

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

GN - General Nuclear Safety and Control
SSR-6 - IAEA Safety Standards 2012 Edition
PTNS, 2015 - Packaging and Transport of Nuclear
Substances, 2015
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

Type II Inspection Worksheet

Use Type: 872 - therapeutic nuclear medicine

Licensee: Report Number:
Licence Number: Inspection Date:
Address: Inspector Name:
City: Province: Postal Code: Use Type Number: 872
Person Seen: Phone Number: Risk Group: 2.00

Description	Regulatory Requirements	Compliance Expectations	Risk
Work Doc: 1 TII - Records			
Change notified Rating:	GN 15 (c) Comments:	Changes of personnel responsible for management and control of licensed activity (RSO, Applicant Authority and Signing Authority) have been reported to the CNSC within 15 days.	M
Laboratory lists Rating:	LC 2569-1 Comments:	A list of rooms where more than 1 Exemption Quantity (EQ) of nuclear substance is used or stored is available.	L
Inventory Rating:	NSRD 36 (1) (a) Comments:	A complete nuclear substance and radiation device inventory is available.	M
Records retained Rating:	NSRD 36 (1) (c), (e), (3), (4) Comments:	(1)(c) Records of transfer, receipt, disposal and abandonment are available. (1)(e) Records of inspection, measurement, test and servicing are available. (3), (4) Records of inspection, measurement, test and servicing are kept on file for three years.	L
Licence details Rating:	NSCA 26 Comments:	Licence activities are conducted in accordance with the licence.	H
Annual Compliance Report Rating:	LC 2916 Comments:	The licensee submits the annual compliance report in the form specified in the appendix of the licence for each year the licence is valid.	M
Records retained Rating:	GN 28 Comments:	(2) The CNSC was notified 90 days prior to the disposal of any prescribed records.	L
Reportable events Rating:	GN 29 Comments:	Incidents and unplanned events have been immediately reported to the CNSC and a detailed written report was submitted within 21 days (refer to NSRD 38).	H

Work Doc: 1 TII - Records

Reporting requirements	PTNS 37-38-40	The consignor, the carrier and the consignee must provide an immediate report to the CNSC (PTNS 37 (1)) and a 21 day report (PTNS 38) when becoming aware of any of the following situations: - failure to comply with the requirements of section 26; - a conveyance carrying radioactive material is involved in an accident; - package damage or tampering or leaking; - radioactive material lost, stolen or loss of control; - radioactive material has escaped from a containment system, a package or a conveyance during transport; - failure to comply with the Act and Regulations can lead to a situation in which the environment, the health and safety of persons or national security is adversely affected; - the level of non-fixed contamination as defined in the IAEA Regulations, during transport exceeds limits; - licensee has provided reports of damage or tampering discovered while opening packages as per PTNS 40(4), (5), (6).	H
Rating:	Comments:		
Training and sufficient workers	GN 12 (1) (a), (b)	There are (a) a sufficient number of trained and (b) qualified workers to carry on licensed activity.	H
Rating:	Comments:		
Worker records retained	NSRD 36 (1) (b), (d), (2)	(1)(b) The name of each worker who handles nuclear substances and/or radiation devices is recorded. (1)(d) Training records for all workers who handle nuclear substances and/or radiation devices are available. (2) Worker training records are kept on file for three years after termination.	M
Rating:	Comments:		
TDG training certificate on file	TDG 6.6, 6.7	A copy of the TDG training certificate is kept on file for two years and is available to the inspector.	M
Rating:	Comments:		
List of NEWs	RP 24	A record including names and job category of each NEW is available.	L
Rating:	Comments:		
Nuclear Energy Workers informed	RP 07	(1) Each NEW has been informed in writing of their NEW designation, of the risks associated with their work, of the regulatory dose limits and of their individual dose. (2) Female NEW has been informed in writing of their rights (RP 07) and obligations (RP 11). (3) A signed acknowledgment form is available for each NEW.	M
Rating:	Comments:		
Ascertainment and recording of doses	RP 05	(1) Personnel doses are ascertained and recorded. (2) Doses are determined by (a) direct measurement or (b) estimation.	H
Rating:	Comments:		
Dose limits	RP 13 (1), 14	Dose limits not exceeded.	H
Rating:	Comments:		
Licensed dosimetry	RP 08	A licensed dosimetry service is used where the effective dose of a NEW will likely exceed 5 mSv in a one-year period.	H
Rating:	Comments:		
Thyroid Monitoring	LC 2046-11	Thyroid screening has been performed within a period of more than 24 hours and less than five days after handling radioiodine in amounts set out in the licence condition.	H
Rating:	Comments:		
Thyroid Screening	LC 2600-3	The thyroid screening method is capable of detecting 1 kBq of radioiodine. If the screening is performed using bioassay, the assay procedure must be approved by the CNSC.	H
Rating:	Comments:		

Work Doc: 1 TII - Records

Thyroid Bioassay Rating:	LC 2601-6 Comments:	Thyroid uptake above 10 kBq of radioiodine has been reported to the CNSC.	H
Shipping doc kept 2 years Rating:	TDG 3.11 Comments:	Shipping documents kept on file for two years.	M
Meter calibrated Rating:	NSRD 20 Comments:	Survey meter that is used has been calibrated within the previous twelve months of its use.	H
Type A package certification Rating:	PTNS 42 Comments:	Type A package design, test results and packaging instructions kept on file for two years after last shipment.	H
Decommissioning Rating:	LC 2571-5 Comments:	Prior to decommission an area, room or enclosure the following items have been confirmed: (a) loose contamination levels meet the licence criteria; (b) release of any room that contains fixed contamination has been approved in writing by the CNSC; (c) all nuclear substances and radiation devices have been removed; and (d) all radiation warning signs have been removed.	H
Act/Regs available Rating:	GN 12 (1) (k) Comments:	A copy of the Act and Regulations (paper or electronic copy) are readily available to all workers.	L
Import Export Restrictions Rating:	LC 2480 Comments:	The licensee is not authorized to import or export all items described in the schedule, Parts A and B, of the Nuclear Non-proliferation Import and Export Control Regulations, and specifically listed in the licence condition.	H
Device use restrictions Rating:	LC 2000-8 Comments:	Prior to the date of the transfer, the licensee was given permission by the CNSC to transfer a device listed in the licence to another licensee. The device listed in the appendix was disposed of at a licenced nuclear waste facility	H

Work Doc: 2 TII - Operation/Storage

Posting of Signs Rating:	RP 21 Comments:	A radiation warning symbol is posted: (a) at the boundary of and at every point of access where there is more than 100 times the Exemption Quantity (EQ) of nuclear substances; or (b) where the radiation dose rate could exceed 0.025 m μ Sv/h.	H
Contact details posted Rating:	NSRD 23 Comments:	The name or job title and a 24 hr. telephone number are posted in a readily visible location where the nuclear substance is stored or used (refer to RP 21).	H
Radiation Warning Sign Rating:	RP 22 Comments:	When a radiation warning symbol is used, it is posted in accordance with regulations.	L
Frivolous posting of signs Rating:	RP 23 Comments:	Radiation warning symbols are not posted where there is no radiation, nuclear substance or prescribed equipment.	L
Storage Rating:	LC 2575-2 Comments:	(a) Access to storage areas containing nuclear substances or radiation devices is restricted to authorized personnel. (b) Dose rates at occupied areas outside storage areas do not exceed 2.5 μ Sv/hr. (c) Dose limits are not exceeded as a result of nuclear substances or radiation devices in storage.	H

Work Doc: 2 TII - Operation/Storage

Security indicators	GN 12 (1) (c), (g), (h), (i), (j)	Provisions are in place to ensure the security of nuclear substances and radiation devices and the health and safety of persons. This may be achieved through restricted access (for example use of locks, alarms, and security systems) and reporting of incidents including loss, theft and sabotage.	H
Rating:	Comments:		
Sealed Source Security Requirements	LC 2490-1	Licensees have in place security measures including: <ul style="list-style-type: none">- Inventory accounting- Access control measures- Up-to-date security plan- Information security measures- Intrusion detection with monitoring and testing- Response protocol- Secure storage of substances and devices- Security awareness program- Vehicle security measures	H
Rating:	Comments:		
Post licence	GN 14	(1) A copy of the licence or an appropriate notice is posted in a conspicuous place at the site of the licensed activity. (2) The complete licence is available at field locations.	L
Rating:	Comments:		
Therapy patient instructions	RP 03	The licensee provides therapy patient with instructions for reducing exposure to others before leaving the treatment centre.	H
Rating:	Comments:		
Patient Room Assignment	LC 2580-1	A private room with a washroom is assigned to each thyroid therapy inpatient.	H
Rating:	Comments:		
Patient Room Reassignment	LC 2583-3	Prior to a therapy patient's room being released for a new patient or for non-radioactive use, the room has been surveyed for contamination. Decontamination is done to ensure levels of non-fixed contamination and fixed contamination meet the licence criteria.	H
Rating:	Comments:		
Patient room area control	LC 2581-0	Dose rates in occupied areas outside of the treated patient's room do not exceed 2.5 µSv/hr. No other patient will receive a dose greater than 500 µSv per hospital stay.	H
Rating:	Comments:		
Patient room access control	LC 2582-1	Access to the therapy patient's room is limited to authorized persons and a clearly visible and legible radiation warning sign and the emergency contact number are posted at the entrance.	H
Rating:	Comments:		
Linen release criteria	LC 2584-2	Linens are released once the contact dose rate has reached 2.5 µSv/h.	H
Rating:	Comments:		
Container/Device labelled	RP 20	Each container or device containing greater than one Exemption Quantity of nuclear substance(s) is labelled with the radiation warning symbol and the required wording.	H
Rating:	Comments:		
Use of equipment & procedures	GN 12 (1) (e)	Licensee ensures equipment, clothing and procedures are used appropriately at the site of the licensed activity.	H
Rating:	Comments:		
Area classification	LC 2110-2	Each area of use is classified in accordance with the licence condition.	H
Rating:	Comments:		

Work Doc: 2 TII - Operation/Storage

Laboratory Procedures Rating:	LC 2570-3 Comments:	An approved radioisotope safety poster is displayed where nuclear substances are handled.	L
Contamination Criteria Rating:	LC 2642-5 Comments:	The licensee can demonstrate that sampling and counting methods can meet licence criteria. No loose contamination is detected in amounts exceeding the limits specified in the licence.	H
Disposal (Nuclear Medicine) Rating:	LC 2162-9 Comments:	Records indicate that all disposals of unsealed nuclear substances are in accordance with the licence condition. Non-radioactive waste containers do not contain radioactive waste (refer to GN 12 (1) (f)).	H
Inaccuracies Notification Rating:	LC 2920-6 Comments:	Changes to documents listed in the licence appendix have been reported to the CNSC.	L
Operation Limitations - General Rating:	LC 2917 Comments:	Activities and procedures, as listed in the licence appendix, are followed.	L
Contamination meter requirements Rating:	LC 2572-1 Comments:	A functional portable contamination meter is available.	H
Survey Meter Requirements Rating:	LC 2058-1 Comments:	A properly functioning survey meter is available at all times.	M
Extremity Dosimeters-Beta Emitters Rating:	LC 2578-1 Comments:	Ring dosimeters provided by a licensed dosimetry service are worn by all workers handling a container which contains more than 50 MBq of the specified nuclear substances (P-32, Sr-89, Y-90 and Sm-153) in the condition.	M
Worker's obligations Rating:	GN 17 Comments:	Every worker: (a) uses equipment, devices, facilities and clothing in a responsible and reasonable manner in accordance with the Act, Regulations and Licence Conditions; (b) complies with procedures and measures established by the licensee; (c) informs the licensee or supervisor of any situation where there may be: (i) an increase in the risk to the environment or the health and safety of persons; (ii) a threat to security; (iii) a failure to comply with regulatory requirements; (iv) sabotage, theft, loss or illegal use or possession of prescribed equipment, or (v) a release into the environment not authorized by the licence; (d) observes and obeys all notices and warning signs; and (e) takes all reasonable precautions to ensure the safety and security of individuals, the environment and the nuclear substances or facilities.	H
ALARA/RP program Rating:	RP 04 (a) Comments:	The licensee has implemented a radiation protection program that keeps doses ALARA and includes: (i) management control over work practices; (ii) personnel qualification and training; (iii) control of occupational and public exposure to radiation; and (iv) planning for unusual situations.	H
Radiation safety Rating:	NSRD 17 Comments:	Referenced emergency procedures are available to workers at the site of licensed activity.	M

Work Doc: 2 TII - Operation/Storage

Device provided & maintained	GN 12 (1) (d)	Required devices have been provided and have been maintained according to manufacturer's instruction.	M
Rating:	Comments:		

Work Doc: 4 TII - Packaging and Transport

Type A package requirements	PTNS 28 (1)	<p>A Type A package must be prepared and labelled in accordance of PTNS 28(1) and associated requirements from SSR-6. Package requirements are as follows:</p> <ul style="list-style-type: none"> - contact dose rate below 2 mSv/h (non-exclusive use) - SSR-6 527; - name of consignor or consignee package - SSR-6 531; - shipping name - SSR-6 532 and TDG 4.11; - activity within limits - PTNS 26(2) and SSR-6 428; - UN number - SSR-6 532 and TDG 4.12; - "Type A" marking - SSR-6 534(b); - VRI code - SSR-6 534(c); - two (I-white, II-Yellow or III-Yellow) labels - SSR-6 538, 539, and TDG 4.6, 4.7; - identify the radionuclide on labels -SSR-6 540 (a); - maximum activity on labels - SSR-6 540 (b)(c) and TDG 4.14; - transport index on labels (II-Yellow and III-Yellow) - SSR-6 540(d) as determined by SSR-6 523-524; - package integrity must not be compromised - PTNS 24(a) and SSR-6 306(b). 	H
Rating:	Comments:		

Excepted packages content/activity	PTNS 26(1)(a)	<p>Excepted packages meet the following criteria:</p> <ul style="list-style-type: none"> - dose rate below 0.005 mSv/h – PTNS 25(4)(a) and SSR-6 516; - activity within limits of PTNS 26(2) and SSR-6 422; - consignor or consignee I.D. - PTNS 28(1)(i) and SSR-6 531; - UN number on package - PTNS 28(1)(i) and SSR-6 532; - package must be accompanied by a shipping document (a log kept by driver is acceptable for UN 2909, 2910, 2911) that identifies the shipping name and UN number - PTNS 29(2)(a) and TDG 1.43; - "RADIOACTIVE" visible inside package(UN2910) upon opening - PTNS 26(1)(a)(i) and SSR-6 424(b)(i). <p>For UN 2908 (Empty Packages):</p> <ul style="list-style-type: none"> - contamination inside an empty package does not exceed 100 times the levels specified in SSR-6 427(c) and PTNS 26(1)(a)(i); - Labels removed PTNS 26(1)(a)(i) and SSR-6 427(d); - package integrity must not be compromised – PTNS 26(1)(a) and SSR-6 306(b). 	H
Rating:	Comments:		

Surface contamination	PTNS 28(1)(c)/SSR-6 508	The package has been tested to confirm surface contamination is below 4 Bq/cm2 for beta and gamma emitters and low toxicity alpha emitters, and 0.4 Bq/cm2 for all other alpha emitters - PTNS 28(1)(c) and SSR-6 508.	H
Rating:	Comments:		

Work Doc: 4 TII - Packaging and Transport

Transport document requirement	PTNS 29(1)	<p>The consignor of radioactive material provides a shipping document that includes the following (refer to TDG 3.5 and SSR-6 546):</p> <ul style="list-style-type: none"> - consignor and consignee names and addresses; - 24 hour contact number; - number of packages; - UN number*; - shipping name*; - Class # 7*; - radionuclide identification*; - form*; - maximum activity*; - category of package*; - transport index*; - competent authority certificate number(s)*. <p>For consignments of more than one package, the required information (*) must be given for each package.</p> <p>- Consignor's certification with printed name of the consignor - PTNS 25(1), TDG 3.6.1.</p>	M
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Rating:	Comments:
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Showing proof of TDG training	PTNS 25 (1)	A person handling dangerous goods must provide their training certificate or copy of it to an inspector immediately upon request.	M
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Rating:	Comments:
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TDG training certificate	TDG 6.1, 6.3, 6.5	<p>The employer is responsible for:</p> <p>6.1(2)(a) ensuring that only an adequately trained worker who holds a valid TDG certificate handle Class 7 dangerous goods ; or</p> <p>6.1 (2)(b) performs those activities in the presence and under the direct supervision of a person who is adequately trained and who holds a training certificate in accordance with this Part.</p> <p>6.3 issuing training certificate that includes:</p> <ul style="list-style-type: none"> - the employer's business address; - the employee's name; - aspects of handling and transporting; - employee and employer signatures; and - the expiry date of the certificate (TDG 6.5). 	M
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Rating:	Comments:
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Package secured in vehicle	PTNS 25 (4)	Consignments are segregated and securely stowed (refer to SSR-6 562, 564, 574 - PTNS 25(1) and TDG 5.4). Category II-Yellow and III-Yellow packages are not carried in compartments occupied by passengers - SSR-6 563.	H
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Rating:	Comments:
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Disclaimer - CNSC licensees may use this worksheet voluntarily to ascertain the CNSC's general expectations regarding regulatory requirements. Such requirements would generally be assessed during a Type I and Type II 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 on-site 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. This worksheet is 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.

APPENDIX A RATING SYSTEM (GRADES)

A - Exceeds requirements

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, such that they do not pose an unreasonable risk to the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed.

B - Meets requirements

Assessment topics or programs meet the intent or objectives of CNSC requirements and performance expectations. There is only minor deviation 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, safety, 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. However those issues are considered to pose a low risk to the achievement of regulatory performance requirements and expectations of the CNSC.

C - Below requirements

Performance deteriorates and falls below expectations, or assessment topics or programs deviate from the intent or objectives of CNSC requirements, to the extent that there is a moderate risk that the programs will ultimately fail to achieve expectations for the maintenance of health, safety, security, environmental protection, or conformance with international obligations to which Canada has agreed. Although the risk of failing to meet regulatory requirements in the short term remains low, improvements in performance or programs are required to address identified weaknesses. The licensee or applicant has taken, or is taking appropriate action.

D - Significantly below requirements

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. Issues are not being addressed effectively by the licensee or applicant. The licensee or applicant has neither taken appropriate compensating measures nor provided an alternative plan of action.

E - Unacceptable

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.

N/A – Not applicable

N/C – Not checked