing that 34 percent, or one-third, of non-compliance issues are not resolved in the time required. Although the selected sample is not representative of all inspection reports, the timeliness of resolving non-compliance issues has the potential to indicate the effective management of regulatory compliance.

Additionally, a review of annual compliance reports in an effort to extract information related to non-compliance was not successful. DNSR staff and management confirmed that annual compliance reports are not used to measure non-compliance and have no direct impact on compliance verification planning.

Efficiency

DNSR staff and management, along with NSRD and Class II licensees, held a variety of perspectives on program efficiency. DNSR staff and management noted that significant improvements have been made since 2004 with the introduction of the risk-informed model. They indicated that further efficiencies could be gained by adapting the current risk model to include a mechanism to deal with new/changing technologies as well as changing licensee compliance histories. Some suggested that licensees with demonstrated good compliance could conduct their own self or peer audits.

Efficiency improvement areas offered by NSRD and Class II licensees surveyed were varied. The most prevalent suggestions were further improvements to consistency/standardization among project officers/inspectors in conducting inspection work, and further streamlining of inspection procedures and frequencies based on use type and the number of devices a licensee holds in the same location.

A comparative study revealed that efficiency gains could be potentially achieved by introducing an information system that would allow the inspection process to be “paperless” and mobile, as in the case of the Florida Bureau of Radiation Control. Better use of information technology systems is consistent with feedback provided by DNSR staff and management, as well as the NSRD and Class II licensees surveyed.

Planned and actual financial resources were examined to measure efficiency. In terms of allocative efficiency, the last few years demonstrate a significant improvement; we also note that CNSC financial information system fidelity has improved due to increased rigour of time coding. The total financial dollars the DNSR expends on compliance verification, per licence, was examined to establish any significant cost variations between fiscal years. The cost of the DNSR Compliance Verification Program is relatively stable; the cost attributable to a licence increases marginally by $200 each fiscal year.

A proxy indicator of efficiency was also generated by comparing the total “head count” of full-time equivalents (FTEs) reported in the Human Resources Information System to the total FTEs reported by the DNSR Compliance Verification Program. This indicator suggests that the direct effort applied by DNSR staff is comparable to the indirect effort (e.g., training, travel) and is stable. This can serve as a reference for future evaluations.

Additionally, the salaried resources attributable to Type I and Type II inspections were compared. They also show a relatively stable profile and can guide efficiency improvement. The cost differences in conducting a Type I and Type II inspection further establish the value of the DNSR adopting a risk-informed model.

Design/delivery for continuous improvement

It is very clear that roles and responsibilities at both the individual and divisional levels are well defined, accessible and appropriate. There is consensus among DNSR staff and management interviewed that roles and responsibilities are accepted by licensees. Moreover, licensees have a good understanding of compliance verification activities based on their experiences with inspections as well as the information they receive from the CNSC to build awareness on the safe use, handling, transport and storage of their licensed substances, devices and/or prescribed equipment.

In terms of the appropriateness of inspections and annual compliance reports, we found that inspections are conducted according to procedure; however, there is a need to re-examine the use of annual compliance reporting.

The document review and interview findings reveal that although performance measures have been established to report licensee performance via annual reports, no system exists to efficiently monitor compliance verification at an aggregate (or global) level. While there are two major reporting initiatives that utilize DNSR data, the data represent a section of verification activities and, even if taken together, are not effective indicators of outcomes.

Recommendations

The following recommendations should be addressed:

1. Develop and implement measures to effectively monitor the global performance of the DNSR Compliance Verification Program.
2. Review the different approaches to inspection work among divisions and clarify the role of an inspector in balancing both facilitator and enforcer responsibilities.
3. Refine the current risk-informed model to respond to positive compliance histories and dynamic factors (new technologies and changes to industrial/commercial trends).
4. Examine ways to gain further efficiencies in the compliance verification process.
5. Review the purpose and usage of annual compliance reports with respect to planning.

1 Introduction

This report presents the findings, conclusions and recommendations of an evaluation of the Directorate of Nuclear Substance Regulation's Compliance Verification Program. The evaluation examines the program's relevance, effectiveness, efficiency and design/delivery for continuous improvement during the period 2007–2012. The conduct of this evaluation was largely undertaken between October 2012 and March 2014.

The evaluation report is organized as follows:

- Section 1: introduction, including program description
- Section 2: evaluation scope and objectives
- Section 3: methodology for the evaluation
- Section 4: management of the evaluation
- Section 5: conclusions and supporting evidence
- Section 6: summary and recommendations

1.1 Program description

1.1.1 Regulating nuclear substances, devices and prescribed equipment at the Canadian Nuclear Safety Commission

Compliance verification has been an integral part of Canada's nuclear regulatory regime since the supervisory organization – currently known as the Canadian Nuclear Safety Commission (CNSC) – first came into existence as the Atomic Energy Control Board (AECB) in 1946. The function of the program was strengthened through the modern legislative framework, under the authority of the *Nuclear Safety and Control Act* (NSCA) in 2000.

The Directorate of Nuclear Substance Regulation (DNSR) at the CNSC is responsible for regulating the production, possession, packaging, transport and use of nuclear substances, radiation devices, Class II nuclear facilities, and prescribed equipment. Nuclear substances, devices and prescribed equipment are used in a wide range of applications in Canada and account for the majority of CNSC licences in any given year. As of March 31, 2012 the CNSC regulated 2,888 licences classified as nuclear substances, devices or prescribed equipment.[5]

The divisions primarily responsible for compliance verification activities within the DNSR are the Accelerators and Class II Facilities Division (ACFD) and the Operations Inspection Division (OID). The Transport and Licensing and Strategic Support Division (TLSSD) conducts inspections related to the packaging and transport of nuclear substances. All these divisions are responsible for desktop reviews, event reviews and enforcement work; however, they differ in terms of the licences managed and the types of inspections typically conducted.

The OID inspects over 1,730 licences on average per year that use nuclear substances, primarily in the industrial sector; however, all other sectors (medical, academic and research, and commercial) are represented in the licensees inspected by the OID. Examples of areas inspected are industrial radiography, fixed and portable gauges, and petroleum exploration. The OID mainly undertakes Type II inspections

[5] Canadian Nuclear Safety Commission, *Annual Report 2011–2012*, pp. 31–36, available at http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/CNSC-2011-2012-Annual-Report_e.pdf.

that require organized (announced) or field (unannounced) onsite observation and review of licensee records performed by one inspector. In a select number of cases and where warranted according to risk framework, Type I inspections are performed.

The ACFD manages over 250 licences and has issued over 100 certificates for prescribed equipment. The ACFD licences, as well as inspects, facilities in the medical and academic/research sector (such as cancer clinics and universities), commercial sector (with radiation therapy devices, radioactive source teletherapy machines and brachytherapy machines, and particle accelerators that produce radioisotopes), and industrial sector (material characterization, petroleum exploration). The ACFD predominately undertakes Type I inspections, which requires at least two project officers to review licensee documentation and records, observe the onsite facility, and conduct a series of key-informed interviews with onsite staff and management. It should be noted, however, that the ACFD also conducts a select number of Type II inspections.

The TLSSD conducts a relatively small amount of inspections, on average 18–20 per year, related to packaging and transport and following the processes identified above.

1.1.2 The Directorate of Nuclear Substance Regulation's risk-informed approach to compliance verification

The DNSR's current risk-ranking model was established in 2004 in an effort to apply effective, efficient and fair regulatory requirements. Previously, no systematic and consistent allocation model had been established. The model was developed in accordance with established policies at that time,[6] and it set out to achieve the following outcomes: (1) establish risk-ranking that recognizes the influence of licensee performance, (2) provide effective administration of regulatory effort based on risk-ranking by usetype, and (3) ensure that licensing and compliance activities are effective, consistent, fully integrated, risk-informed and communicated to stakeholders.[7]

Each type of licensed activity was evaluated against five[8] risk types and was assigned a weighting factor[9] to develop an overall risk value. Issues considered in weighting include certain aspects such as the form of the material (sealed source, open source, or radiation device), where the material is used (public or controlled facility), and history of problems with the licensed activity. Other weighting factors, such as compliance histories, are used in determining overall risk values for individual licensees. By using risk values and weighting factors, overall risks are calculated for each licensed activity.[10]

The basis of a risk-informed approach is that licensed activities deemed to be of high or medium risk are subject to a higher degree of regulatory control. This control includes more frequent and in-depth

[6] CSA – Q850/97 – *Risk Management: Guideline for Decision-Makers*; Treasury Board Risk Management Framework; CNSC Corporate Compliance Program; and the Operations Branch Integrated Risk Management Framework.
[7] Directorate of Nuclear Substance Regulation, *Development of the Risk-Based Regulatory Program*, February 2005, E-doc #1254511, p. 14.
[8] Risk types were technical risk, legal risk, political risk, stakeholder confidence and credibility risk, and organizational effectiveness and efficiency risk; see Directorate of Nuclear Substance Regulation, *Development of the Risk-Based Regulatory Program*, , pp. 23–25.
[9] A weighting factor is a coefficient assigned to licensed activities to represent their relative importance in terms of risk.
[10] Canadian Nuclear Safety Commission, *Nuclear Substances in Canada: A Safety Performance Report for 2011, (Appendix A – Regulatory Process for Nuclear Substances)* March 2013, available at http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/INFO-0826-Nuclear-Substances-in-Canada-A-Safety-Performance-Report-2011_e.pdf, p. 85.

inspections, and other activities to verify compliance with the NSCA, regulations and licence conditions. Table 1 below identifies the verification activities associated with each risk rank.

Table 1: Risk ranking and associated compliance verification activities

Risk ranking	Context	Annual compliance report	Type II inspection	Type I inspection
Low	Low risk usetypes are not intended to be inspected	X		
Medium	Moderate risk usetypes require a Type II inspection	X	X	
High	High risk usetypes require a Type I and a Type II inspection	X	X	X

Data source: DNSR, February 2005, *Risk-Based Regulatory Program*, pp. 38–39 (for a description of verification methods).

Furthermore, a grading protocol was developed and implemented to rank licensees' performances in a number of safety and control areas (SCAs). Each inspection activity provides a grade of performance against each SCA criterion. Table 2 below defines the performance ratings and descriptions used to describe a licensee's graded result from annual compliance reports and inspection reports. The compliance rate is used to track performance operationally and the reporting rate is used to communicate performance in the Nuclear Substances Safety Performance reports.

Table 2: Performance ratings and descriptions

Compliance rate	Reporting rate	Description
A	FS - Fully Satisfactory	Assessment topics or programs meet and consistently exceed applicable CNSC requirements and performance expectations. Performance is stable or improving. Any problems or issues that arise are promptly addressed.
B	SA - Satisfactory	Assessment topics or programs meet the intent or objectives of CNSC requirements and performance expectations. There are only minor deviations from requirements or the expectations for the design and/or execution of the programs, but these deviations do not represent an unreasonable risk to the maintenance of health, security, environmental protection, or conformance with international obligations to which Canada has agreed. That is, there is some slippage with respect to the requirements and expectations for program design and execution.
C	BE - Below Requirements	Performance is deteriorating and falling below expectations, or assessment topics or programs deviate from the intent or objectives of CNSC requirements.
D	UA - Unacceptable	Assessment topics or programs are significantly below requirements, or there is evidence of continued poor performance, to the extent that whole programs are undermined. This area is compromised. Without corrective action, there is a high probability that the deficiencies will lead to an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed.
E		There is evidence of an absence, total inadequacy, breakdown, or loss of control of an assessment topic or a program. There is a very high probability of an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. An appropriate regulatory response, such as an order or restrictive licensing action, has been or is being implemented to rectify the situation.

Data sources: *Nuclear Substances in Canada: A Safety Performance Report for 2011*, March 2013, p. 86 (for comparison of compliance rate and reporting rate); *Risk-Based Regulatory Program*, February 2005, p. 40 (for description of performance ratings).

1.1.3 Directorate of Nuclear Substance Regulation's Compliance Verification Activities

Compliance verification is essential to ensuring that possession, transport and use of nuclear substances, prescribed equipment and radiation devices are carried out in a safe manner to protect the health and

safety of workers and the public as well as to maintain security and protect the environment. Through undertaking compliance verification, most immediately, the DNSR seeks to:

- identify and plan high-priority, risk-informed compliance verification activities
- identify non-compliance and correct without undue delay according to risk level
- conduct inspections in a timely, transparent and risk-informed manner
- promote awareness of regulations and scientific, technical guidance internally and externally
- share best practices and lessons learned internally and with licensees

The DNSR intends to achieve these five results through four areas of activity. The first activity involves developing and reviewing the DNSR's compliance plan. Annually, Type I and Type II inspections are planned and prioritized on a risk-informed basis. Information on the licensee's operational activity is gathered through mandatory annual compliance reports submitted by licensees, the CNSC's expert opinions on the known inherent risks associated with a particular substance or device, and the compliance history of licensees.

The second activity, collecting annual licensee operational data, involves a mandatory licensing requirement from the CNSC to licensees to submit annual data on their operations. Assessments of annual compliance reports are conducted and maintained on LOUIS, the internal database used to organize data related to licensees.

The third activity involves conducting Type I and Type II inspections. The CNSC has adopted a risk-informed regulatory program and as such may not inspect all licensees every year. Type I inspections are a systematic, documented process to determine, through objective evidence, whether a licensee program, process or practice complies with regulatory requirements, whereas Type II inspections are used to verify the operational performance results of licensee processes.

The last activity, disseminating scientific, technical and regulatory information, involves facilitating compliance awareness among licensees and internally among CNSC staff.

For further illustration on how activities link to outcomes, please refer to the program logic model exhibited in appendix B.

1.2 Resources

The resources the CNSC provides to the DNSR for the administration of compliance verification activities are listed below in table 3. The total resources spent during the period March 31, 2007 to March 31, 2013 amount to approximately $18.2 million. A further breakdown of resources was calculated in support of this evaluation and can be found in section 5.3, "Efficiency."

Table 3: DNSR Compliance Verification Program financial resources (non-salary and salary), 2007–2008 to 2012–2013

Fiscal year / resource	2007–08	2008–09	2009–10	2010–11	2011–12	2012–13
Non-salary (in millions of $)	0.34	0.51	0.42	0.42	0.51	0.49
Salary (in millions of $)	2.3	2.6	2.7	2.7	2.6	2.7
TOTAL	**2.6**	**3.1**	**3.1**	**3.1**	**3.1**	**3.2**

Data sources: Non-salary financials obtained from Freebalance and Corporate Planning and Management Reporting System. Salary allocation to DNSR compliance verification is based on percentage of compliance salary allocated to compliance verification.

1.3 Governance

The DNSR is responsible for regulating the production, possession, packaging, transport and use of nuclear substances, radiation devices, Class II nuclear facilities, and prescribed equipment. The Directorate is composed of four divisions, of which two carry out the majority of compliance verification responsibilities. These two divisions are (1) the OID, which is responsible for conducting compliance inspections of activities involving nuclear substances and radiation devices, as authorized under licences issued by the Nuclear Substances and Radiation Devices Licensing Division (NSRDLD), and (2) the ACFD, which is responsible for licensing and conducting compliance inspections of authorized activities involving Class II and prescribed equipment. The OID and ACFD are each managed by a director and composed of staff who carry out compliance verification activities. It should be noted that the TLSSD also conducts inspections on packaging and transport of nuclear substances.

The Director General of the DNSR is a member of the Operations Management Committee (OMC) and reports on activities on a routine basis. The OMC – co-chaired by the Vice President of the Regulatory Operations Branch and the Vice President of the Technical Support Branch – provides direction regarding the performance of the DNSR's compliance policies, processes and procedures.

The Management Committee, composed of vice presidents from all CNSC branches (Regulatory Affairs Branch, Regulatory Operations Branch, Technical Support Branch, and Corporate Services Branch), as well as the Senior General Counsel and Commission Secretary, provides strategic direction on all compliance verification activities, including those under the mandate of the DNSR.

1.4 Stakeholders

There are a number of internal and external stakeholders of the DNSR Compliance Verification function.

Internal stakeholders consist of:

- those who conduct compliance verification activities, namely, project officers/inspectors from the ACFD, the OID and, to a lesser degree, the TLSSD and the NSRDLD
- directors and officers of the ACFD and OID who initiate compliance verification activities and identify project officers/inspectors as leads of those activities
- the Director General, providing leadership and expertise in regulation, licensing and compliance, covering nuclear substances at the CNSC

Supporting compliance verification activities, the licensing staff located in the NSRDLD aid project officers/inspectors and management by providing technical information related to licensing requirements/guidance.

DNSR compliance verification activities are further supported by Directors General and the vice presidents of the Regulatory Operations Branch and the Technical Support Branch participating in the OMC, which provides leadership, direction and oversight to the development, implementation and improvement of regulatory programs and associated operational activities.

Additionally, members of the Management Committee and the Commission, as decision-making authorities, support the regulatory work and strategic direction of DNSR compliance verification activities.

External stakeholders consist of Nuclear Substances and Radiation Devices (NSRD) licensees and Class II licensees who possess/use regulated substances, devices and/or prescribed equipment. NSRD and Class II licensees are accountable for their employees' safety. Supporting the regulated activity of licensees, third-party consultants offer training and subject matter advice on the operation and use of radiation substances, devices and prescribed equipments; as such, they are stakeholders of the requirements and guidance developed and maintained by the CNSC. Additionally, organizations such as the Canadian Organization of Medical Physicists and the joint CNSC/Industry Radiography Working Group serve to advance issues relating to their members, who often include stakeholders of the nuclear industry.

The ultimate stakeholder, or beneficiary, of the DNSR Compliance Verification Program is the Canadian public. By ensuring licensees are operating safely and adhering to regulatory requirements, the health and safety of the public is protected.

2 Evaluation Scope and Objectives

The objectives of this evaluation are to assess relevance, effectiveness, efficiency, and design/delivery for continuous improvement of the DNSR Compliance Verification Program during the period from March 31, 2007 to March 31, 2012. Additional data to reflect amounts spent in FY 2012–13 were added post-evaluation to provide additional evidence.

2.1 Evaluation questions

The CNSC is designated as a "small department or agency"[11] under the Treasury Board Policy on Evaluation, April 1, 2009, and is not required to assess the DNSR Compliance Verification Program established by the five core issue areas.[12] Nevertheless, the CNSC views the five core issue areas as a best practice and has adopted its structure in making assessments of its programs and initiatives. This evaluation addresses the following issues: continued need for the program, achievement of expected outcomes, efficiency, and design/delivery for continuous improvement.

During the planning phase for this evaluation, June 2012 to September 2012, the evaluation function at the CNSC consulted with the Evaluation Working Group (EWG) and the Evaluation Advisory Committee (EAC)[13] to validate the evaluation framework, including the evaluation matrix (see appendix C), in order to guide the evaluation. The following evaluation questions were agreed upon:

Relevance

- Has DNSR established clear and measurable short-term and long-term objectives for compliance verification?
- Is there a continued need for DNSR Compliance Verification?

[11] The CNSC is designated as a small department or agency 42.1, which requires the evaluation of all ongoing grants and contributions using the assessment and reporting requirements established in the Treasury Board Policy on Evaluation, April 1, 2009.

[12] The five core issue areas comprise the following: continued need for program, alignment with government priorities, alignment with federal roles and responsibilities, achievement of expected outcomes, and demonstration of efficiency and economy. See the Treasury Board's Directive on the Evaluation Function, *Annex A – Core Issues to be Addressed in Evaluations*, April 1, 2009,http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=15681&section=text#appA.

[13] Composed of CNSC Directors General from the Directorate of Assessment and Analysis, Directorate of Nuclear Cycle and Facilities Regulation, and the Strategic Planning Directorate, as well as the Director of Evaluation and the Lead Evaluator.

Effectiveness

- Has DNSR established its ability to identify and plan high-priority and risk-informed verification activities?
- Have non-compliance issues been identified and corrected or justified without undue delay according to risk level?
- Are inspections conducted in accordance with established procedures?
- To what extent are internal and external stakeholders aware of regulations and scientific, technical guidance concerning DNSR compliance verification?
- To what extent are best practices and lessons learned shared internally and externally?

Efficiency and economy

- Have program resources been utilized to optimize outputs?
- How efficient is the DNSR Compliance Verification Program?

Continuous improvement

- How effective is the ongoing performance measurement system of the program?
- Were DNSR Compliance Verification Program roles and responsibilities (a) well defined and accessible? (b) appropriate? (c) respected by DNSR staff and licensees?

3 Evaluation Approach and Methodology

The program evaluation matrix (see appendix C) outlines which methods were used to capture data for each of the evaluation indicators. The evaluation matrix includes the use of multiple lines of evidence and complementary research methods as a means to ensure the reliability of the information and data collected. Five main lines of inquiry were employed in this evaluation, including both quantitative and qualitative methods: a document and program data review, interviews with key DNSR staff and management, a Web-based survey of NSRD and Class II licensees, a financial review, and a comparative study. A description of the data sources is described below, by line of inquiry.

3.1 Data sources

3.1.1 Document and program data review

The review was utilized for the purposes of describing the program and its activities, outputs and mandate; assessing relevance; establishing production of outputs leading to achievement of outcomes; and assessing design and delivery.

Identified sources include, but are not limited to:

- CNSC Departmental Performance Reports and Reports on Plans and Priorities
- CNSC Safety Performance Reports on the Use of Nuclear Substances
- DNSR finances
- LOUIS database
- DNSR internal planning documents
- DNSR process and procedural documents
- DNSR presentations to stakeholders
- DNSR Risk-Based Regulatory Program

The extraction of data for the purposes of this evaluation was achieved with the help of a subject matter expert in LOUIS who programmed the relevant parameters to obtain the information. Currently, LOUIS (or any other system) does not allow for the generation of aggregate results.

A customized template was developed to populate findings and conclusions from the document review. This enabled the extraction and analysis of relevant information according to evaluation questions and indicators.

3.1.2 Interviews

For the purposes of addressing program relevance, productivity of outputs leading to achievement of outcomes, efficiency, and an assessment of design and delivery, key informant interviews were conducted with CNSC staff and management (see appendix E for interview questions). Staff included a wide range of DNSR inspectors, project and program officers from all divisions undertaking verification activities, and coordinators and management including the vice president overseeing this regulatory area, the Director General of DNSR and all directors of DNSR. The focus of the interview respondent selection was based upon DNSR staff who undertakes compliance verification activities; this base was expanded to include respondents from supporting functions such as licensing (NSRDLD) and transport (TLSSD) in order to gather a fuller understanding of verification within the regulation process. In total 34 interviews were conducted, illustrated in table 4 below.

Table 4: Interviews conducted with DNSR staff and management

Interview group	Number of interviews
Management	7
Staff – Accelerators and Class II Licensing Division	8
Staff – Operations Inspection Division	11
Staff – Transport Licensing and Strategic Support Division	4
Comparison Studies (Other Regulators)	4
TOTAL	34

An interview guide was drafted based on the evaluation matrix presented in the evaluation framework, as well as on findings and conclusions based upon the document review. The guide was pre-tested with members of the EWG for feedback on content, clarity, length and flow. The guide was tailored to each interview group, depending on the participant's scope of responsibilities in relation to the program. As such, not all participants were asked the same number of interview questions.

Interview respondents were sent an engagement letter in advance of the interview. Interviews took place January 27, 2012 to February 22, 2012. Interview respondents were assured of their anonymity (according to Canadian privacy and access to information laws) before each interview commenced, and findings were reported in an aggregate manner, with no references to an individual interviewee.

A customized template was developed by the evaluator to populate findings and conclusions from the interviews; this enabled the extraction and analysis of relevant information according to evaluation questions and indicators.

3.1.3 Survey of NSRD and Class II licensees

For the purposes of addressing program relevance, productivity of outputs leading to achievement of outcomes, efficiency, and design/delivery, a Web-based survey was conducted. The survey sample included a total of 677 participants belonging to one of two categories: (a) NSRD licensee or (b) Class II licensee. The average survey respondent has held a NSRD or Class II licence for greater than seven years.

A survey guide was drafted, based on the evaluation matrix presented in the evaluation framework and the findings and conclusions based on the document review. The guide was pre-tested with members of the EWG for feedback on content, clarity, length and flow.

Participants were sent an engagement letter four weeks before the survey was launched outlining the intention of the survey, how survey results were to be used, logistical details regarding accessing the survey, and privacy and anonymity considerations. A short reminder email was also sent to all participants when the survey was launched (on January 2, 2013). The survey was available to participants for the duration of three weeks; it was accessible via a specialized hyperlink emailed to each participant. The specialized hyperlink allowed the participant to leave and go back into the survey at any time, in order to complete or change information before it was submitted.

Overall, there was a 54 percent response rate for the survey. The response rate by category of participants is listed in table 5 below. It should be noted that inferential statistics were not used to describe the survey data. The same size was sub-categorized into NSRD licensees and Class II licensees, the latter of which did not exhibit the required sample size to demonstrate normal distribution characteristics.

Table 5: NSRD and Class II licensees surveyed

Category of respondent	Number of recipients	Number of respondents	Response rate (%)
NSRD licensee	593	320	54
Class II licensee	84	43	51
TOTAL RESPONSES	677	363	54

The individual response rates, by survey question, are detailed in appendix F.

A customized template was developed by the evaluator to populate findings and conclusions from the survey; this enabled the extraction and analysis of relevant information according to evaluation questions and indicators.

3.1.4 Financial review

For the purpose of addressing efficiency, specifically the allocation of resources, financial information relating to FTEs and non-salary financials was reviewed.

Financial information was obtained from the senior financial analyst for the DNSR. The budgeted (planned) information was obtained from annual planning data and the utilized (actual) information was obtained from LOUIS for the demonstration of FTEs, and from Freebalance and the Corporate Planning and Management Reporting System (CPMRS) for the demonstration of non-salary financials.

3.1.5 Comparative study

For the purposes of addressing best practices and alternatives of a compliance verification risk-informed model[14] in terms of established procedures and gains in efficiency, the comparative study examined two nuclear regulatory organizations and one domestic, other regulatory organization:

[14] The comparative study adopted the risk-informed regulatory model utilized by the International Atomic Energy Agency, *Risk Informed Regulation of Nuclear Facilities: Overview of the Current Status*, Safety Standards Series (Vienna: International Atomic Energy Agency, 2005), p. 2, available at http://www-pub.iaea.org/MTCD/Publications/PDF/TE_1436_web.pdf.
A risk-informed regulatory model aims to integrate, in a systematic manner, quantitative and qualitative, deterministic and probabilistic safety considerations to obtain a balanced decision. In particular, there is explicit consideration of both the likelihood of events and their potential consequences, together with such factors as good engineering practices and sound managerial arrangements. The basis components of risk, likelihood and consequence are based on sound knowledge or data from experience, or derived from a formal, structured analysis such as a PSA.

- U.S. Nuclear Regulatory Commission (NRC) – Florida Bureau of Radiation Control (BRC)
- U.K. Health and Safety Executive (HSE) – Ionizing Radiation Program
- Canadian Food Inspection Agency (CFIA) – Meat Inspection Program

The study included a review of relevant program information collected from each of the regulatory organizations, peer-reviewed publications, and publications produced by international bodies and industry organizations, as well as key informant interviews with selected staff from each of the regulatory organizations included in this study.

The selection of key informants from the two nuclear regulatory organizations in support of this comparative study was achieved with the aid of subject matter experts within the CNSC's International Relations unit.

3.2 Limitations of the evaluation methodology and mitigation strategies

The evaluation methodology was designed to provide multiple lines of evidence in order to identify relevant evaluation findings. The data and information were collected to respond to the evaluation questions and indicators. As in all evaluations, there are limitations and considerations that should be noted.

Lack of performance data
During the planning phase it was identified that the CNSC does not have a performance measurement strategy in place for the DNSR Compliance Verification Program. As such, there was no documentation of the benefits and measures to assess performance of intended results. In order to be able to effectively evaluate the DNSR Compliance Verification Program, there need to be credible and reliable performance data that are collected on an ongoing basis to inform results.

Mitigation strategy: A logic model was created and supported by an evaluation matrix, identifying issues, questions, indicators and data sources. Both the logic model and evaluation matrix were validated by the EWG and EAC.

Aggregate data not available in LOUIS
During the conduct phase it was identified that the LOUIS system that is used to record and monitor licensee information does not report compliance histories in aggregate. Compliance histories are only accessible on a case-by-case basis, inefficient for the purposes of informing an evaluation.

Mitigation strategy: The lead evaluator contacted a computer programming expert at the CNSC to develop parameters that were then coded into the LOUIS system to retrieve available aggregate compliance information. Numbers were verified by working with the Directorate planning officer, who pulled numbers used to create the DNSR annual reports.

4 Management of the Evaluation

4.1 Roles and responsibilities

The lead evaluator is responsible for managing all phases of the evaluation (planning, conduct and reporting), developing all evaluation deliverables (including the terms of reference, data collection templates and instruments), contracts, correspondence to interview and survey participants, draft evaluation reports, final evaluation report, technical support in developing the management action plan, and briefing materials to inform senior management of evaluation findings, conclusions and recommendations.

The EWG is composed of two directors and four staff from the DNSR. The primary role of the EWG is to help coordinate timely data collection and pilot test the interview guide. Furthermore, the EWG played a key role in validating the Evaluation Terms of Reference (including logic model and matrix) before the evaluation commenced and in validating the draft evaluation report for technical content before the Evaluation Advisory Committee (EAC).

The EAC is composed of three Directors General; representing the DNSR, the Directorate of Regulatory Improvement and Major Projects Management, and the Strategic Planning Directorate (Head of Evaluation). The primary role of the EAC is to provide strategic management input to help validate the Evaluation Terms of Reference (including the evaluation questions and logic model), as well as the evaluation report and management response to evaluation recommendations, via the management action plan, before the Departmental Evaluation Committee's (DEC) and the CNSC president's approval.

The Management Committee serves as the CNSC DEC, and is responsible for the timely validation of evaluation reports and management action plans. The DEC is supported secretarially by the Head of Evaluation and includes the president of the CNSC, the deputy head responsible for approval of all CNSC evaluation reports and management action plans.

4.2 Contracts and associated procedures / considerations

A Task and Solutions Professional Services (TSPS) contract was utilized to support the evaluation in conducting the comparative analysis and interviews. The contract supported the evaluation function's lead evaluator in producing a timely evaluation report and offset time available to lead other evaluations.

4.3 Timelines

The timelines for planning and conducting this evaluation are outlined in table 6 below, categorized by planning phase (pink), conducting phase (green), and reporting phase (yellow). Approving the evaluation report required more time than anticipated due to various input from the EWG and EAC members. No changes were made to the report's findings or recommendations during the approval process.

Table 6: Evaluation timelines

Year	2012				2013											
Phase	Planning				Conducting				Reporting							
Activity/Month	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
Review and approve Evaluation Terms of Reference																
Develop data collection tools																
Collect documentation and data																
Develop and issue TSPS contract																
Select survey participants																
Select interview participants																
Conduct document and program																

data review																
Conduct financial review																
Conduct survey																
Obtain interview analysis																
Obtain comparative study analysis																
Draft evaluation report																
Approve evaluation report																

5 Findings and Conclusions

5.1 Relevance

Evaluation questions explored in this section include:

- Has DNSR established clear and measurable short-term and long-term objectives for compliance verification?
- Is there a continued need for DNSR Compliance Verification?

Conclusion

The DNSR Compliance Verification Program's long-term objectives are clear: ensure compliance and ensure the health and safety of persons and protection of the environment. There is a need for the program to identify and implement short-term objectives that would serve to align activities to the longer-term objectives. By identifying and implementing short-term objectives, the program will be able to report performance of its activities and outputs in a timely manner. Successful achievement of short-term objectives will make it easier to measure the program's long-term objectives.

The DNSR Compliance Verification Program is the only Canadian program verifying that holders of nuclear substances, devices and prescribed equipment adhere to regulatory requirements in order to protect the health and safety of workers and the public, maintain security, and protect the environment to ensure safety of workers and the public. Surveyed DNSR licensees stated that the sharing of expertise and knowledge between DNSR project officers/inspectors and licensees directly impacts the ability of the licensee to ensure the safe use and handling of substances/devices.

DNSR staff and management, as well as NSRD and Class II licensees, offered potential changes or areas where potential improvement could be made in moving forward. Although there was no clear consensus on which areas were the most important, suggestions included:

- periodically review the DNSR regulatory model so as to ensure that inspection frequencies and types of inspections are based upon an up-to-date licensee risk profile
- review the inspection approach among all divisions in the DNSR (includes the licensing–inspection functions)
- review the role of inspections in the OID (extent of field inspection work and balancing the facilitator and enforcer roles[15])

[15] Interview participants described two, sometimes competing, roles that an inspector can undertake during an inspection. An inspector can act as a facilitator to educate the licensee in areas of non-compliance or potential non-compliance and, on the other hand, an inspector can act as an enforcer to penalize the licensee in areas of non-compliance.

Supporting evidence

Has DNSR established clear and measurable short-term and long-term objectives for compliance verification?

The DNSR Compliance Verification Program's long-term objectives are clear: ensure compliance and ensure the health and safety of persons and protection of the environment. There is, however, a need for the program to identify and implement short-term objectives that would serve to align activities to the longer-term objectives.

The activities of the DNSR Compliance Verification Program are mandated through the *Nuclear Safety and Control Act* (NSCA),[16] and a clearly intended result is established in the Departmental Performance Reports and Reports on Plans and Priorities, years 2007 through 2012 – "A high level of compliance by licensees with the regulatory framework."

DNSR staff and management were asked to describe the objectives of the DNSR Compliance Verification Program. Both groups' responses were consistent with the CNSC mandate; however, objectives were described in slightly different terms, and all were long-term objectives. Slightly over half of the respondents described the objective as ensuring that licensees and others complied with the regulations and terms of their licences. In describing the compliance objective, three respondents also referenced "international obligations". There is, however, a need to identify and implement short-term objectives, which are not well articulated to program staff. No other short- or long-term objectives have been articulated in documentation.

Is there a continued need for DNSR Compliance Verification?

DNSR staff and management and NSRD and Class II licensees described a variety of useful impacts of the DNSR Compliance Verification Program. These impacts included promoting compliance and oversight, ensuring the safety of workers and the public, increased licensee knowledge of the safe handling of substances/devices, reinforcement of the role of the Radiation Safety Officer within the licensed facility, increased standardization and uniformity among the industry, and assured security for employees and the general public.

The DNSR staff and management interviewed were asked to describe the most useful and significant impacts of the DNSR Compliance Verification Program. The majority of interview respondents felt that the most useful and significant impact is the ensured safety of workers and the public. Others felt that compliance is the most useful and significant impact, followed by the DNSR's "open" and "consistent" approach to compliance verification as the most useful and significant impact.

NSRD and Class II licensees who were surveyed were asked to provide the key benefits experienced by CNSC compliance verification activity. Responses, in order of prevalence, were as follows:

- The CNSC, as an arm's-length organization, offers compliance and oversight that is not undertaken by any other party: 35 percent

[16] Government of Canada, *Nuclear Safety and Control Act*, 1997, Section 9, available at http://laws-lois.justice.gc.ca/eng/acts/N-28.3/FullText.html.

- Safety is ensured for employees and the general public: 23 percent
- CNSC staff expertise and knowledge are shared: 18 percent
- Improves awareness among licensee staff and reinforces role of the Radiation Safety Officer (RSO) within the licensed facility: 14 percent
- Promotes standardization and uniformity among the industry: 8 percent
- Security is assured for employees and the general public: 2 percent

DNSR staff and management and NSRD and Class II licensees provided feedback on any potential changes required to compliance verification activities. Although both parties articulated this slightly differently, three potential changes were:

> **(1) Periodically review the DNSR regulatory model so as to ensure that inspection frequencies and types of inspections are based upon an up-to-date licensee risk profile**
> **(2) Review the inspection approach among all divisions in the DNSR (includes the licensing–inspection functions)**
> **(3) Review the role of inspections in the OID (extent of field inspection work and balancing the facilitator and enforcer roles)**

DNSR staff and management were asked if they felt there were any changes required to DNSR compliance verification activities. Slightly over half felt that changes were required; these are listed in order of prevalence:

- Licensing–-Inspection Functions: 17 percent of interviewees from across the Directorate raised concerns about how closely linked the licensing and inspection functions should be. The ACFD assigns its officers both licensing and compliance functions. The OID, for the most part, only conducts compliance activities, whereas NSRDLD delivers its licensing functions. OID's western office has two licence officers in the office, which allows for more interaction between the licensing and compliance functions, as officers are more readily able to consult one another on specific cases. There was no consensus among interview respondents as to what the "right" model should be.
- Information Technology Updates: 14 percent of interviewees from across the Directorate felt that the IT tools needed to be updated – specifically, LOUIS.
- Role of Inspections in OID: 14 percent of interviewees stated that there was a need to review one or more elements of the OID inspection approach. This included the frequency of conducting Type II field inspections (includes direct observation of work in progress and document review) versus predominant Type II (includes document review), the balancing of facilitator versus enforcer role (finding the right approach to enforcing the law or improving health and safety),[17] inspection reports (current forms are too detailed), and coordinator's role (an FTE needs to be responsible for ongoing monitoring and planning).
- Review of Risk-Informed Model: a small number (7 percent) felt the need to adopt a regular five-year review cycle of the risk-informed model, which would include revising minimum standards for inspection frequencies, and the introduction of dynamic factors (e.g., trends in usetypes).

[17] Interview participants described two, sometimes competing, roles that an inspector can undertake during an inspection. An inspector can act as a facilitator to educate the licensee in areas of non-compliance or potential non-compliance and, on the other hand, an inspector can act as an enforcer to penalize the licensee in areas of non-compliance.

Similarly, NSRD licensees and Class II licensees were asked if any changes were required on behalf of the CNSC. Slightly over half of respondents felt that there were no changes required. Respondents who felt changes were required provided the following suggestions:

- There is a need to streamline regulatory practices, tailoring them to each licence usetype – 28 percent
- Standardize the way in which inspections are undertaken among CNSC staff – 23 percent
- CNSC should make better use of its website and clarify current content to make it more user-friendly – 21 percent
- CNSC should act as a guide in addition to being a regulator – 10 percent
- Correspondence between CNSC to licensees should be more frequent and timely – 10 percent
- CNSC should consult the industry on new requirements and changes – 6 percent
- There is a need to increase the number of inspectors conducting inspections – 2 percent

5.2 Effectiveness

Evaluation questions explored in this section were as follows:

- Has DNSR established its ability to identify and plan high-priority and risk-informed verification activities?
- Have non-compliance issues been identified and corrected or justified without undue delay according to risk level?
- Are inspections conducted in accordance with established procedures?
- To what extent are internal and external stakeholders aware of regulations and scientific, technical guidance concerning DNSR compliance verification?
- To what extent are best practices and lessons learned shared internally and externally?

Conclusion

The DNSR Compliance Verification Program is mature and relatively stable. The risk-informed model, designed in 2004, has largely been implemented in accordance with the intended design. Overall, the program is effective at describing the state of licensee compliance; licensees have exhibited a high rate of compliance over the five-year time frame of 2007–2008 to 2011–2012.

In reference to the desired immediate outcomes described by program staff, the DNSR Compliance Verification Program has fully demonstrated three outcomes: internal and external stakeholders are aware of regulations and scientific and technical guidance; inspections are conducted in a transparent and risk-informed manner; and best practices and lessons learned are shared with internal and external stakeholders. In terms of identifying and planning high-priority and risk-informed verification activities, evidence indicates that the program could benefit from refinement of the risk-informed model. Although the program identifies non-compliances efficiently, some non-compliance issues persist beyond the limits established for rectification by the licensee; improved oversight may help to identify these situations and focus attention as needed.

Awareness. The DNSR Compliance Verification Program has implemented successful mechanisms to increase awareness of regulations; scientific and technical guidance are reaching the intended internal and external stakeholders. These mechanisms, ranging from one-on-one correspondence to formalized stakeholder working groups, contribute to fostering a culture of safety.

Transparency. The DNSR has established a variety of process and procedural documents to standardize the way in which Type I and Type II inspections are carried out. Among surveyed DNSR licensees, there is a high degree of transparency – most licensees indicated that inspections are conducted in a consistent manner. The development and implementation of inspection processes and procedures is a key element of effective regulation, and the DNSR is consistent in this area when compared to other regulators that were examined.

Best-Practice Sharing. The DNSR has implemented a variety of mechanisms to share best practices and lessons learned with internal and external stakeholders. Internal to DNSR, modes of engagement include operational meetings, technical review meetings, annual DNSR meetings, and major event summaries where staff and management actively engage in sharing and learning about best practices and lessons learned to date. Externally, the DNSR shares best practices and lessons learned with licensees and the broader radiation safety community through presentations and poster sessions at national venues, participates in the Federal/Provincial/Territorial Radiation Protection Committee, delivers an annual national outreach initiative for licensees, and organizes the Industrial Radiography Working Group.

Risk-Informed Model. Multiple lines of evidence indicate the need for the DNSR to refine its risk-informed model. The last major re-examination of the DNSR's risk-informed regulatory model occurred eight years ago (2004) and was built upon known characteristics of various licensed activities. These characteristics were used to create usetypes and associated "static" inspection frequencies for each type. In order for the model to be applied effectively, however, there is a need to accommodate more dynamic factors such as the positive and negative risks associated with new technologies, changing industrial/commercial trends, and licensee compliance history.

Rectification of Non-Compliances. An analysis of all inspection data located in LOUIS during the five-year time period of 2007–08 to 2011–12 concluded that licensees are in compliance with regulatory requirements, on average, 85 percent of the time. Non-compliance issues arise, on average, in 15 percent of inspections and in most cases correspond to a "C" compliance rate, denoting performance is deteriorating or falling below expectations. Overall, there is a relatively low rate of non-compliance, as established by DNSR compliance verification activities. The DNSR, however, does not track the timeliness of non-compliance issues that have been identified, corrected or justified in an "aggregate" or summary fashion. Instead, timeliness is managed on a case-by-case basis.

Provided that the OID and ACFD together manage the regulatory compliance of thousands of licences every year, a case-by-case examination of inspection reports would be inefficient to assess for the purposes of this evaluation. A selected sample was constructed for the purpose of testing timeliness to assess all inspection reports; the sample was selected from two usetypes during the five-year period. The selected sample yielded the result that 34 percent, or one-third, of non-compliance issues are not resolved in the time required (30 days). The timeliness of resolving non-compliance issues is important for the effective management of regulatory compliance; while the selected sample is not representative of all inspection reports, it suggests there could potentially be gaps introduced by a sole reliance upon inspectors to close inspections.

Additionally, the review of annual compliance reports in an effort to extract information related to non-compliance was not successful. DNSR staff and management confirmed that annual compliance reports are not used to measure non-compliance and have no direct impact on compliance verification planning.

Supporting evidence

Has DNSR established its ability to identify and plan high-priority and risk-informed verification activities?

The mechanisms that the DNSR has established for prioritization and risk-ranking in compliance planning may be improved upon by more effective use of licensee history (i.e., those with consistently "good" performance and those with consistently "bad" performance).

The DNSR's current risk-ranking model was established in 2004 in an effort to apply effective, efficient and fair regulatory requirements. The model was developed by first compiling an exhaustive list of licensed activities established from the NSCA, various Nuclear Substances and Control (NSC) regulations, and licence conditions, which served to group the over 70 licensed activities into 12 usetypes.[18] The licensed usetypes were then ranked by a team of subject matter experts using supporting data from the U.S. NRC and adapted to the Canadian context; judgments were made based on the impact if non-compliance were to occur for each applicable regulatory requirement.

The document review and interview findings established that the risk-informed model specified the minimum frequency and type of inspections to be conducted in each five-year licence cycle, depending on the risk level for the licensed usetype. A low-risk usetype would be required to only submit an Annual Compliance Report (ACR), a medium-risk usetype would be required to submit an ACR and undertake a Type II inspection, and a high-risk usetype would be required to submit an ACR and undertake a Type II inspection and a Type I inspection.

The OID is expected to conduct Type II inspections annually for every high-risk licensee within its mandate. Similarly, the ACFD is committed to one Type I inspection of every Class II facility in the five-year cycle, plus a Type II inspection every two to three years. The minimum requirements are built into the planning tools utilized by both divisions: the OID uses the verification planning tools built into the LOUIS system, whereas the ACFD plans its verification activities through Excel spreadsheets. By extension, these minimum requirements serve as basic assumptions for resource allocation, budgeting and priority setting.

Complementing this base ranking, a performance ranking was established to measure the licensees' compliance with risk-ranked requirements. The compliance, for each regulatory requirement, was given a weighted grade of A, B, C, D, or E. The "A" grade established excellent compliance, whereas an "E" grade established severe non-compliance. The interviews confirmed that DNSR personnel take into account licensees' negative compliance histories in the planning and prioritization of their compliance verification activities.[19] All the respondents said that such a history would likely lead to an increase in the frequency and/or type of inspection (e.g., raising a planned Type II inspection to a Type I inspection). It was also noted that a history of persistent or otherwise serious non-compliance could result in an escalation of enforcement actions.

When DNSR staff and management were asked about compliance history more broadly in terms of how it impacts verification planning, the following responses suggest that the current approach may be insufficient in these respects:

> (1) The directorate does not have policies/procedures to specifically define what constitutes "bad" compliance history, nor are there guidelines that define or suggest any thresholds that would help determine what responses should be considered in any category of circumstances.

[18] Licensed activities deemed similar and established from the same regulatory requirements, and posing the same risks, were grouped in the same usetype.

[19] Negative compliance histories are taken into account; however, positive compliance histories are not factored into planning and prioritization of compliance verification activities.

(2) The existing policy/procedures leave project officers/inspectors considerable scope to escalate interventions in response to "bad" histories, but little scope to respond in a compensatory manner to "good" histories.

The respondents' discussion of these issues suggests that the consequences of the current compliance history regime are inconsistent across divisions and that there are inefficiencies arising from the allocations of compliance verification resources to licensees who demonstrate successively good compliance and those who have exhibited a higher risk of non-compliance.

The evaluation noted that these issues are known within the DNSR and are being considered as part of a wider review of the risk-informed regulatory program and its implementation within the directorate.

The majority of the respondents were of the opinion that the DNSR has established its ability to effectively identify and prioritize compliance on a risk-informed basis. At the same time, a significant number also saw opportunities to expand the risk-informed model to take greater account of "dynamic" factors: positive and negative risks associated with new technologies, changing industrial/commercial trends, and licensee compliance history.

DNSR staff and management were asked if they felt that the DNSR has established its ability to effectively identify and prioritize compliance on a risk-informed basis. Approximately two-thirds of interview respondents expressed that the risk-informed model for identifying and planning activities is effective; however, many comments offered ways in which it could be improved. Respondents who felt that the current risk-informed model was ineffective at identifying and prioritizing compliance echoed similar comments about where improvements could be made. The similarities in suggested improvements suggest that the difference between a "yes" and "no" response is associated with the degree of significance placed on the need to implement the suggested improvements. Improvement areas include:

(1) A need to better accommodate the positive and negative risks associated with new technologies – the current risk level is based on the maximum permitted use under the licence, but some university facilities, for example, have actual use rates that are much lower.
(2) Changing industrial/commercial trends – radiographers are not all alike: some are large firms that frequently work on multiple sites, whereas others are small firms that work occasionally.
(3) Positive compliance history – many of the high-risk licensees are responsible and have "positive" compliance histories; however, they are still consistently treated as high-risk.

Overall, the improvement areas suggest a need to expand the risk-informed model to accommodate these "dynamic" factors that characterize risk.

Have non-compliance issues been identified and corrected or justified without undue delay according to risk level?

The evaluation attempted to inform non-compliance issues identified, corrected or justified without undue delay using two sources of data: non-compliances identified in ACRs and non-compliances identified in inspections reports. DNSR staff and management interviewed report that ACRs rarely identify non-compliance issues and that the information contained in them is not used in risk-informed compliance planning. An examination of all inspection data located in LOUIS during the time frame April 1, 2007 to March 31, 2012 concluded that non-compliance issues comprise approximately 15 percent of all inspections. The DNSR does not track the timeliness of non-compliance issues that have been identified, corrected or justified at an aggregate or summary level.

The program data review was intended to examine the number of non-compliances identified through mandatory ACRs that licensees submit to the CNSC each year. Due to a number of issues related to how annual compliance reports are programmed in LOUIS, it was not possible to generate compliance versus non-compliance based on these reports. As a mitigation strategy, DNSR staff and management were interviewed as proxies to obtain information on issues related to non-compliance from ACRs.

DNSR staff and management were asked, "When ACRs identify a non-compliance issue, how does your Division incorporate this information into its risk-informed verification planning?" The respondents stated that the ACRs had no direct impact on compliance verification planning.[20] It was noted that the reports were reviewed, but mostly as part of the general records review done as a project officer/inspector prepares for a specific inspection. In the words of one respondent, "project officers/inspectors look at them, but they rarely have any real value in terms of identifying noncompliance or verification planning."

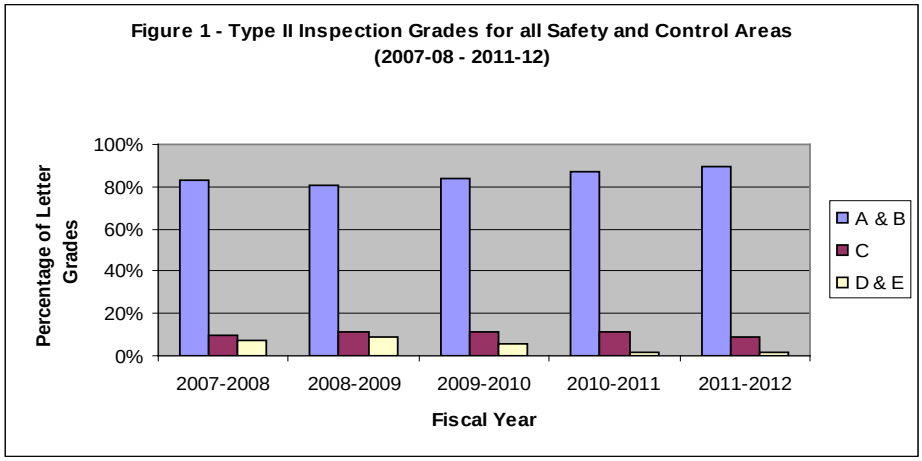
The process for registering, tracking and closing non-compliance issues varies according to division in the DNSR. Historically, the ACFD has utilized MS Word tools to record and control information about Type I inspections and related action items. All Type II inspections, those managed by the OID as well as ACFD, have been recorded in LOUIS. In late 2012, LOUIS was complemented by another database known as the Regulatory Information Bank (RIB/BIR) System to register, track and close orders as well as to track serious enforcement actions. LOUIS and RIB/BIR both link related reports and correspondence in E-Access so that the licensee's entire history can be traced.

For the purpose of this evaluation, all inspection grades located in LOUIS were examined during the time frame of April 1, 2007 to March 31, 2012. Upon each inspection, an inspector provided grades for each safety and control area.[21] For all Type II inspections, these grades are populated in LOUIS under each licensee's profile, using a five-letter system.[22] Upon examining all 7,633 Type II inspections during this five-year time frame, 85 percent of licensees met or exceeded requirements and 15 percent were below, significantly below or unacceptably below requirements. As illustrated in figure 1 below, over the five-year time frame, inspection grades A and B (exceed or meet requirements) have increased, inspection grades of C (below requirements) have remained relatively constant, and inspection grades D and E (significantly below or unacceptably below requirements) have decreased. In other words, risk-significant non-compliances have decreased over time.

[20] While ACRs have no direct impact on compliance verification planning, it was noted by DNSR management that ACRs are used to update the National Sealed Source Registry inventory as well as systems maintained by the Financial Administration Directorate at the CNSC.

[21] During the time frame of 2007 to 2010, the CNSC assessed compliance against 12 SCAs. In 2011, the SCAs were redefined into 14; compliance has been assessed from 2011 onwards against this total.

[22] Canadian Nuclear Safety Commission, *Nuclear Substances in Canada: A Safety Performance Report for 2010*, March 2012, p. 79. The five-letter rating system consists of: A – exceeds requirements, B – meets requirements, C – below requirements, D – significantly below requirements, and E – unacceptable.

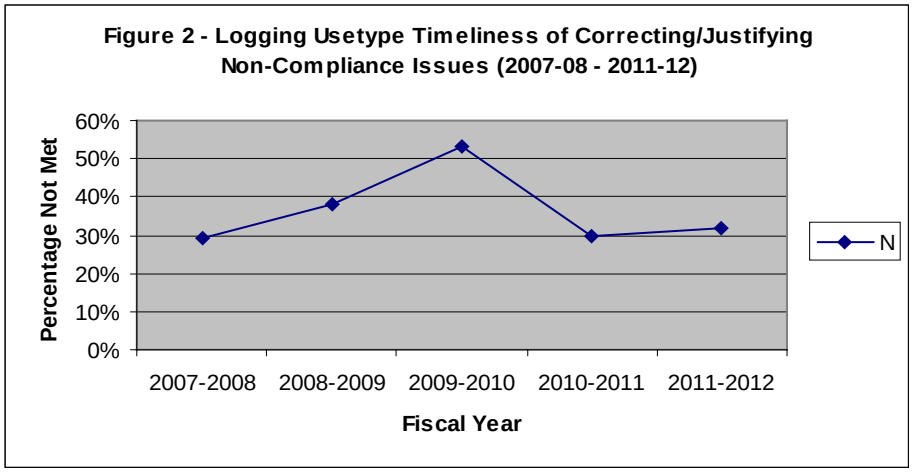


Data source: All LOUIS inspection grades for all safety and control areas during the period 2007–08 to 2011–12.

Timelines regarding when non-compliance issues have been corrected or justified without undue delay are not tracked in an aggregate manner. The information is available only by examining each individual inspection report.

At the end of each inspection, the inspector leaves the licensee with a copy of a preliminary inspection report containing the inspection findings and grades. A final report is sent to the licensee within 30 business days. Where the licensee has not met the expected requirement, a follow-up action is required on its part to correct the issue. A required response time is illustrated in the inspection report and signifies that the licensee is required to submit a follow-up response to the CNSC by that date.

Because the OID and ACFD together manage the regulatory compliance of thousands of licences every year, a case-by-case examination of inspection reports would be impractical. A selected sample examining all inspections related to two usetypes used for logging, one managed by the OID and one managed by the ACFD, were selected to assess whether non-compliance issues were corrected or justified without undue delay. During the time frame 2007–08 to 2011–12, 34 percent, or one-third, were not met on time. Of those that were not met, most were not received within one day, up to three weeks from the date required. Tracking the response time over this five-year period (Figure 2) illustrates that the percentage of dates not met increased from 2007–08 to 2009–10, with a significant decrease between 2009–10 and 2010–11.



Data source: Selected sample of inspection reports extracted from LOUIS for logging usetypes 504 and 816

Are inspections conducted in accordance with established procedures?

The DNSR and the divisions conducting compliance verification activities have developed several process and procedural documents that, together, form the framework for conducting inspections and other related compliance verification activities.

The NSCA and regulations define the scope of DNSR inspection work, whereas the processes and procedures developed by the Directorate and the divisions define, in greater detail, regulated requirements and responsibilities of the regulator. It was noted that during the evaluation time period, the OID was in the process of developing various procedural documents completed in March 2013 that are consistent with the *CNSC Conduct of Inspections* document. Table 7 below outlines the number of process and procedural documents by type.

Table 7: Number of process and procedural documents defining DNSR inspection work by type

Nuclear Safety and Control Act	Regulations	Regulatory document	Guidance documents (GD, G, S, INFO docs)	Directive	DNSR processes and procedures	ACFD procedures	OID Procedures
1	5	1	21	1	8	2	7

DNSR staff and management and NSRD and Class II licensees were consistent in their affirmations that inspections are conducted in a transparent manner. Specific inspection steps were detailed in order to elicit reliable responses from surveyed licensees that inspections are conducted according to established procedures.

DNSR staff and management were asked what mechanisms, if any, are taken to ensure inspections are conducted in a manner that is transparent to stakeholders. All interview respondents identified specific procedures and practices that, taken together, ensure inspections are carried out in a transparent manner. Due to the variances in licensees managed by the OID and ACFD and, subsequently, the differences in inspection types, specific procedures and practices vary somewhat.

The OID conducts the majority of Type II inspections, involving one inspector attending the offices/sites of several licensees within a period of a few days. The OID applies similar transparency features that include:

- The inspector schedules the inspection visit in advance,[23] describing the process and identifying the documents and records, and the storage areas, that they will need access to during the inspection.
- The licensee is given access to the worksheets that detail what the inspector will be looking for and the criteria that will be applied for the relevant usetype (the worksheets are public documents and have been published on CNSC's website).
- At the conclusion of the inspection, the inspector leaves the licensee with a copy of the preliminary report that identifies any non-compliance or weakness.

[23] The majority of inspections the OID undertakes reportedly are not field inspections and therefore can be scheduled in advance.

- The final report is sent to the licensee, detailing the inspection finding, the evidence in support of the findings, and the corrective measures required, if any.

The ACFD conducts the majority of Type I inspections, involving a multi-day visit to a medical or research facility by a team of DNSR project officers. The key transparency features of a Type I inspection process include:

- The project leader contacts the licensee weeks in advance to jointly schedule the inspection work and confirm details, including the identities of the inspection team members, the personnel to be interviewed, the team's facility requirements (meeting/interview rooms, access to secure areas, etc.), the activities the project officers will observe, and the team's testing plans.
- In advance of the inspection, the licensee is given copies of the worksheet templates that detail all of the criteria that the team will use.
- There is always an opening session for all staff members at the licensed facility to hear about the inspection process.
- There is a daily debrief for the licensee's key personnel.
- Before leaving the site, the team gives the licensee Radiation Safety Officer (RSO) a preliminary report, detailing inspection findings, at a closing meeting.
- The final report is sent to the licensee, detailing the inspection finding, the evidence in support of the findings, and the corrective measures required, if any.

NSRD and Class II licensees were asked if their inspections were conducted in a transparent manner, with 90 percent of respondents responding affirmatively. The remaining 10 percent of respondents who answered that their inspections were not conducted in a transparent manner, or who expressed that they did not know, were asked to define which inspection step lacked transparency.

The inspection steps were defined as:

1. conduct an opening discussion with the licensee
2. collect inspection facts
3. communicate potential and actual findings with licensee onsite
4. provide detailed inspection report to licensee

The most frequent step selected was the third: communicating potential and actual findings with the licensee onsite. Respondents identified the need for the report to be carefully constructed and well referenced so that there is not a considerable difference between the preliminary/field report and the final report received.

Comments on the remaining steps, in order of prevalence, were: further training of project officers/inspectors was required, specifically for 811 and 812 usetypes (and that there needs to be further consistency among project officers/inspectors when conducting inspections); that inspection grades C, D and E are too subjective and further definitions are needed to ensure clarity among them; and, where applicable, the inspection date and time should be planned so that the requisite staff can be onsite and that project officers/inspectors should communicate observations while they incur to allow for learning.

The DNSR is similar to other jurisdictions in its inspection processes and procedures.

Elements of the Floridian and British radiation compliance verification programs and the Canadian Food Inspection Agency (CFIA) meat inspection program were compared to the DNSR Compliance

Verification Program, as presented in the CNSC Inspection Process Overview[24] and risk-informed framework.[25]

The DNSR risk-informed model closely parallels elements of the compliance verification policies and procedures implemented by Florida's BRC under the state agreement with the U.S. NRC. The notable differences highlighted in this comparison, as illustrated in Table 8 below, include the recent assessment of the NRC that highlighted less reliance in the future on deterministic effects in some areas of decision making, which will likely result in adjustments to the frequency of scheduled inspection.

Table 8: Comparative study – Risk-informed model and inspections

Comparators	BRC – Florida	HSE – United Kingdom	CFIA – Canada
Compliance and Enforcement Policies	There is no separate compliance and enforcement policy; compliance and enforcement is articulated in legislation, procedures and practices. The legislation does identify administrative penalties and is prescribed by the determination of three factors: severity of the violation, actions taken by the licensee to correct the violation, and any previous violations.	Implemented a detailed enforcement management model, intended to: promote enforcement consistency by confirming parameters; promote proportionality and targeting by confirming risk-based criteria; help inspectors assess their decisions; allow peer review of enforcement action; and clarify decision-making roles. The model is built around the concept of risk-gap analysis that provides a framework to prioritize actions against potential for actual harm, followed by achieving compliance with regulations.	Implemented a compliance and enforcement policy to guide agency's response to non-compliance. The policy outlines an escalating approach to enforcement, including: issue notice of violation, apply an administrative monetary penalty, suspend or cancel the licence, recommend to the Public Prosecution Service of Canada the prosecution of violators, and seize and detain shipments and products, where needed.
Compliance Monitoring and Verification Practices	Relies on periodic inspections of all licensees studied in accordance with the risk level for each type of use of regulated materials. The risk determinative, completed by the U.S. NRC, is based on science (stochastic and deterministic effects), design (whether the source is sealed or not, the type of shielding) and similar considerations.	Relies on incident reports, trends analysis (dose rates across user groups), and intelligence, including complaints from the public or employees.	Adopted a "supervisory" model whereby continuing observation of onsite work (task to be conducted, the risk associated with the operations conducted on each shift, and the number and frequency of the shifts) is conducted. Its policies and procedures sets out the level and frequency for each facility and process. For example, the minimum level of monitoring for a facility that is processing, packaging and labelling meat products is 390 hours per year.
Inspection Policies and Procedures	Has established inspection process and protocols that are consistent with guidance provided by the U.S. NRC Inspections Manual.	Has established operational circulars and guidance documents for inspections.	Has established inspection procedures and process, which is supported by the Compliance Verification System – a task-based inspection tool to verify regulatory compliance.
Risk Assessment Policy and Procedures	Risk considerations (deterministic effects) have played a key role in determining the minimum inspection frequency for different	Risk consideration has played a key role in determining the level and type of corrective action or enforcement measure imposed.	Risk consideration has played a key role in determining compliance activities, in general. Risk takes into account the product and/or process,

[24] Canadian Nuclear Safety Commission, 2012, *CNSC Inspection Process Overview – Conducting an Inspection* (E-doc-#3817913), Ottawa: Canadian Nuclear Safety Commission.
[25] Directorate of Nuclear Substance Regulation, 2004, *Development of the Risk-Based Regulatory Program*, Canadian Nuclear Safety Commission.

	usetypes. Recently published a paper assessing the current risk framework and found there could be less reliance on deterministic effects in some areas of decision making. This will likely result in adjustments to the frequency of inspection schedule in the future.		the licensee's controls and its compliance history.

To what extent are internal and external stakeholders aware of regulations and scientific, technical guidance concerning DNSR compliance verification?

DNSR staff engage stakeholders through a variety of awareness initiatives. These include the various presentations that staff deliver to targeted groups each year and the creation of the Industrial Radiography Working Group to promote radiation safety awareness among industrial radiographers.

The program data review revealed there are various modes for which stakeholder engagement occurs that are above and beyond the information presented and published on the CNSC website, materials included in a licence and provided to the licensee, and one-on-one correspondence between CNSC staff and licensees. This engagement impacts stakeholder's awareness of regulations and scientific, technical guidance regarding DNSR compliance verification.

The DNSR has successfully implemented a joint CNSC / Industrial Radiography Working Group (IRWG), combining members of industry and DNSR staff, with the intention of promoting a strong radiation safety culture among industrial radiographers licensed by the CNSC. Since 2009, the joint CNSC/IRWG has met on a biannual basis to discuss informational/compliance promotions products developed by the CNSC to increase awareness among the industrial radiographer community and consult on upcoming CNSC regulatory requirements and guidance affecting industrial radiographers.

Additionally, the ACFD and OID conduct approximately two presentations per year to targeted stakeholder groups across Canada. The ACFD frequently presents to the Canadian Organization of Medical Physicists, the Canadian Radiation Protection Association, L'Association Québécoise des Physicien(ne)s Médicaux Cliniques, and the Western Canadian Radiation Therapy Conference. OID stakeholder groups tend to be more variable and include, as examples, the GE Health Symposium, Golder Associates and Team Industrial Services. Yet another source of information shared with licensees is the DNSR newsletter, which is published at least two times a year, and the compliance performance information presented in *Nuclear Substance in Canada: A Safety Performance Report*.

All DNSR staff and management and the majority of the NSRD and Class II licensees surveyed have a sound understanding of the regulatory basis for conducting compliance verification activities. The top three information sources that licensees access are the CNSC website, one-on-one correspondence received from CNSC staff, and licence materials.

DNSR staff and management were asked if they understood the regulatory basis for conducting compliance verification. All those interviewed responded to this question in the affirmative. Most commonly, they referred to the quality of the training that they receive and the design of worksheets that directly link all the criteria to specific sections of the regulations.

NSRD and Class II licensees were asked if they understood the applicable requirements included in their licence, and where they usually accessed requirements and guidance applicable to their licence. The majority of respondents (95 percent) understood the applicable requirements, whereas 5 percent felt that they did not. Of the licensees surveyed, most of them access requirements and guidance online from the CNSC website. Following, in order of prevalence, respondents access requirements and guidance from CNSC staff, their licence materials, a third-party consultant, the Canadian Radiation Protection Association or other similar organization,[26] or other sources. "Other" includes online RSO listservs, their own organization's documentation such as the radiation safety manual, internal knowledge of their staff, the manufacturer, the International Atomic Energy Agency, the U.S. NRC website, the Health Canada website, general website searches of "TDG regulations", and the Justice Canada website.

To what extent are best practices and lessons learned shared internally and externally?

The DNSR has developed and implemented a variety of mechanisms to share best practices and lessons learned internally, as well as externally, to deliver information promoting compliance and a cultural of safety among licensees.

DNSR staff and management were asked if they have tools and/or processes in place to share lessons learned and best practices internally. All interview respondents (27) were able to describe a forum for which best practices and lessons learned were shared. These are:

- **Operational meetings:** Respondents from all DNSR divisions identified their regularly scheduled operational meetings as vehicles for sharing lessons learned.
- **Technical Review meetings:** The ACFD has established a requirement that its inspection reports must be presented to and approved by a meeting of staff before they can be signed off and sent to a licensee. The inspection leader, in addition to presenting the report, is responsible for capturing any issues identified in the discussions, then adding them to the inventory maintained by the Project Officer. The Technical Review meetings serve a dual purpose: peer review of the inspection report presented, as well as refining inspection procedures, improving skills and techniques, and reducing inconsistencies as a whole.
- **Quality Assurance committee:** The DNSR established this committee to ensure staff collectively identifies issues and solutions within its mandate. The committee formulates recommendations to management for changes and action (e.g., creation of the portable gauge group to develop strategies to deal with the high incidence of lost and damaged equipment).
- **Annual DNSR meetings:** These annual two-day events offer opportunities for sharing and learning; the agenda includes presentations and poster sessions by staff.
- **Major events:** The OID and TLSSD, upon successfully leading a formal lessons-learned exercise in response to the Altona incident,[27] plans to conduct a similar exercise for any future events.

In addition, DNSR staff and management were asked to describe any tools or processes in place to share lessons learned and best practices externally. Interview respondents consistently identified the following tools and processes:

[26] Respondents often cited the Canadian Industrial Radiation Safety Association as an organization where the licensee obtains requirements and guidance applicable to its license.

[27] The Altona incident refers to the surface contamination of uranium concentrate found on a shipment of sealed source containers from Canada to China in January 2011. The CNSC monitored the cleanup of the contaminate and followed up with a formal lessons-learned document to govern any future occurrences. See *DNSR Lessons Learned: Closing the File*, presented to Management Committee on March 28, 2013, E-doc #:4108519.

- presentations and poster sessions on recent developments, trends and other subjects at national venues such as the Canadian Organization of Medical Physicists (COMP) and the Canadian Radiation Protection Association (CRPA)
- contributing to dialogues with other regulators through the Federal/Provincial/Territorial Radiation Protection Committee and Transport Canada's Federal/Provincial/Territorial Task Force
- annual national outreach initiative hosted by the DNSR and targeted predominately to high-risk licensees
- Industrial Radiography Working Group hosted by the DNSR, which includes a selection of industry stakeholders of that sector
- quarterly DNSR newsletter and bulletin, posted online at CNSC website
- Safety Performance Reports on the use of Nuclear Substances, presented online at CNSC website
- the Nuclear Substances section of the CNSC website

5.3 Efficiency

Under the Treasury Board Evaluation Policy (April 1, 2009), efficiency is defined as maximizing the outputs produced with a fixed level of inputs or minimizing the inputs used to produced a fixed level of outputs.[28]

Evaluation questions explored in this section include:

- Have program resources been utilized to optimize outputs?
- How efficient is the DNSR Compliance Verification Program?

Conclusion

Altogether, DNSR staff and management and NSRD and Class II licensees surveyed held varied attitudes about program efficiency. DNSR staff and management noted that significant improvements have been made since 2004 with the introduction of the risk-informed model; however, they acknowledged that further efficiencies could be gained by adapting the current risk model to include a mechanism to deal with new/changing technologies as well as positive licensee compliance histories. It was also suggested that licensees with demonstrated good compliance could conduct their own self or peer audits.

Efficiency improvement areas offered by NSRD and Class II licensees were varied. The most prevalent were further improvements to consistency/standardization among project officers/inspectors in conducting inspection work, and the further streamlining of inspection procedures and frequencies based on usetype and number of devices a licensee holds in the same location.

The comparative study suggested that efficiency gains could be achieved by introducing an information system that would allow the inspection process to be "paperless" and mobile (as in the case of the Florida BRC). Improving the use of information technology systems is consistent with feedback provided by DNSR staff and management, as well as NSRD and Class II licensees.

[28] Treasury Board of Canada Secretariat, Policy on Evaluation, April 1, 2009, http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=15681&section=text#appA.

Planned and actual financial resources were examined to measure efficiency. In terms of allocative efficiency (budget usage), the last three years demonstrate an improving capacity to budget and allocate resources. The total financial dollars the DNSR expends on compliance verification by licence was examined to establish any significant cost variations between fiscal years. The cost of the DNSR Compliance Verification Program is relatively stable; the cost attributable to a licence increases marginally by $200 each fiscal year.

In addition to an assessment of planned and actual financial resources, two important observations were made using proxy indicators. The total FTE "head count" reported by the Human Resources Information System was compared to the total compliance verification effort reported by the DNSR Compliance Verification Program. The ratio of the two suggests that direct effort to other internal directorate costs is about 1:1 and was stable over the evaluation time period.

Additionally, salaried resources attributable to Type I and Type II inspections were compared to the number of inspections conducted. Of course, there are considerable differences in the scope of Type I and Type II inspections – namely, a Type I inspection is an in-depth review, often involving more than one licence, and includes a full site assessment and interviews with the RSO, staff and management. A Type II inspection, on the other hand, is not a full site assessment and typically does not involve RSO, staff and management interviews. While there is some general increase in cost of each inspection time over the time period, the increase was relatively marginal. The cost differences in conducting a Type I and Type II inspection further establish the value of the DNSR adopting a risk-informed model; yet, at the same time, these differences support further efficiency improvements (Type I is always expensive, while Type IIs are so frequent that reducing numbers may achieve significant savings).

Supporting evidence

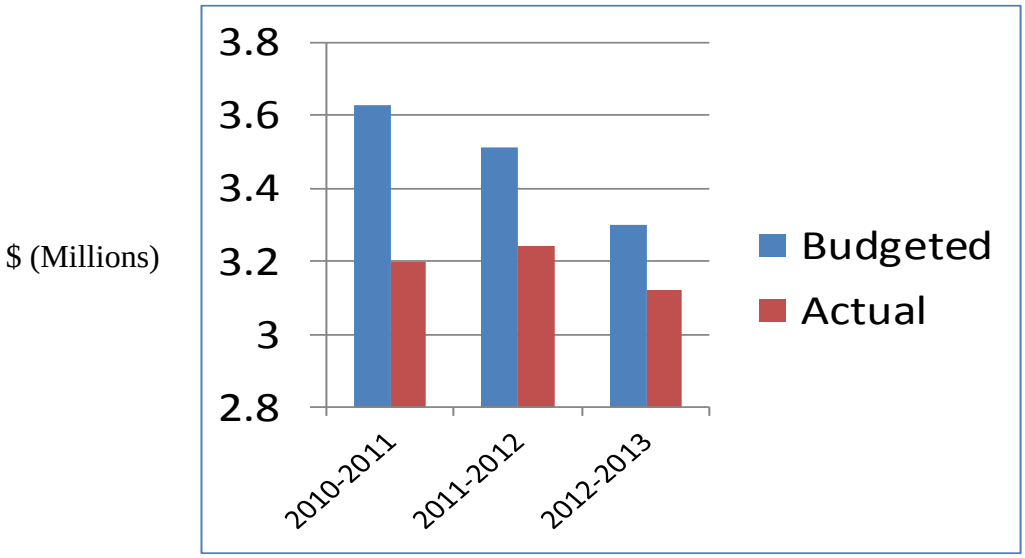
Have program resources been utilized to optimize outputs?

The DNSR Compliance Verification Program planning has significantly improved in the last two years and the cost of the program is relatively stable.

The resources utilized for compliance verification were obtained from the Senior Financial Analyst for DNSR. All financial resources gathered in support of this financial review were verified by the Director General and directors of the DNSR. The budgeted (planned) information was obtained from annual planning data and the utilized (actual) information was obtained from the time reporting database, located in LOUIS, for the demonstration of salary financials, and Freebalance and the Corporate Planning and Management Reporting System (CPMRS) for the demonstration of non-salary financials.

The total salaried and non-salaried financial resources utilized during the period March 31, 2007 to March 31, 2013 amounts to $18,236,139. The budgeted (planned) and actual (expended) non-salary financial resources are illustrated in figure 3 below. The fluctuations between budgeted and actual between fiscal year 2007–08 and 2009–10 varied greatly, with a percentage variance of approximately 150 percent. Interviews with key informants indicated the quality of this cost data was questionable; therefore it was not considered. On the other hand, fluctuations between fiscal years 2010–11 and 2012–13 did not vary by any degree of significance. The percentage variance between the last two fiscal years examined is approximately 10 percent. Overall, DNSR Compliance Verification Program planning has significantly improved in the last two years.

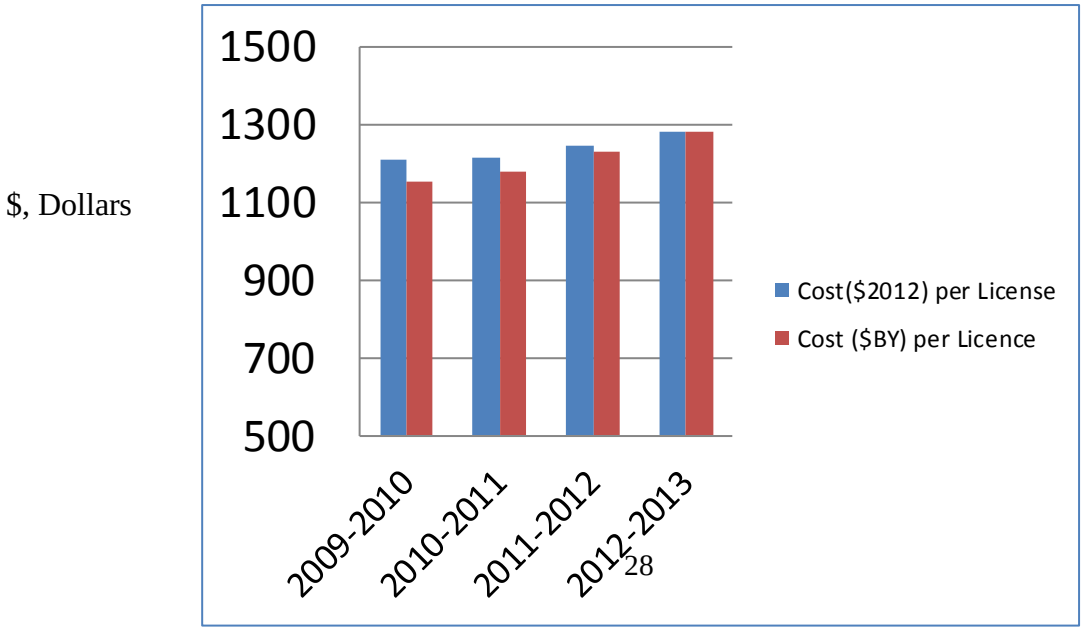
Figure 3: Total program budgeted versus actual costs (salary and non-salary), FY 2010/11 – 2012/13



Data sources: All budgeted salary (based on FTEs) and non-salary financials obtained from Responsibility Centre (RC) allocated to DNSR compliance verification. Actual salary financials obtained from CPRMS. Actual non-salary financials obtained from Freebalance.

The total salaried and non-salaried resources were applied to the number of licences managed by the DNSR in order to understand the cost of compliance verification activity applied to a licence. Over a four-year time frame, the average cost of managing a licence remained relatively stable, with an increase of approximately 6 percent (after inflation) over the four-year time frame depicted in Figure 4. As indicated in the 2012 *Safety Performance Report for Nuclear Substances*, some licence consolidation (i.e., a reduction in the number of licences but not licensees) was reported, which accounts for the apparent increase.

Figure 4: Costs of compliance verification activities per licence



Data sources: Total licences managed obtained from 2012 DNSR *Safety Performance Report* (see also appendix G). Salary and non-salary compliance verification costs were obtained from CPMRS. Dollars shown in constant year (2012); dollars using annual REG6 salary band changes as inflation adjustment (blue), and actual budget year (BY) data (red).

The CNSC does not have established measures for efficiency. To gauge changes in the ratio of outputs to inputs over the time period, the evaluation looked at two indicators:

a. a comparison of actual FTEs (effort) used by the DNSR for all activities (regulatory framework development, licensing and certification, all compliance activity – as well as training, etc.), to the effort reported for compliance verification alone

b. a comparison of the effort applied to conduct Type I and Type II inspections

Figure 5 below illustrates the total number of FTEs used by the DNSR for all activities, in comparison to the amount of effort applied to compliance verification activity.

Figure 5: DNSR's total and compliance verification effort used, FY 2009/10 – FY 2013/14

Figure 5(a)

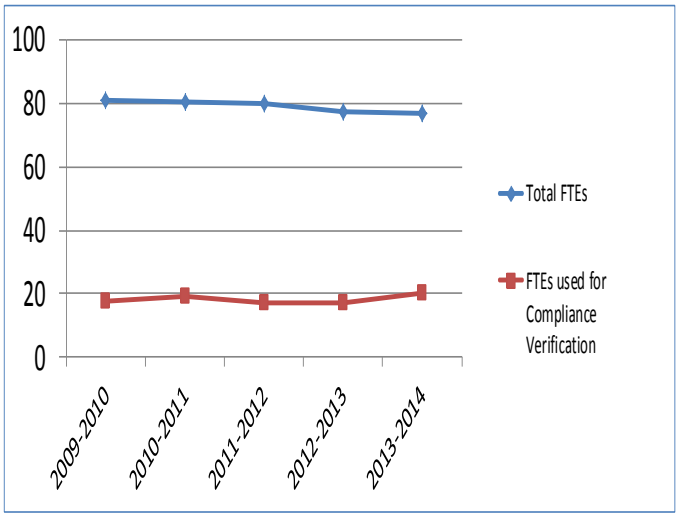
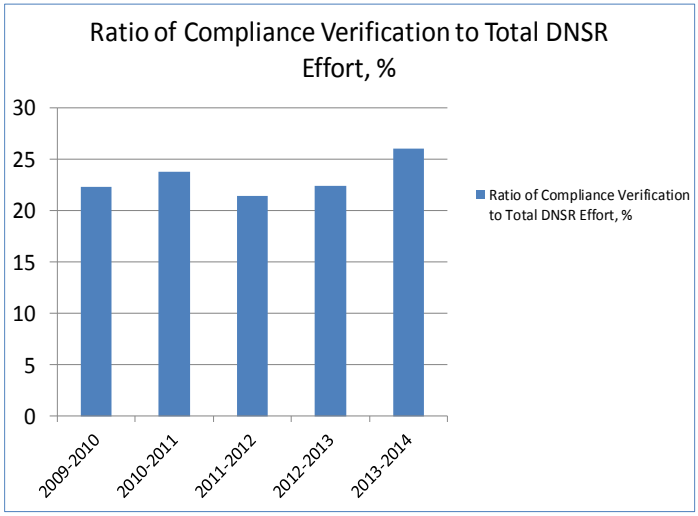


Figure 5(b)



Data source: All FTE usage obtained from LOUIS time reporting database. NOTE: The time accounting system was changed in 2009, resulting in better data capture.

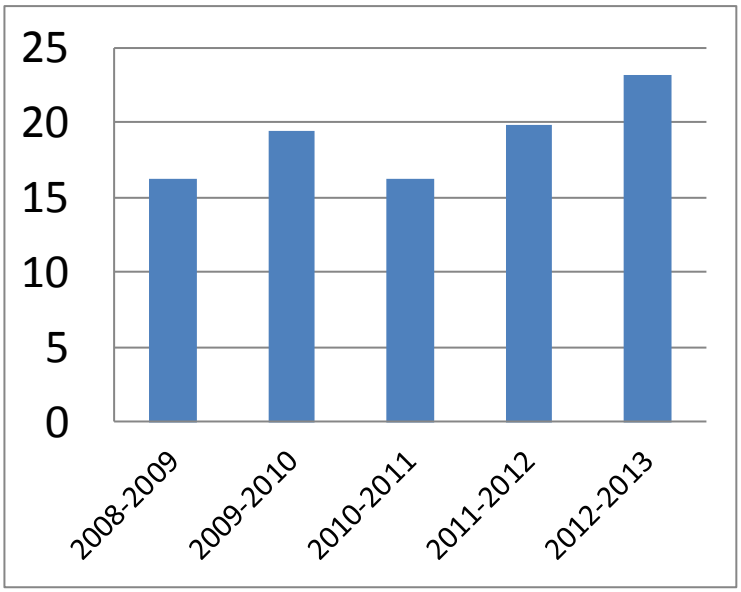
Figure 5(b), which is simply the ratio of the data shown in Figure 5(a), shows that the amount of effort applied directly to compliance variation does not fluctuate significantly, either year to year or over the time frame studied. This relatively stability suggests that this indicator may be a good baseline from which to measure the impact of any proposed efficiency improvement aimed at decreasing effort applied

for compliance verification. This indicator also has the advantage of not being subject to monetary inflation.

To situate further the potential for efficiency improvements, however, a proxy efficiency indicator was developed by using as an output measure the number of Type I or II licences inspected, against an input of effort applied (as measured by FTEs). Note there is a distinction between the inspection reports issued and the number of licences inspected, as program staff recommended that the latter better reflects the way inspections are actually conducted (multiple licences may be inspected for a specific site visit).

There are considerable differences in the scope of Type I and Type II inspections; namely, a Type I inspection is an in-depth review, often involving more than one licence and including a full site assessment and interviews with the RSO, staff and management. A Type II inspection, on the other hand, is not a full site assessment and typically does not involve RSO, staff and management interviews.

Figure 6: Number of licences inspected per FTE utilized, Type I

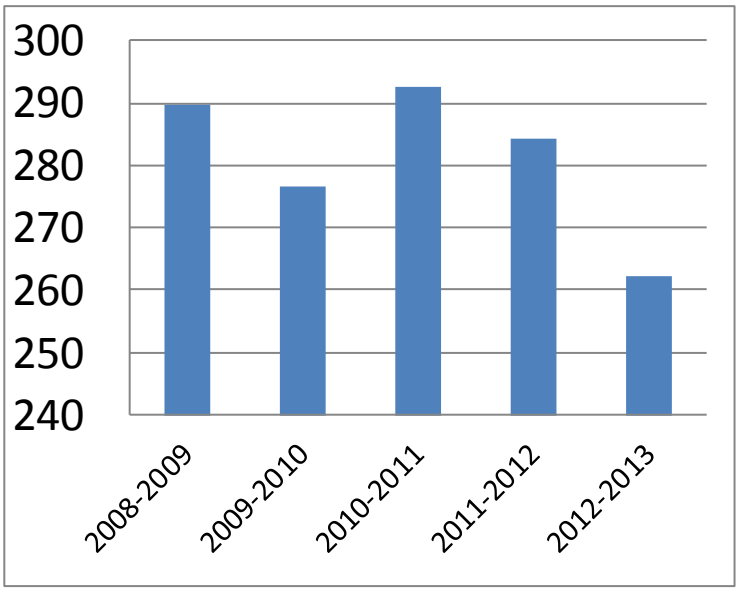


Data source: FTE utilization from LOUIS; inspection data provided by DNSR.

As shown in Figure 6, there is a slight upward trend over the five years depicted, indicating that some efficiency gains are being made, but is also noteworthy that the number of licences inspected is relatively small and differences in usetypes inspected may result in greater variability.

Figure 7 depicts the similar indicator for Type II inspections for all usetypes during the period 2008–09 to 2012–13. In this case, there is an apparent downward trend, but overall observed variability is much less than is the case for Type I inspections (maximum variance from the average of 7 percent), due to the large number of inspections conducted. The overall inference would be that the indicator is showing a stable situation.

Figure 7: Number of licences inspected per FTE utilized, Type II



Data source: FTE utilization from LOUIS; inspection data provided by DNSR.

Together, these indicators suggest there is a suitable baseline to gauge whether further efficiency improvements are effective, and that the overall picture with respect to compliance verification resource usage is stable.

DNSR staff and management interviewed have varied opinions on the efficiency of the DNSR Compliance Verification Program. Since the introduction of the risk-informed model post-2004, the program has seen an improvement in overall compliance, and many stakeholders assessed that the number of inspections undertaken per year has been optimized. On the other hand, approximately one-half of interview respondents felt that efficiencies could be further gained by implementing a new information technology system to track and report activities, adapting a new risk model to take into consideration dynamic factors such as licensee compliance history, which could reduce the volume of documentation inspectors must produce.

DNSR staff and management were asked if they felt that the DNSR Compliance Verification Program is efficient. Approximately one-half of respondents felt that the Compliance Verification Program is efficient (i.e., resources used to optimize outputs). Evidence used to support this view included the shift DNSR undertook in 2004 with prioritizing compliance activities based on higher-risk licensed activities, the number of inspections undertaken have provided a limited number of project officers/inspectors, and that overall compliance is improving.

The remainder of respondents felt there was room for improvement. In order of prevalence, efficiency could be gained through:

- implementing a new information technology system to efficiently track and report compliance verification activities

- adapting a new risk-ranking model to take into consideration the dynamic factors (e.g., compliance histories) in order to reduce the proportion of licensees requiring inspections on a yearly basis
- reducing the volume of documentation that project officers/inspectors must produce

How efficient is the DNSR Compliance Verification Program?

The DNSR could achieve clear efficiency gains in introducing an information system, which would allow the inspection process to be "paperless" and mobile, as in the case of the Florida Bureau of Radiation Control.

A comparison exercise, examining three regulators – the U.K.'s HSE, the Florida BRC and the CFIA meat inspection program – was undertaken in order to determine if there were any alternative design/delivery approaches that could, in turn, be incorporated into the DNSR's compliance verification to increase efficiency. The study originally attempted to identify financial and performance data that would have allowed for the quantification and comparison of efficiency ratios to occur. Unfortunately, the comparator financial and performance data were not readily available. In the absence of substantial quantifiable information, the study sought information about any program, policy or administrative innovations that any of the comparative programs have planned that would point toward significant opportunities for greater DNSR efficiency.

As illustrated in Table 9 below, the Web-based Information Management Inspection Support and Reporting System, implemented by the Florida BRC, has allowed the inspection process to go "paperless" and mobile. There are clear efficiency gains that the DNSR Compliance Verification Program could achieve by introducing similar information technology supports to its inspection activities.

Table 9: Comparative study – Efficiency

Comparators	BRC – Florida	HSE – United Kingdom	CFIA – Canada
Information technology	Since 2009, the BRC implemented the Information Management Inspection Support and Reporting System to allow for the inspection process to be "paperless" and mobile. Inspectors, supplied with PC tablet computers, now work from their home offices using the system to access licence information, compliance history, inspection worksheets for usetypes, reporting forms and templates, etc. Inspectors are able to complete and forward inspection reports for review and approval within 24 hours of completing an exit interview, and documents destined to licensees can be delivered electronically, without data re-entry.	There is no overall information system implemented for tracking compliance; however, the HSE allows licensees to submit notifications and incident reports directly to departmental databases.	Since 2008, the CFIA has implemented an online Compliance Verification System, namely to organize tasks, track licensee history, provide staff with clearly defined tasks and enhance uniform delivery, and verify licensee compliance.

There was some support in DNSR staff and management for alternative ways to increase efficiency. OID staff generally stated there is need for the DNSR to re-examine the risk-informed model so that licensees with demonstrated good compliance histories would use a smaller proportion of

DNSR resources. Other alternatives suggested, to a lesser extent, are the introduction of self or peer audits for licensees and reducing the paper documentation process for licensees with consistently good performance.

DNSR staff and management were asked if there were any alternative ways in which DNSR could achieve the same objectives of compliance verification and increase efficiency. The majority, 66 percent, assessed that there were no alternative approaches that would increase efficiency. Of the 34 percent who offered alternative approaches, respondents suggested greater efficiency could be gained by adapting the risk-informed model so that licensees with good performance histories would use a smaller proportion of DNSR resources. Other suggestions focused on redesigning the inspection process to gain further efficiencies: for instance, reducing the "paper burden" associated with gathering, reviewing and reporting licensees' positive behaviour by focusing on documenting licensees that have shown non-compliance. Generally, OID staff interviewed tended to find that compliance verification was less efficient than the ACDF staff who were interviewed.

NSRD and Class II licensees surveyed held varied attitudes toward the efficiency of conducting inspections. While a small percentage (16 percent) had views that tended toward inefficiency, responses on areas of improvement were consistent. The top two areas of suggested improvement were improvements to the consistency/standardization in conducting inspections, and streamlining the inspection procedure and associated frequencies by licensee profile and the number of devices a licensee holds in the same location.

NSRD and Class II licensees were asked to rate how efficient the CNSC is at conducting inspections and collecting annual compliance reports. Approximately one-half of NSRD and Class II licensees surveyed felt that the CNSC is extremely efficient in conducting inspection work, and 35 percent said that the CNSC is somewhat efficient. Of the lower-bound responses, 10 percent felt neutral; 2 percent felt that the CNSC is somewhat inefficient; 2 percent felt the CNSC is extremely inefficient; and 2 percent were not sure.

The respondents who ranked the CNSC somewhat efficient to extremely inefficient provided consistent comments that can be used to improve efficiency across rankings. They were, in order of prevalence:

- improve consistency/standardization among project officers/inspectors when conducting inspection
- streamline inspection procedure and frequency based on licensee profile and number of devices licensee holds in the same location
- request documentation, electronically, from licensee before inspection occurs (OID specific)
- schedule inspections with licensee ahead of time and to occur during normal office hours
- provide greater clarity on licensee requirements
- increase frequency of communication to the licensee
- improve knowledge of project officers/inspectors of industry
- improve professionalism and friendliness among project officers/inspectors
- send final inspection report in a timely manner
- examine trends in industry with similar usetypes and utilize as part of inspection
- make use of technology (e.g., tablet, smart phone) to transcribe information in order to improve inspection observation and analysis
- streamline the preliminary and final report to just one report

Overall, NSRD and Class II licensees thought efficiency could be improved through annual compliance reports (ACRs). The most prevalent areas of improvement cited for the program to

focus on were to provide acknowledgement that an ACR has been received, improve the correspondence when the ACR is due, and introduce an online submission system for licensees (Note: the online system was introduced post-evaluation).

NSRD and Class II licensees were asked to rate how efficient the CNSC is in collecting annual compliance reports, on a scale of 1 to 5, where 1 is extremely efficient and 5 is extremely inefficient: 39 percent felt that the CNSC is extremely efficient in collecting ACRs from licensees. Following this, 28 percent felt the CNSC was somewhat efficient; 15 percent felt neutral; 4 percent felt the CNSC was somewhat inefficient; 2 percent felt the CNSC was extremely inefficient, and 12 percent did not know.

Of the respondents who ranked the CNSC somewhat efficient to extremely inefficient, there was consistency in comments about areas of potential improvement. They were, in order of prevalence:

- provide acknowledgement to licensee that the ACR has been received
- improve ACR correspondence to licensee that ACR is due during a specified time period (e.g., include email to RSO, include phone call, send reminder 2 months, not 4 months, before ACR is due)
- introduce online submission of ACRs
- reduce time CNSC takes to review the ACR
- improve quality of ACR receipt process on part of CNSC (licensee has received notice that ACR was overdue when ACR was sent before due date)
- eliminate ACR process, as same information is required during licence renewals
- reduce frequency and streamline process of ACRs when licensee experiences no change to report from previous year
- provide WEB-EX training sessions for licensees on ACRs
- clarify requirements for 811 usetypes
- reduce number of CNSC staff licensee interacts with to 1 point of contact

5.4 Design/delivery for continuous improvement

Evaluation questions explored in this section include:

- How effective is the ongoing performance measurement system of the program?
- Were DNSR Compliance Verification Program roles and responsibilities (a) well defined and accessible? (b) appropriate? (c) respected by DNSR staff and licensees?

Conclusion

It was clear from evaluation evidence that roles and responsibilities at both the individual and divisional levels are well defined, accessible and appropriate. There is consensus among DNSR staff and management that roles and responsibilities are accepted by licensees. Licensees have a good understanding of compliance verification activities based on their experience with inspections as well as the information they receive from the CNSC to build awareness on the safe use, handling, transport and storage of their licensed substances, device and/or prescribed equipment.

In terms of the appropriateness of inspections and annual compliance reports, it was found that inspections are conducted according to procedure; however, there is a need to re-examine the usefulness of annual compliance reporting for planning purposes. In the case of NSRD licensees, there are reported redundancies created in the information submitted in ACRs and that is submitted in the Sealed Source Tracking System (SSTS). Additionally, for both NSRD and Class II licensees, there is a need to tailor

annual compliance reporting to licensee profiles, which could lead to a reduction in the frequency of reporting.

The document review and interview findings revealed that there is no performance measurement system to monitor compliance verification at an aggregate level. Although there are two major reporting initiatives that utilize DNSR data, the data represent only a section of verification activities and, even when taken together, are not complete indicators of outcomes.

Supporting evidence

How effective is the ongoing performance measurement system of the program?

The document review and interview findings revealed that there is no performance measurement system in place to monitor compliance verification at an aggregate level. Although there are two major reporting initiatives that utilize DNSR data, the data represent a section of verification activities that, even if taken together, are not effective indicators of outcomes.

Some compliance indicators are reported in the *Nuclear Substances in Canada: A Safety Performance Report* and in the CNSC Departmental Performance Reports and Reports on Plans and Priorities. These indicators, even if viewed together, do not measure all outcomes the DNSR is trying to achieve. All indicators reported represent measures of activities (e.g., Type I Inspection Report issued within 60 business days, dosimetry rates). There are divisional specific initiatives that can be tied to a future performance measurement system: the OID has developed service standards that will be used to inform planning,[29] and the ACFD has implemented a licensee feedback survey that can be utilized to monitor stakeholder satisfaction with the Type I inspection process.

In interviews with DNSR staff and management, respondents were unable to identify any procedures, guides or similar documents that might resemble a formalized performance measurement system. Many respondents were clearly guessing in an attempt to provide a response, while a few who had some familiarity with the concept simply indicated that they were not aware of such documents. This indicates that an initiative to introduce, document and explain performance measurement principles to staff would be useful.

Were DNSR Compliance Verification Program roles and responsibilities: (a) well defined and accessible? (b) appropriate? (c) respected by DNSR staff and licensees?

Overall, there is broad consensus among DNSR staff and management that the roles and responsibilities of the divisions within DNSR are well defined and clear, and that they are current and well documented.

DNSR staff and management were asked if they thought that roles and responsibilities are well defined within their division, and 96 percent stated “yes”. Respondents provided examples of the procedural documents that they use on an ongoing basis for relevant information. Several noted that these procedural documents are currently being updated, a process that would result in further clarification. Only one

[29] During the evaluation time period, the service standards were in the process of being drafted. As of March 2013, the service standards have been finalized.

interviewee did not feel that roles and responsibilities were well defined for their job description and was not aware of any consistent documentation that highlighted them.

All DNSR staff and management interviewed affirmed that formal statements of their roles and responsibilities were appropriate to their actual activities and work assignments.

Overall, DNSR staff and management responded positively when asked if they felt that their roles and responsibilities accurately reflected their actual activities and work assignments. Three respondents did, however, outline areas that could be improved. Specifically, the work description governing the OID coordinator's responsibilities does not adequately reflect the increased responsibility for special projects and planning, and the boundaries between licensing and inspection functions could be clearer.

Some NSRD and Class II licensees opined that the usefulness of annual compliance reports could be improved. There is a need to examine the universal status that all licensees should report annually on compliance. In particular, there are reported redundancies created in the ACR process and Sealed Source Tracking System (SSTS) inventory, and there is a need to tailor reporting to licensee profiles. Additionally, there are areas of improvement offered by making reporting available to licensees online and by providing acknowledgement of receipt of ACRs from CNSC to the licensee.

The survey of Class II and NSRD licensees included questions to measure the appropriateness of ACRs. Licensees were asked to rate the usefulness of ACRs as a mechanism to aide in the regulation of their licensed activities: 25 percent felt that annual compliance reports are extremely useful, 42 percent said somewhat useful, 19 percent felt neutral, 9 percent said somewhat not useful, 6 percent not at all useful, and less than 1 percent did not know. One-quarter of respondents who ranked the ACRs from somewhat useful to not at all useful provided comments to qualify their rankings.

Comments provided were similar across rankings:

- ACRs are redundant to what is reported through the SSTS, as well as what is covered in inspections – 36 percent (31/87)
- there is a need to streamline annual compliance reporting, tailoring them to each licensee profiles (this may or may not impact frequency) – 31 percent (27/87)
- make annual compliance reporting available online – 20 percent (17/87)
- provide acknowledgement to the licensee that the ACR has been received – 9 percent (8/87)
- quality of annual compliance reporting and control system on behalf of CNSC needs to be re-examined (controlling errors) – 5 percent (4/87)

DNSR staff and management agreed that their roles and responsibilities are generally respected and that most licensees have a good understanding of compliance verification activities based on their experience of being inspected and the CNSC's proactive informational activities.

Interviewed DNSR staff and management were asked if roles and responsibilities are respected internally by staff and management and externally by licensees. All CNSC staff and management interviewed responded in the affirmative in both instances. It should be noted that this may not be the case with small carriers; while the evaluation focuses on licensees, staff from TLSSD were also interviewed and reserved concerns that small carriers likely did not understand compliance verification. Carriers are regulated, but are not required to obtain a licence.

NSRD and Class II licensees surveyed feel that inspection steps are being followed according to procedure.

Class II and NSRD licensees were asked if their CNSC inspections followed the following steps:

1. Conduct an opening discussion with licensee (introduce: inspectors, CNSC mandate, inspection process, proposed schedule)
2. Collect inspection facts (monitor and observe licensee: performance and activities, records and other documents, conduct discussions with personnel, conduct sampling and measurement)
3. Communicate potential and actual findings with licensee onsite
4. Provide a detailed inspection report to licensee

Ninety-five (95) percent (325/345) of surveyed respondents stated that their inspection followed these steps, whereas 4 percent (15/345) stated their inspection did not follow the required steps, and 1 percent (5/345) were not sure. Of the 5 percent of respondents who did not respond yes, they further clarified which step was not followed. The majority selected Step 1, conducting an opening discussion, saying it was not adequately conducted – specifically, properly informing the licensee that the inspector has arrived onsite (signing in, informing office) and communicating to the licensee why the inspector is onsite, what the inspector will be observing, and why the inspector is performing the inspection (including mandate of the CNSC). Following, in order of prevalence, respondents selected Step 4, commenting on the poor quality of final report; Step 2, commenting that the inspectors seemed to be unfamiliar with maintenance of the nuclear device; and Step 3, commenting that the preliminary report is not left onsite.

6 Summary and Recommendations

Overall, there is a continued need for the DNSR to continue with compliance verification activities to ensure licensees are complying with regulation in order to protect the health and safety of workers and the public, maintain security and protect the environment. The mechanisms the DNSR has implemented to increase awareness of radiation safety are reaching intended internal and external stakeholders.

While further improvements can be made to increase the standardization and consistency of inspection work, the initiatives DNSR has undergone to establish various processes and procedures, particularly those covering inspection work, have attributed to a high degree of transparency experienced by licensees who have undergone inspections performed by DNSR project officers/inspectors. The development and implementation of processes and procedures is a key element of effective regulation.

There is a need for the DNSR to establish effective measures to monitor its performance in achieving its outcomes. Short-term objectives for compliance verification need to be articulated and communicated. Currently, there is no performance measurement system in place to monitor compliance verification at an aggregate level. Additionally, timeliness in correcting/justifying non-compliance issues is not tracked at an aggregate level, and there is support from interview and survey participants to further streamline the frequency and type of inspections based on licensee history. Trending data on licensee history are paramount in making these adjustments. A performance measurement system would support management in making informed decisions, namely to accurately identify and control non-compliance incidents and measure on an ongoing basis the dynamic factors characterizing the nuclear substances industry and licensees. In turn, a performance measurement system would ensure the risk-informed model is robust and adaptive to the environment in which it is applied.

There is a need to review the inspection approach among divisions in the DNSR. Currently, there are three different approaches in operation: one that combines both licensing and compliance functions, one that separates licensing from compliance, and one that includes licensing officers in the same regional office, which makes one-to-one communication more efficient. Additionally, it was demonstrated that there is variation in how individual inspectors conduct their activities with licensees. Some inspectors

take on a facilitator role to educate the licensee on non-compliance or potential non-compliance issues, whereas other inspectors take on an enforcer role and penalize the licensee based on non-compliance issues.

Moving forward, the improvement that should be made and is consistently demonstrated in evaluation evidence is a refining of the risk-informed model. The last re-examination occurred eight years ago, and although there were considerable positive impacts noted from the establishment of the model, there is a need expressed by all DNSR staff and management as well as NSRD and Class II licensees to incorporate dynamic factors associated with the industry and licensees. These factors include new technologies, changing industrial/commercial trends, and licensee compliance history. Through a re-examination exercise, the DNSR should improve its ability to identify and plan high-priority, risk-informed verification activities and gain efficiencies by using fewer resources for licensees who successively demonstrate good compliance history.

Furthermore, the evaluation noted efficiencies that could be gained by implementing a "paperless" inspection process and having inspectors work out of mobile offices. The degree to which this is adaptable to the Canadian system should be examined; it is likely that further efficiencies could be gained.

There is a need to articulate and communicate the purpose and value of annual compliance reporting. Annual compliance reports have no direct impact on compliance verification planning. Additionally, there is duplicative information collected in annual compliance reports and the Sealed Source Tracking System, and it was found that communication between the CNSC and the licensee can be improved (e.g., acknowledgement that the report has been received, and effective timing of reminders to the licensee when it is due).

The following is recommended:

- Recommendation #1: Develop and implement measures to effectively monitor the aggregate performance of the DNSR Compliance Verification Program.
- Recommendation #2: Review the different approaches to inspection work among divisions and clarify the role of an inspector in balancing both facilitator and enforcer responsibilities.
- Recommendation #3: Refine the current risk-informed model to respond to positive compliance histories and dynamic factors (new technologies and changes to industrial/commercial trends).
- Recommendation #4: Examine ways to gain further efficiencies in the compliance verification process.
- Recommendation #5: Review the purpose and usage of annual compliance reports with respect to planning.

Appendix A – Management Action Plan

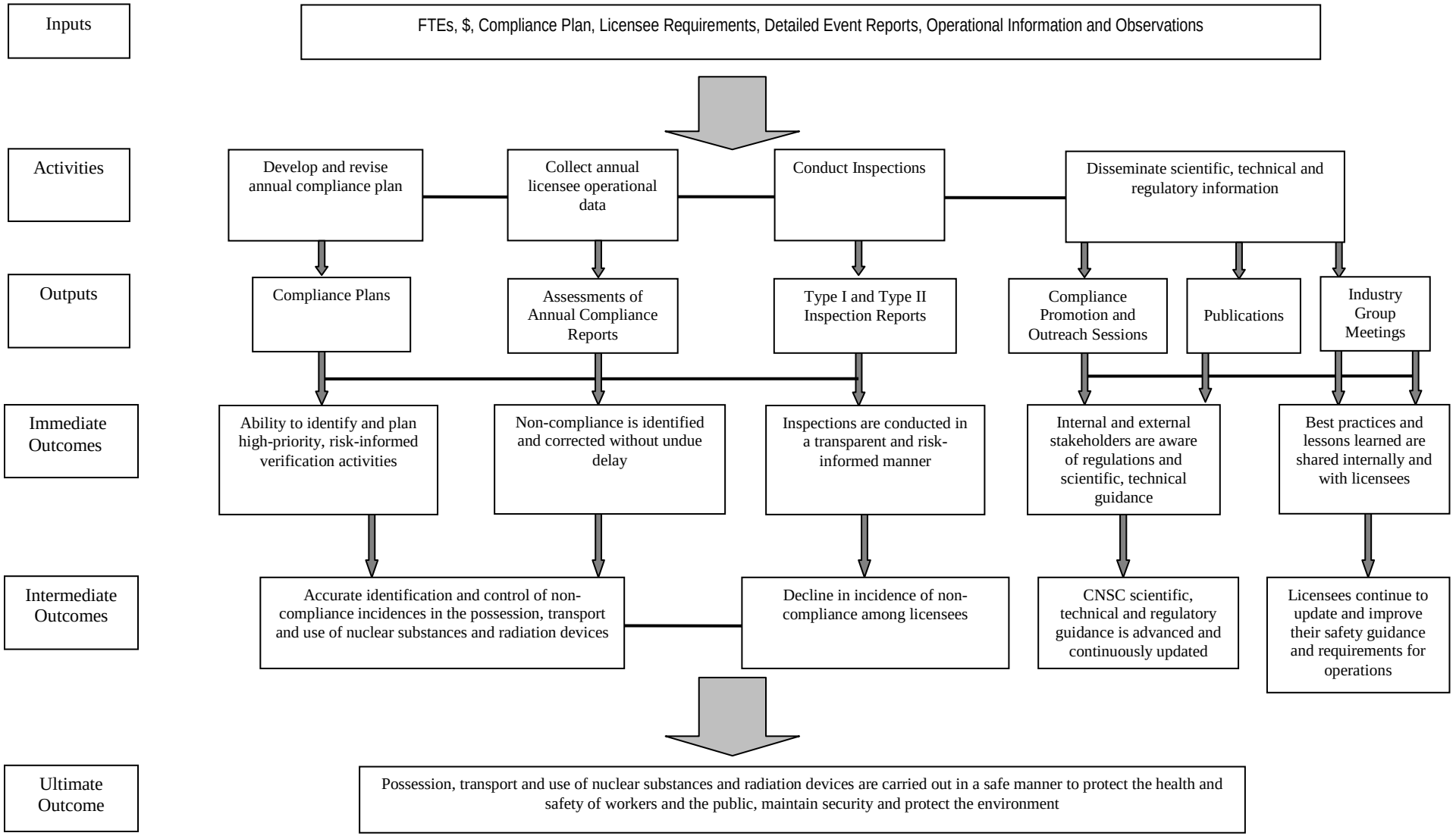
#	Recommendation	Type of recommendation	Response	Planned actions	Responsibility	Expected date of completion (M/D/Y)	Measures of achievement
1	Develop and implement measures to effectively monitor the global performance of the DNSR Compliance Verification Program.	Program Design	Accepted	1.1 Identify short-term objectives for compliance verification. 1.2 Communicate the articulated short-term objectives to DNSR staff. 1.3 Assess what additional performance measurement system can be put in place to monitor compliance verification at an aggregated level. 1.4 Implement feasible global performance measurement for DNSC compliance verification.	ROB – DNSR Director General	1.1 November 30, 2014 1.2 December 31, 2014 1.3 December 31, 2014 1.4 March 31, 2015	Monitoring of actions and completion dates will be tracked in the DNSR Project List (e-docs #3231781). Completion of actions will be identified by documentation in e-docs.
2	Review the different approaches to inspection work among Divisions and clarify the role of an inspector in balancing both facilitator and enforcer responsibilities.	Program Design	Accepted	2.1 Review licensing and compliance functions within the Directorate to ensure consistency and justify variation. 2.2(a) Document inspector roles and responsibilities for	ROB – DNSR Director General	2.1 December 31, 2014 2.2(a) December 31, 2014	Monitoring of actions and completion dates will be tracked in the DNSR Project List (e-docs #3231781). Completion of actions will be identified by documentation in e-

				enforcement and for facilitating information to licensees. 2.2(b) Communicate inspector roles and responsibilities for enforcement and for facilitating information to licensees.		 2.2(b) March 31, 2015	docs.
3	Review the current risk-informed model to respond to positive compliance histories and dynamic factors (new technologies and changes to industrial/commercial trends).	Program Design	Accepted	3.1 Review the risk profile of the line items that form the inspection worksheets for all usetypes. 3.2 Assess risk-ranking usetypes for licensing purposes, to complete the work done in 3.1 above. 3.3 Assess how positive licensee compliance history can be taken into account when planning inspections or assessing regulatory oversight. 3.4 Assess how dynamic factors will be identified and tracked, such that they can be	ROB – DNSR Director General	3.1 December 31, 2014 3.2 December 31, 2014 3.3 December 31, 2014 3.4 December 31, 2014	Monitoring of actions and completion dates will be tracked in the DNSR Project List (e-docs #3231781). Completion of actions will be identified by relevant documentation in e-docs.

				considered when planning inspections or assessing regulatory oversight. 3.5 Update the DNSR risk-informed model document accordingly, and implement as part of operations.		3.5 December 31, 2014	
4	Examine ways to gain further efficiencies in the compliance verification process.	Program Delivery	Accepted	4.1 Paperless licensing and compliance service delivery has been implemented in ACFD and TLSSD. Work is underway to achieve paperless service delivery in NSRDLD (licensing, certification and compliance). 4.2 Paperless service delivery in OID (compliance) will be implemented with the Mobile Inspection Kit in place.	ROB – DNSR Director General	4.1 March 31, 2015 4.2 Completion as per IMTD project plan schedule.	Monitoring of actions and completion dates will be tracked in the DNSR Project List (e-docs #3231781). Completion of actions will be identified by documentation in e-docs.
5	Review the purpose and usage of annual compliance reports with respect to planning.	Program Delivery	Accepted	5.1(a) Review the purpose and usage of annual compliance reports with respect to planning, and duplication with SSTS. 5.1(b) Communicate purpose and usage of		5.1 (a) December 31, 2014 5.1(b) March 31, 2015	Monitoring of actions and completion dates will be tracked in the DNSR Project List (e-docs #3231781). Completion of actions will be identified by documentation in e-

				annual compliance reports to DNSR staff and licensees. 5.2 Review how to acknowledge receipt of annual compliance reports. 5.3(a) Review the time when to send reminder letter to licensees. 5.3(b) Implement the reviewed time as required.		 5.2 December 31, 2014 5.3(a) December 31, 2014 5.3(b) March 31, 2015	docs.

Appendix B – Logic Model



Appendix C – Evaluation Matrix

Relevance: *Assessment of the extent to which the program continues to address a demonstrable need and is responsive to the needs of stakeholders*

Evaluation question	Success factors (i.e., what should be observed)	Indicators	Collection methods
1. Has DNSR established clear and measurable short-term and long-term objectives[30] for compliance verification?	The program has established short-term and long-term objectives that are clear among program staff and management and are measured.	1.1 Identification of short-term and long-term objectives that are clear and are measured	Document review
		1.2 Congruence on opinions that DNSR has established clear and measurable short-term and long-term objectives for compliance verification	Interviews
2. Is there a continued need for DNSR compliance verification?	There is congruence established between program staff, management and licensees opinions regarding usefulness and impact of DNSR compliance verification activities.	2.1 Program staff and management opinions on the appropriateness, usefulness and impact of DNSR compliance verification activities	Interviews
		2.2 Licensees' opinions on the appropriateness, usefulness and impact of DNSR compliance verification activities	Survey

Performance – Effectiveness: *Assessment of progress toward expected outcomes with reference to performance targets, program reach and program design, including the linkage and contribution of outputs to outcomes*

Evaluation question	Success factors (i.e., what should be observed)	Indicators	Collection methods
3. Has DNSR established its ability to identify and plan high-priority and risk-informed verification activities?	An effective mechanism is established within compliance planning that utilizes a prioritization and risk-informed framework.	3.1 Mechanism for prioritization and risk-ranking is established in compliance planning	Document review
		3.2 Congruence on opinions that the program has established its ability to identify and plan high-priority and risk-informed verification activities	Interviews
4. Have non-compliance issues been identified and	Annual compliance reporting and inspections	4.1.a # of licensee non-compliance issues	Program data

[30] An objective is a documented clear, specific, measurable, attainable end that a program plans to achieve. An objective may be achieved in a short temporal period (e.g., 1–3 years) or long temporal period (e.g., over 5 years) and underlies all planning and strategic activities.

corrected or justified without undue delay?	have identified non-compliance issues and the program has corrected/justified all within established time frames.	identified through annual compliance reporting per year 4.1.b # that have been tracked according to risk level	
		4.2.a # of licensee non-compliance issues identified through Type I and Type II inspection reports per year 4.2.b. # that have been tracked according to risk level	
5. Are inspections conducted in accordance with established procedures?	There is demonstrable evidence to show that inspections are conducted in accordance with the CNSC document *Conducting Inspections*.	5.1 # of established processes and procedures	Document review
		5.2 Comparison of DNSR compliance verification risk-informed model to other risk-informed models	Case studies
		5.3 Congruence on opinions of program staff and management that inspections have been conducted in a transparent manner	Interviews
		5.4 Congruence on opinions of licensees that inspections have been conducted in a transparent manner	Survey
6. To what extent are internal and external stakeholders aware of regulations and scientific, technical guidance concerning DNSR compliance verification?	Industry group meetings, publications disseminated and compliance promotion and outreach sessions conducted each year have contributed to internal and external stakeholder awareness of regulations and scientific, technical guidance concerning DNSR compliance verification.	6.1 # of industry group meetings per year	Document review

		6.2 # of publications by type disseminated per year	
		6.3 # of compliance promotion sessions provided per year	
		6.4 # of outreach sessions provided per year	
		6.4 Congruence on opinions of program staff and management that they are aware of regulations and scientific, technical guidance concerning DNSR compliance verification	Interviews
		6.5 Congruence on opinions of licensees that they are aware of regulations and scientific, technical guidance concerning DNSR compliance verification	Survey
7. To what extent are best practices and lessons learned shared internally and externally?	DNSR has a mechanism in place to share lessons and best practices with program staff and management and licensees.	7.1 A mechanism is implemented to share lessons and best practices	Interviews
		7.2 Lessons and best practices are shared and applied	

Performance – Efficiency: *Assessment of resource utilization in relation to the production of outputs and progress toward expected outcomes*

Evaluation question	Success factors (i.e., what should be observed)	Indicators	Collection methods
8. Have program resources been utilized to optimize outputs?	Resources are spent according to plan.	8.1 Resource utilization (planned versus actual program dollars (FTE time based on risk level and O&M) by output)	Financial analysis

	Congruence on opinions is established between program staff and management on satisfaction with program efficiency.	8.2 Congruence on opinions of program staff and management on satisfaction with efficiency (resources used to optimize outputs)	Interviews
9. How efficient is the DNSR Compliance Verification Program?	Comparison exercise comparing DNSR compliance verification model to that of other models reveals alternative design/delivery approaches, if any exist (to increase efficiency).	9.1 Comparison of DNSR compliance verification model to alternative design/delivery models (to increase efficiency)	Case studies
	Opinions of program staff and management and licensees are gathered on ways to improve efficiency, if any exist.	9.2 Opinions of program staff and management on ways to improve efficiency	Interviews
		9.3 Opinions of licensees on ways to improve efficiency	Survey

Design/Delivery for Continuous Improvement: *Ways to improve the effectiveness of program delivery*

Evaluation question	Success factors (i.e., what should be observed)	Indicators	Collection methods
10. How effective is the ongoing performance measurement system of the program?	The program has a performance measurement system in place that is utilized for planning and decision-making purposes.	10. Demonstrable performance measurement system and evidence of use in planning and decision making	Document review
			Interviews
11. Were DNSR Compliance Verification Program roles and responsibilities (a) well defined and accessible? (b) appropriate? (c) respected by DNSR staff and licensees?	Roles and responsibilities are documented and accessible to program staff and management, appropriate to the tasks and activities associated with compliance verification, and respected by both program staff and management as well as licensees.	11.1 Roles and responsibilities are documented and accessible to program staff and management	Document review
		11.2 Congruence in the opinions of program staff and management that roles and responsibilities were well defined	Interviews
		11.3 Congruence in the opinions of program staff and management that roles and responsibilities were appropriate	Interviews
		11.4 Congruence in the opinions of program staff and management that roles and responsibilities were respected internally and by licensees	Interviews
			Survey

Appendix D – Document List

Canadian Food Inspection Agency, *Audit of the Implementation of the Meat Compliance Verification System*, http://www.inspection.gc.ca/english/agen/eval/2011/cvssvcevale.shtml.

Canadian Food Inspection Agency, *Draft: The Improved Food Inspection Model: The Case for Change. Ottawa: Canadian Food Inspection Agency*, http://www.inspection.gc.ca/DAM/DAM-aboutcfia-sujetacia/STAGING/text-texte/acco_modernization_casechange_pdf_1337316954606_eng.pdf.

Canadian Food Inspection Agency, *Meat Hygiene Manual of Procedures - Chapter 1*, http://www.inspection.gc.ca/english/fssa/meavia/man/ch1/table1e.shtml.

Canadian Food Inspection Agency, Meats Program Division, *Federally Registered Meat Establishments*, http://www.inspection.gc.ca/english/fssa/meavia/regliste.shtml#prov.

Canadian Food Inspection Agency, *Enforcement and Compliance Activities*, http://www.inspection.gc.ca/about-the-cfia/accountability/enforcement-and-compliance/eng/1299846323019/1299846384123**.**

Canadian Food Inspection Agency, *Compliance and Enforcement Operational Policy*, http://www.inspection.gc.ca/about-the-cfia/accountability/enforcement-and-compliance/operational-policy/eng/1326788174756/1326788306568.

Canadian Nuclear Safety Commission, *Decision Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms, GD-52*, May 2010.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Air Activation and Ozone Production from High Energy Medical Linear Accelerators*, CRPA Annual Conference, May 8-13, 2011.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Amendments to Class II Regulations*, Presentation at CRPA, 2008.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Come Together, Right Now*, Poster Presentation at COMP Conference, 2007-08.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Food Irradiation*, 2011-12.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Radiological Consequences of Atmospheric Releases at PET Isotope Production Facilities*, presentation at COMP Conference, 2011.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Regulation of Class II Radiotherapy Facilities*, presentation at WESCAN Annual Conference, Abbottsford, British Columbia, April 1, 2011.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Type I Inspection*, presentation at AQPMC, November 2007.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Type I Inspection Evaluation Form*, August 2012.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Type I Inspection Procedure*, February 2012, E-doc #: 3658706.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Accelerators and Class II Facilities Division, *Type II Inspection Procedure*, February 2012, , E-doc #: 3855898.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, *CNSC Lab Sample Collection Procedure*, June 2010, E-doc#: 3814878.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substances Regulation, *Compliance and Enforcement Framework*, Version 1.1, May 2003, E-doc#: 3487671.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, *Development of the Risk-Based Regulatory Program*, February, 2005, E-doc#: 1254511.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, *DNSR Web Reporting for Lost, Stolen or Found Sealed Sources,* August 2011, E-doc#: 3512441.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, *Guidelines for Inspector Access to Licensed Locations*, September 2009, E-doc#: 3429787.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, *Procedure for External Notifications,* March 2013, E-doc#: 3553155.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, *Protocol between the DNSR and the DSS Regarding Security Inspections of DNSR Licensees,* July 2012, E-doc#: 3922916.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, *Select and Apply Enforcement Tools,* January 2010, E-doc#: 3320246.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Compliance Summary for 2011,* September 2012.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Coordinator's Meeting Minutes*, Mississauga: April 21-22, 2009.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Coordinator's Meeting Minutes*, Laval: September 16-17, 2009.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Coordinator's Meeting Minutes*, Kingston: September 15-16, 2010.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Coordinator's Meeting Minutes*, Ottawa: August 10, 2011.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Coordinator's Meeting Minutes*, Ottawa: June 5-7, 2012.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Industrial Radiography Team*, presentation to TISI, Oakville, Ontario, November 3, 2011.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Nuclear Medicine Regulatory Compliance*, presentation at Nuclear Medicine Symposium, Mississauga, Ontario, March 31, 2012.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Business Rules and Standards* (draft), March 2013, E-doc#: 3960614.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Development and Monitoring of an Inspection Plan* (draft), March 2013, E-doc #: 3974143.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Follow-up to Inspection Procedure* (draft), March 2013, E-doc #: 3973984.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Guidance for Staff Participating in Inspections* (draft), March 2013, E-doc#: 3974223.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Guidance for the Development of Inspection Criteria* (draft), March 2013, E-doc #: 3974196.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Guidance on Handling Feedback from Licensees* (draft), March 2013, E-doc #: 3974171.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operation Inspection Division, *OID Guidance for Providing Recommendations to Licensees* (draft), March 2013, E-doc #: 3974213.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Guidance on Storage of Information* (draft), March 2013, E-doc#: 3974185.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Inspection Planning and Logistics* (draft), March 2013, E-doc#: 3960483.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Inspection Procedure* (draft), March 2013, E-doc#: 3934265.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Inspection Tools and Equipment* (draft), March 2013, E-doc #: 3974158.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *OID Principles for Choosing an Inspection Type* (draft), March 2013, E-doc #: 3974128.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Portable Gauge Working Group*, presentation, Kingston, Ontario, September 15-16, 2010.

Canadian Nuclear Safety Commission, Directorate of Nuclear Substance Regulation, Operations Inspection Division, *Portable Gauge Working Group*, presentation, Ottawa, Ontario, June 15-16, 2011.

Canadian Nuclear Safety Commission, *INFO-0483, Responding to Accidents Involving Portable Gauges.*

Canadian Nuclear Safety Commission, *INFO-0728-1, Basic Level: Use of Unsealed Nuclear Substances*.

Canadian Nuclear Safety Commission, *INFO-0728-2, Intermediate Level: Use of Unsealed Nuclear Substances.*

Canadian Nuclear Safety Commission, *INFO-0728-3, High Level: Use of Unsealed Nuclear Substances.*

Canadian Nuclear Safety Commission, *INFO-0728-4, Nuclear Medicine: Use of Unsealed Nuclear Substances.*

Canadian Nuclear Safety Commission, *INFO-0742, Proper Care and Use of Personal Dosimeters.*

Canadian Nuclear Safety Commission, *INFO-0743, Spill Procedures.*

Canadian Nuclear Safety Commission, *INFO-0744, Guidelines for Handling Packages Containing Nuclear Substances.*

Canadian Nuclear Safety Commission, *Management Resources and Results Structure – Performance Measurement Framework, 2012-2013*.

Canadian Nuclear Safety Commission, *Managing Compliance Process Maps V1.0*, May 15, 2008.

Canadian Nuclear Safety Commission, *Nuclear Substances in Canada: A Safety Performance Report for 2008 and 2009*, September 2011, http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/CNSC-DNSR-2008-09-Nuclear-Substances-Safety-Report-Sept-2011_e.PDF.

Canadian Nuclear Safety Commission, *Nuclear Substances in Canada: A Safety Performance Report for 2010*, March 2012, http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/INFO-0826-Nuclear-Substances-in-Canada-A-Safety-Performance-Report-2010_e.pdf.

Canadian Nuclear Safety Commission, *Overview of: Conducting an Inspection*, March 2012, E-doc#: 3817913.

Canadian Nuclear Safety Commission, *Overview of: Conducting a Technical Assessment*, December 2011, E-doc #: 3816452.

Canadian Nuclear Safety Commission, *Regulatory Document on Thyroid Screening for Radioiodine, RD-58*, July 2008.

Canadian Nuclear Safety Commission, *Regulatory Guide on Applying for a Licence (Diagnostic Nuclear Medicine, Therapeutic Nuclear Medicine, Human Research Studies), C-292,* April 2002.

Canadian Nuclear Safety Commission, *Regulatory Guide on Ascertaining and Recording Radiation Doses to Individuals, G-91*, June 2003.

Canadian Nuclear Safety Commission, *Regulatory Guide on Certification of Exposure Device Operators, G-229*, March 2004.

Canadian Nuclear Safety Commission, *Regulatory Guide on Developing and Using Action Levels, G-228*, March 2001.

Canadian Nuclear Safety Commission, *Regulatory Guide on Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)", G-129*, October 2004.

Canadian Nuclear Safety Commission, *Regulatory Guide on Making, Reviewing and Receiving Orders under the Nuclear Safety and Control Act, G-273*, May 2003.

Canadian Nuclear Safety Commission, *Regulation Guide on Radiation Safety Training Programs for Workers Involved in Licensed Activities with Nuclear Substances and Radiation Devices, and with Class II Nuclear Facilities and Prescribed Equipment, G-313*, July 2006.

Canadian Nuclear Safety Commission, *Regulatory Guide on Security Programs for Category I or II Nuclear Material of Certain Nuclear Facilities, G-274*, March 2003.

Canadian Nuclear Safety Commission, *Regulatory Guide on Transportation Security Plans for Category I, II, or III Nuclear Material, G-208*, March 2003.

Canadian Nuclear Safety Commission, *Regulatory Policy on Compliance, P-211*, May 2001.

Canadian Nuclear Safety Commission, *Regulatory Policy on Considering Cost-benefit Information, P-242*, October 2000.

Canadian Nuclear Safety Commission, *Regulatory Policy on Human Factors, P-119*, October 2000.

Canadian Nuclear Safety Commission, Operations and Inspection Division, *Risk-Informed Inspection Frequencies*.

Health and Safety Executive, *OC 560/53: The Ionising Radiations Regulations 1999: Site Radiography 7-Day Notification and Waiver,* http://www.hse.gov.uk/foi/internalops/ocs/500-599/560_53.htm.

Health and Safety Executive, *HSE Staffing by Division/Directorate*, http://www.hse.gov.uk/aboutus/reports/1011/staffing.htm.

Health and Safety Executive, *Operational Procedure – Inspection*, http://www.hse.gov.uk/foi/internalops/og/ogprocedures/inspection/index.htm.

Health and Safety Executive, Field Operations Division, *OC 130/6 - HSE enforcement policy statement*, http://www.hse.gov.uk/foi/internalops/ocs/100-199/130_6.htm.

Health and Safety Executive, Field Operations Division, *OC 130/5 - Enforcement management model (EMM): General guidance on application to health risks,* http://www.hse.gov.uk/foi/internalops/ocs/100-199/130_5/#When-to-use.

Health and Safety Executive, *Risk management: Principles and guidelines to assist HSE*, http://www.hse.gov.uk/risk/theory/alarp1.htm.

Health and Safety Executive, *OC 130/11 - Enforcement management model (EMM) application to ionising radiations*, http://www.hse.gov.uk/foi/internalops/ocs/100-199/130_11/index.htm.

Government of Canada, Canadian Food Inspection Agency, *2012–13 Estimates Part III — Report on Plans and Priorities*, http://www.tbs-sct.gc.ca/rpp/2012-2013/inst/ica/ica-eng.pdf.

Government of Canada, Parliament of Canada, *Meat Inspection Regulations, 1990*, http://laws-lois.justice.gc.ca/PDF/SOR-90-288.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Departmental Performance Report*, April 2007 – March 2008, http://www.tbs-sct.gc.ca/dpr-rmr/2007-2008/inst/csn/csn-eng.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Departmental Performance Report*, April 2008 – March 2009, http://www.tbs-sct.gc.ca/dpr-rmr/2007-2008/inst/csn/csn-eng.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Departmental Performance Report*, April 2009 – March 2010, http://www.tbs-sct.gc.ca/dpr-rmr/2008-2009/inst/csn/csn-eng.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Departmental Performance Report*, April 2010 – March 2011, http://www.tbs-sct.gc.ca/dpr-rmr/2010-2011/inst/csn/csn-eng.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Departmental Performance Report*, April 2011 – March 2012, http://www.nuclearsafety.gc.ca/eng/readingroom/reports/departmental/dpr-2011-2012/dpr.cfm.

Government of Canada, Canadian Nuclear Safety Commission, *Report on Plans and Priorities*, April 2007 – March 2008, http://www.tbs-sct.gc.ca/rpp/2007-2008/CNSC-CCSN/cnsc-ccsn-eng.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Report on Plans and Priorities*, April 2008 – March 2009, http://www.tbs-sct.gc.ca/rpp/2008-2009/inst/csn/csn-eng.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Report on Plans and Priorities*, April 2009 – March 2010, http://www.tbs-sct.gc.ca/rpp/2009-2010/inst/csn/csn-eng.pdf.

Government of Canada, Canadian Nuclear Safety Commission, *Report on Plans and Priorities*, April 2010 – March 2011, http://www.tbs-sct.gc.ca/rpp/2010-2011/inst/csn/csn-eng.pdf.

Government of Canada, *Class II Nuclear Facilities and Prescribed Equipment Regulations*, 2000, http://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-205/index.html.

Government of Canada, *General Nuclear Safety and Control Regulations*, 2000, http://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-202/index.html.
Government of Canada, *Nuclear Safety and Control Act*, 1997, http://laws.justice.gc.ca/PDF/N-28.3.pdf.

Government of Canada, *Nuclear Substances and Radiation Devices Regulations*, 2000, http://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-207/index.html.

Government of Canada, *Packaging and Transport of Nuclear Substances Regulations*, 2000, http://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-208/index.html.

Government of Canada, Parliament of Canada, *Meat Inspection Regulations, 1990*, http://laws-lois.justice.gc.ca/PDF/SOR-90-288.pdf.

Government of Canada, *Radiation Protection Regulations*, 2000, http://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-203.

Lui, C., M. Cunningham, G. Pangburn, and W. Rechley, *A Proposed Risk Management Regulatory Framework* (NUREG-2150), Washington D.C.: United Stated Nuclear Regulatory Commission, 2012, http://pbadupws.nrc.gov/docs/ML1210/ML12109A277.pdf.

State of Florida, Department of Health, Bureau of Radiation Control, *Radiation Control*, http://www.doh.state.fl.us/environment/radiation/index.html.

State of Florida, Department of Health, Bureau of Radiation Control, *Regulatory Guide 6.20, Revision 5: Radioactive Materials License Fees*, http://www.myfloridaeh.com/radiation/radmat/RegGuide6-20.doc.

State of Florida, Department of Health, Division of Emergency Preparedness and Community Support, "About," http://www.doh.state.fl.us/demo/index.html.

State of Florida, Department of Health, "Organizational Chart," http://www.doh.state.fl.us/Admin/HRM/DOHOrgChart.pdf.

State of Florida, Florida Legislature, *Florida Radiation Protection Act*, Public Health, Chapter 404 Radiation, http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0400-0499/0404/0404.html.

Government of Canada, *Nuclear Safety and Control Act 1997*, http://laws.justice.gc.ca/PDF/N-28.3.pdf.

Office for National Statistics, "UK Census," http://www.ons.gov.uk/ons/guide-method/census/2011/uk-census/index.html.

Office for National Statistics, "The countries of the UK," http://www.ons.gov.uk/ons/guide-method/geography/beginner-s-guide/administrative/the-countries-of-the-uk/index.html.

Office of Nuclear Regulation, "Office for Nuclear Regulation," http://www.hse.gov.uk/nuclear/operational/inspection/index.htm.

United Kingdom, Health and Safety Executive, *Annual Report and Accounts 2011/12*, http://www.hse.gov.uk/aboutus/reports/1112/ar1112.pdf.

United Kingdom, Care Quality Commission, *Ionising Radiation (Medical Exposure) Regulations 2000: A report on regulatory activity in 2011*, http://www.cqc.org.uk/sites/default/files/media/documents/20120202_irmer_annual_report_2011_final.pdf.

United Kingdom, Department for Work and Pensions, *Good Health and Safety, Good for Everyone: The next steps in the Government's plans for reform of the health and safety system in Britai*n, http://www.dwp.gov.uk/docs/good-health-and-safety.pdf.

United Kingdom, Health and Safety Executive, *Annual Report and Accounts 2011/12,* http://www.hse.gov.uk/aboutus/reports/1112/ar1112.pdf.

United Kingdom, Health and Safety Executive, *HSE Staffing by Division/Directorate,* http://www.hse.gov.uk/aboutus/reports/1011/staffing.htm.

United Kingdom, Health and Safety Executive, Field Operations Division, *OC 130/5 - Enforcement management model (EMM): General guidance on application to health risks,* http://www.hse.gov.uk/foi/internalops/ocs/100-199/130_5/#When-to-use.

United Kingdom, Health and Safety Executive, Field Operations Division, *OC 130/6 - HSE enforcement policy statement,* http://www.hse.gov.uk/foi/internalops/ocs/100-199/130_6.htm.

United Kingdom, Health and Safety Executive, Field Operations Division, *OC 130/11 - Enforcement management model (EMM) application to ionising radiations,* http://www.hse.gov.uk/foi/internalops/ocs/100-199/130_11/index.htm.

United Kingdom, Health and Safety Executive, Field Operations Division, *OC 560/49: Ionising radiations regulations 1999 - Industrial radiography: A guide to inspection,* http://www.hse.gov.uk/foi/internalops/ocs/500-599/560_49.htm#para.

United Kingdom, Health and Safety Executive, Field Operations Division, *OC 560/53: the Ionising Radiations Regulations 1999: Site Radiography 7-Day Notification and Waiver,* http://www.hse.gov.uk/foi/internalops/ocs/500-599/560_53.htm.

United Kingdom, Health and Safety Executive, *Operational Procedure – Inspection,* http://www.hse.gov.uk/foi/internalops/og/ogprocedures/inspection/index.htm.

United Kingdom, Health and Safety Executive, *Risk management: Principles and guidelines to assist HSE* http://www.hse.gov.uk/risk/theory/alarp1.htm.

United Kingdom, Office for National Statistics, *The countries of the UK,* http://www.ons.gov.uk/ons/guide-method/geography/beginner-s-guide/administrative/the-countries-of-the-uk/index.html.

United Kingdom, Health and Safety, *The Ionising Radiations Regulations 1999,* http://194.109.159.7/tna/20100803102923/http://legislation.gov.uk/uksi/1999/3232/made/data.pdf.

United Kingdom, Health and Safety Executive, *Work with ionising radiation - Ionising Radiations Regulations 1999: Approved Code of Practice and guidance,* 2000, http://www.hse.gov.uk/pubns/priced/l121.pdf.

United Kingdom, Office for National Statistics, *UK Census*, http://www.ons.gov.uk/ons/guide-method/census/2011/uk-census/index.html.

United Kingdom, Office of Nuclear Regulation, *Office for Nuclear Regulation*, http://www.hse.gov.uk/nuclear/operational/inspection/index.htm.

United States Nuclear Regulatory Commission, *Integrated Materials Performance Evaluation Program Review of the Florida Agreement State Program: March 28 – April 1, 2011*, http://nrc-stp.ornl.gov/reviews/11fl_imp.pdf.

United States Nuclear Regulatory Commission, Office of Enforcement, *NRC Enforcement Policy*, January 28, 2013, http://pbadupws.nrc.gov/docs/ML1234/ML12340A295.pdf.

United States Nuclear Regulatory Commission, *NRC Inspection Manual Chapter 2800: Materials Inspection Program*, November 15, 2010, http://www.nrc.gov/reading-rm/doc-collections/insp-manual/changenotices/2010/imc2800.doc.

Appendix E – Interview Questions

1) *Can you describe the objectives of DNSR's compliance verification program?*

2) *In your opinion, do you feel that roles and responsibilities of your Division are well defined?*

3) *Do you feel that roles and responsibilities are respected internally by staff and management?*

4) *Do you feel that DNSR compliance verification activities are understood by licensees?*

5) *How does compliance history impact verification planning? Provide examples.*

6) *Do you feel that DNSR has established its ability to effectively identify and prioritize compliance on a risk-informed basis? What tools and processes drive this ability / what tools and processes need to be improved?*

7) *In your Division, how are non-compliances issued from Type I and Type II inspections stored? How are they followed up? How are they closed?*

8) *Where annual reports on compliance identify a non-compliance issue, how does your Division incorporate this information into its risk-informed verification planning?*

9) *What mechanisms, if any, are taken to ensure inspections are conducted in a transparent manner to stakeholders? What aspects ensure inspections are transparent / are there areas that can be improved?*

10) *Do you feel that you understand the regulatory basis for conducting compliance verification? What challenges exist that affect your understanding / are there any scientific or technical guidance that will allow you to fulfill these activities?*

11) *Could you describe the key performance indicators used by your Division / Directorate? How are performance data used by DNSR managers and others? Are there documents that spell out the performance indicators, data collection and reporting process?*

12) *In your opinion, do you feel that the DNSR compliance verification program is efficient?*

13) *Do you feel it is effective? Demonstrate through examples.*

14) *Are there any alternatives ways in which DNSR could achieve the same objectives of compliance verification and increase efficiency?*

15) *Does your Division have tools and/or processes in place to share lessons learned and best practices internally?*

16) *Does your Division have tools and/or processes in place to share lessons learned and best practices externally?*

17) *In your opinion, are there any changes required to DNSR compliance verification activities?*

18) In your opinion, what is the most useful and significant impact of the DNSR compliance verification program?

Appendix F – Results from Survey

1. Take this survey in English or French / Prenez ce sondage en anglais ou francais

	English	French
NSRD Licensees	268	52
Class II Licensees	34	9
Total	302	61

2. How many years have you held, at least, one licence with the Canadian Nuclear Safety Commission?

	Less than 1 year	1-3 years	4-7 years	Greater than 7 years	I don't know
NSRD Licensees	0	21	22	271	2
Class II Licensees	0	6	3	34	0
Total	0	27	25	305	2

3. How many licences do you hold with the Canadian Nuclear Safety Commission?

	1 licence	2-5 licences	6-10 licences	More than 10 licences	I don't know
NSRD Licensees	198	107	11	6	0
Class II Licensees	16	20	4	3	0
Total	214	127	16	9	0

4. Has the Canadian Nuclear Safety Commission ever conducted an inspection of your NSRD/Class II licence?

	Yes	No	I don't know
NSRD Licensees	307	3	4
Class II Licensees	40	3	0
Total	347	6	4

5. In the past 5 years, how many times where you inspected?

	1 time	2-5 times	6-25 times	More than 25 times	I don't know
NSRD Licensees	11	204	62	13	4
Class II Licensees	11	21	5	2	0
Total	22	225	67	15	4

6. When was your last inspection?

	Less than 6 months ago	1-2 years ago	3-5 years ago	Greater than 5 years ago	I don't know
NSRD Licensees	133	167	4	0	1
Class II Licensees	12	21	5	1	0
Total	145	188	9	1	1

In summary, upon arriving on-site an inspector should include the following steps in the inspection:

(1) Conduct an opening discussion with licensee (introduce: inspectors, CNSC mandate, inspection process, proposed schedule)
(2) Collect inspection facts (monitor and observe: licensee performance and activities, records and other documents; conduct discussions with personnel; conduct sampling and measurement)
(3) Communicate potential and actual findings with licensee on-site
(4) *Provide a detailed inspection report to licensee*

7. Do you feel that your last inspection followed these steps?

	Yes	No	I don't know
NSRD Licensees	288	14	4
Class II Licensees	37	1	1
Total	325	15	5

8. Were any inspection steps not followed? Check all that apply.

	1.Conduct an opening discussion with the licensee	2.Collect inspection facts	3.Communicate potential and actual findings with licensee on-site	4.Provide detailed inspection report to licensee
NSRD Licensees	10	3	2	4
Class II Licensees	0	0	1	1
Total	10	3	3	5

9. Do you feel that any of the inspection steps are not transparent?

	Yes	No	I don't know
NSRD Licensees	18	278	9
Class II Licensees	3	33	3
Total	21	311	12

10. Were any inspection steps not transparent? Check all that apply.

	1.Conduct an opening discussion with the licensee	2.Collect inspection facts	3.Communicate potential and actual findings with licensee on-site	4.Provide detailed inspection report to licensee
NSRD Licensees	11	13	16	10
Class II Licensees	1	0	2	3
Total	12	13	18	13

11. On a scale of 1 to 5, where 1 is extremely efficient and 5 is extremely inefficient, how efficient is the Canadian Nuclear Safety Commission in conducting inspection work?

	Extremely efficient	Somewhat efficient	Neutral	Somewhat inefficient	Extremely inefficient	I don't know
NSRD Licensees	150	105	33	7	2	7
Class II Licensees	20	16	0	1	0	1
Total	170	121	33	8	2	8

12. Do you feel that you understand the applicable requirement included in your licence?

	Yes	No
NSRD Licensees	291	17
Class II Licensees	40	1
Total	331	18

13. Where do you usually access requirements and guidance applicable to your licence? Check all that apply.

	Online at CNSC website	CNSC staff have provided materials	Your licence	Canadian Radiation Protection Association or other organization	Third Party Consultant	Other (please specify)
NSRD Licensees	269	204	262	70	106	44
Class II Licensees	39	29	34	5	4	0
Total	308	233	296	75	110	44

As part of the Canadian Nuclear Safety Commission's regulation of nuclear substances and devices, all licensees are required to submit annual compliance reports.

Annual compliance reports collect various records such as dose summaries and inventories from licensees and provide assurance to the Canadian Nuclear Safety Commission that the licensee has met specific regulatory requirements and is maintaining control of licensed material and activities.

14. Have you ever submitted an annual compliance report on behalf of a licensee?

	Yes	No	I don't know
NSRD Licensees	295	12	0
Class II Licensees	40	1	0
Total	335	13	0

15. After submitting an annual compliance report, how have you been in contact with the Canadian Nuclear Safety Commission? Check all that apply.

	During an inspection	Phone-call	E-mail	You contacted the CNSC	Not in contact	I don't know	Other (please specify)
NSRD Licensees	119	103	199	66	27	6	0
Class II Licensees	9	17	26	10	4	1	2
Total	128	120	225	77	31	7	2

16. On a scale of 1 to 5, where 1 is extremely useful and 5 is not at all useful, how useful are annual compliance reports as a mechanism to aide in the regulation of your licensed activities?

	Extremely useful	Somewhat useful	Neutral	Somewhat not useful	Not at all useful	I don't know
NSRD Licensees	68	124	54	24	22	2
Class II Licensees	8	17	9	4	1	0
Total	76	141	63	28	23	2

17. On a scale of 1 to 5, where 1 is extremely efficient and 5 is extremely inefficient, how efficient is the Canadian Nuclear Safety Commission in collecting annual compliance reports from licensees?

	Extremely efficient	Somewhat efficient	Neutral	Somewhat inefficient	Extremely inefficient	I don't know
NSRD Licensees	111	78	49	13	1	40
Class II Licensees	14	15	5	2	0	4
Total	125	93	54	15	1	44

Appendix G – Compliance Program Data

Type II Inspection Grades (2007–08 to 2011–12)

Fiscal year	Measure	A	B	C	D	E
2007–08	#	5	7,717	942	445	150
	%	5%	83%	10%	5%	2%
2008–09	#	4	8,794	1,191	738	175
	%	3%	81%	11%	7%	2%
2009–10	#	7	8,337	1,095	468	79
	%	7%	83%	11%	5%	1%
2010–11	#	9	10,015	1,291	284	27
	%	7%	86%	11%	2%	0%
2011–2012	#	13	10,065	998	193	17
	%	11%	89%	9%	2%	0%

Licences Managed by the DNSR (2007–08 to 2011–12)

Year	Total licences
2008	2,966
2009	2,713
2010	2,622
2011	2,550
2012	2,513

Source: CNSC, March 2014, *Nuclear Substances in Canada: A Safety Performance Report for 2012*.

Total Type I and Type II Licences Inspected (2007–08 to 2012–13)

	2007–08	2008–09	2009–10	2010–11	2011–12	2012–13
Type II Inspections*	1,324	1,483	1,430	1,679	1,621	1,668
Type I Inspections*	67	32	70	39	33	25
Annual Compliance Reports (ACRs) – desktop reviews	2,263	1,424	641	2,660	3,222	1,986

*Number of licences inspected (not the number of inspections, as one or more licences can be part of a single inspection).

(Page intentionally blank for printing purposes)