



# Audit of Compliance Enforcement

Office of Audit and Ethics

*Recommended by the Audit Committee on January 25, 2011 for approval by the President*

*Approved by the President on April 15, 2011*

January 25, 2011



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## **Executive Summary**

The Audit Committee approved the audit of compliance enforcement as part of the Office of Audit and Ethics *Risk-Based Audit Plan 2009-2010 to 2011-2012*. Within this plan, other parts of the Canadian Nuclear Safety Commission's (CNSC) compliance framework, such as licensing and verification, are planned for future years.

Assuring compliance with legislation, regulations and licensing requirement is one of the CNSC's core business processes and is carried out through promotion (now referred to as clarity of requirements), verification and enforcement.

The CNSC defines enforcement as any action taken by its inspection staff after an inspection or other compliance action has been conducted and deficiencies have been identified. Enforcement actions are designed to restore compliance with the *Nuclear Safety and Control Act* (NSCA), regulations, licence conditions, etc.

### **Objective**

The objective of the audit was to assure the CNSC has established a comprehensive and effective control framework and compliance with the NSCA and regulations and/or the conditions of licences issued by the Commission Tribunal.

### **Scope**

The audit examined the management framework supporting enforcement activities (including procedures, tools, risk management activities, guidance and training of inspectors) and enforcement actions by CNSC inspection staff (a sample of enforcement actions was examined to ensure that policies and procedures were followed).

The examination phase of the audit was conducted between January and May 2010. The findings and conclusions are based on a comparison of the conditions that existed as of April 2010 and an analysis of the enforcement actions taken between April 1, 2008 and March 31, 2009.

### **Approach**

The audit approach included interviews with senior managers and staff, and reviews of relevant documents, policies and procedures, and files.

An advisory panel of CNSC technical experts was established to advise the audit team on matters related to enforcement activities and related program issues.

The audit was conducted in accordance with internal auditing standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing.<sup>1</sup>

## **Overall conclusions**

The audit focused on:

- 1) the framework of management controls for enforcement activities
- 2) the compliance of enforcement actions with requirements of the NSCA and the established CNSC policies, procedures and guidelines
- 3) the effectiveness of enforcement actions in resolving non-compliance issues

A summary of the findings is presented below:

### Framework of management controls

The audit found that an enforcement framework of management controls, (i.e. policies, procedures, standards and guidance and training to inspectors) is in place.

Areas for improvement include:

- implementing measures to demonstrate the effectiveness of enforcement actions in resolving non-compliance issues
- continued investment in and support of the action tracking initiative and ensuring the new system supports the measurement of the effectiveness of compliance enforcement activities

### Compliance of enforcement action with legislation, CNSC policies, procedures and guidelines

The audit found that enforcement actions taken by CNSC staff complied with the requirements of the NSCA, the CNSC's *Regulatory Policy on Compliance* (P-211) and other procedures and guidelines.

Areas for improvement include:

- improving documentation practices to ensure information used for evidentiary and archival purposes is complete and accessible

### Effectiveness of enforcement actions

The audit found that enforcement actions taken by inspection staff were effective in resolving the non-compliance issues raised. This conclusion is based on an

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<sup>1</sup> This audit was conducted in accordance with the International Standards for the Professional Practice of Internal Auditing. However, the Office of Audit and Ethics of the CNSC has not undergone an external assessment at least once in the past five years or been subject to ongoing monitoring or to periodic internal assessments of its internal audit activities that would confirm its compliance with the standards.

examination of 846 enforcement actions (please refer to sections 1.2 and 1.3 for an explanation of “enforcement actions” in the context of this audit.

Areas for improvement include:

- implementing measures to demonstrate the effectiveness of enforcement actions in resolving non-compliance issues

Recommendations addressing the areas of improvement noted for each line of audit enquiry are contained in the appropriate section of this audit report.

# 1 Background

The Canadian Nuclear Safety Commission (CNSC) regulates the nuclear industry in Canada under the authority of the *Nuclear Safety and Control Act* (NSCA). The CNSC regulates the use of nuclear energy and materials to protect health, safety and security of Canadians and the environment, and to implement Canada's international commitments on the peaceful use of nuclear energy.

The nuclear industry encompasses nuclear power plants, uranium mines and mills, research reactors, fuel cycle facilities, and medical, academic and industrial applications.

The authority to use nuclear materials or energy is given only to applicants that meet the licensing requirements of the CNSC. Licence conditions include responsibility for safety, control, supervision, and licensee compliance.

The CNSC's Regulatory Operations Branch (ROB) is responsible for licensing and assuring compliance. ROB comprises three directorates which regulate different segments of the nuclear industry:

1. The Directorate of Power Reactor Regulation (DPRR) is responsible for oversight of nuclear power reactors.
2. The Directorate of Nuclear Cycle and Facilities Regulation (DNCFR) is responsible for oversight of uranium mining and processing facilities, nuclear substance processing facilities, waste management facilities, non-power reactors, research and test facilities, and Class I accelerators.
3. The Directorate of Nuclear Substances Regulation (DNSR) is responsible for the production, possession, transport and use of nuclear substances and radiation devices for educational, industrial and medical applications.

## 1.1 Licensing

There are several stages in the lifecycle of nuclear facilities. Specific licences must be obtained from the CNSC for site preparation, construction, operation, decommissioning or abandonment of a nuclear facility. The CNSC requires similar licences for the possession, use, transport or storage of nuclear substances.

## 1.2 Assuring compliance

A licensee must meet the requirements of the NSCA, as well as any associated regulations and conditions of their specific licence, to be considered in compliance. Non-compliance occurs when the licensee contravenes these conditions or from non-

conformity with any policies, procedures, standards, etc. related to a regulatory requirement.

The CNSC carries out various activities to support compliance with regulations and related requirements. These compliance activities include:

- promotion (now referred to as clarity of requirements) – encouragement of voluntary adherence to regulatory requirements through information exchange
- verification – inspections and other oversight functions that verify a licensee's activities are properly conducted, including planned Type I inspections (detailed audits), Type II inspections (routine inspections), assessments of information submitted by the licensee to demonstrate compliance, and other unplanned inspections in response to special circumstances or events
- enforcement – actions the CNSC takes to encourage and/or compel licensees or persons to comply with regulatory requirements, with enforcement action taken depending on the severity of the non-compliance

The audit focused on enforcement activities, the details of which are described below.

### **1.3 Enforcement actions**

For non-compliance issues, the enforcement actions available to the CNSC inspection staff range from issuing a written notice up to and including legal prosecution.

The most commonly used tools are written notices which include:

- recommendations – suggestions for improvement to practices
- action notices – requests to resolve safety and security concerns
- directives – official requirements for licensees to address issues of non-compliance

If the written notices do not produce an appropriate outcome, more vigorous enforcement tools can be used. For a detailed description of the enforcement actions available, please see Appendix D.

Most enforcement actions are taken following inspections. Upon the completion of an inspection, a report is given to the licensee which includes any non-compliance issues identified during the inspection, the type of actions required to address these issues, and a timeframe to resolve them.

The licensee must respond to each actionable issue. The issue is considered closed only when the CNSC is satisfied that the action taken by the licensee has properly addressed the non-compliance.

## **2 About the Audit**

The Audit Committee approved the audit of the CNSC compliance enforcement framework as part of the Office of Audit and Ethics *Risk-Based Audit Plan 2009-2010 to 2011-2012*.

### **2.1 Objective**

The objective of the audit was to provide assurance that the CNSC has established a comprehensive and effective control framework to enforce compliance with the NSCA, its associated regulations, and the licence conditions issued by the Commission Tribunal.

### **2.2 Scope**

The audit focused on three lines of audit enquiry:

1. Has a comprehensive framework of management controls for enforcement activities been established?
2. Are enforcement actions conducted consistently and in accordance with requirements of the NSCA and established CNSC policies, procedures and guidelines?
3. Are enforcement actions effective?

In addition to management systems and controls, the audit examined a sample of enforcement actions undertaken between April 1, 2008 and March 31, 2009. The enforcement actions tested were selected from a series of inspections completed during that period. A sample of inspections was selected based on an assessment of the risk associated with the type of licensee regulated by each directorate.

Other aspects of compliance, licensing processes, compliance verification (inspection) and reporting processes will be the subject of future audits, which are currently planned for 2011-2012. The audit did not examine the export and import of risk-significant radioactive sealed sources as this was the subject of another recent internal audit entitled, *Audit of Sealed Sources Controls*.

The examination phase of the audit was conducted between January and May 2010. The audit findings and conclusions are based on a comparison of the conditions that existed as of May 2010 with pre-established audit criteria.

## **2.3 Audit criteria**

Audit criteria for management controls were derived from the Office of the Comptroller General's *Core Management Controls: A Guide for Internal Auditors* and the Committee of Sponsoring Organizations (COSO) Internal Control and Enterprise Risk Management frameworks.

The criteria used to assess the compliance of enforcement actions with the CNSC regulatory framework are based on the NSCA and its associated regulations, and CNSC policies, procedures and related standards. The audit criteria are presented in Appendix B.

## **2.4 Approach and methodology**

Audit methodology included:

- interviews with managers and staff
- reviews of relevant documents including legislation, regulation, policies and processes, procedures, documented controls, documented enforcement activities, and performance information
- file reviews

An advisory panel of technical experts was established to serve as a forum for the audit team to obtain information and advice on audit coverage and significant issues. The advisory panel was comprised of three directors – one from each directorate. The members of the advisory panel were selected by the Executive Vice-President and Chief Regulatory Operations Officer, Regulatory Operations Branch and the Chief Audit Executive.

The audit was conducted in accordance with internal auditing standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing.<sup>2</sup>

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### 3 Audit Results

The audit results are presented by the three lines of audit enquiry:

- 3.1 existence of a management framework
- 3.2 compliance of enforcement actions with requirements of the NSCA and established CNSC policies, procedures and guidelines.
- 3.3 effectiveness of enforcement actions

#### 3.1 Management framework

The first line of audit enquiry was to determine if a comprehensive framework of management controls for enforcement activities had been established.

**Line of Audit Enquiry 1:** Has a comprehensive framework of management controls for enforcement activities been established?

Criteria 1: Are operational plans and objectives for enforcement activities in place?

The audit found that enforcement activities are one part of the “assure compliance” program activity. Enforcement activities are tied to inspection activity planning. Resource requirements are projected based on historical information. Performance objectives for enforcement activities are included in the overall compliance planning process.

We conclude that operational plans and objectives for enforcement activities are in place.

Criteria 2: Are enforcement policies, procedures, standards and tools established, communicated and practised?

The audit found that the CNSC, under the authority of the NSCA, issued a regulatory policy on compliance (P-211) which establishes the philosophy, principles and fundamental factors related to its compliance program. In 2009, the *Select and Apply Enforcement Tools* guide, which defines the enforcement process and tools, was issued to CNSC staff. The guide covers the complete spectrum of enforcement actions available to the CNSC, from written notices up to and including prosecution under the applicable legislation.

In addition, the Directorate of Nuclear Substances Regulation (DNSR) *Compliance Enforcement Framework* (May 2003) provides guidance to DNSR staff on the evaluation of non-compliance events and on the determination of appropriate compliance enforcement actions to be taken. The enforcement matrix in Appendix 2 of the framework provides guidance on the enforcement actions to be taken based on the risk associated with the non-compliance.

The Directorate of Power Reactor Regulation (DPRR) *Power Reactor Regulatory Compliance Process* (February 2008) also provides guidance on enforcement specifically related to power reactors. The enforcement matrix listed in Appendix D to the Process describes the enforcement actions that can be taken, based on the risks associated with the non-compliance.

The staff of the Directorate of Nuclear Cycle and Facilities Regulation also follows Appendix D of the DPRR *Power Reactor Regulatory Compliance Process* enforcement matrix when determining enforcement actions.

Several methods are used for sharing this information with staff, including inspector training (as discussed in 3.1.4), email notices, newsletter articles, intranet postings, and information items at staff meetings. Awareness sessions/presentations are also held on occasion.

We conclude that enforcement policies, procedures, standards and tools established are communicated and practiced.

Criteria 3: Is the authority, responsibilities and accountabilities for enforcement activities formally defined, communicated and understood/assigned?

The NSCA establishes the authority for the CNSC to carry out compliance activities and functions. The Select and Apply Enforcement Tools regulatory guide outlines enforcement responsibilities and authorities for the CNSC staff, inspectors, directors, directors general, designated officers and lead investigators.

The authority, responsibilities and accountability of CNSC staff is communicated through:

- the CNSC inspector training programs
- the CNSC management system manual published on the intranet
- through staff meetings

The authority to exercise the powers and responsibilities under the NSCA with respect to compliance enforcement is assigned to inspector and designated officer positions.

An inspector is designated under the NSCA based on the recommendation of a designated officer. Once issued to the inspector, the inspector certificate is valid for a period of five years.

We conclude that the authority, responsibilities and accountabilities for enforcement activities are formally defined and communicated.

Criteria 4: Are guidance and training in enforcement techniques provided to employees?

The inspector is the key staff member responsible for applying the enforcement approach and selecting the appropriate enforcement technique. Therefore, our focus was on the level of training on enforcement techniques provided to inspectors. Enforcement techniques are designed to facilitate the return to compliance by the licensee when a non-compliance event occurs. The use of a graduated enforcement approach based on risk significance is initiated when compliance is found to be unsatisfactory.

CNSC inspectors are designated under the NSCA once they have attained the requisite knowledge – through completion of the required training and demonstration that they are qualified to be designated. Each candidate inspector participates as a trainee in a number of inspections as part of their training and development. The training on enforcement techniques is included in the overall inspector training process. The inspector designation process was not audited.

In June 2009, a new CNSC inspector training and qualification program was introduced. This program formalized many of the existing training practices and identified gaps where new courses were required. One of these was a new core enforcement process course, which was initially offered in the fall of 2010 as part of the “conduct inspection” initiative under the Harmonized Plan<sup>3</sup> (HP).

We conclude that guidance and training in enforcement techniques is provided to employees.

Criteria 5: Is there a documented approach to risk management in place?

The NSCA and its associated regulations define the responsibilities of the CNSC for managing risks in the public interest. The 2005 CNSC regulatory policy *P-299, Regulatory Fundamentals*, describes the principles that govern the CNSC’s approach to regulating the nuclear industry. This policy specifically refers to regulation of persons, organizations and activities in a manner that is consistent with the risk posed by their activity.

<sup>3</sup> The Harmonized Plan for Improvement Initiatives (HP) is a corporate, client-driven, improvement plan that integrates and aligns all cross-functional the CNSC improvement initiatives into a single prioritized plan.

In 2009, the Integrated Regulatory Review Service of the International Atomic Energy Agency<sup>4</sup> (IAEA) completed a review of the CNSC regulatory practices. In their report, they recognized the development and implementation of the CNSC risk-informed decision-making process (RIDM) and tools as good practice. The RIDM process is consistent with the Canadian Standards Association's *Risk Management Guideline* (CAN/CSA-Q850).

The RIDM process is used to assess the safety significance of inspection findings with prescribed enforcement measures based on safety significance and risk. All three directorates have implemented a risk-informed decision-making methodology for dealing with regulatory decisions.

Staff also use a risk-informed decision-making process when determining the type of enforcement action needed to resolve non-compliance events. This process is defined in the Select and Apply Enforcement Tools guide.

A corporate central registry (action tracking tool) of regulatory actions, risk significance and regulatory priority is being developed under the HP initiative. This tool will capture and track licensing and compliance commitments, conditions and actions across all directorates. The data gathered in the tracking tool core will serve as the foundation for completion of the Regulatory Information Bank project, which will provide enhanced information for decision making.

We conclude that a documented approach to risk management is in place.

**Criteria 6: Is there a framework for measuring, monitoring and reporting on enforcement activities?**

As mentioned earlier, enforcement activities are included in plans and budgets for compliance program activities. Since enforcement activities are a result of other compliance assurance activities, they are not necessarily predictable or quantifiable for planning purposes. Resource requirements are estimated based on historical data and the known ongoing workload carried forward from planning period to planning period. Management had not established specific objectives or performance indicators that can be used to evaluate the effectiveness or efficiency of enforcement activities.

Each directorate has its own approach to ensuring the quality and consistency of enforcement actions taken in response to non-compliance findings. This is accomplished through peer or management reviews of inspection reports and the subsequent actions taken to resolve non-compliance issues. The resolution of non-compliance issues is monitored by each directorate as part of its ongoing compliance enforcement activities.

<sup>4</sup> The IAEA is the world's centre of cooperation in the nuclear field. It was set up as the world's *Atoms for Peace* organization in 1957 within the United Nations family. The Agency works with its member states and multiple partners worldwide to promote safe, secure and peaceful nuclear technologies.

At the time of the audit, different systems were being used to track enforcement activities. Each directorate addressed its need to track and manage inspection findings and related enforcement actions through the use of existing systems, the development of new databases or spreadsheets, and other simple tools.

Similarly, enforcement activities are reported in a variety of ways in each directorate.

When the audit work was completed in May 2010, a CNSC-wide system for capturing, monitoring and reporting on compliance commitments and actions was not yet put in place. The need for such a system was being addressed as part of the CNSC Harmonized Plan. The action tracking tool component of the Regulatory Information Bank project should provide the capability to capture and track actions and compliance commitments. The first phase of the system development initiative was implemented in July 2010. Once completed, the new system is expected to meet the needs of the CNSC with respect to capturing, monitoring and reporting the various licensing and compliance commitments, conditions and actions.

We conclude that there is a framework for measuring, monitoring and reporting on enforcement activities.

### **Conclusion – management framework**

An overall framework of management controls for enforcement activities is in place. Areas that could be improved include establishing objectives and indicators to demonstrate the effectiveness of enforcement actions in resolving non-compliance events. In support of this, improved activity tracking, monitoring and reporting are required.

### **Recommendations**

It is recommended that CNSC management:

- 1) implement measures to demonstrate the effectiveness of enforcement actions in resolving non-compliance issues
- 2) continue to invest and support the action tracking initiative and ensure the new system supports the measurement of the effectiveness of compliance enforcement activities

### **Management response**

1) The recommendation is accepted and action is already underway. Director-level leadership committees have been created for the major facilities that will permit increased oversight of enforcement actions. The action tracking tool (see response 2 below) will provide better information to these committees to assess the effectiveness of compliance enforcement actions. This tool will be in place by the end of 2011.

2) The action tracking initiative remains a management priority under the Harmonized Plan. The tracking tool will allow management to assess the effectiveness of compliance enforcement activities. Piloted in the fall of 2010, it will be rolled out for testing to all staff by the end of the first quarter of 2011.

### **3.2 Compliance of enforcement actions**

The second line of audit enquiry was to determine if enforcement actions are conducted in accordance with the NSCA and established CNSC policies, procedures and guidelines.

An enforcement action is taken by CNSC staff to encourage and/or compel licensees or persons to comply with regulatory requirements. The type of enforcement action taken depends on the significance of the non-compliance.

The type of enforcement action required by CNSC policies and procedures is determined by an assessment of the significance of the non-compliance in terms of its consequences to the environment, health, safety, security and legal obligations.

Enforcement techniques range from discussion/meetings, letters, written notices and orders up to and including prosecution. The complete set of enforcement tools available to CNSC staff is described in Appendix D. The most commonly used technique is the written notice, which includes recommendations, action notices and directives.

There are three types of written notices:

- recommendations – these are suggestions to effect improvement based on good industry practice and are not subject to enforcement
- action notices – are requests to the licensee to correct a non-compliance that can compromise safety, security or the environment
- directives – require the licensee to take action to correct a non-compliance with governing regulations, license conditions, codes, standards or to address a sustained failure by meeting its own standards for achieving licence requirements

#### **Testing approach**

In the audit, a sample of inspection reports conducted by CNSC inspector staff was examined in each of the three directorates between April 2008 and March 2009. The sample size for each directorate was determined based on an assessment of the risk of non-compliance.

From the review of the selected inspection files, the resulting enforcement actions were identified and tested to determine if the key requirements of the CNSC policies, procedures and guidelines were followed.

The file review focused on the actions the CNSC took to regulate the issues reported as a result of Type I<sup>5</sup> and Type II<sup>6</sup> inspections.

We examined the inspection reports and subsequent actions taken to determine if enforcement actions were consistent and in accordance with CNSC policies and if the process complied with CNSC guidelines.

### **Enforcement criteria**

The main enforcement criteria were derived from the CNSC's Select and Apply Enforcement Tools guide. These are:

- The selected enforcement actions must be based on both the significance of the non-compliance and the level of enforcement activity that may be required to resolve the issue.
- All information regarding enforcement is filed in the licensee file and in the CNSC electronic records management system for evidentiary and archival purposes, including:
  - notes of discussions and meetings held with the licensee
  - compliance promotion (clarity of requirements) or informational letters
  - written reports with findings, enforcement action and response due date together with:
    - a copy of a hand-written report (external report) that is left with the licensee immediately upon completion of the inspection
    - an official inspection report signed by the appropriate CNSC authority
  - letters or other documents showing the actions planned by the licensee in response to the findings
  - letter(s) to the licensee confirming the CNSC's acceptance of remedial action and, ultimately closure of the action item

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<sup>5</sup> Type I inspections are systematic, planned and documented processes to determine whether a licensee program, process or practice complies with regulatory requirements.

<sup>6</sup> Type II inspections are planned and documented activities to verify the results of licensee processes and not the processes themselves. They are typically routine inspections of specified equipment, facility material systems or of discrete records, products or outputs from licensee processes.

**Line of Audit Enquiry 2:** Are enforcement actions conducted consistently and in accordance with requirements of the NSCA and established CNSC policies, procedures and guidelines?

**Test results**

**Directorate of Nuclear Substance Regulation**

The Directorate of Nuclear Substance Regulation (DNSR) oversees regulatory compliance in the production, possession, transport and use of nuclear substances and radiation devices for educational, industrial and medical applications.

During the period sampled, DNSR conducted 13 Type I inspections. From this population, a sample of four reports was examined. These four reports contained 30 written notices. Notices included recommendations (suggestions to improve practices), action notices (requests to correct safety or security issues) and directives (request to take action to correct a non-compliance issue).

INSPECTIONS			WRITTEN NOTICES		
Type	2008-2009	Sample	Recommendations	Action Notices	Directives
Type I	13	4	21	2	7
Total			30		

During the period sampled, the DNSR conducted 1,370 Type II inspections. From this population, a sample of 30 reports was examined. The sample selection was based on the risk associated with safety control areas (SCA). Each safety area is graded A to E, with grades C, D and E requiring action by the licensee. These are generally associated with written notices. Our sample examined areas graded only with a C, D or E.

INSPECTIONS			SCA grades C-D-E
Type	2008-2009	Sample	
Type II	1,370	30	595

The audit found the enforcement actions taken complied with the requirements of the NSCA and CNSC policies, procedures and guidelines.

The audit team identified an opportunity to improve the documentation practices followed to ensure the information used for evidentiary and archival purposes is complete and accessible. For example, in one instance the letter to the licensee confirming acceptance of remedial action was not on file. As well, the scanned copies of several of the handwritten inspection reports were illegible.

**Directorate of Nuclear Cycle and Facilities Regulation**

The mandate of the Directorate of Nuclear Cycle and Facilities Regulation (DNCFR) is to oversee regulatory compliance in the operation of uranium mining and processing facilities, nuclear substance processing facilities, waste management facilities, non-power reactors, research and test facilities, and Class I accelerators.

During the period sampled, the directorate conducted eight Type I and 128 Type II inspections. From this population, four Type I and nine Type II reports were examined. In these 13 reports, there were a total of 93 issues that required action. In all instances, the enforcement tool used was a written notice.

INSPECTIONS			WRITTEN NOTICES		
Type	2008-2009	Sample	Recommendations	Action Notices	Directives
Type I	8	4	13	15	5
Type II	128	9	13	20	27
Total	136	13	26	35	32
Total			93		

The audit found the enforcement actions taken complied with the requirements of the NSCA and CNSC policies, procedures and guidelines.

Again, the audit team identified that there is an opportunity to improve the documentation practices being followed to ensure information used for evidentiary and archival purposes is complete and accessible. For example, out of the 13 inspection reports we examined, we found:

- four reports did not have copies of the letters sent to the licensee confirming acceptance of remedial action
- six reports did not have notes of discussions and meetings held with the licensee

**Directorate of Power Reactor Regulation**

The mandate of the Directorate of Power Reactor Regulation (DPRR) is to oversee regulatory compliance at nuclear power reactors in Canada.

The audit team examined a sample of four inspection reports from a total of six Type I and 155 Type II inspection reports completed from April 2008 to March 2009. The sample included one report from each of the Bruce, Pickering, Gentilly and Point Lepreau facilities. The four reports contained 128 written notices, some of which required action by the licensee.

INSPECTIONS		WRITTEN NOTICES			
Type	2008-2009	Sample	Recommendations	Action Notices	Directives
Type I	6	1	7	7	0
Type II	155	3	54	53	7
Total	161	4	61	60	7
		Total	128		

We found the enforcement actions taken complied with the requirements of the NSCA and CNSC policies, procedures and guidelines.

Again, there is an opportunity to improve the documentation practices being followed as a way to ensure information used for evidentiary and archival purposes is complete and accessible.

**Conclusion – compliance of enforcement actions**

Overall, the enforcement actions taken comply with the requirements of the NSCA and CNSC policies, procedures and guidelines in force at the time.

The *Select and Apply Enforcement Tools* guide requires that all information regarding enforcement be filed in the licensee file and in the CNSC electronic records management system for evidentiary and archival purposes. In our review of the sample for each area, we found a few instances where this was not the case. For example, the electronic scanned copy of the handwritten inspection report was not always legible even though the paper copy on file was legible.

Therefore, there is an opportunity to improve documentation practices to ensure information used to support the decisions taken and the successful resolution of issues is complete and accessible.

**Recommendations**

It is recommended that:

- 3) the Regulatory Operations Branch (ROB) review the current procedures and processes for documenting the results of inspections, along with the related enforcement actions and their disposition, to ensure all supporting evidence is properly filed and available for future reference

**Management response**

3) The recommendation is accepted and action has already been taken. As part of the Harmonized Plan (HP) initiative on inspector training, a decision was made to have all Type 1 inspections led by a designated inspector for the facility/activity. This means that

most inspections are to be done by full-time inspectors. The procedure for Type 1 inspections is being updated to reflect this change and the importance of proper documentation is being strengthened in the procedures.

Further, an HP initiative on “conduct of inspections” is underway with the goal of developing common processes on inspections. The initiative includes a review of current procedures and will provide clear guidance to inspections on proper documentation of inspection results. This guidance is targeted for completion in September 2011.

In addition, ROB and the Corporate Services Branch (ITSB) are evaluating the use of electronic instruments such as tablets, where electronic copies of the inspection report will be generated, thereby reducing the scanning of handwritten reports to be filed.

### **3.3 Effectiveness of enforcement actions**

**Line of Audit Enquiry 3: Are enforcement actions effective?**

Enforcement is one component of the CNSC compliance program and was put in place to ensure licensees exhibit a high level of compliance with the CNSC regulatory framework. Enforcement comes into play where compliance is unsatisfactory.

The CNSC uses a graduated enforcement approach, based on risk, to ensure the effective and timely response and accountability for addressing non-compliance issues. The expectation is that this approach will result in a timely correction of identified deficiencies.

In our examination of 51 inspection reports selected from all three directorates, we found that all 846 issues raised were resolved through use of written notices.

We also found that, in all but two cases, the issues were resolved within the timeframe specified in the inspection report. These two cases were eventually resolved to the CNSC’s satisfaction.

<b>INSPECTIONS</b>		<b>SAMPLE</b>	<b>WRITTEN NOTICES ISSUED</b>
Type	2008-2009		
Type I	27	9	77
Type II	1,653	42	769
<b>Total</b>	<b>1,680</b>	<b>51</b>	<b>846</b>

## **Conclusion – effectiveness of enforcement actions**

Based on the results of the tests conducted on our audit sample, the enforcement actions that CNSC inspection staff took were effective in resolving the non-compliance issues raised in the inspection reports.

However, given the risk and number of enforcement actions, a system to monitor or follow up on a regular basis would provide better oversight and a higher level of compliance assurance. This issue was addressed in the recommendations made under section 3.1 of this report.

## **4 Conclusion**

### **Management framework**

The audit found that an overall framework of management controls for enforcement activities is in place. The areas that could be improved include establishing objectives and indicators to measure the effectiveness of enforcement actions in resolving non-compliance events. There is no system in place to allow for regular tracking and reporting on the effectiveness of enforcement actions in achieving the performance objectives of the “assure compliance” activity of the CNSC compliance program.

It is recommended that:

1. management implement measures that would demonstrate the effectiveness of enforcement actions in resolving non-compliance issues
2. the CNSC continue to invest in and support the action tracking initiative and ensure that the new system supports the measurement of the effectiveness of compliance enforcement activities

### **Compliance of enforcement actions**

The audit found that enforcement actions complied with the requirements of the NSCA and CNSC policies, procedures and guidelines in force at the time of the audit. There is an opportunity to improve the documentation of information that supports the resolution of issues and to ensure that it is complete and accessible by staff.

It is recommended that:

3. the Regulatory Operations Branch review the current procedures and processes for documenting the results on inspections, the related enforcement actions and their disposition, and ensure all supporting evidence is properly filed and available for future reference

### **Effectiveness of enforcement actions**

Based on the results of tests conducted on our audit sample, the enforcement actions taken by CNSC inspection staff were effective in resolving the non-compliance issues raised in the inspection reports.

A system to monitor regular enforcement activities would provide a higher level of assurance that these activities are achieving the performance objectives of the “assure compliance” activity of the CNSC compliance program.

This issue is addressed in recommendations 1 and 2 above.

## Appendix A – Recommendations and Management Action Plan

### Management Framework

<p><b>Recommendation:</b> Management should implement measures to demonstrate the effectiveness of enforcement actions in resolving non-compliance issues.</p>		
Unit Responsible	Management Action Plan (MAP)	Timeline
	<p>Director-level leadership committees have been created for the major facilities to permit increased oversight of enforcement actions. The action tracking tool (see response B) below) will provide better information to these committees to assess the effectiveness of compliance enforcement actions. The tracking tool was piloted in the fall of 2010 and will be rolled out to all staff by the end of the first quarter of 2011.</p>	<p><b>This item of the action plan has been completed</b></p>

**Recommendation:** The CNSC should continue to invest in and support the action tracking initiative and ensure that the new system supports the measurement of the effectiveness of compliance enforcement activities.

Unit Responsible	Management Action Plan (MAP)	Timeline
	The action tracking initiative remains a management priority under the Harmonized Plan. The tracking tool will allow management to assess the effectiveness of compliance enforcement activities. The tracking tool was piloted in the fall of 2010 and will be rolled out for testing to all staff by the end of March 2011.	<b>March 31, 2011</b>

**Recommendation:** The Regulatory Operations Branch (ROB) should review the current procedures and processes for documenting the results on inspections, the related enforcement actions and their disposition, and ensure all supporting evidence is properly filed and available for future reference.

Unit Responsible	Management Action Plan (MAP)	Timeline
	As part of the Harmonized Plan (HP) initiative on inspector training, a decision was made to have all Type 1 inspections led by a designated inspector for the facility/activity. This means most inspections are to be done by full-time inspectors. The procedure for Type 1 inspections is being updated to reflect this change and the importance of proper documentation is being strengthened in the procedures.	<b>This item of the action plan has been completed</b>
	Further, an HP initiative on conduct of inspections is underway with the goal of developing common processes for inspections. The initiative includes a review of current procedures and will provide clear guidance to inspections on proper documentation of inspection results. This guidance is targeted for completion in	<b>September 30, 2011</b>

	<p>September 2011.</p> <p>In addition, ROB and the Corporate Services Branch (ITSB) are evaluating the use of electronic instruments such as tablets where electronic copies of the inspection report will be generated, thereby reducing the scanning of handwritten reports to be filed.</p>	<p><b>January 31, 2012</b></p>
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## **Appendix B – Audit Criteria**

Line of Audit Enquiry # 1 – Has a comprehensive framework of management controls for enforcement activities been established?

1. Are operational plans and objectives for enforcement activities in place?
2. Are enforcement policies, procedures, standards and tools established, communicated and practised?
3. Is the authority, responsibilities and accountabilities for enforcement activities formally defined, communicated and understood/assigned?
4. Are guidance and training in enforcement techniques provided to employees?
5. Is there a documented approach to risk management in place?
6. Is there a framework for measuring, monitoring and reporting on enforcement activities?

Line of Audit Enquiry # 2 – Are enforcement actions conducted consistently and in accordance with requirements of the NSCA and established CNSC policies, procedures and guidelines?

1. Do enforcement actions conform to the requirements and regulations of the NSCA and to established CNSC policies, procedures and guidelines?
2. As specified in regulatory policy P-211, are enforcement actions conducted consistently within each of the three service lines – the Directorate of Power Reactor Regulation, the Directorate of Nuclear Cycle and Facilities Regulation and the Directorate of Nuclear Substances Regulation?

Line of Audit Enquiry # 3 – Are enforcement actions effective?

1. Do enforcement actions cause licensees or other persons to comply with the NSCA and regulations, licence conditions and orders issued under the NSCA?
2. Do enforcement actions lead to the timely resolution of instances of non-compliance?

## Appendix C – Glossary of Terms

ATT (Action Tracking Tool)	Web-based application (.Net) designed as a central repository to track and report on regulatory action items.
Compliance	Conformity by regulated persons with the requirements of the <i>Nuclear Safety and Control Act</i> (NSCA), the CNSC regulations, licences, decisions, certificates and orders made under the NSCA.
Enforcement	All activities necessary to compel a licensee to resume compliance and to avoid further non-compliance with the NSCA and CNSC regulations, licences, decisions, certificates and orders made under the NSCA.
Non-compliance	A contravention of the NSCA and CNSC regulations, licences, decisions, certificates and orders made under the NSCA. Non-compliance may result from a direct contravention of a regulatory requirement or from non-conformity with the compliance criteria of the policies, procedures, standards, instructions etc. established in support of the regulatory requirement.
Regulatory Policy on Compliance P-211	A regulatory policy which describes the basic principles and directives for establishing and conducting the Canadian Nuclear Safety Commission (CNSC) compliance program. The program is aimed at securing compliance by licensees to regulatory requirements made under the <i>Nuclear Safety and Control Act</i> .
Type I inspection	A systematic, planned and documented process to determine, through objective evidence, whether a licensee program, process or practice complies with the regulatory requirements as expressed in the compliance criteria associated with the inspection. Audits and evaluations are synonyms for Type I inspections.
Type II inspection	A planned and documented activity to verify the results of licensee processes and not the processes themselves. They are typically routine (item-by-item) inspections and rounds, usually of specified equipment, facility material systems, or discrete records, products or outputs from licensee processes.

## **Appendix D – Enforcement Tools**

### **Written notices**

- **Recommendation:** A written suggestion to effect an improvement based on good industry practice. A recommendation is not an indication of non-compliance with regulatory requirements, and the recipient is not obligated to accept the recommendation. A recommendation is not subject to enforcement action.
- **Action notice:** A written request that the licensee should take action to correct a non-compliance which is not a direct contravention of governing regulations, licence conditions, codes or standards, but which can compromise safety, security or the environment.
- **Directive:** A written request that the licensee should take action to correct a non-compliance with governing regulations, licence conditions, codes, standards, or address a general or sustained failure to adhere to approved documents, policies, procedures, instructions, programs, or processes, established by the licensee, in order to meet licensing requirements.

### **Formal requests**

A request made under *General Nuclear Safety and Control Regulation (GN)*, article 12(2), consists of a formal letter issued by the Commission Tribunal or a person authorized by the Commission Tribunal requesting a specific action, modification or installation with a response required within a specified time. This type of request is usually issued in instances when a written notice has received a response or when additional information is required in a timely manner to determine if the CNSC must take quick additional action.

### **Licensing actions**

In accordance with section 25 of the NSCA, the Commission Tribunal may, on its own motion, renew, suspend in whole or in part, amend, revoke or replace a licence under the prescribed conditions described in *GN* article 8. In general, this option is used for situations that do not require urgent action but when it is deemed necessary to restore compliance. If required, an order may be issued to have the licensee implement immediate corrective action while the request for licensing action is being processed.

### **Orders**

The NSCA (sections 35, 37-43 and 46- 47) describes the circumstances under which orders can be given as well as the procedures for orders. An order is a powerful legal instrument used to compel someone to act in the interest of health, safety, security, the environment, or to maintain compliance with international obligations.

## **Prosecution**

Prosecution is the laying of charges against a person in accordance with legislation. Prosecutions are generally only used after considering other enforcement actions and only for non-compliances with significant consequences for health, safety, security, the environment, or for the compliance with international obligations.