



DRAFT
REGULATORY
GUIDE

**CNSC Type I Inspections of Activities and
Devices for Nuclear Substances and
Radiation Device Licensees
Group 2.4 Licensees**

G-302-2.4

(Use Types: 862, 872, 875)

July 2004

REGULATORY DOCUMENTS

The legal framework within which the Canadian Nuclear Safety Commission (CNSC) operates includes the *Nuclear Safety and Control Act (Act)*, its Regulations and other legal instruments such as licences, certificates and orders. The legal framework is supported by regulatory documents issued by the CNSC, the main classes of which are:

Regulatory Policy (P): a document that describes the philosophy, principles or fundamental factors that underlie the CNSC's approach to its regulatory mission. It provides direction to CNSC staff and information to stakeholders.

Regulatory Standard (S): a document that describes CNSC requirements. It imposes obligations on the regulated party, once it is referenced in a licence or other legally enforceable instrument.

Regulatory Guide (G): a document that indicates acceptable ways of meeting CNSC requirements, as expressed in the *Act*, Regulations, regulatory standard or other legally-enforceable instrument. It provides guidance to licensees and other stakeholders.

Regulatory Notice (N): a document that provides licensees and other stakeholders with information about significant matters that warrant timely action.

DRAFT REGULATORY GUIDE

CNSC Type I Inspections of Activities and Devices for Nuclear Substances and Radiation Device Licensees Group 2.4 Licensees

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About this Document

The purpose of the proposed Regulatory Guide is to help Nuclear Substance and Radiation Device Licensees to understand the typical elements of a Canadian Nuclear Safety Commission (CNSC) Type I inspection of licensed activities and devices. The information is provided through the inclusion in the Guides of facsimiles of the worksheets that CNSC inspectors use to capture and document the results of their respective inspections.

Comments

The CNSC invites affected stakeholders and interested persons to assist in the further development of this draft regulatory document by commenting in writing on the document's content and usefulness. The draft regulatory guide is being issued for a one year public consultation and trial use period.

Direct your comments to the postal or e-mail address below by **June 30, 2005**, referencing file 1-8-8-302, and guide G-302-2.4. The CNSC will take the comments received on this draft into account when developing it further. These comments will be subject to the provisions of the federal *Access to Information Act*.

Document Availability

This document and other similar guides can be viewed on the CNSC Website at www.nuclearsafety.gc.ca. To order a printed copy of the document in English or French, please contact:

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REGULATORY GUIDE

**Group 2.4 Licenses
G-302-2.4**

CNSC TYPE I INSPECTIONS OF ACTIVITIES AND DEVICES FOR NUCLEAR SUBSTANCES AND RADIATION DEVICE LICENSEES

Issued for public consultation and trial use by the
Canadian Nuclear Safety Commission
July 2004

CNSC TYPE I INSPECTIONS OF ACTIVITIES AND DEVICES FOR NUCLEAR SUBSTANCES AND RADIATION DEVICE LICENSEES

1.0 PURPOSE

The purpose of this Regulatory Guide is to help Nuclear Substance and Radiation Device Licensees to understand the typical elements of a Canadian Nuclear Safety Commission (“CNSC”, “Commission”) “Type I” inspection of licensed activities and devices, carried out pursuant to the *Nuclear Safety and Control Act* (“NSC Act”, “Act”), the applicable regulations and specific licence conditions authorized by the *Act* and regulations.

2.0 SCOPE

This Regulatory Guide sets out, for various activities and devices for Nuclear Substance and Radiation Device licensees, the typical elements of a CNSC “Type I” inspection of licensed activities and related programs, processes or practices. The information is provided through the inclusion in the Guides of facsimiles of the worksheets that CNSC inspectors use to capture and document the results of their respective inspections.

3.0 DEFINITION

A “Type I inspection” means all verification activities related to on-site audits and evaluations of a licensee’s programs, processes and practices.

4.0 RELEVANT LEGISLATION

The facsimiles of the inspection worksheets for the licensed activities or radiation devices reference, for each listed element of the respective Type I inspection, the relevant provision of the *Act*, the regulations or various licence conditions.

5.0 DISCLAIMER

CNSC licensees may use these worksheets voluntarily to ascertain the CNSC’s general expectations regarding regulatory requirements. Such requirements would generally be assessed during a Type I inspection of licences issued pursuant to the Nuclear Substances and Radiation Devices Regulations. The expectations listed for each regulatory requirement are only provided as a guide. Similar worksheets will be used by CNSC staff for inspections. Inspections, will, however, be carried out on a case-by-case basis in the context of the licensed activities and the circumstances of individual situations. These worksheets are not intended to limit the scope of CNSC inspections or the powers of CNSC inspectors. Licensees should contact the CNSC to obtain information regarding their specific regulatory requirements.

CNSC INSPECTIONS OF ACTIVITIES AND DEVICES FOR NUCLEAR SUBSTANCES AND RADIATION DEVICE LICENSEES

Explanatory Information for Type I and Type II Inspection Worksheets

Type I and Type II Inspection worksheets are intended for use by CNSC Inspectors who are familiar with the terminology and abbreviations appearing on the worksheets. The information below is provided for the benefit of licensees and others who may be interested in the documents.

Worksheet Columns

Risk Column:

provides the Safety and Control Area numbering (SCA 1, SCA 2, SCA 3, etc.) and the level of risk associated with the requirement.

Safety and Control Area numbering is as follows:

1. Radiation Protection
2. Emergencies and Unplanned Events
3. Environmental Protection
4. Fire Protection
5. Training and Qualification
6. Operational Procedures
7. Organization and Management
8. Quality Management
9. Non-Radiological Health and Safety
10. Public Information Programs
11. Security
12. International Obligations/Safeguards
13. Packaging and Transport

Levels of Risk are as follows:

- High (Risk Group 3) – immediate health, safety, or security risk
- Medium (Risk Group 2) – health, safety or security risk, but not immediate
- Low (Risk Group 1) – not health, safety or security risks - administrative issues

Description Column:

provides a brief written description of the regulatory requirement

Requirements Column:

provides the source of the regulatory requirement (Act, regulations, licence conditions)

Order Column:

boxes marked with a check mark mean that non-compliance with the particular requirement could result in an Order being issued by the CNSC

Compliance Expectations Column:

provides brief instructions to the Inspector on what to verify

Other Relevant Information**Compliance Expectations**

in some cases, the information will be licensee specific, so details will not be listed on the worksheets. For example, when verifying Radiation Protection Program components, the CNSC Licensing Specialist (LS) may highlight the components of the program requiring verification. This particular information is available to the Inspector from written submissions by the licensee.

Other Abbreviations

in addition to the abbreviations listed at the top of the worksheets, prefixes have been added to many of the regulatory requirements under the *Packaging and Transport of Nuclear Substances Regulations* (PTNS) and the *Transport of Dangerous Goods Regulations* (TDG) identified in the Requirements column. These prefixes have been added to provide further clarification on the particular area of interest for the requirement.

The prefixes are:

- CoO – consignor
- D – document
- EP – excepted package
- T – training
- TA – Type ‘A’ package
- TB – Type ‘B’ package
- TD – transport document
- TM – transport mode

Other abbreviations appearing in the worksheets are:

- LC – licence condition
- LS – licensing specialist
- TS – technical specialist

Type I Inspection Worksheet

Rating A - Exceeds requirements
 B - Meets requirements
 C - Below requirements
 D - Significantly below requirements
 E - Unacceptable
 N/A - Not Applicable
 N/C - Not Checked

Abbreviations

RP - Radiation Protection
 SCA - Safety and Control Area
 LC - Licence Condition

GN - General Nuclear Safety and Control
 TS-R-1 - IAEA Safety Standard 1996 Edition (Revised)
 PTNS - Packaging and Transport of Nuclear Substances
 TDG - Transport of Dangerous Goods Regulations

NSCA = Nuclear Safety and Control Act
 NSRD - Nuclear Substances and Radiation Devices
 CII - Class II Nuclear Facility and Prescribed Equipment

Use Type: 862, 872, 875

Licensee No/Name:
 Licence Number:
 Address:
 City: Province: Postal Code:
 Person Seen:
 Phone Number:

Report Number:
 Inspection Date:
 Inspector Name:
 Usetype Number: 872
 Risk Group: 2.00

Risk	Description	Requirements	Order	Compliance Expectations	Information Gathering Methods			
					Interviews	Observations	Documents Review	Records Review
SCA: 1 Radiation Protection								
H	Thyroid monitoring	LC 2046-7	<input type="checkbox"/>	Verify that a process has been implemented to ensure screening takes place.	Interview RSO and workers regarding thyroid screening.		Examine RS manual for a procedure or procedure description.	Examine thyroid screening records if applicable.
	Rating:	Comments:						
H	Patient room - assignment	LC 2580-0	<input type="checkbox"/>	Verify that a process is implemented to assign private room and washroom to I-131 patients.	Interview RSO and workers regarding room assignments		Review written procedures.	
	Rating:	Comments:						
H	Patient room area control	LC 2581-0	<input type="checkbox"/>	Verify that a process is implemented to ensure dose rates around patient rooms is less than license limit.	Interview RSO and staff regarding dose rates around patient rooms.		Review written procedures.	
	Rating:	Comments:						
H	Patient room reassignment	LC 2583-1	<input type="checkbox"/>	Verify that a process is implemented to ensure patient rooms surveyed and decontaminated before reassigning.	Interview RSO and staff regarding practices when reassigning rooms.		Review written procedures.	
	Rating:	Comments:						
H	Linen release criteria	LC 2584-2	<input type="checkbox"/>	Verify that a process is implemented to ensure dose rate on linen sent to laundry less than licence limit.	Interview RSO and staff regarding practices of sending linen to laundry.		Review written procedures.	
	Rating:	Comments:						

SCA: 1 Radiation Protection

H	Thyroid screening MDA	LC 2600-1	<input type="checkbox"/>	Verify that the thyroid counting setup can detect 1 kBq of I-125 and I-131.	Ask RSO about MDA and how it was determined.	Observe a thyroid count of a person or a phantom.	Examine procedures in the RS manual.	Examine Q.C. records of thyroid instrument.
	Rating:	Comments:						
H	Thyroid bioassay	LC 2601-4	<input type="checkbox"/>	Verify that if a screening level exceeded that a bioassay was performed.	Interview workers and RSO about screening levels exceeded and actions taken.		Examine RS manual.	Examine thyroid screening records.
	Rating:	Comments:						
H	Contamination criteria	LC 2642-2	<input checked="" type="checkbox"/>	Verify that a process is in place to ensure contamination is controlled.	Interview RSO, permit holders and workers regarding contamination control methods.	Observe RSO and workers perform contamination monitoring.	Examine RS manual for contamination monitoring procedures.	Examine contamination monitoring records.
	Rating:	Comments:						
H	Contamination precaution	LC 2920-0	<input type="checkbox"/>	Verify measures are in place to ensure workers wear protective clothing when handling NS.	Interview RSO and workers regarding practices using protective clothing.	Observe staff working with NS.	Review written procedures.	
	Rating:	Comments:						
H	Contamination monitoring	LC 2920-0	<input type="checkbox"/>	Verify measures are in place to ensure contamination monitoring is performed.	Interview RSO and workers regarding contamination monitoring practices.	Observe contamination monitoring.	Review written procedures.	Review contamination monitoring records.
	Rating:	Comments:						
H	R.P. Program	RP 04 (a)	<input type="checkbox"/>	Verify the Radiation Protection program submitted in the licence application and supporting documentation from the licensee, has been implemented by the licensee. Specific Radiation Protection Audit criteria may be used as a licensee performance measurement tool with appropriate notice and disclosure given to the licensee.	Interview personnel at all levels of the organization about the operation of the occupational RP program.	Conduct field observations to verify that radiation policies and procedures are implemented appropriately.	Review radiation protection manual, guiding policies, radiation work procedures.	Review dose records, incident/event reports, calibration records, employees qualifications and training records.
	Rating:	Comments:						
H	Ascertaining of dose directly	RP 05 (2) (a)	<input type="checkbox"/>	Direct measurements made when applicable and greater than 2 mSv/a.	Interview staff, RSO, management regarding use of dosimeters.	Observe workers and note use of dosimeters.		
	Rating:	Comments:						
H	Dose limits/body	RP 13 (1)	<input type="checkbox"/>	Verify that licensee has a process to ensure workers do not receive a dose above dose limit.	Interview staff, RSO and management regarding any overexposures and what measures are in place.			Review dose records.
	Rating:	Comments:						

SCA: 1 Radiation Protection

H	Dose limits/organs	RP 14	<input checked="" type="checkbox"/>	Verify that licensee has a process to ensure workers do not receive a dose above dose limit.	Interview staff, RSO and management regarding any overexposures and what measures are in place.			Review dose records.
	Rating:	Comments:						
H	Container/device labeled	RP 20(1)(a)	<input type="checkbox"/>	All containers and devices labelled with RWS as required.	Question workers and RS staff regarding labels.	Observe labelling of containers or devices.		Review licensee procedures regarding labels.
	Rating:	Comments:						
M	Observe & obey notices (workers)	GN 17 (d)	<input type="checkbox"/>	No workers ignore or bypass warning signs and notices.	Interview staff and supervisors regarding attention to signs.	Observe staff working to note if signs obeyed.		
	Rating:	Comments:						
M	Survey meter	LC 2058-0	<input type="checkbox"/>	Verify that a survey meter is readily available and that it functions correctly.				
	Rating:	Comments:						
M	Extremity dosimetry	LC 2578-0	<input type="checkbox"/>	Verify that a process is in place to ensure ring dosimeters worn as required.	Interview RSO and workers regarding use of isotopes requiring ring dosimeter and if they are used.	Observe use and availability of ring dosimeters.	Examine RS manual for ring dosimeter procedures.	Examine dosimetry records for evidence of ring dosimeter use.
	Rating:	Comments:						
M	Therapy patient instructions	RP 03	<input type="checkbox"/>	Verify that a process is in place to ensure patients and caregivers are given instructions regarding dose and contamination control.	Interview RSO and workers regarding info given to patients.			Review instruction sheets given to patients.
	Rating:	Comments:						
M	Nuclear substances releases	RP 04 (b)	<input type="checkbox"/>	Verify that the determination of NS releases described in the license application and supporting documents has been implemented.	Interview personnel at all levels of the organization about the RP program related to releases of NS.	Conduct field observations to verify that radiation policies and procedures are implemented appropriately.	Review radiation protection manual, guiding policies, radiation work procedures.	Review nuclear substance release records.
	Rating:	Comments:						
M	Doses measured	RP 05 (1)	<input type="checkbox"/>	Measures implemented to measure and record all radiation doses.	Question RSO and workers about the measurement of radiation doses.	Observe workers use of personal dosimetry instruments and devices.	Review radiation protection manual (section on dosimetry), guiding policies, and workers RP training manual.	Review the organization's dosimetry records.
	Rating:	Comments:						
M	Action level	RP 06	<input type="checkbox"/>	Actions required by the license are taken when action levels exceeded.	Question RSO and staff if they are aware of action levels, the required responses, and if the action levels have been exceeded.		Review document(s) that provide 1. the CNSC approved action levels, and 2. what specifically is to be done when the levels are exceeded.	Review records if they exist of cases where action levels have been exceeded (to determine if the 3 licensee actions specified in the regs have been taken).
	Rating:	Comments:						

SCA: 1 Radiation Protection

M	Container/device source details	RP 20 (1) (b)	<input type="checkbox"/>	Required details are on all labels.	Question workers and RS staff regarding labels.	Observe labelling of containers or devices.	Review licensee procedures regarding labels.	
	Rating:	Comments:						
L	Ascertaining of dose indirect	RP 05 (2) (b)	<input type="checkbox"/>	Doses estimated where applicable (public and Non-NEWs).	Interview staff, RSO, management regarding estimates of doses to NEWs or non-NEWs.	Observe general working or storage areas and note considerations for non-NEWs.	Review radiation protection manual (section on dosimetry), guiding policies, and workers RP training manual.	Review the organization's dosimetry records.
	Rating:	Comments:						

SCA: 2 Emergencies and Unplanned Events

H	Reportable incidents	GN 29	<input type="checkbox"/>	Licensee has a process in place to ensure that incidents are reported.	Interview management and staff regarding occurrence of reportable incidents and whether they were reported.		Is there a procedure dealing with reporting to the CNSC?	Review reports in CNSC file or Licensee's File.
	Rating:	Comments:						
H	Patient room access control	LC 2582-1	<input type="checkbox"/>	Verify that a process is implemented to ensure no unauthorized access to patient room. Also door marked with RWS.	Interview RSO and staff regarding practices to limit access to patient rooms and placing signs.		Review written procedures.	
	Rating:	Comments:						
H	Device incidents	NSRD 21	<input checked="" type="checkbox"/>	All devices are inspected or tested following an accident.	Question staff regarding accidents with radiation devices.	Observe devices to note condition.	Review procedures to see if there is a procedure to follow after accident with a radiation device.	Note any accidents in the CNSC files.
	Rating:	Comments:						
M	Failed leak test	NSRD 18 (3)	<input type="checkbox"/>	Measures are in place to respond to failed leak test.	Interview management on their knowledge of reporting obligations to the CNSC. Question workers regarding leak tests.	Observe a leak test being conducted (if possible).	Review the work procedures - review training material.	Review records of leak testing being conducted and the results - review reports to CNSC (if any).
	Rating:	Comments:						

SCA: 3 Environmental Protection

H	Control releases	GN 12 (1) (f)	<input type="checkbox"/>	Measures are implemented to control releases as described in license documentation.	Interview RS staff and workers regarding releases of radioactive material.	Observe how releases are controlled.	Review procedures related to radioactive releases.	Review records of radioactive releases.
	Rating:	Comments:						
H	Disposal (Nuclear Medicine)	LC 2162-2	<input type="checkbox"/>	Verify that measures are in place to control disposal within licence limits	Interview staff and RSO regarding disposal practices.	Observe disposal of NS.	Review written procedure on disposal.	Review disposal records.
	Rating:	Comments:						
H	Decommissioning	LC 2571-2	<input type="checkbox"/>	Verify that a process is in place to ensure locations are decommissioned in accordance with limits.	Interview RSO and workers regarding decommissioning procedures and limits.	Perform radiation and/or contamination surveys of decommissioned locations.	Examine RS manual for decommissioning procedures.	Examine decommissioning records.
	Rating:	Comments:						

SCA: 3 Environmental Protection

H	Contamination meter requirements	LC 2572-1	<input type="checkbox"/>	Verify that a process is implemented to ensure availability of properly functioning contamination meter at each licenced location.	Interview workers and RSO regarding contamination meter functioning and availability.	Observe contamination meter for functionality and availability.	
	Rating:	Comments:					
H	Sufficient workers	GN 12 (1) (a)	<input type="checkbox"/>	The number of qualified workers on-site coincides with the number specified in accepted documentation (i.e. licence application or change notifications)	Interview a few key workers and managers.		Organization charts - Employee lists (positions).
	Rating:	Comments:					
H	Mandatory training	GN 12 (1) (b)	<input type="checkbox"/>	Verify all workers are provided training to carry out licensed activities prior to access to or use of Nuclear Substances.	Question workers - trainers.	Workers carrying out work procedures (skills) - workers' knowledge.	Training policy - training program description - work procedures. Training records.
	Rating:	Comments:					
M	Nuclear Eenergy Workers informed	RP	<input type="checkbox"/>	Measures implemented to inform NEWs (risks, dose limits, status, pregnancy) and obtain written acknowledgement.	Interview workers to determine if they received the RP information and signed written acknowledgement. (Note- experience has shown many workers forget they have signed these.)	Review the employee radiation protection training documentation - get a copy of the written handout that is provided to employees.	Review the employee training records - check records of new employee's training.
	Rating:	Comments:					

SCA: 6 Operational Procedure

H	Use of equipment & procedures	GN 12 (1) (e)	<input type="checkbox"/>	Measures are implemented to ensure that workers are using necessary equipment and following procedures.	Interview workers regarding their use of required equipment, devices, clothing and procedures.- Interview workers and supervisors regarding supervision.	Observe workers using required equipment, clothing and procedures.- Observe level of supervision of workers.	Documents containing policies and procedures on use of equipment, devices, clothing.- training manuals. Records of non-compliance events - (regarding compliance with policies, procedures on use of equipment, devices, clothing and procedures).
	Rating:	Comments:					
H	Authorized transfer	GN 13	<input type="checkbox"/>	Ensure means are in place to verify receivers of nuclear substances or radiation devices are licensed.	Interview owners/managers/RSO regarding the transfer (disposal or sale etc.) of devices or sources.		Review any documents that provide the policy and procedures to follow on transfers of devices or sources. Review records kept of the actual transfer of devices or sources.
	Rating:	Comments:					
H	Worker's use of protection	GN 17 (a)	<input checked="" type="checkbox"/>	No workers work without appropriate equipment.	Interview staff and supervisors regarding use of protective equipment.	Observe staff working to note if equipment used.	
	Rating:	Comments:					
H	Procedures followed	GN 17 (b)	<input checked="" type="checkbox"/>	All workers follow established procedures.	Interview staff and supervisors regarding use of procedures.	Observe staff working to note if procedures followed.	Review procedures to be observed.
	Rating:	Comments:					

SCA: 6 Operational Procedure

H	No transfer of uncertified device	NSRD 11 (2)	<input checked="" type="checkbox"/>	Measures implemented to ensure that no uncertified devices transferred.	Question staff and RSO about transfer procedures.		
	Rating:	Comments:					
M	Device provided & maintained	GN 12 (1) (d)	<input type="checkbox"/>	All necessary devices to carry out licensed activities have been provided.	Interview employees on the availability and physical condition of devices.	Radiation survey meters- TLDs, PADS? - note physical condition -	Documents listing required devices.
	Rating:	Comments:					
M	Training records	NSRD 36 (1) (d)	<input type="checkbox"/>	All worker training records available.	Ask RSO about the training records.		Review the training records for workers.
	Rating:	Comments:					
M	Licensed dosimetry	RP 08	<input type="checkbox"/>	A licensed dosimetry service is used for workers who have a reasonable probability of reaching 5 mSv/a.	Question RS staff about the dosimetry service. Enquire if there is a reasonable probability of anyone receiving 5 mSv.		
	Rating:	Comments:					
L	Pregnant NEW	RP 11 (1)	<input type="checkbox"/>	Verify that a process is in place to ensure all pregnant NEW's inform the licensee when becoming aware.	Question staff if they are aware of the requirement to inform licensee.		
	Rating:	Comments:					

SCA: 7 Organisation and Management

H	Worker's precautions	GN 17 (e)	<input type="checkbox"/>	Not specifically verified. Note for evidence of unsafe acts or procedures.		Note any unsafe acts or situations while making observations.	
	Rating:	Comments:					
M	Change notified	GN 15 (c)	<input type="checkbox"/>	Ensure that means are in place to notify the CNSC when contact person or responsible person is changed.	Ask RS and Administrative staff how the CNSC are notified regarding changes.		Review procedures for CNSC notifications.
	Rating:	Comments:					

SCA: 11 Security

H	Security	GN 12 (1) (g)	<input type="checkbox"/>	Measures have been implemented to alert licensee for theft, etc. Physical, lockable barrier in place for every storage location.	Question staff regarding the security measures.	Observe security measures.	Inventory control of devices containing radioactive sources and nuclear substances.
	Rating:	Comments:					
H	Sabotage	GN 12 (1) (h)	<input type="checkbox"/>	Measures have been implemented where there is a risk of sabotage.	Question staff regarding the security measures.	Observe security measures.	Inventory control of devices containing radioactive sources and nuclear substances.
	Rating:	Comments:					

SCA: 11 Security

M	Instruct workers on physical security	GN 12 (1) (j)	<input type="checkbox"/>	All workers have been provided instruction regarding local security procedures.	Interview workers on their knowledge of their obligations towards physical security at the site.	Review training manuals for inclusion of the physical security at the site and workers' obligations.
Rating:		Comments:				

SCA: 12 International Obligations/Safeguards

H	Import restrictions	LC 2402-0	<input type="checkbox"/>	Verify that a process is in place to prevent unauthorized imports.	Interview RSO about import process, occurrences. Interview workers about imports.	Examine RS manual for import procedures.
Rating:		Comments:				

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