nordion
SCIENCE ADVANCING HEALTH

Nordion Class 1B Facility

License Number: NSPFOL-11A.04/2015

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Annual License Compliance and Operational Performance Report to the Canadian Nuclear Safety Commission for the period JANUARY 2011 to DECEMBER 2011

Submitted: March 31st, 2012
To: Ms. Ann Erdman

Signatures

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Approved by: [redacted] Date: _____ yy/mm/dd

ABSTRACT

This Annual Compliance and Operational Performance Report (ACOPR) provides performance and operational information for Nordion's Class 1B Facility. It reports annual performance against the Nuclear Safety and Control Act, applicable regulations, relevant safety and operational programs and the license conditions of the Nuclear Processing Facility Operating License issued by the Canadian Nuclear Safety Commission (License NSFPOL-11A.04/2015). It demonstrates that Nordion is operating and will continue to operate in a safe manner.

As per Nordion's license condition on annual reporting, this report contains the following information:

- The operation and maintenance of the facility, a summary of facility and equipment performance and changes, changes to operating policies, organization, occurrences, personnel radiation exposures and releases of nuclear substances and releases of hazardous substances from the facility.
- Changes to the emergency procedures, changes that affect or may affect the facility's emergency response arrangements, training activities, drill and exercise activities and unplanned events in which the facility's emergency response organization was tested.
- The results of the effluent monitoring and personnel radiation exposures of the facility.
- The results of environmental monitoring.
- A summary of non-radiological health and safety activities, information on minor incidents and lost-time incidents.

The key points of this report are as follows:

- There were no major issues in 2011. The facility has operated according to its original design criteria. There were no physical design changes to any structural areas of the building or changes to the designated active areas.
- Conformance to internal training requirements was extremely high in 2011.
- Testing of the radiation devices and instrument maintenance was performed at the required frequency and results were satisfactory. There were no observed trends related to equipment performance in 2011.
- The Environment, Health and Safety Committee met on a regular basis to review the environmental and safety aspects of the operations and to review and approve Final Safety Analysis Reports (FSARs).
- All measurable radiation dose received by personnel and the public were within the regulatory limit of 50 mSv/yr. and no internal dose levels or limits were exceeded.
- There were a total of 37 contamination incidents in 2011. All elevated levels of contamination were monitored and contained within the Active Area.
- There were three instances in which there was potential to exceed a regulatory limit or action level in 2011. For the first instance, there were no corrective actions as it was concluded that no Nordion employees received a dose in excess of 1 mSv. For the second instance, there were no corrective actions as the elevated dose was determined to be non-personal. For the third instance, there were several corrective actions regarding the policy for wearing TLDs and the processes for reviewing dosimetry results.
- Various improvements were made to the Radiation Protection Program, Conventional Health and Safety Program, Environmental Protection Program and Fire Protection Program. These programs fall within the scope of the QA Management Program.
- There were no disabling injuries in 2011. Incident and severity rates were among the best ever recorded at the Kanata site in the 2011 fiscal year.
- There were no instances of exceeding environmental regulatory limits or action levels in 2011. The maximum annual release of airborne from any one radionuclide was Xe-135m at 0.92% of the DRL.
- A number of improvements were made to nuclear security.
- In 2011, Nordion received three external communications.
- In 2011, Nordion complied with each site-specific reporting requirement with two exceptions. These exceptions involved sealed source reporting. Both of these instances were reportable under Section 6.1 (g) of the site license (NSPFOL-11.A.04/2015).

In 2011, Nordion's Class 1B Facility operated within the requirements of the Nuclear Safety and Control Act, the applicable regulations and the conditions of the operating license issued by the CNSC.

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1. INTRODUCTION

1.1 General Introduction

Nordion is a major global supplier of radioisotopes used in nuclear medicine for diagnostic and therapeutic purposes, industrial applications, and research and development activities. The Class 1B Facility is comprised of two major production operations, one involving the processing of radioisotopes used in nuclear medicine and the other involving sealed sources used in cancer therapy and irradiation technologies.

1.1.1 Summary of Production and Operational Limits

Nordion's license NSPFOL-11A.04/2015 does not include any production and operational limits.

1.1.2 Summary of Performance

Nordion operated in compliance with the Nuclear Safety and Control Act in 2011 as there were no non-compliances with the Act. Each of the EHS objectives and targets were met in 2011. The objectives are reviewed yearly at the Annual Joint Environmental Management System and Quality Assurance (QA) Program for Safety Review. Refer to Section 2.3.1 for a summary of the EHS Objectives and Targets for 2011.

1.1.3 Summary of Activities

The [redacted] process was validated and is awaiting health agency approval prior to transition to operations. The TheraSphere® process in Room 1234 was approved for routine operations. Please refer to Section 2.4 for further information.

1.1.4 Issues and Corrective Actions

There were no major issues in 2011. Seven lesser occurrences were documented as Investigations 11-03, 11-07, 11-09, 11-16, 11-21, 11-26 and 11-27. Refer to Appendix A.

1.1.5 Reportable Incidents

A list of reportable incidents, their causes and corrective actions are provided in Appendix A.

1.1.6 Compliance with other Regulatory Agencies

Nordion applied to Environment Canada in March 2011 for Precautionary Permits to Charge a Fire Extinguishing System for in-cell fire suppression systems containing halon. These permits were approved and received on April 19, 2011 and permit Nordion to refill halon fire extinguishing systems until April 14, 2012.

In August 2011, Nordion submitted an application for a Comprehensive Certificate of Approval (Air & Noise) to the Ontario Ministry of the Environment. Nordion received the approved Comprehensive Certificate of Approval (Air & Noise) from the Ontario Ministry of the Environment in November 2011. Nordion reports to the Workplace Safety Insurance Board (WSIB) whenever a reportable occupational injury or illness occurs. In 2011, there were five medical treatments reported to the WSIB. WSIB may inspect Nordion's Occupational Health and Safety programs at any time; however, no inspections were held in 2011. This is in compliance with the Workplace Safety and Insurance Act.

In compliance with Part 2 of the Canadian Labour Code, there were no reportable occupational injuries or illnesses that required to be reported to the Human Resource Skills Development Centre (HRSDC).

Transport Canada conducted an inspection of Nordion's Emergency Response Assistance Plan (SE-ERP-008) in 2011. The Emergency Response Assistance Plan has been approved by Transport Canada.

1.2 Facility Operation

1.2.1 Facility Operation

The facility has operated according to its original design criteria in 2011. There were no investigations in 2011 related to facility operation.

1.2.2 Personnel Performance

The number of corrective actions related to training would be an indication of how effectively personnel performed compared to their duties and how well personnel followed procedures. During 2011, seven of the 58 corrective actions initiated (12%) were related to training. Four of the seven training corrective actions were categorized as inadequate training, identified in audits or investigations of areas including Procurement, Sr-82, Non-Production Radioactive Material Inventory and Sealed Source Tracking. Two were categorized as training not performed and were initiated as a result of an external ISO 14001 audit and an internal investigation. The remaining training corrective action was categorized as training not understood and was a result of a compliance investigation. There were three minor comments on the Manager Self-assessment checklists regarding outstanding training and there were no comments that Standard Operating Procedures (SOPs) were not being followed.

1.2.3 Summary of Modifications and Repairs

Modifications and repairs that were carried out in 2011 included:

- Installing security fencing and motorized gates around the perimeter of the building.
- Modifying Room 1234 to accommodate the TheraSphere® process in Cell 31.
- Installing additional shielding to the walls and ceiling area of Room 1308 to reduce external radiation fields from the Gammacell 220.

1.2.4 Internal and External Audits

As part of the QA Program for Safety and the Environmental Management System, Nordion annually conducts internal audits to identify and correct potential environmental, health and safety related issues. In 2011, Nordion conducted a total of eleven internal EHS audits. These audits included process audits as well as policy and program audits. In addition, Nordion conducted a total of eleven safety inspections. In 2011, there were a total of eight external audits. Out of a total of 58 EHS related corrective actions initiated in 2011, 22 were a result of internal audits and 18 were a result of external audits.

1.2.4.1 Internal Audits

The following internal audits were conducted in 2011:

1. R&D Process – numerous Environmental Management System (EMS) and QA safety elements were audited.
2. There was one EMS program level audit in 2011. The audit was concerned with the EHS policy, communications, documentation, monitoring and measurement, evaluation of compliance, management review, environmental aspects, objectives, targets and programs, legal requirements, and emergency preparedness and response.
3. One QA Safety program level audit was conducted. The following Quality Assurance Program for Safety elements were reviewed: organization and responsibilities, manager self-assessment, use of experience, and program definition.
4. Operational Transportation Audit.
5. Physical Inventory Taking (PIT) of safeguarded material.
6. Non-production Radioactive Material Inventory (NPRMI) Audit.
7. Trustworthy & Reliability Audit of Carriers.

8. Annual Review of Radiation Safety Program for New York State.
9. Re-audit of Procurement (Training).
10. Internal EHS Audit Program.
11. Process Safety Audit of the I-131 process.

1.2.4.2 External Audits

The following external audits were conducted in 2011:

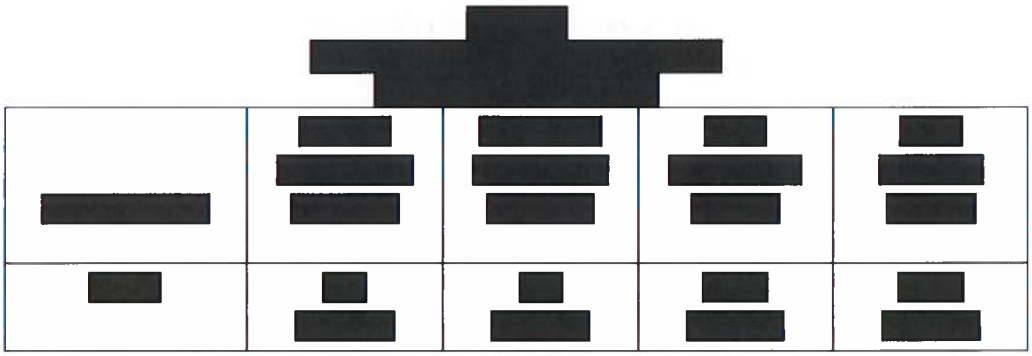
1. On January 13, 2011 the CNSC conducted a Security Inspection. No findings were identified during this inspection.
2. On January 17, 2011 the CNSC conducted a Sealed Source Inventory Inspection. There were four action notices, one request for additional information and one recommendation as a result of this inspection.
3. On February 28, 2011 the CNSC conducted an Annual Inspection. There were six action notices and one recommendation.
4. On May 27, 2011 Transport Canada conducted an inspection of compliance with TDG requirements related to emergency response assistance plans (ERAP). Recommendations were provided.
5. On June 20-22, 2011 BSI conducted an inspection of ISO 14001:2004 compliance. There were two minor non-conformances identified and two opportunities for improvement.
6. On September 22, 2011 the CNSC conducted an inspection during a full-scale emergency response exercise. There were no action notices and 10 recommendations as a result of this inspection.
7. On October 3, 2011 the CNSC conducted an audit of Nordion's Nuclear Material Accounting Reporting Procedures. There were three corrective actions, three general comments and one follow-up item as a result of this audit.
8. At least once every three years a third party review of compliance to EHS legislative requirements is conducted at Nordion. The last audit was conducted on November 8-11, 2011. There was one major non-nuclear finding, five minor findings and three administrative type findings as a result of this audit.

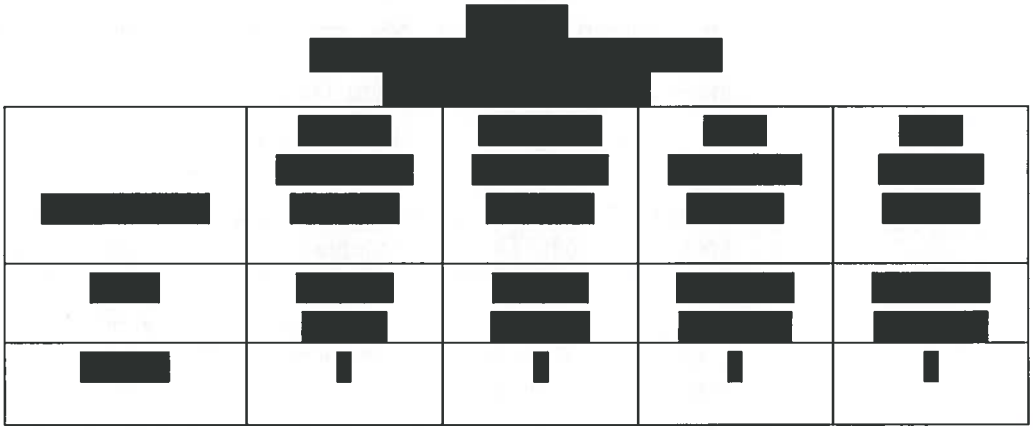
1.3 Production or Utilization

Activities conducted in the Kanata Operations Building (KOB) relating to the procurement, possession, processing and shipping of radioactive materials are conducted under Nuclear Substance Processing Facility Operating Licence, NSPFOL-11A.04/2015. The facility is comprised of the KOB, which houses the Nuclear Medicine Production Facility (NMPF) and Cobalt Operations Facility (COF), and the Kanata Radiopharmaceutical Manufacturing Facility (KRMF).

1.3.1 Sealed Source Manufacturing/Radioisotope Processing

[redacted]





1.3.2 Processing > 1 Petabecquerel (PBq)

1.3.3 Acquisitions of Finished Sealed Radioactive Sources

1.3.4 Sealed Sources/Devices > 50 Megabecquerels (MBq)

1.4 Facility Modifications

1.4.1 Changes to the Facility Buildings, Processes and Equipment

1.4.1.1 Changes to Designated Active Area

In 2011, there were no changes to the designated active areas in the Kanata Operations Building (KOB), or Kanata Radiopharmaceutical Manufacturing Facility (KRMF).

1.4.1.2 Structural/Functional Changes Affecting Emissions

In 2011, Nordion had no capital projects that affected the emissions of the facility.

1.4.1.3 Structural/Functional Changes Affecting Active Area Ventilation

In 2011, Nordion made no modifications to the Nuclear Ventilation System.

1.4.1.4 Structural/Functional Changes Affecting the Active Liquid Waste System

During 2011, there were no structural or functional changes in the active liquid waste system program.

1.4.2 Changes to Procedures Related to Operations Safety and Control

One of the more significant changes to procedures in 2011 was the implementation of an improved design of in-cell roughing filters. The new design is demonstrating an improvement in Iodine–131 releases to the environment.

1.4.3 Changes to the Training Programs

Nordion released new EHS training courses in 2011. These were provided using a computer based training software. Courses included Emergency Alarms and Response Training which is required training for all employees and Behavioural Observation Training for Managers.

1.4.4 Changes to the Organizational Structure and Key Personnel

EHS personnel are organized into an EHS Compliance Group and an EHS Operations Group. The personnel of these two groups are comprised of the following:

EHS Compliance

- Vice-President QA EHS Compliance
- Administrative Assistant (2)
- Manager, Compliance, Environment, Health & Radiation Safety
- Environmental Specialist
- EHS Specialist
- Manager, Compliance, Facility & Transportation Licensing
- Nuclear Transportation Specialist
- Senior Licensing Coordinator
- Safety Analyst
- Training Specialist (Term)
- Environmental Health & Safety Specialist (Term)

EHS Operations

- Director, QA EHS Operations
- Administrative Assistant
- Manager, Radiation Surveyors & Contamination Monitoring
- Radiation Surveyor (3)
- Junior Radiation Surveyor
- Senior Radiation Surveyor (2)
- Radiation and Contamination Monitor (7)
- Senior Radiation & Contamination Monitor (3)
- Company Physician
- Occupational Health Specialist
- Fitness Coordinator
- Senior Radiation Safety & Training Specialist
- Manager, Corporate Security
- Information Security Analyst
- Security Supervisor
- Security Officers (13)
- Switchboard Operator
- Switchboard Operator, Casual

The term positions of Training Specialist and Environmental Health & Safety Specialist were added to the EHS Compliance group and the positions of Switchboard Operator and Switchboard Operator, Casual were added to the EHS Operations group. The position of Junior Radiation Surveyor was to replace a Senior Radiation Surveyor.

2. SAFETY AND CONTROL AREA

2.1 Management System

2.1.1 Review of Quality Assurance/Management Program Activities

In 2011, Nordion conducted a total of eleven internal EHS audits. These audits are described in Section 1.2.4.1.

2.1.2 Review of Quality Assurance/Management Program Effectiveness

The annual management review of the Environmental Management System and the QA Program for Safety was conducted May 31, 2011.

The management review involves the evaluation of actions from the previous meeting, the Environment Health & Safety Policy (CPM-6-06), adequacy of resources, environmental health and safety objectives and targets, changing circumstances and recommendations for improvement.

Results of the 2011 annual review concluded that:

1. A majority of the outstanding actions from the previous meeting had been completed and closed (there were two actions outstanding at the time of the meeting).
2. The Environment, Health and Safety Policy (CPM-6-06) was reviewed and it was determined that the policy did not require further review and update.
3. Resource requirements for the Environmental Management System and QA Program for Safety were discussed. The Committee agreed that the most critical issues are resourced adequately. Funds are available for safety related issues. One challenge is that the number of regulatory requirements is increasing.
4. There is one outstanding 2009 environmental objective and target related to the replacement of the halon fire suppression systems with a non-ozone depleting alternative.
5. The 2011 environmental objectives and targets were met with the exception of the objective to reduce waste to landfill or long-term storage. The target was to achieve a 65% diversion rate for waste; however, due to higher than normal volumes of construction waste as a result of unplanned renovations at the site the diversion rate achieved was only 55%.
6. The 2011 environmental objectives and targets were reviewed and it was determined that they were on target at the time of the meeting.
7. 2012 EHS objectives were discussed and it was determined that they would be finalized in the fall.

There were no recommendations for improvements identified during this meeting. There were eight actions identified during the meeting.

2.1.3 Summary of Quality Assurance/Management Program Improvements

In 2011, changes or revisions were made to the Radiation Protection Program, Conventional Health and Safety Program, and the Environmental Protection Program as discussed in Sections 2.7, 2.8, and 2.9, respectively.

2.2 Human Performance Management

2.2.1 Training Program Effectiveness

The number of scheduled participants for internal safety training was 637. By the end of 2011, 637 scheduled participants completed the training, including refresher training. Therefore, the attendance completion rate in 2011 was 100%. The details of the training are documented in Table 4, below. There were no incidents in 2011 that demonstrated a lack of effectiveness in these training programs.

Nordion has designed and maintains a variety of radiation safety training courses. New employees who are not classified as Nuclear Energy Workers (NEWs) receive a basic course on Health, Safety and Environment, Level I, which provides information on the facilities, emergency response procedures/alarms, and basic procedures to follow for safety in the workplace. Nuclear Energy Workers receive a NEW Indoctrination Course. To be authorized to enter the Active Area unescorted, the employee must complete and pass a written test, as evidence of understanding the principles of radiation protection and Nordion safe work practices. NEW retraining and retesting are conducted on a three year frequency. In addition, NEWs are provided with a half day Radiation Instrumentation Workshop, dealing specifically with the selection and use of radiation survey and contamination meters for the Active Area.

Supplementary training programs are provided to all personnel working on behalf of Nordion depending on the nature of the job and the requirements specified by their Manager. These programs include such topics as "Working with Radioiodines", emergency response awareness, care and use of respirators, material handling training, and working safely with fume-hoods. A summary of the training programs and the number of participants is provided in Table 4.

Employees who transport, handle, or offer dangerous goods for transport are trained in the Transportation of Dangerous Goods (TDG) requirements. The training program includes a one day classroom training course that is required once on employment or upon job change. Retraining is conducted on a 2-year frequency and is accomplished through self-study. The self-study program is separated into three levels. Employees are required to complete the self-study refresher training level that is appropriate for their job function. For each training course, participants must complete and pass a written test, as evidence of understanding the course contents.

Table 4
Safety Training Programs – 2011

Program	Duration	Number of Participants	Refresher Training Overdue at end of 2011	Refresher Training Overdue at end of March 2012
Nuclear Energy Worker Indoctrination	6 Hours	13	Not Applicable	Not Applicable
Health, Safety and Environment Level II	Self Study	121	0	0
Radiation Instrumentation Workshop	3 Hours	84	0	0
Radiation Safety Review for Operators	Half Day	22	0	0
Safe Handling of Radioiodines	2 Hours	69	0	0
Transport of Dangerous Goods Level I	Self Study	6	0	0
Transport of Dangerous Goods Level II	Self Study	4	0	0
Transport of Dangerous Goods Level III	All Day In-Class (Once Upon Employment Self Study thereafter	41	0	0
TDG for Contractors	All Day	5	0	0
Transportation Regulations	2 Hours	58	0	0
Working with BETA	1 Hour	83	0	0
Crane	Half Day	15	0	0
Pallet	Half Day	26	0	0
Forklift	Half Day	18	0	0
Contractor Radiation Safety Training	Half Day	21	0	0
Contractor Radiation Safety Update Training	2 Hours	18	0	0
HEGS Safety Training	2 Hours	3	0	0
In-Depth Security Awareness	2 Hours	30	0	0

2.2.2 Verification of Minimum Number of Responsible Personnel During Operations and Similar Activities

Nordion's license does not specify a minimum number of responsible personnel required during operations.

2.3 Operating Performance

2.3.1 Effectiveness of Licensed Activities

The licensed activities were carried out according to Nordion's programs and procedures. There were no significant unplanned events and no major non-conformances. Nordion's programs in place for auditing and capturing non-conformances identified issues in areas that required corrective actions. These processes functioned as expected.

Summaries of the 2011 EHS Program objectives and Health and Safety Objectives are shown in Tables 5 and 6. Each of the EHS Objectives listed in Table 5 were met in 2011. Table 6 shows Health and Safety Objectives that EHS requires of Directors and Managers and employees of high risk areas. A system is in place to ensure that the performance reviews are completed. The completion of manager self-assessments is audited annually. EHS regularly follows-up with Managers to ensure they are reviewing health and safety issues with employees and to remind them that EHS staff are available to provide updates at team meetings. Deviations, Change Forms and complaints are reviewed yearly at the Annual Joint Environmental Management System and QA Program for Safety review.

Table 5
2011 EHS Program Objectives and Results

Applicable Nordion Job Function	Objective	Measures and Targets	Result
All Directors and Managers	Minimize the number and extent of occupational injuries, environmental and radiation incidents.	• The number of incidents ≤ 12 • Lost time injuries ≤ 0.8 per 200,000 hours worked • The severity of lost-time injuries to < 10 days per 200,000 hours worked	5 (Rolling 12)*0 0
All Directors and Managers of Operations, Facilities, or Nuclear Energy Worker employees	Minimize the use and release of hazardous materials to the environment.	• Radioactive materials emissions to ≤ 7.5% of the Derived Release Limits (DRL) • No non-compliant sanitary sewer emissions of non-radioactive hazardous materials	0.76 % DRL 0
	Maintain radiation doses to employees as per ALARA principle.	• Average Active Area employee dose rate < 2 mSv/yr • Maximum employee dose rate < 8 mSv/yr • Radiation Incidents < 5/year	0.47 mSv (Rolling 12) 6.18 mSv (Rolling 12) 0

* Results compiled over fiscal year, from November 1, 2010 to October 31, 2011.

Table 6
2011 Health and Safety Objectives

Applicable Nordion Job Function	Objective	Measures and Targets
All Directors and Managers	Ensure all managers of high risk areas conduct /document regular self assessments of their management processes and safety performance.	• Mid-Year and Year-End performance reviews
All Directors and Managers of Operations, Facilities, or Nuclear Energy Worker employees	Ensure all managers actively consider impacts to the environment and health and safety.	• Environment, health and safety impacts are assessed as part of product realization planning and risks are mitigated through application of ALARA and pro-active planning. • Opportunities for minimizing waste (hazardous and non-hazardous) are assessed and implemented as feasible.
All High Risk Employees	Communicate monthly with teams about environment, health and safety performance and impacts. Openly evaluate employee environment, health safety concerns.	• Environment, health & safety information and concerns are discussed regularly at team meetings. • Health and safety concerns are assessed with the results of the evaluation communicated to the employee(s). • Deviations, CFs, Non-conformances and Complaints are assessed for EHS risks against targets and reported accordingly. • Routinely invite EHS Representatives to team meetings to discuss EHS topics and/or concerns.
	Work safely at all times. It is unacceptable to take risk in order to get the job done.	• Work follows Nordion applicable EHS standards and procedures, and is performed with care and attention to safety principles.
	Report the occurrence of workplace injuries, unsafe conditions and near misses.	• All workplace injuries and observed unsafe conditions & near misses are reported immediately to the direct Supervisor.
	Correct co-workers who are working unsafely.	• Following Nordion values, coach co-workers who are seen working unsafely.
	Identify opportunities to reduce environmental impacts.	• Identify opportunities for reducing waste, and using less harmful materials where feasible.

2.3.2 Effectiveness in Implementing Operational Controls

EHS operational controls are documented in a specific series of documents (SE-OP series) and added to routine production documents for safety critical steps. These procedures are routinely updated using Nordion's change control process when safety improvements are identified.

2.3.3 Summary of Safety Inspections and Audits

Refer to Section 1.2.4 for a summary of the safety inspections and audits.

2.3.4 Radiation Devices and Instruments Maintenance

Performance of the following equipment, alarms and monitoring devices is checked at various frequencies throughout the year. Test results are indicated to be satisfactory if the tested item functioned within acceptable parameters.

2.3.4.1 Ventilation

Duplex fan tests are conducted every 6 months. This involves testing of more than 100 fans which form part of the NVS. Testing in 2011 was performed at the required frequency and results were satisfactory.

In-situ testing of HEPA filters and charcoal adsorbers (CADs) is required at a minimum once annually, but two testing campaigns were done for both in 2011.

Table 7 details the results of Nuclear Ventilation System Filter testing and replacement. The filters summarized in Table 7 are credited with mitigating releases in Nordion's Safety Analysis reports.

Table 7
NVS Filter Efficiency Testing/Replacements

	Q1/Q2 HEPA	Q1/Q2 CAD	Q3/Q4 HEPA	Q3/Q4 CAD
Filters in fleet	236	72	236	72
Number tested	232	65	234	65
Filters which passed testing	231	65	232	65
Filters which failed testing	1	0	2	0
Failed filters replaced during test cycle	1	0	2	0
Not tested	4	7	2	7
Total replaced during this cycle	22	0	7	2
Filters (systems) removed from service	0	0	0	0
New Filters (systems) Added	0	0	0	0

Comments Q1/Q2 HEPA: Four filters were not tested, either because they are not in use or not set-up for testing. All four are in place for non-critical systems. 20 filters were replaced due to the change in pressure across the filters. One filter was replaced due to high leak rate (not a fail) discovered in Q3/Q4 2010.

Comments Q1/Q2 CAD: Six trench filters were not tested, but are changed every three years as per SE-OP-021. One CAD filter on System 5 was not tested as it is not in use.

Comments Q3/Q4 HEPA: Two filters were not tested, both in place for non-critical systems. Two systems were improved to allow testing (non-critical systems). Seven filters were replaced; five due to delta P and two due to failure. One newly installed filter failed testing on installation and was replaced.

Comments Q3/Q4 CAD: Two filters were removed from service due to age as per SE-OP-021. See Q1/Q2 CAD comments for why filters were not tested.

Nuclear Medicine in-cell charcoal roughing filters are on a preventative maintenance schedule and replaced by cell technicians typically every 6 months. The replacement of these filters is described in Table 8. These filters are not credited with mitigating releases in Nordion's Safety Analysis reports.

Table 8
Roughing Filter Change-outs

Filter Type	Results
Nuclear Ventilation System Roughing filters	21 replaced
Cobalt Production In-cell filters	0 in-cell HEPA filters were replaced.

2.3.4.2 Back-up Power Facilities

The emergency generators which supply emergency power to KOB, Kanata Radiopharmaceutical Manufacturing Facility (KRMF) and the Heating Plant are tested monthly. Testing in 2011 was performed at the required frequency and results were satisfactory.

2.3.4.3 Radiation Evacuation Alarms

Radiation evacuation alarms are tested weekly and quarterly by the Radiation Surveyors. They are additionally tested annually by Facilities and Site Services staff. Testing in 2011 was performed at the required frequency and results were satisfactory.

2.3.4.4 Radiation Alarms

The radiation alarms are scheduled for testing on a weekly basis and were tested every week in 2011. The tests verify that the alarms sound at the preset alarm levels and that the alarms register on the Metasys monitoring system. If the alarms do not function as required, adjustments to the alarm levels and/or the Metasys are conducted immediately by Facilities and Site Services personnel.

2.3.4.5 Sprinkler System Fire Alarms

The sprinkler system fire alarms in KOB, KRMF and the Heating Plant are tested every month. Testing in 2011 was performed at the required frequency and results were satisfactory. All dry systems were tested and verified in good operating condition in 2011 as required by National Fire Protection Association (NFPA).

2.3.4.6 Fire Alarm Panels

The fire alarm panels for KOB, KRMF and the Heating Plant are tested and verified by the manufacturer [redacted] once a year.

The fire alarm panels that monitor the KOB, KRMF and the Heating Plant are tested monthly. Testing in 2011 was performed at the required frequency and results were satisfactory.

2.3.4.7 Contamination Monitoring Equipment

Handheld contamination monitoring equipment is maintained twice a year. Area monitors are checked on a daily basis. Testing in 2011 was performed at the required frequency and results were satisfactory.

2.3.4.8 Contamination Control Equipment

The hand and foot monitors are calibrated twice a year, checked daily, tested weekly and serviced on a routine basis and repaired as required, typically two to three times a year. Testing in 2011 was performed at the required frequency.

2.3.4.9 Environmental Monitoring Equipment

Environmental monitoring equipment is tested on a weekly basis. If required, repairs to equipment are carried out immediately after the testing by Facilities and Site Services personnel.

2.3.4.10 Trends

There were no observed trends related to equipment performance in 2011.

2.3.5 Non-Production Sealed and Un-Sealed Source Inventory

The inventory of non-production sealed and unsealed sources is provided in Appendix B.

2.3.6 Effectiveness of the Nuclear Criticality Safety Program (NCSP)

Not applicable.

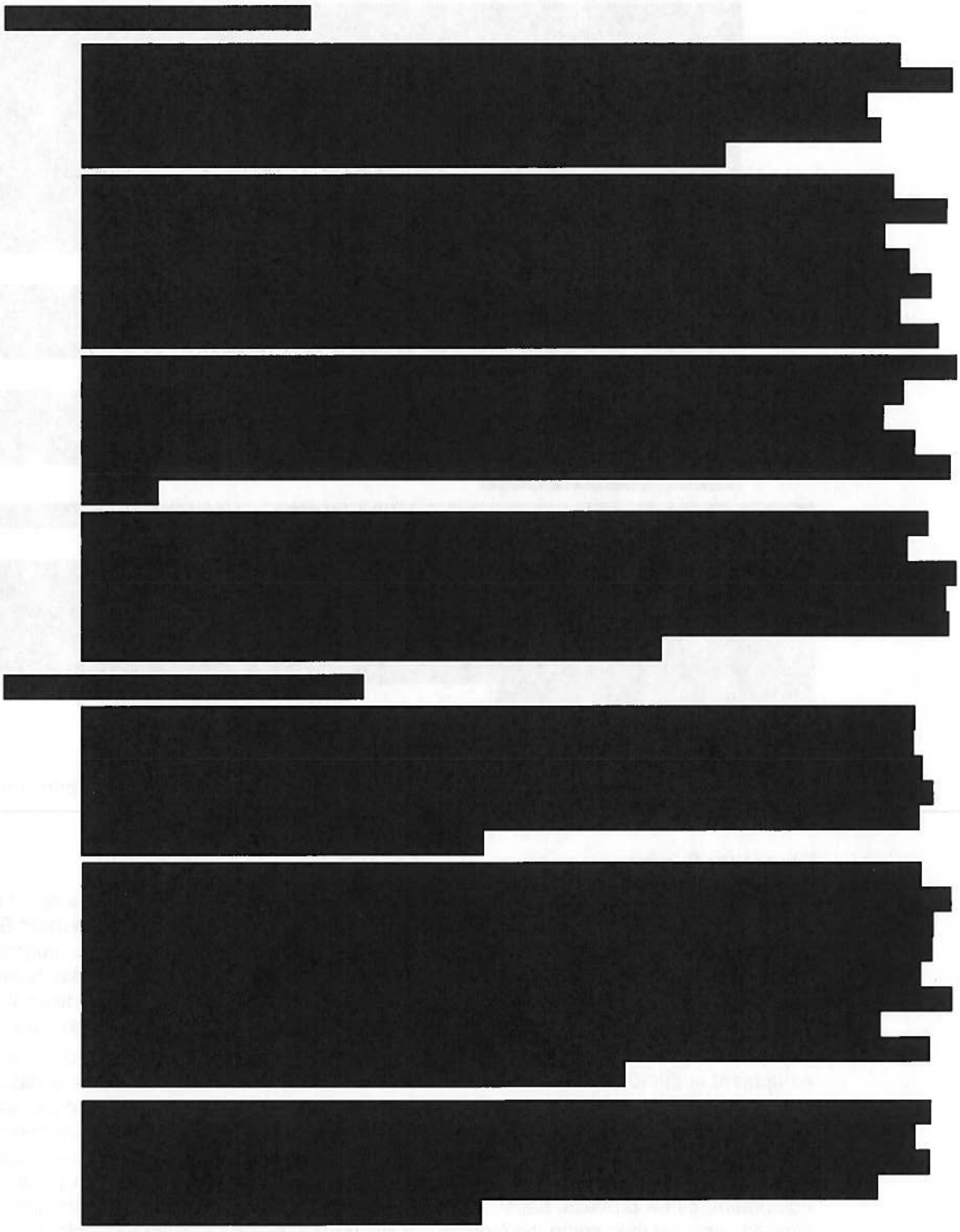
2.3.7 Emergency Drills Related to Nuclear Criticality

Not applicable.

2.4 Safety Analysis

Nordion has an established Environment, Health and Safety (EHS) Committee comprised of managers and senior professionals that review new/amended processes which might have an impact on health, safety, and environment. Activities that relate specifically to CNSC licensing and the radiation protection of workers, the public and the environment, are addressed in the EHS Committee meetings typically held on a bi-monthly basis with ad hoc meetings arranged as required. Typical agendas include Safety Analysis Reports, significant changes (repairs/modifications) to existing facilities, Radiation Incident Report reviews, safety procedures, and review of CNSC licensing requirements (radiation monitoring, ALARA program, emissions, dosimetry, project approval, etc.). In 2011, the EHS Committee met on 10 occasions (six regular meetings plus four ad hoc meetings).

Final Safety Analysis Reports (FSARs) are prepared by project leaders to encompass risk analysis and safety and environment reviews. FSARs must be approved by the EHS Committee before a new process goes into full production. Primary focus is placed on the Nuclear Medicine Production Facility (NMPF) FSAR and the Cobalt Operations FSAR, since these are the two main documents covering the production operations. Revisions to these documents are reviewed and approved internally, and submitted to the CNSC for approval. Secondary FSARs (for each individual production process) are reviewed and approved internally as per an established review schedule.



2.5 Physical Design

In 2011, within the boundaries of the active area for Nordion's production facilities, there were no physical design changes to any structural areas of the building.

2.6 Fitness for Service

The management structure of Nordion's Preventative Maintenance Program was not altered in 2011. Nordion continues to use Microwest's "Advanced Maintenance Management System" (AMMS) to control Nordion's maintenance activities. The AMMS software was upgraded to the current version. The upgrade was validated in conjunction with Microwest. Maintenance performance is reviewed monthly for outstanding activities and is acted on by team leaders. This continues to prove effective as during 2011, there were no major equipment failures.

Every year a detailed review is carried out at the senior management level to discuss aging equipment at the KOB. This review takes into account three criteria: safety of facility, regulatory requirements and site improvements. Projects are prioritized into three categories and funds are allocated as required to approved projects. During the 2011 review, it was determined that the underground condenser water piping which was 40 years old, had reached its life expectancy and it was decided that it should be replaced with new PVC piping engineered for this use. This aging equipment review process, because of the link to the Senior Management team and Finance, has worked very well in keeping the Nordion facility up-to-date with current technology.

Following Nordion's Standard Operating Procedures for the verification of equipment has proved successful during 2011. There were no equipment failures.

2.7 Radiation Protection

2.7.1 Dose Control Data

2.7.1.1 Occupational External Dosimetry

Currently Nordion is using Luxel+ or optically stimulated luminescent (OSL) dosimeters as TLD technology. Nordion's Radiation Protection Manual states that the traditional term "TLD" may be used interchangeably with OSL or other CNSC approved dosimeters.

All employees who regularly work in the Active Area are classified as NEWs and are assigned monthly TLDs. NEWs are trained to work in various production processes and move from one production area to another during the year. In the Nuclear Medicine Operations, personnel may receive exposure from working with more than one radionuclide. Those working with radionuclides where there is concern for extremity exposure to radiation are assigned extremity TLDs. Other employees who normally work outside the Active Area and visit the Active Area on a regular basis are also classified as NEWs, but are assigned quarterly TLDs.

All measurable radiation dose received by personnel were within the regulatory limit of 50 mSv/yr in 2011.

Contractors who are given access to the Active Area are called "Contractor NEWs" at Nordion. Technically, they are NEWs as they are trained, tested and have security clearance, but are subject to the regulatory dose limit and Action Levels of non-NEWs. For accuracy of review, their doses are reported in a separate group and their results are not broken down in Tables 9 and 10. Maximum and average doses for Contractor NEWs are listed in Table 11.

Tables 9 and 10 provide dosimetry data with employees grouped in various ranges of exposure. Data on the maximum and average doses for all employees who received a measurable radiation dose are shown in Table 11.

Table 9
Personnel Dosimetry
Number of Employees

								Extremity						
Dose Range (mSv)		Whole Body			Skin			Right Hand				Left Hand		
		2011	2010	2009	2011	2010	2009	2011	2010	2009		2011	2010	2009
< 0.2		192	193	201	180	176	186	111	110	110		110	116	113
0.2 - < 0.5		39	45	52	48	57	63	15	13	12		12	16	13
0.5 - < 1.0		30	40	31	30	40	31	9	16	22		15	14	20
1.0 - < 5.0		49	46	44	52	51	48	28	33	25		28	27	23
5.0 - < 20.0		1	0	0	1	0	0	8	8	9		5	7	8
20.0 - < 50.0		0	0	0	0	0	0	0	0	0		0	0	0
> 50		0	0	0	0	0	0	0	0	0		0	0	0

Table 10
Breakdown of Whole Body Radiation Doses 5.0 to < 20 mSv

Dose Range	5<8 mSv	8<10mSv	10<15 mSv	15<20 mSv
2011	1	0	0	0
2010	0	0	0	0
2009	0	0	0	0

Table 11
Maximum and Average Whole Body Doses (mSv)

	Maximum			Average			CNSC Regulatory Limits
	2011	2010	2009	2011	2010	2009	
Active Area Personnel (NEWs)	5.08	4.86	4.63	0.64	0.65	0.62	50/yr; 100/5yr
Non-Active Area Personnel (NEWs)	0.79	1.47	1.95	0.06	0.12	0.14	50/yr; 100/5yr
Non-NEWs (Contractors)	0.45	0.36	0.55	0.05	0.05	0.34	1/yr

2.7.1.2 Internal Occupational Radiation Doses

Nordion's bioassay program includes thyroid monitoring on a scheduled routine basis and whole body counting or urine analysis if air/contamination monitoring indicates it is needed.

During 2011, there were no cases of employees exceeding Nordion's administrative investigation level of 1000 Bq I-125 or I-131.

No whole body counting or urinalysis was required in 2011.

There were no employees who recorded internal doses exceeding any of the dose limits in Sections 13 and 14 of the Radiation Protection Regulations.

2.7.2 Significance of Results for the Dose Control Data

A further breakdown of dose trends by group, for the last five years is provided in Figures 1 to 18 at the end of this report. The graphical trends show group average, individual maximum and group cumulative doses. For brevity, only groups with individual maximums greater than or equal to 1 mSv/annum are included. In practice, if a graph appears anomalous, the actual data is examined, as group trends can be perturbed by changes in staff (transfers between groups, etc.). This trend data is reviewed yearly at the Annual Joint Environmental Management System and QA Program for Safety Review.

The doses for most groups are stable or trending downward. The doses for a few groups are slightly increasing as shown in Figures 3, 4, and 5. This data was examined in detail and it was concluded that no changes to work practices were warranted. In general, the results follow processing levels. An interruption in one product line, Sr-82 has also contributed to lowering doses to some Nuclear Medicine Groups in 2011.

2.7.3 Contamination Control Data

The contamination control program for the Active Area includes routine sampling and monitoring on a daily basis of the floors, benches, fume-hoods, glove-boxes, support/service areas, and on a weekly basis, change-rooms and inactive floors. Regular sampling, by wipe testing, of the corridors and office areas is conducted several times daily to ensure areas are maintained contamination free and, should contamination be found, to decontaminate immediately to the levels specified in the decontamination procedure. In addition, equipment leaving the Active Area is monitored by wipe test and/or direct measurement to provide assurance that equipment leaving the Active Area meets administrative and regulatory requirements.

During 2011 operations, there were instances where elevated levels of contamination (above "clean on swipe") were monitored and contained within the Active Area. Most were due to routine operations such as the replacement of manipulators and associated boots on a cell, decontamination of materials/equipment and shielding containers, and tracking of contaminants from a cell, glove-box, or fume-hood when product or samples were being removed.

There were a total of 37 contamination incidents in 2011. This number is comparable to the lower number of incidents of previous year. The total number of contamination incidents is lower for 2010 and 2011 due to reduced production of I-131, Ir-192 and Mo-99 and due to a change in the procedure. Starting in 2010, the levels at which an observed activity is classified as a contamination incident were re-defined.

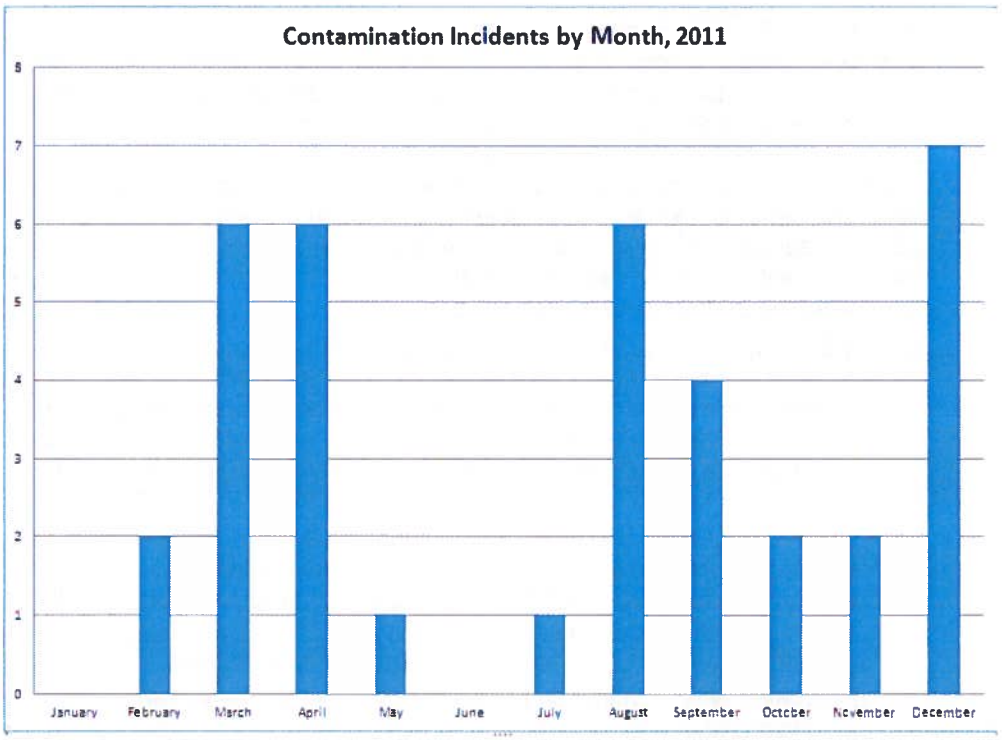
The distribution of contamination incidents in 2011 is shown in Tables 12 and 13 and illustrated in the below figure.

Table 12
Breakdown of Contamination Incidents by Contamination Level

Year	Not recorded	<500 cpm	>500 cpm, <2,000 cpm	>2,000 cpm, <10,000 cpm	> 10,000 cpm, < 50,000 cpm	>50,000 cpm	Annual Total
2007	1	10	22	15	6	10	64
2008	0	16	35	22	5	5	83
2009	4	5	35	23	7	5	79
2010	1	2	18	15	4	3	43
2011	0	11	11	9	3	3	37

Table 13
Breakdown of Contamination Incidents by Radionuclide

Year	Not recorded	C-14	Co-60	I-125	I-131	Mo-99	Y-90	Decayed Mo-99
2007	1		15	6	19	14	1	
2008	1	2	15	2	21	29	3	
2009	1	0	21	1	20	10	9	
2010	0	0	3	1	13	3	8	5
2011	1	0	7	3	6	12	3	0
Year	**Ir-192**	**In-111**	**Lu-177**	**Xe-133**	**Sr-82**	**Sr-90**	**Eu-152**	**Annual Total**
2007	3	0	0	1	3	1	0	64
2008	5	0	0	3	0	1	0	82
2009	10	1	0	0	4	1	1	78
2010	2	0	0	1	7	0	0	43
2011	0	2	2	0	0	0	1	37



2.7.4 Facility Radiological Conditions

The radiation survey program involves radiation measurements within the Active Area, and on the perimeter and exterior of the KOB. Within the Active Area, radiation surveys are conducted on a daily basis, throughout all the labs/rooms. Areas where radiation fields are above 2.5 mrem/hr (0.025 mSv/hr) are posted with radiation warning signs, indicating the radiation fields. In addition, surveys are conducted at employee work areas, at cells, glove-boxes, and fume-hoods, during production and test operations, to ensure radiation fields during processing are within acceptable levels. Special surveys are conducted on new processes/equipment to provide information on the safety performance of new operations. Detailed surveys are conducted on each of the Cobalt Operations cells every three years, to check for integrity of the cells and ensure radiation levels are within acceptable levels.

On a monthly basis, radiation surveys have been conducted on the perimeter of the Active Areas, and within the Inactive Office Areas. The monthly survey also includes measurement of radiation fields outside the KOB to ensure conditions have not changed in the operations that may impact the environment/exterior exposure. All the monthly surveys were conducted in 2011.

2.7.5 Exceedances of Regulatory Limits or Action Levels

There were three instances in which there was a potential to exceed a regulatory limit or action level in 2011. These are documented as Investigations 11-07, 11-16 and 11-21. Refer to Appendix A. For the first instance, there were no corrective actions as it was concluded that no Nordion employees received a dose in excess of 1 mSv from using the room the Environmental TLD was monitoring. For the second instance, there were no corrective actions as the elevated dose was determined to be non-personal. For the third instance, there were several corrective actions regarding the policy for wearing TLDs and the processes for reviewing dosimetry results (refer to Appendix A for further details).

2.7.6 Radiation Protection Program Effectiveness

The Radiation Protection Program is reviewed by conducting process audits and process safety audits. Refer to Section 1.2.4.1 and 1.2.4.3. Data and performance of the Radiation Protection Program is reviewed regularly at EHS Committee meetings.

2.7.7 Radiation Protection Program Improvements

Several improvements to the Radiation Protection Program were executed in 2011. The emergency response kits were upgraded to improve their portability, improved respiratory fit testing equipment and air samplers were purchased, the KOB delay tank level indicators and monitoring systems were upgraded and a liquid scintillation counting unit was obtained that will be dedicated to radiation safety. Also, the microsphere vacuum was designed to aid in decontaminating hot cells. In addition, the radiation safety booklet was updated and redistributed to all Active Area employees.

2.7.8 Radiation Protection Program Performance

The objectives, goals and targets of the Radiation Protection Program are shown in Table 5 of Section 2.3.1. The targets average and maximum NEW dose and environmental releases were met in 2011. These targets are tracked as key performance indicators at EHS Committee meetings and in Monthly Operational reports. The targets are reviewed yearly at the Annual Joint Environmental Management System and QA Program for Safety Review. Refer to Section 3.2 Table 22 for a summary of the initiatives and targets for the upcoming year.

2.7.9 Continuous Improvements Under ALARA Performance

ALARA objectives and performance is reviewed at EHS Committee meetings and all activities in the ALARA program are described in SE-RP-002, "Keeping Radiation Exposures and Doses "As Low as Reasonably Achievable (ALARA)". This procedure was followed in 2011, and performance against targets is demonstrated in Table 5 of Section 2.3.1.

2.7.10 Radiation Protection Training Program and Effectiveness

Refer to Section 2.2.1.

2.8 Conventional Health and Safety

2.8.1 Conventional Health and Safety Program Effectiveness

The Conventional Health & Safety Program is reviewed by conducting program audits, process audits, regular inspections by both employees and management, and a review of revised safety programs is performed by the Policy Health & Safety Committee. The Policy Health & Safety Committee is also responsible for reviewing the Hazard Prevention Program and updating the Hazard Assessment and Ranking system. In addition, the EHS Management Committee sets targets each fiscal year in the areas of Medical Treatment Incidents, Lost Time Incidents and Severity Rates. Refer to sections 1.2.4.1 and 1.2.4.3 for a description of audits and inspections.

2.8.2 Conventional Health and Safety Committee Performance

The Kanata Operations Building (KOB) Workplace Health and Safety Committee is represented by union and management and typically meets on a monthly basis. The KOB Health & Safety Policy Committee is represented by union and management and typically meets on a quarterly basis.

The KOB Workplace Health and Safety Committee met nine times. The KOB Health & Safety Policy Committee met on seven occasions in 2011. The accomplishments for 2011 were that the Safety Policy Committee continued to review the Hazard Prevention Program and made improvements in the following areas: Lead Control Program, Asbestos Management Program and the Work Reintegration Program. In addition, the Committee participated in the creation of the Security Monitoring and Violence in the Workplace Programs.

2.8.3 Conventional Health and Safety Program Improvements

Improvements to the Conventional Health and Safety Program in 2011 included the following:

- Updating the First Aid Program to include the new AED program
- Commencing the Confined Space Program and placing signage at all identified confined space locations
- Modifying the Chemical Handling and Storage program and implementing training
- Performing ergonomic training for the Research and Development and Quality Control Chemistry groups
- Asbestos training for new Facilities employees
- Modifying the S&E Xpress to a monthly newsletter including information on environment, wellness, security and safety and incentives for employees
- Developing and delivering Behaviour Observation Training for Managers
- Performing Loading Dock Assessments for Cobalt and Stores personnel
- Launching a Webex session for employees on Mental Health in the Workplace
- Completing the Chemical Inventory Database

2.8.4 Hazardous Occurrences

During 2011, there were no disabling injuries.

Five minor injuries were sustained that did not result in any time lost, but required physiotherapy or prescription medicine. Four of the minor injuries were due to overexertion while the fifth resulted in a cut hand from breaking laboratory glassware. Corrective actions included a review by the Policy Health & Safety Committee and the conducting of formal ergonomic reviews of several processes using manipulators. In addition, information sessions were held by the Company Doctor to discuss proper work practices and ergonomics in general.

2011 incident and severity rates were among the best ever recorded at the Kanata site.

2.9 Environmental Protection

2.9.1 Air and Water Release Monitoring

The environmental monitoring program is designed to monitor and measure effluent releases to the environment and to determine radiation levels in areas exterior to the KOB. The program includes the following elements:

a) Continuous monitoring of process ventilation, exhausts ductwork, and stack emissions by use of in-situ detectors and samplers and computerized recording

b) Weekly air sampling and analyses for KOB exhaust stack emissions

c) Holding tanks for Active Area liquid effluent to allow sampling, analysis, and authorized release of liquid effluent

d) Environmental TLD program

e) Soil sampling (which is performed every two years and was performed in 2010).

Ventilation and stack sampling is conducted by using particulate and/or activated charcoal filters, depending on the physical and chemical nature of the radionuclide. Radioiodine sampling involves the use of activated charcoal filter cartridges, and analyses by gamma measurement. Particulates are sampled by use of cellulose filter papers and analyzed by gamma measurement.

All production operations are contained within cells, glove-boxes and/or fume-hoods. Ventilated air from these containment systems is filtered through roughing and HEPA filters and, where appropriate, activated charcoal adsorbers. These systems are designed with redundant fan/motor and filtration units that include pre-filters, primary and secondary filtration units. The NVS has been designed and is maintained to prevent the unnecessary release of radioisotopes to the atmosphere.

2.9.1.1 Airborne Effluent

Allowable releases to the environment are limited to the values in SE-OP-029 (4), "Derived Release Limits". A revised version of SE-OP-029 (5) has been submitted to the CNSC for approval. Some radionuclides are reported using SE-OP-029 (5) as values for these radionuclides were not listed in the previous version (Version 4). A summary of airborne releases is provided in Table 14.

In 2011, the maximum annual release of airborne from any one radionuclide was Xe-135m at 0.92% of the DRL. No Action Levels were exceeded in 2011. Since the submission of SE-OP-029 (5), the Canadian Standards Association (CSA) has published a new standard for calculating DRLs. In early 2012 a revised SE-OP-029 which follows the revised CSA standard will be submitted to the CNSC for approval.

Table 14
Airborne Releases

Year	C14 (GBq/a)	Co-60 (GBq/a)	I-125 (GBq/a)	I-131 (GBq/a)	Xe-133 (GBq/a)	Xe-135 (GBq/a)	Xe-135m (GBq/a)
2007	960.9	0.0048	1.09	2.41	43559	41038	57240
2008	635.4	0.005	0.26	1.98	67193	48677	60845
2009	37.8	0.006	0.47	1.05	26407	14439	20444
2010	43.1	0.006	0.37	0.99	9066	6407	9366
2011	67.9	0.006	0.38	0.29	34967	17239	27688

	C14	Co-60	I-125	I-131	Xe-133	Xe-135	Xe-135m
DRL (GBq/a) Using SE-OP-029 (4)	**	78	990	1110	2.90E+07	**	**
% DRL (2011)	**	0.01%	0.04%	0.03%	0.12%	**	**
% Action Level (2011)	**	0.01%	0.08%	0.05%	0.24%	**	**

** No limit established for these isotopes in SE-OP-029 (4)

	C14	Co-60	I-125	I-131	Xe-133	Xe-135	Xe-135m
DRL (GBq/a) Using Draft SE-OP-029 (5)	9.95E+04	1.17E+04	1.22E+03	1.13E+03	4.27E+07	5.00E+06	3.00E+06
% DRL (2011)	0.07%	0.00%	0.03%	0.03%	0.08%	0.34%	0.92%
% Action Level (2011)	0.14%	0.00%	0.06%	0.05%	0.16%	0.69%	1.85%

2.9.1.2 Liquid Effluent

Allowable liquid effluent releases to the environment are also limited to values in SE-OP-029 (4), "Derived Release Limits". The five year variation in activities released is listed in Table 15.

No Action Levels or Administrative Levels were exceeded in 2011. All liquid effluent releases have been below the Nordion action levels and well within CNSC licensed limits. A summary of liquid releases, expressed as a % DRL, is provided in Table 15.

The City of Ottawa is informed whenever a release to the sanitary sewer takes place. In addition, a monthly summary report of the activity levels released is provided to the City of Ottawa.

Table 15
Liquid Releases (GBq/a)

Year	Litres	β<1MeV	β>1MeV	I-125	I-131	Mo-99	Co-60	Nb-95	Zr-95	Cs-137
2007	986058	0.373	0.083	0.008	0.015	0.122	0.028	0.0006	0.0005	0.0002
2008	1087471	0.481	0.086	0.007	0.014	0.127	0.029	0.0005	0.0005	0.0005
2009	1130670	0.424	0.096	0.008	0.016	0.144	0.034	0.0006	0.0004	0.0007
2010	1510764	0.569	0.129	0.011	0.021	0.180	0.044	0.001	0.001	0.001
2011	1024391	0.395	0.088	0.007	0.013	0.116	0.027	0.001	0.001	0.0004

	β<1MeV*	β>1MeV*	I-125	I-131	Mo-99	Co-60	Nb-95*	Zr-95*	Cs-137*
DRL (GBq/a)	7780	105,000	14,700	10,800	467,000	64,100	64,100	64,100	64,100
2011 % DRL	5.07E-03	8.36E-05	4.79E-05	1.23E-04	2.49E-05	4.26E-05	1.73E-06	1.07E-06	6.81E-07
% Action Level	1.01E-02	1.67E-04	9.57E-05	2.46E-04	4.99E-05	8.52E-05	3.45E-06	2.15E-06	1.36E-06

* The DRL for Sr-90 is used for β<1MeV and the DRL for Y-90 is used for β>1MeV. Nb-95, Zr-95 and Cs-137 are contaminants which are expected to be present in small quantities or non-detectable. Although we do not formally monitor for these contaminants, their presence was detected by the analysis method used to check the liquid effluent samples for our major isotopes. DRLs are required for only the major isotopes. The majority of the recorded releases are the minimum detectable activities being conservatively reported as real values insread of using zero. This number is then directly proportional to volumes released.

2.9.1.3 Environmental TLDs

The locations of environmental TLDs (Landauer model X9) are shown on Figures 19 and 20 and listed in Table 16. Environmental TLDs were placed in these locations as they monitor the fields at representative points at the perimeter of the Kanata site. These locations are detailed in procedure SE-OP-012, "Environmental and Office Monitoring Dosimeters". The environmental TLD placement corresponds roughly to the historical locations of these dosimeters, which is useful for trending. The placement of these TLDs is unchanged from 2006. The dosimeters are deployed to generally cover the points of a compass and preferentially to the east of the facility, which is the direction of the prevailing winds. The TLDs are also placed in residences of Nordion employees. No specific trends can be inferred from the data.

Table 16
Environmental TLD Results

Location		Totals				
		2011 (mSv)	2010 (mSv)	2009 (mSv)	2008 (mSv)	2007 (mSv)
16	R.E. BUILDING, ROOM 5513	0.08	0.01	0.064	-0.054	-0.004
17	POLE, NORTH CORNER	0.163	0.02	0.147	0.014	-0.141
18	HEATING PLANT, ROOF	-0.0124	m	-0.069	-0.137	-0.253
19	HYDRO POLE, SOUTH-WEST	0.012	m	0.031	0.127	0.003
20	TREE, EAST CORNER	0.0	m	0.011	-0.039	0.039
21	THERAPY SYSTEMS, ROOM 209	ND	0.04	0.163	0.159	0.119
32	RESIDENCE	0.025	m	-0.038	-0.021	0.020
57	RESIDENCE	ND	*	*	*	*
33	RESIDENCE	-0.061	m	*	0.036	*
35	RESIDENCE	0.077	0.01	*	*	*
58	NATIONAL CAR RENTAL	0.03	m	0.051	0.121	0.081

* missing TLD.
m = less than 0.01 mSv
ND = not deployed

2.9.2 Significance of Air and Water Release Monitoring Results

Unlike in 2009 and 2010, Mo-99 production was mostly uninterrupted throughout the year, but production quantities were smaller than in 2007 and 2008 leading directly to the observed changes in noble gas (Xe-133/-135/-135m) air releases. C-14 production stopped toward the end of 2008; and therefore, a decrease in C-14 releases for 2009 through 2011 is observed. The C-14 production cell was dedicated to another process in 2009. C-14 monitoring will stop after the C-14 production glove-boxes and fume-hoods are dismantled. Releases for I-125 are stable, but releases of I-131 are lower in spite of increased production levels of I-131 year over year. This reduction of I-131 releases is due to the use of new in-cell charcoal roughing filters which are present in the new I-131 processing facility. These in-cell roughing filters are now present in Cells 7 to 10 (Mo-99), Cells 41 and 42 (I-131) and Cells 22A and 22B (Sr-82). It is Nordion's intention to install this improved design in all new or retrofitted ventilation designs where practicable. No other specific trends were noted.

Lower volumes of water were released from the facility in 2011 compared to 2010. Nordion employs a conservative practice of assuming the Minimum Detectable Activity (MDA) is always released. Nordion's practice of assuming releases equivalent to the MDA explains why the year over year trend very closely follows the number of litres released. The next largest factor is variation in the MDA between the Cobalt Operations Facility and the Nuclear Medicine Facility. A small percentage of the release reported is activity detected over the MDA.

2.9.3 Exceedances of Regulatory Limits or Action Levels

There were no instances of exceeding environmental regulatory limits or action levels in 2011.

2.9.4 Discussion on Environmental Protection Program Effectiveness

The Environmental Protection Program is evaluated on an annual basis. In 2011, this review was held during the Annual Joint Environmental Management System and QA Program for Safety Review held May 31, 2011. The results of the review are identified in Section 2.1.2 items 3, 4, 5 and 6.

Refer to Section 1.2.4 for a summary of internal and external inspections, audits and reviews.

2.9.5 Environmental Protection Program Improvements

Improvements to the Environmental Protection Program in 2011 included:

- Implementing a process to conduct routine environmental inspections to identify areas for improvement and/or concerns. A total of 10 fire and environmental inspections were conducted in 2011.
- Monitoring sanitary sewer discharges for non-radioactive contaminants. Results of the analysis were measured against the current City of Ottawa Sewer Use by-law. One exceedance was identified (Total Phosphorous) This was investigated and determined to be a result of non-routine (high number) studies/test being conducted of our glassware washer. This exceedance and the cause of the exceedence were reported to the City of Ottawa.
- Nordion maintains ISO 14001: 2004 certification and in 2011 Nordion was subject to a routine maintenance audit of the system. There were two minor non-conformances identified during the course of this audit. One was the result of a minor lapse in the organization's process for raising CAPAs from internal audit non-conformances. The second related to an equipment calibration process and that it did not consistently ensure that all equipment was calibrated in a timely manner.

2.9.6 Environmental Program Performance

A description of the Environmental Protection Program Initiatives is provided in Table 17, along with the results/outcome.

A summary of initiatives and targets for the upcoming year is provided in Table 18.

Table 17
2011 Environmental Objectives

Objective	Result / Outcome
Reduce the use of hazardous and other environmentally harmful materials (Ottawa and Vancouver)*	Expected reduction of 5% by 2015
Reduce Waste (Ottawa and Vancouver)*	Expected reduction of non-hazardous waste by 5% by 2015 Expected reduction of hazardous waste by 5% by 2015
Reduce Energy Use (Ottawa site)	In 2011 a project was conducted to evaluate the feasibility of recycling the heat from the Cobalt pools to heat the facility.

** Standardized by revenue to allow for growth. Baseline year of 2010. Hazardous material refers to hazardous chemicals and excludes radiological materials.*

Table 18
2012 Environmental Objectives and Targets

Objective	Target
Ensure all managers actively consider impacts to the environment and health and safety.	• Opportunities for minimizing waste (hazardous and non-hazardous) are assessed and implemented as feasible.
Minimize the use and release of hazardous materials to the environment.	• Reduce Hazardous waste by 5% by 2015. • Reduce non-hazardous waste by 5% by 2015. • Reduce use of hazardous and other environmentally harmful materials by 5% by 2015.
Identify opportunities to reduce environmental impacts.	• Identify opportunities for reducing waste, and using less harmful materials where feasible.

2.9.7 Well and Soil Sampling and Measuring/Monitoring

Soil sampling is conducted at least every two years to determine the presence/absence of radioactive materials in the soil. In 2010, Co-60 was detected in samples; however, the levels found were much less than the exemption levels outlined in IAEA RS-G-1.7, "Application of the Concepts of Exclusion, Exemption and Clearance".

Groundwater sampling results (non-radiological) conducted in 2011 demonstrated that there were no significant changes to groundwater.

2.10 Emergency Management and Response

2.10.1 Emergency Preparedness Program Activities

Nordion has an extensive emergency preparedness program to respond to various types of emergency situations, including on-site and off-site emergencies. During 2011 a number of emergency response (ER) exercises were conducted to test these emergency response plans and provide training to employees having responsibilities within the plans. Drills and activities which took place in 2011 included:

- On-site meetings and tours with City of Ottawa Fire Services.
- A test of the Emergency Response Fan-Out Phone List was performed in December 2011 to ensure accuracy of telephone numbers listed, to determine availability of personnel and to estimate response time. Findings from this drill indicated that there were adequate emergency response personnel from the key support groups available. Further to this, there was also at least one person available from each of the additional support groups. This drill also indicated that a majority of personnel surveyed had access to the emergency response contact numbers if they had needed them.
- Emergency response training is ongoing (refer to Section 2.10.2 for additional information).
- A computer based training course on emergency alarms and response was provided to all employees at the Ottawa site.
- A chemical spill response drill was conducted.
- A full-scale emergency response exercise involving external agencies (Ottawa Fire Services, HAZMAT and Paramedics) was conducted under the observation of the CNSC.

2.10.2 Emergency Preparedness Training Program and Effectiveness

All new employees and contractors are provided with emergency response training prior to being granted a security badge.

During 2011, the following emergency response training was provided to employees and those working on behalf of Nordion:

- Fire Warden and Marshall Training – 20 Participants
- ER Personnel – 75 Participants
- New Employee/Contractors Emergency Alarm and Response Training – 108 Participants
- 2011 Emergency Alarms & Response Training – 444 Participants
- Fire Department Advisory Training – 2 Participants

2.10.3 Fire Protection Program Activities and Effectiveness

The fire safety plan is tested annually. This test involves evacuation of the three buildings (KOB, RE Building and Heating Plant) by activation of the building fire alarm system. From the tests conducted in 2011, it was found that during drills some of the areas did not always have Fire Wardens and/or Marshals due to the low number of people in the area or buildings. During the full-scale evacuation held in the KOB, it was identified that:

- Additional training, awareness and exercises involving external agencies is required
- Better communication of risks to external agencies is required
- More exercises for training employees and ER personnel are required
- During future exercises, a more structured debrief session is required
- A protocol for moving the Emergency Operations Centre (EOC) to the incident site with the emergency responders for the first part of any exercise or event is required
- A protocol for what needs to be done when Fire Wardens do not complete the sweep of an area is required
- Contamination zones should be established that outside agencies can identify/understand i.e. visible demarcation.
- Better identification system for key ER personnel is required i.e. vests with Incident Command naming conventions
- Restructure/rework of the Site Emergency Response Plan is required to better align with Incident Command System which outside agencies work to and are familiar with
- Investigate relocating EOC and METASYS closer to the site of an emergency to enable more efficient response during emergencies
- The role of Fire Department Advisor needs to be reviewed to ensure whoever is in the role has the knowledge and expertise required to address the needs of external agencies
- A protocol needs to be established for calling 9-1-1 and clearly identifying the facility risks to enable emergency responders to provide a more efficient response
- Clarification of Facilities personnel role in investigating a fire event is required
- Investigate a better means for First Aid responders to communicate or get updates during an emergency
- Communications to employees could be more timely
- Clarification of who has authority for giving the all clear and when the all clear should be given following and emergency or exercise is required

Nordion's Inspection, Testing and Maintenance report is submitted to the CNSC annually. This report was submitted to the CNSC in December 2011 with no deviation identified.

2.10.4 Fire Protection Program Improvements

In 2011, Nordion made the following improvements to the Fire Protection Program:

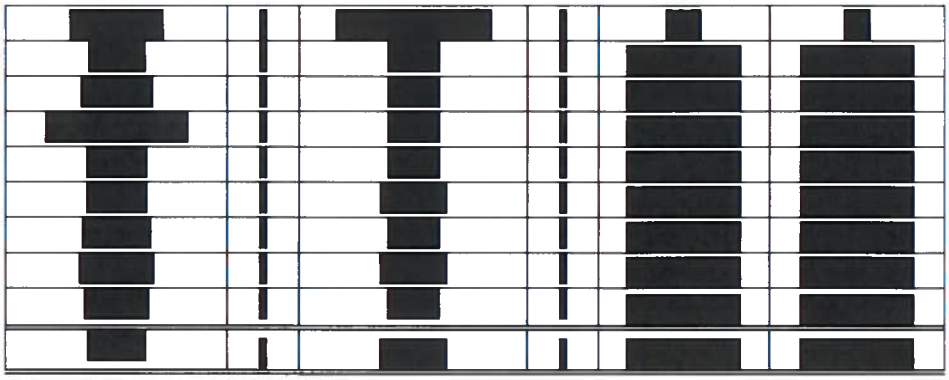
- The Fire Protection Program was revised and submitted to the CNSC in May 2011.
- All remaining corrective actions resulting from Nordion's Fire Hazard Analysis were completed in 2011.
- Nordion conducted ten routine fire and environmental inspections in 2011.

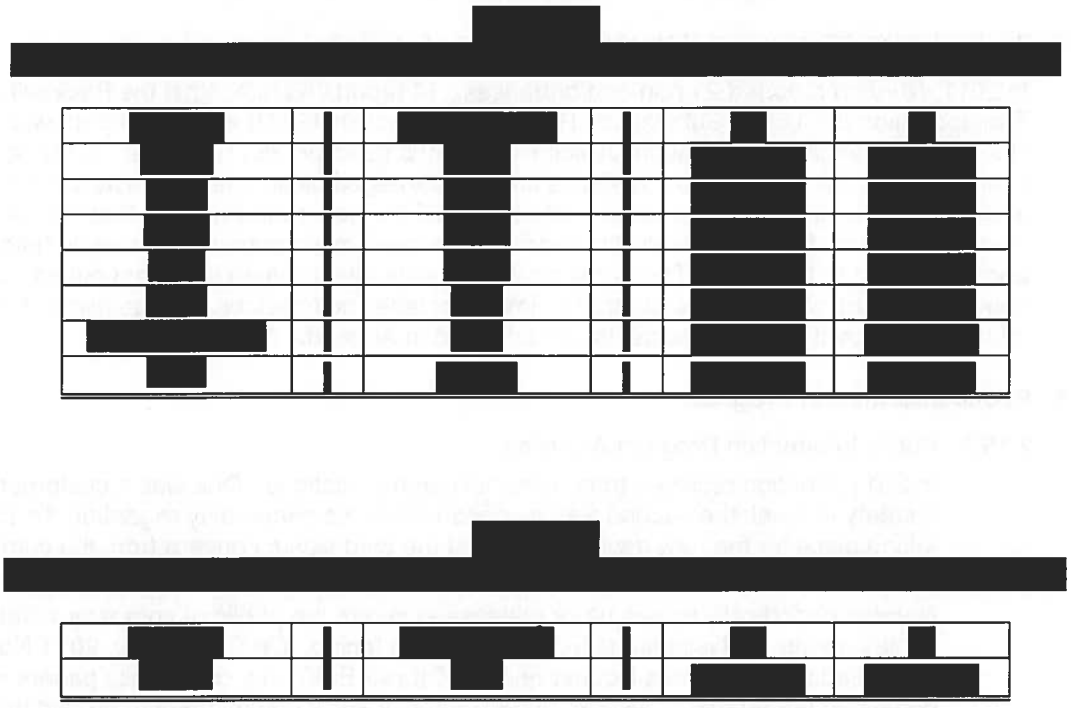
2.11 Waste Management

Nordion production facilities have been designed and operated in a manner to prevent radioactive waste being released to municipal garbage or sewer systems and to ensure that releases to the environment via air or water emissions are within limits approved by the CNSC. All radioactive waste that was generated through the production operations was collected and sent to the CNSC approved radioactive waste management facility at AECL's Chalk River Laboratories (CRL), Energy Solutions Canada in Brampton, Ontario or Ontario Power Generation (OPG) Bruce Power in Tiverton, Ontario.

Due to the nature of radioisotope production that involves decay and contamination products, identification of individual isotopes and their respective quantities in waste material is difficult. Nordion has worked with AECL to identify waste streams that are determined by the major isotope product in a given facility. Data for the actual waste activity levels are estimated from activity in the production volume and waste streams.

Waste from other radioisotope licensees is not transferred to Nordion for subsequent disposal. However, spent sealed sources may be returned to Nordion where they may be reprocessed or included with other product material for disposal.





2.12 Nuclear Security

Details of Nordion security and all of the security improvements of 2010 were provided in the Nordion Physical Security Report for 2010. These safeguards and improvements were reviewed with CNSC Security during an inspection on January 13, 2011. Significant additional improvements were made in 2011 that will be detailed in the next Physical Security Report, to be submitted in March, 2012. New improvements include fencing around the facility, improved lighting, additional security cameras and other improvements that are prescribed information.

2.13 Safeguards and Nuclear-proliferation

Nordion has a program in place for the management of safeguarded material at the Nordion Ottawa site. The program meets the safeguards requirements of specified license conditions, CNSC Nuclear Non-Proliferation Import and Export Control Regulations, the Nuclear Safety and Control Act and General Nuclear Safety and Control Regulations and was recently revised to meet the safeguards requirements of the CNSC regulatory document RD-336, "Accounting and Reporting of Nuclear Material".

In 2011, two safeguards inspections were conducted by the CNSC. The first safeguards inspection was the Physical Inventory Taking - Evaluation (PIT-E) conducted on September 15, 2011. There were no follow-up items required as a result of this inspection.

The second inspection was an audit of Nordion's Nuclear Material Reporting Procedures conducted October 3, 2011. There were three corrective actions, three general comments and one follow-up item as a result of this audit. The corrective actions were related to errors and/or areas not addressed in the procedures and ensuring the requirements are followed regarding reporting and signing of reports. All corrective actions have been completed. The follow-up item required that the signed PIT reports be re-submitted. These forms were provided to the CNSC Safeguards Accounting and Technology Division October 4, 2011.

2.14 Packaging and Transport of Nuclear Substances

In 2011, Nordion reported 21 non-conformances. 14 reports were against the Packaging and Transportation of Nuclear Substances Regulations (Section 19 (1)) and one report was against the Nuclear Substance and Radiation Device Regulations (Section 38 (1)). Seven of the reported non-conformances were external to Nordion's control (damaged packages, conveyance involved in an accident, improper carrier, or improper labelling). Of the non-conformances that fell within Nordion's control, four were related to exposure devices (maintenance, and source holder issues) and ten related to transport. The transport issues were either due to shipment outside of approved conditions (four), over-dispensing (three), improper labelling (one), or leakage (two). Further information regarding these incidents can be found in Appendix A.

2.15 Public Information Program

2.15.1 Public Information Program Activities

In 2011, Nordion received three external communications. One was a customer request for a safety manual; the second was a concern from the community regarding the blasting taking place for the new development and the third was a concern from the community regarding the new fencing installed around the building.

Nordion periodically issues news releases to inform the public of company initiatives, achievements and issues the business may be facing. On October 20, 2011 Nordion posted ads in the Kanata Kourier and the Ottawa EMC, key community papers with a combined readership of 48,236, underlining Nordion's commitment to protect the safety of employees, the community and the environment. The ads noted that Nordion is certified to ISO 14001, an international standard for environmental management systems. The ad also directed people to the Nordion website, provided the names of key contacts within Nordion and overall, encouraged the public to contact Nordion with any questions, comments, or concerns.

Nordion continues to update and enhance the corporate website to include more information in the Corporate Social Responsibility section including more on the safety programs, environmental management system, and an FAQ section. The Safety section outlines Nordion's commitment to radiation, employee, public and environmental safety. It also outlines the regulators for the facility with links to their homepages. The Environmental Management page outlines the commitments made to environmental stability, including Nordion's ISO 14001:2004 certification, which demonstrates Nordion's commitment to improving environmental performance. The FAQ section answers common questions posed by the general public.

The site receives several hundred page views each month with the majority of visitors (55-60%), representing new visitors.

There were no Nordion media articles relating to environment, health, and safety issues/topics during 2011.

2.15.2 Public Information Program Initiatives

On October 11, 2011, Nordion hired a Senior Manager of Corporate Communications, a communications team role tasked with enhancing Nordion's public information program. In fiscal 2012, this individual is currently developing new initiatives to extend Nordion's commitment to keeping the public informed of EHS related issues.

2.16 Site-Specific Information

Nordion's site-specific reporting requirements are as follows:

- Nordion shall make and submit reports to the Commission regarding safeguarded material in accordance with RD-336, "Accounting and Reporting of Nuclear Material".
- Nordion shall annually update and submit the Annual Physical Security Report by March 31, of the following calendar year.
- Nordion shall report the transfer, receipt, export or import of sealed sources if the activity exceeds the threshold limits as indicated in the site license and within the specified timeframes as detailed in the site license.

In 2011, Nordion complied with each site-specific reporting requirement with two exceptions. These two exceptions involved sealed source reporting. Both of these instances were reportable under Section 6.1 (g) of the site license (NSPFOL-11.A.04/2015).

Investigation report 11-03 documents an event where four returned Ir-192 sealed sources with activities exceeding 21.6 Ci upon receipt were not reported to the CNSC SSTS within 48 hours of receipt as required by Nordion's site license. The root cause was determined to be operator error, inattention to detail. The corrective actions involved the Production Manager reviewing with the Production Technicians the requirements of the sealed source reporting procedure, ensuring that the backlog of sources pending receipt that existed at the time was cleared and ensuring moving forward that all incoming sealed sources are assessed as they arrive. Follow-up with Customer Service was also conducted to ensure that they are reminding customers to include the source information with their shipments.

Investigation Report 11-26 documents an event where one Ir-192 sealed source with an activity exceeding 21.6 Ci upon receipt contained within a re-directed industrial radiography device received at Nordion was not reported to the CNSC SSTS within 48 hours. The subsequent transfer of this source to a Canadian customer was not reported to the CNSC SSTS on the day of shipment. The root causes were determined to be communication; accountability for the policy needs improvement and procedures not followed. To address these root causes, Customer Service formally re-enforced with the customer Nordion's requirements, Customer Service formalized communications between Customer Service, and Operations and Production and Customer Service personnel were reminded of their responsibilities regarding the sealed source reporting policy.

The Financial Guarantee, as approved by the Commission and based on the facility's Decommissioning Plan, is still valid.

3. FUTURE PLANS AND CONCLUDING REMARKS

3.1 Improvement Plans and Future Outlook

[redacted]

3.2 Safety Performance Objectives for Following Year

Nordion plans to replace its in-cell halon fire suppression system with a more environmentally friendly argon fire suppression system.

There are no projected changes to the organizational structure for 2012.

Nordion's 2012 EHS Program Objectives and Targets and Health and Safety Objectives are shown in Tables 22 and 23. For 2012, the number of incidents was lowered from ≤ 8 to ≤ 6, lost time injuries was lowered from ≤ 0.8 to ≤ 0.6 (rolling three year average) per 200,000 hours worked and the severity of lost-time injuries was lowered from < 10 to < 5 days (rolling three year average) per 200,000 hours worked. An additional target regarding the submission of dosimeters was added. The other targets remain unchanged for the 2012 fiscal year.

Table 22
2012 EHS Program Objectives and Targets

Applicable Nordion Job Function	Objective	Measures and Targets
All Directors and Managers	Minimize the number and extent of occupational injuries, environmental and radiation incidents.	• The number of incidents ≤ 6 • Lost time injuries ≤ 0.6 per 200,000 hours worked (3-yr rolling) • The severity of lost-time injuries to < 5 days per 200,000 hours worked (3-yr rolling)
All Directors and Managers of Operations, Facilities, or Nuclear Energy Worker employees	Minimize the use and release of hazardous materials to the environment.	• Radioactive materials emissions to ≤ 7.5% of the Derived Release Limits (DRL). • No non-compliant sanitary sewer emissions of non-radioactive hazardous materials • Reduction in the use of hazardous materials and the generation of hazardous and non-hazardous waste
	Maintain radiation doses to employees as per ALARA principle.	• Average Active Area employee dose rate ≤ 2.0 mSv/yr for all sites • Maximum employee dose rate ≤ 8 mSv/yr • Radiation Incidents ≤ 5/year

Table 23
2012 Health and Safety Objectives

Applicable Nordion Job Function	Objective	Measures and Targets
All Directors and Managers	Ensure all managers of high risk areas conduct / document regular self-assessments of their management processes and safety performance.	• Mid-Year and Year-End performance reviews
All Directors and Managers of Operations, Facilities, or Nuclear Energy Worker employees	Ensure all managers actively consider impacts to the environment and health and safety.	• Environment, health and safety impacts are assessed as part of product realization planning and risks are mitigated through application of ALARA and pro-active planning. • Opportunities for minimizing waste (hazardous and non-hazardous) are assessed and implemented as feasible. • Ensure all near misses are reported and appropriate corrective actions(s) are taken.
	Communicate monthly with teams about environment, health and safety performance and impacts. Openly evaluate employee environment, health safety concerns.	• Environment, health & safety information and concerns are discussed regularly at team meetings. • Health and safety concerns are assessed with the results of the evaluation communicated to the employee(s). • Deviations, CFs, Non-conformances and Complaints are assessed for EHS risks against targets and reported accordingly. • Routinely invite EHS Representatives to team meetings to discuss EHS topics and/or concerns.
All High Risk Employees	Work safely at all times. It is unacceptable to take risk in order to get the job done.	• Work follows Nordion applicable EHS standards and procedures, and is performed with care and attention to safety principles. • Wear all applicable personal protective equipment (PPE). • Submit all dosimeter(s) and rings for monitoring on time (i.e. no later than one month following end of monitoring period without good reason, such as extended illness or company travel, etc.).
	Report the occurrence of workplace injuries, unsafe conditions and near misses.	• All workplace injuries and observed unsafe conditions & near misses are reported immediately to the direct Supervisor. • Immediately report all near-misses to your Manager
	Correct co-workers who are working unsafely.	• Following Nordion values, coach co-workers who are seen working unsafely.
	Identify opportunities to reduce environmental impacts.	• Identify opportunities for reducing waste, and using less harmful materials where feasible

3.3 Concluding Remarks

The key points of this report are as follows:

- There were no major issues in 2011. The facility has operated according to its original design criteria. There were no physical design changes to any structural areas of the building or changes to the designated active areas.
- Conformance to internal training requirements was extremely high in 2011.
- Testing of the radiation devices and instrument maintenance was performed at the required frequency and results were satisfactory. There were no observed trends related to equipment performance in 2011.
- The Environment, Health and Safety Committee met on a regular basis to review the environmental and safety aspects of the operations and to review and approve Final Safety Analysis Reports (FSARs).
- All measurable radiation dose received by personnel and the public were within the regulatory limit of 50 mSv/yr. and no internal dose levels or limits were exceeded.
- There were a total of 37 contamination incidents in 2011. All elevated levels of contamination were monitored and contained within the Active Area.
- There were three instances in which there was potential to exceed a regulatory limit or action level in 2011. For the first instance, there were no corrective actions as it was concluded that no Nordion employees received a dose in excess of 1 mSv. For the second instance, there were no corrective actions as the elevated dose was determined to be non-personal. For the third instance, there were several corrective actions regarding the policy for wearing TLDs and the processes for reviewing dosimetry results.
- Various improvements were made to the Radiation Protection Program, Conventional Health and Safety Program, Environmental Protection Program and Fire Protection Program. These programs fall within the scope of the QA Management Program.
- There were no disabling injuries in 2011. Incident and severity rates were among the best ever recorded at the Kanata site in the 2011 fiscal year.
- There were no instances of exceeding environmental regulatory limits or action levels in 2011. The maximum annual release of airborne from any one radionuclide was Xe-135m at 0.92% of the DRL.
- A number of improvements were made to nuclear security.
- In 2011, Nordion received three external communications.
- In 2011, Nordion complied with each site-specific reporting requirement with two exceptions. These exceptions involved sealed source reporting. Both of these instances were reportable under Section 6.1 (g) of the site license (NSPFOL-11.A.04/2015).

In 2011, Nordion's Class 1B Facility operated within the requirements of the Nuclear Safety and Control Act, the applicable regulations and the conditions of the operating license issued by the CNSC.

Figure 1: Cobalt Production Technicians

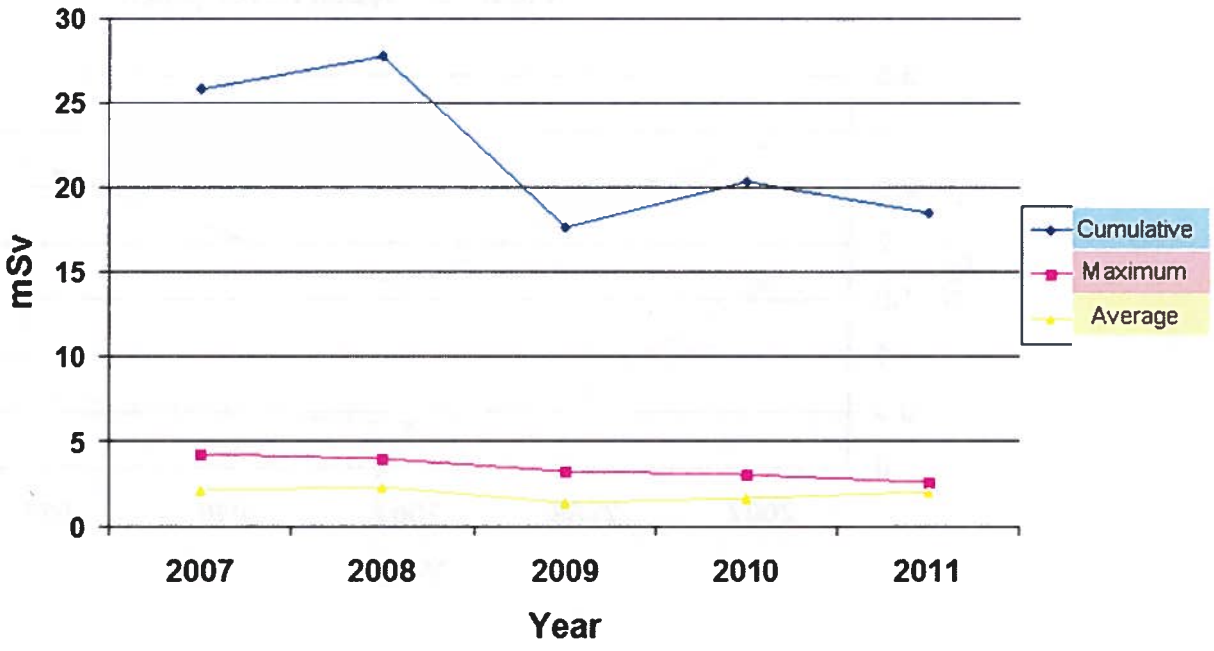


Figure 2: Cobalt Monitoring, Decontam and Shipping

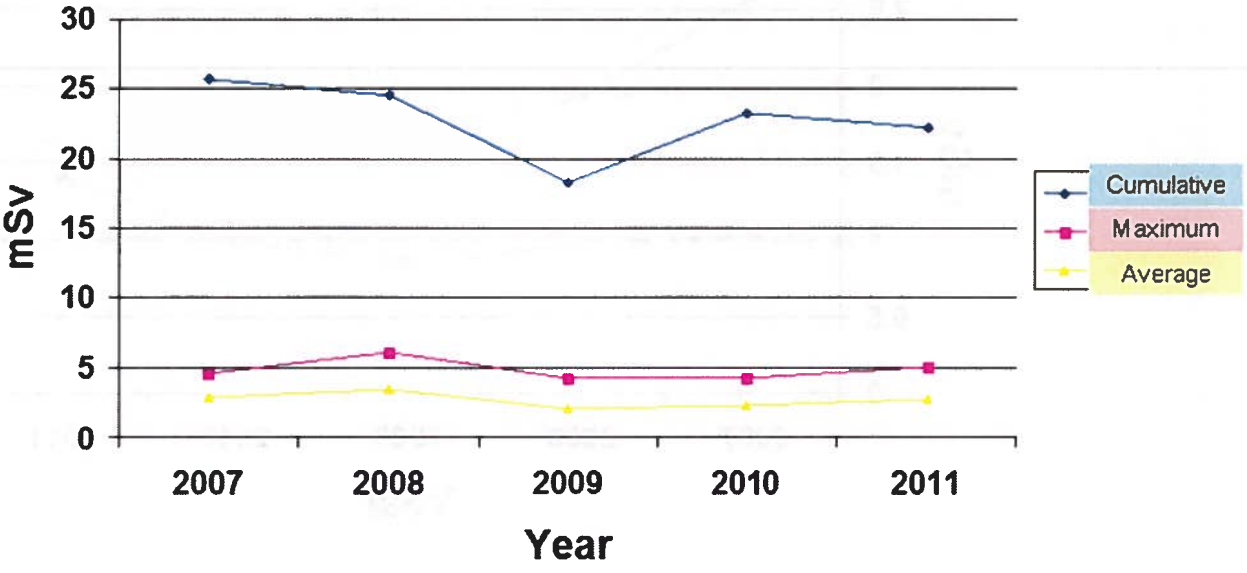


Figure 3: Cobalt Development

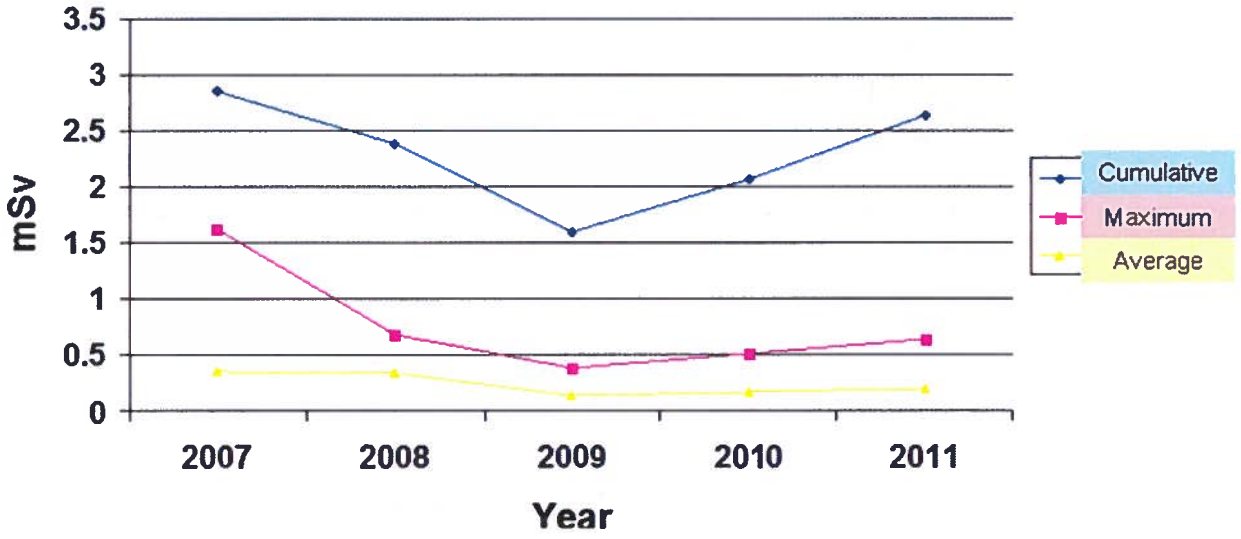


Figure 4: QC Cobalt

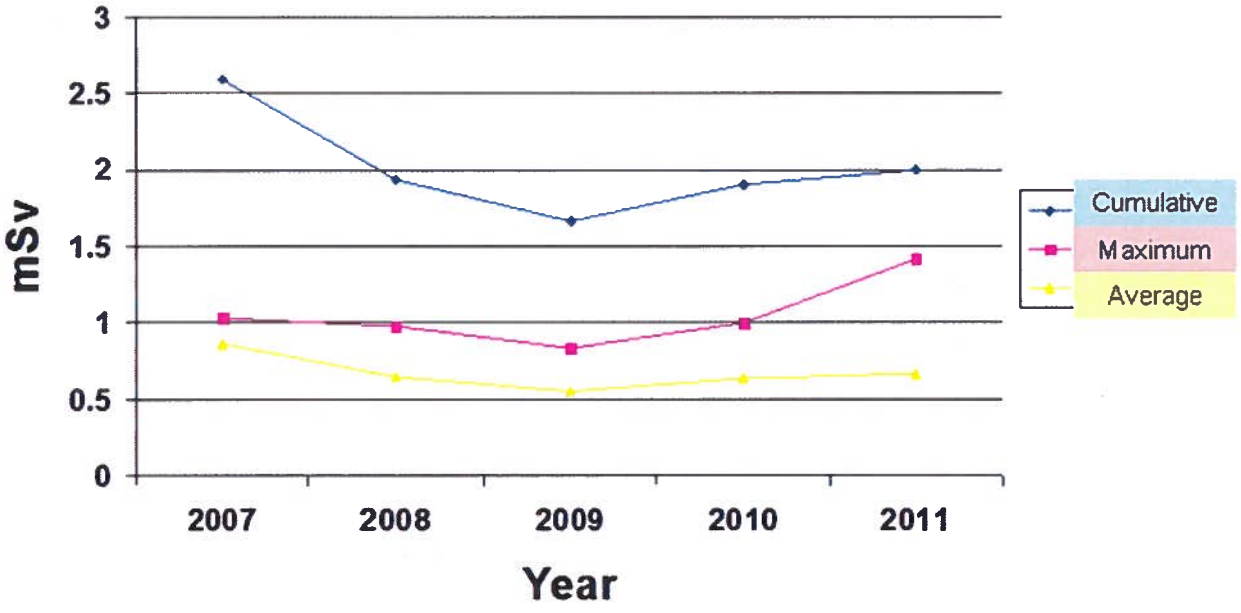


Figure 5: Radiopharm Development

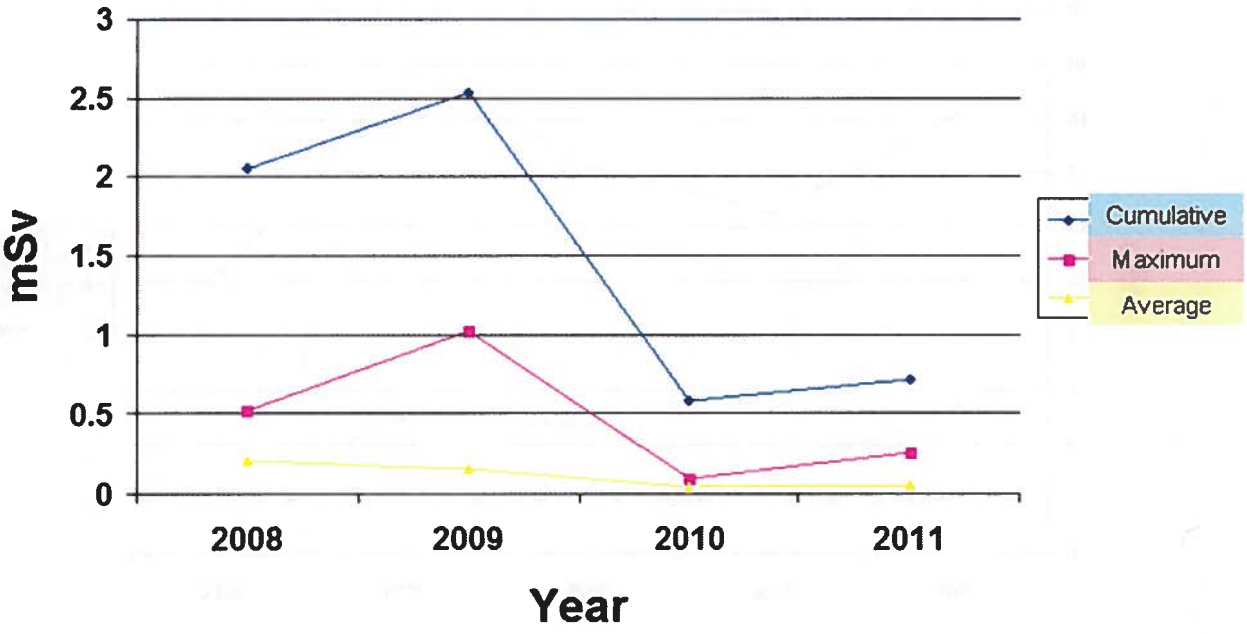


Figure 6: Technical Support

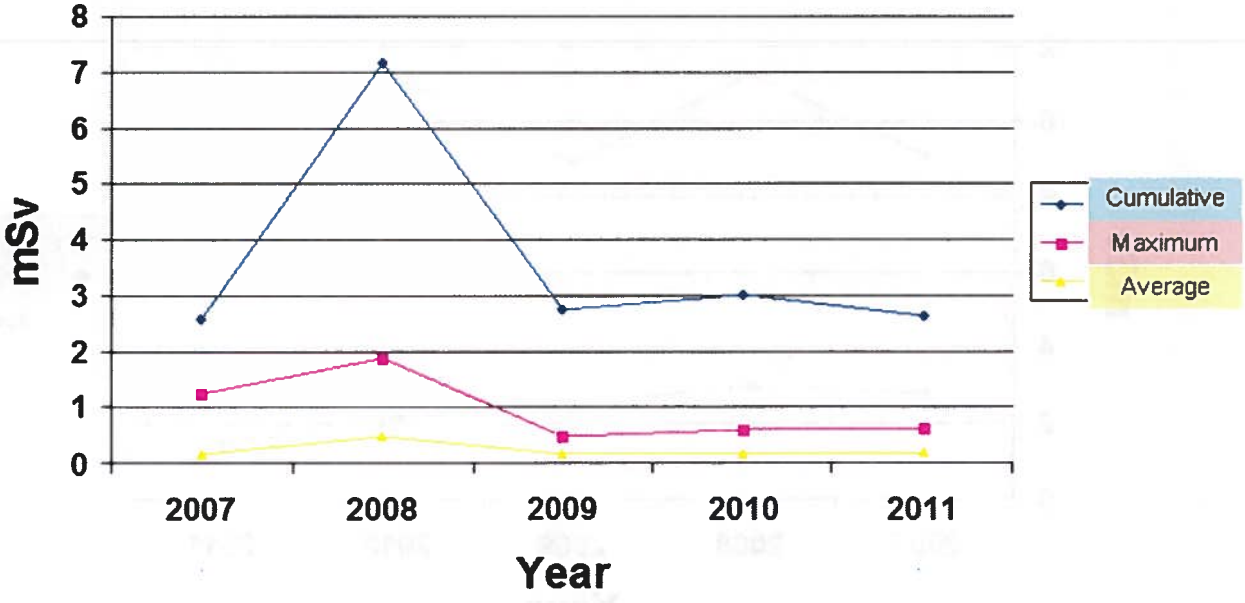


Figure 7: Nuclear Medicine Shippers, Waste, Containers

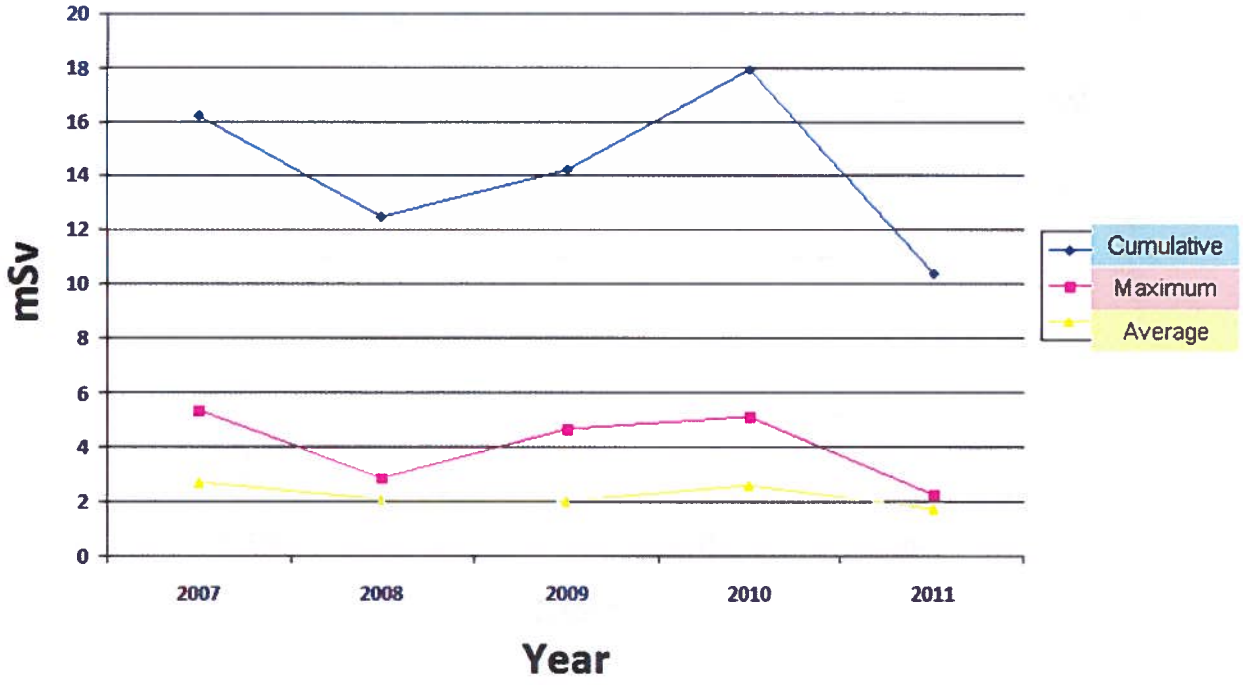


Figure 8: I-131, Ir-192 & Miscelaneous Production Technicians

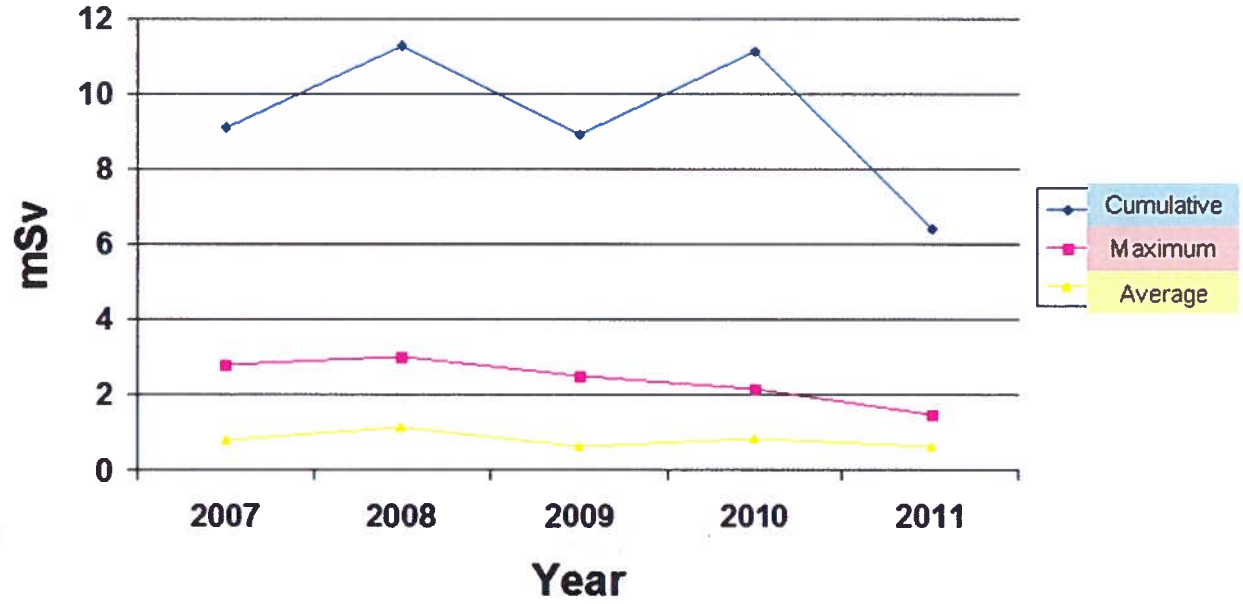


Figure 9: Mo-99/I-125 Production Technicians

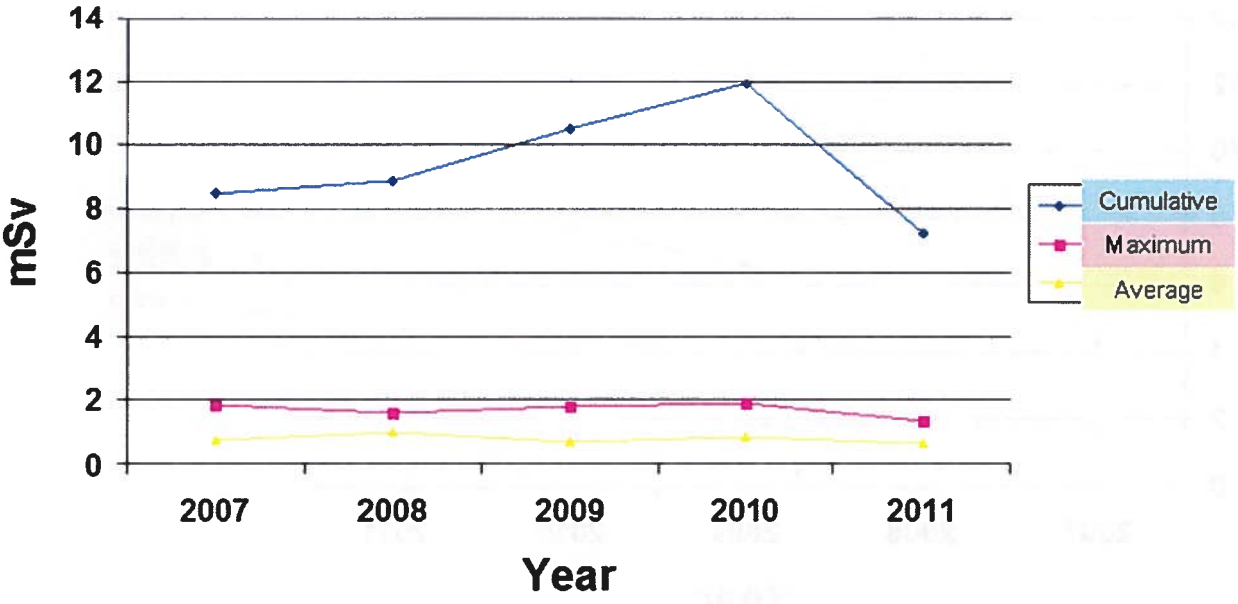


Figure 10: Radiopharm Production Technicians

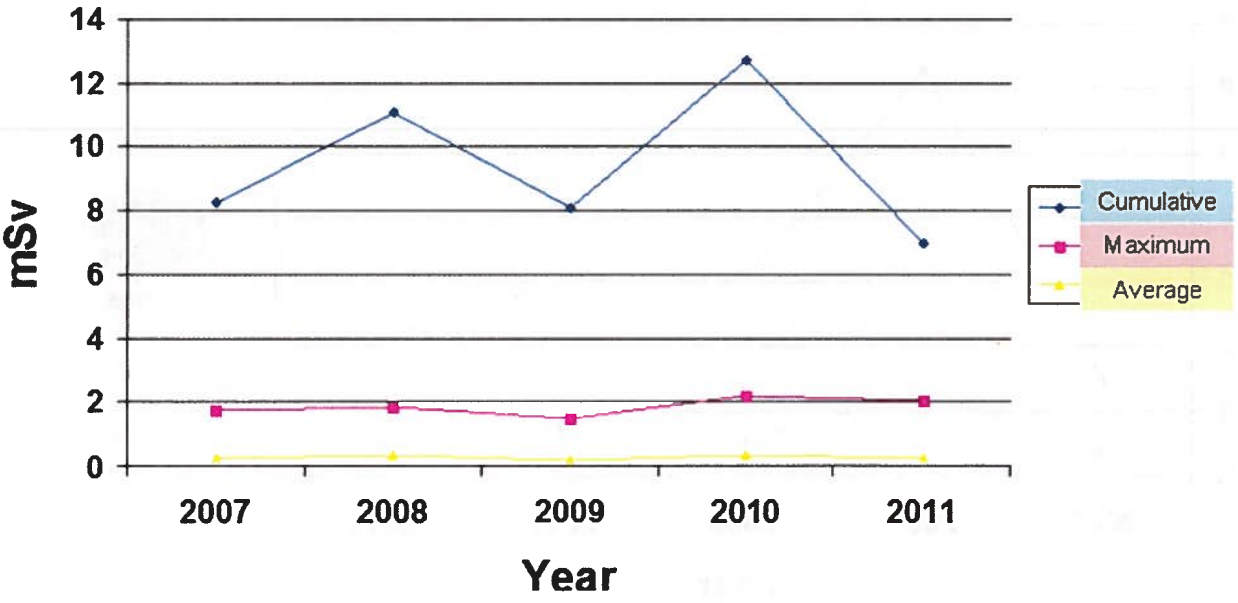


Figure 11: Machinists

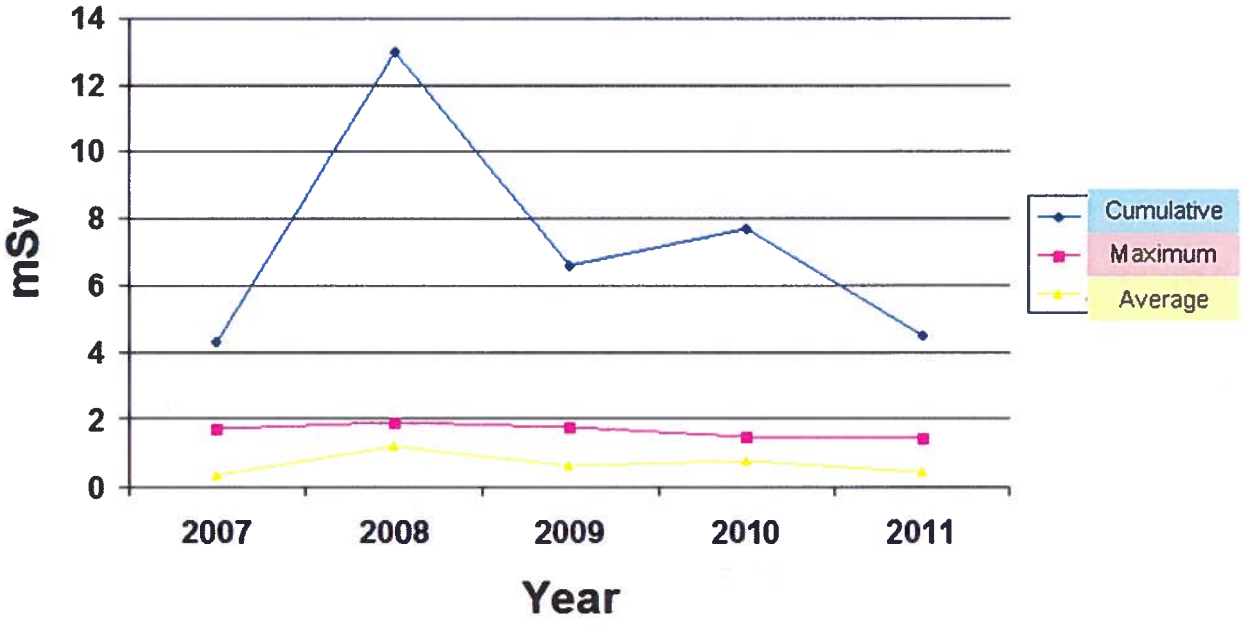


Figure 12: Nuclear Medicine QC

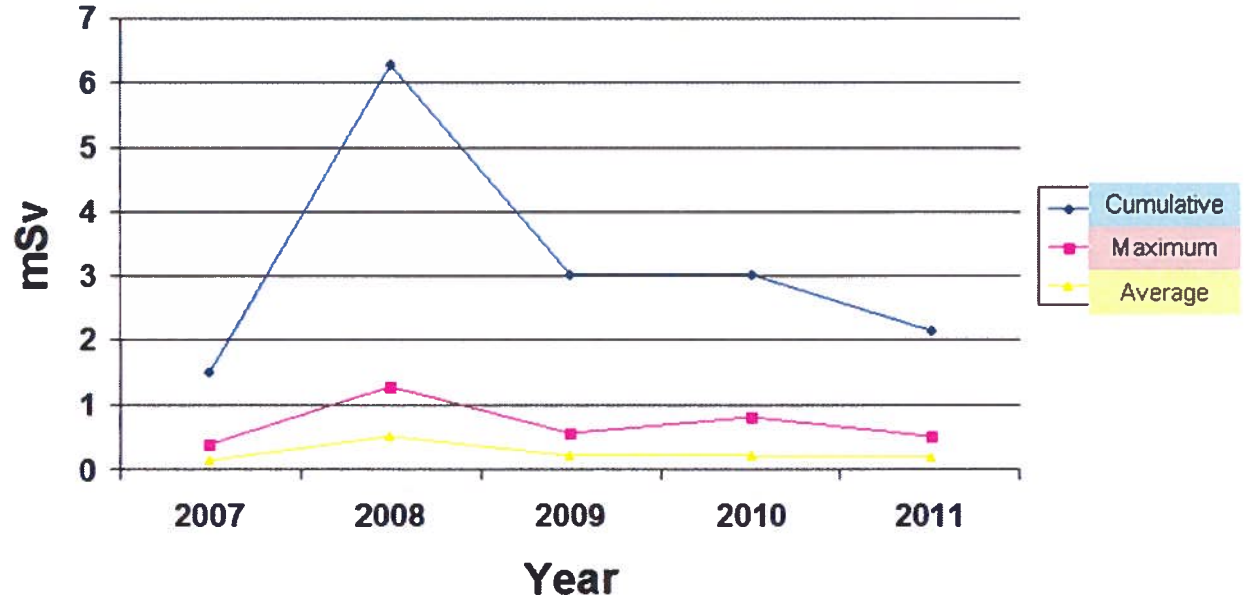


Figure 13: Surveyors

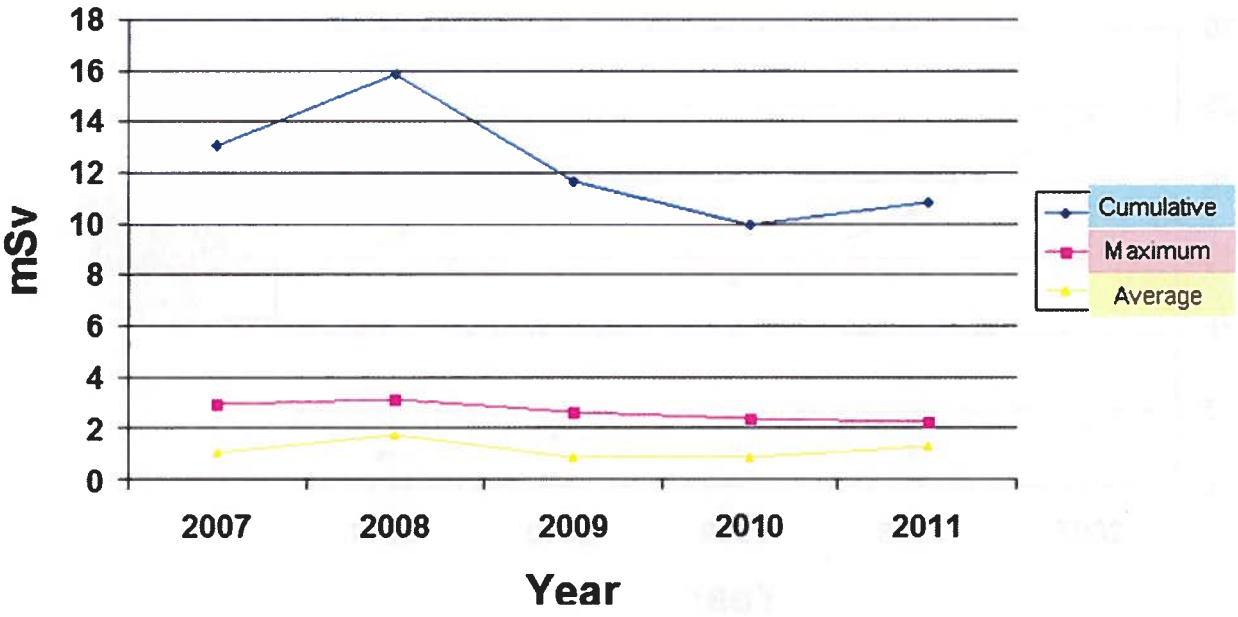


Figure 14: Nuclear Medicine Operators, Helpers

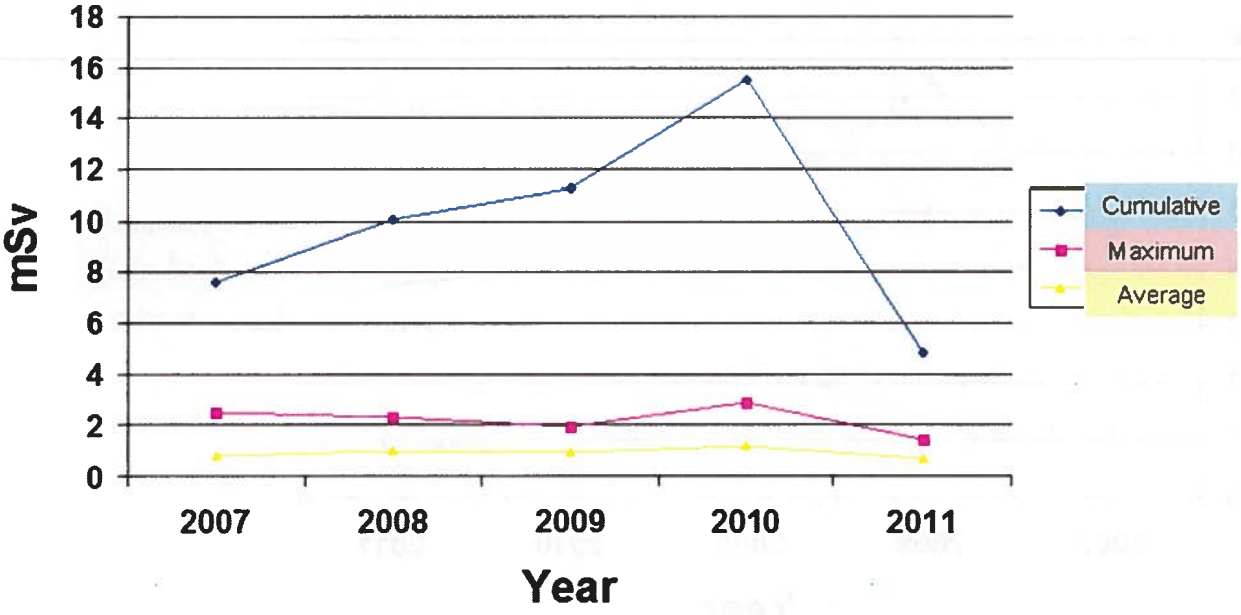


Figure 15: Nuclear Medicine Radiation and Contamination Monitors

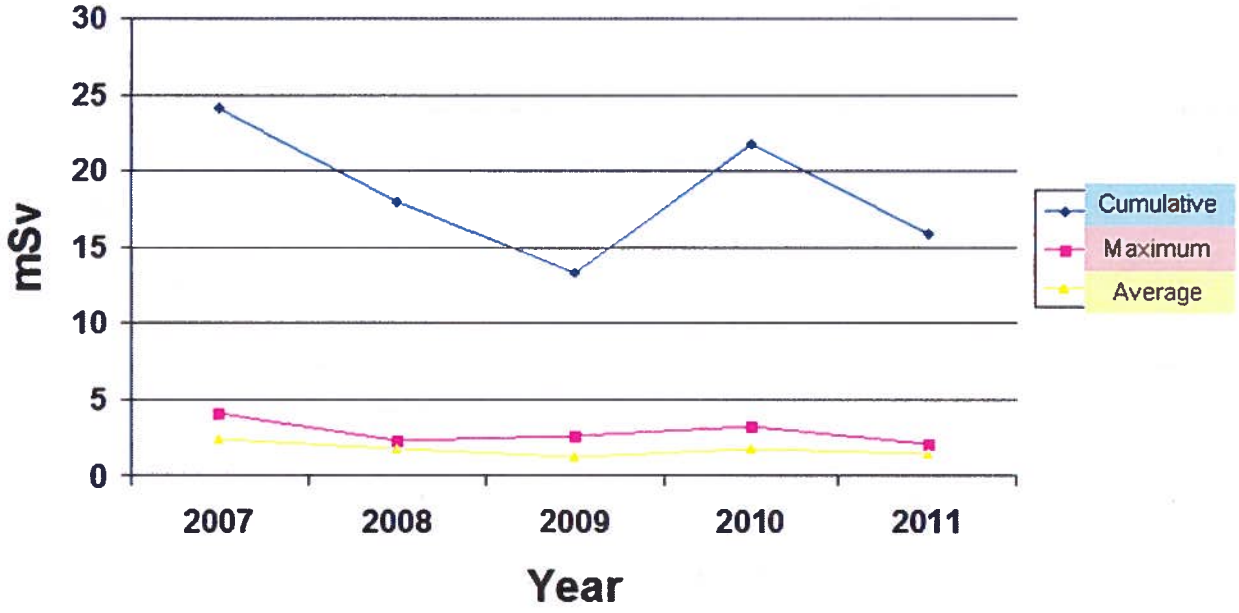


Figure 16: Maintenance & Motor Pool

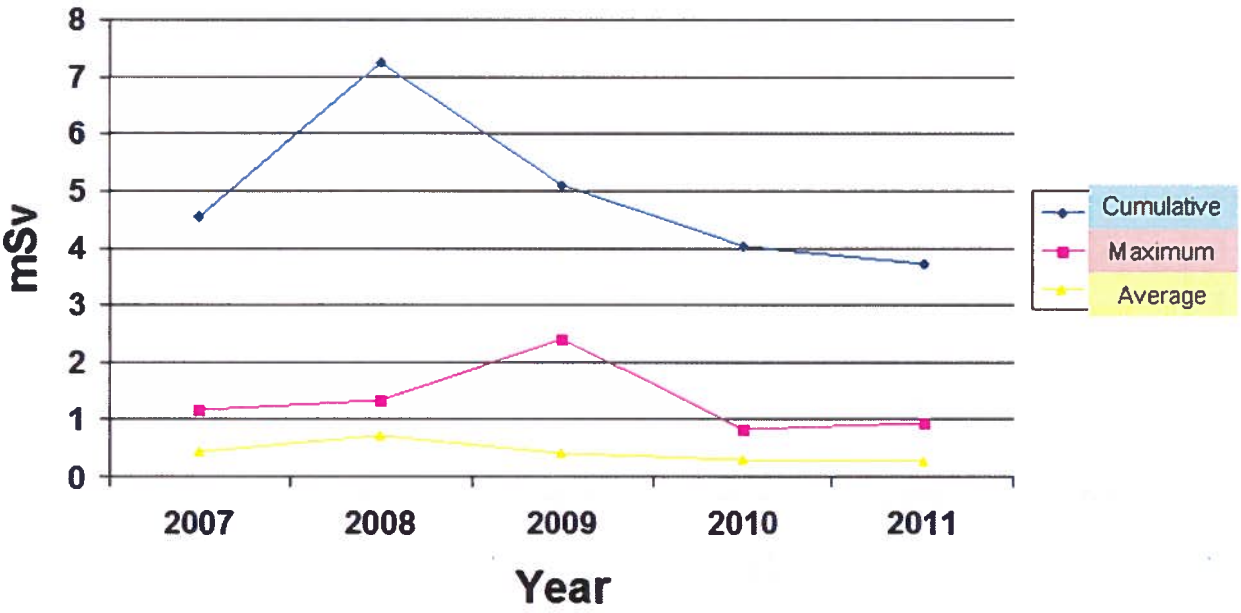


Figure 17: Maintenance & Electronic Calibration Lab

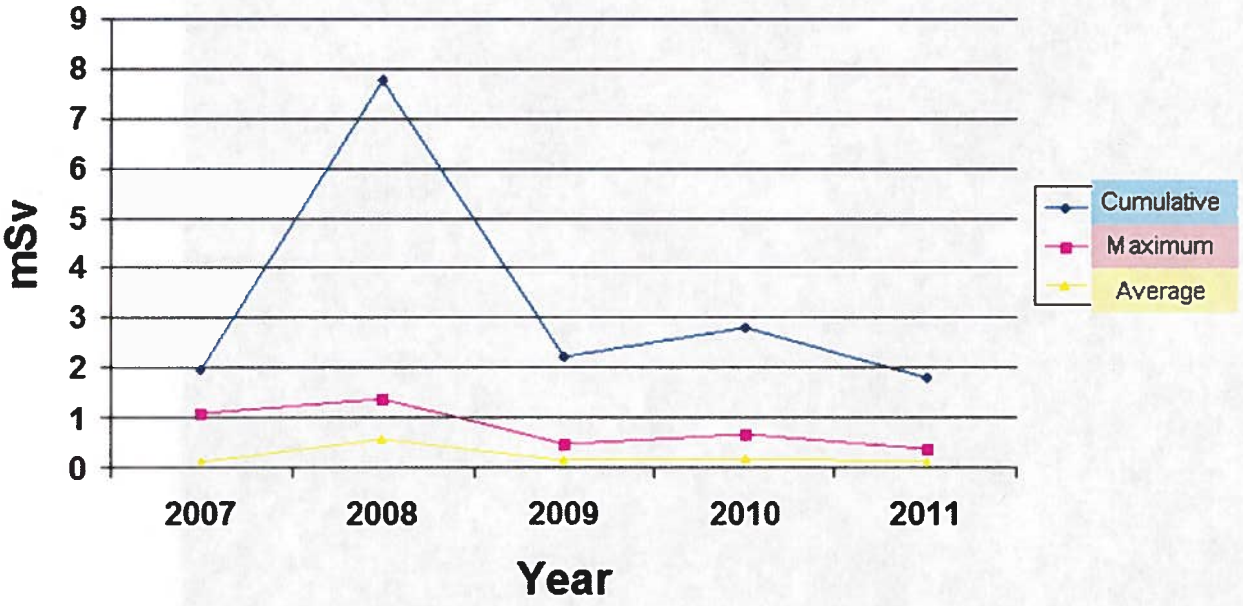
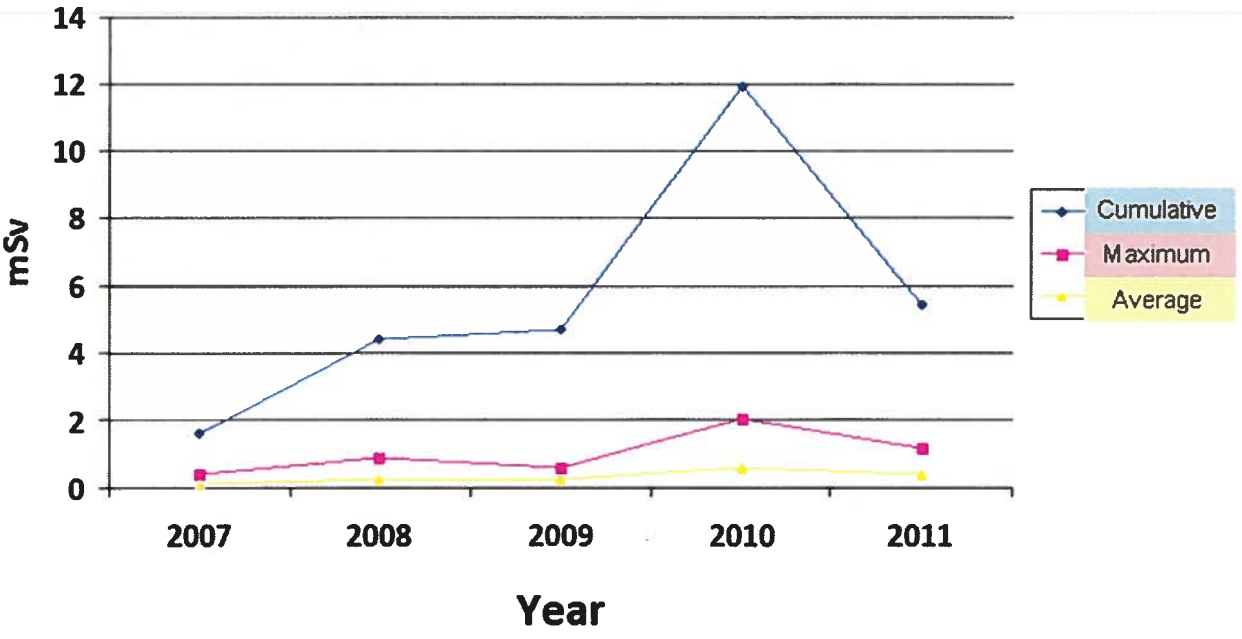


Figure 18: Radiopharm QC Chemistry



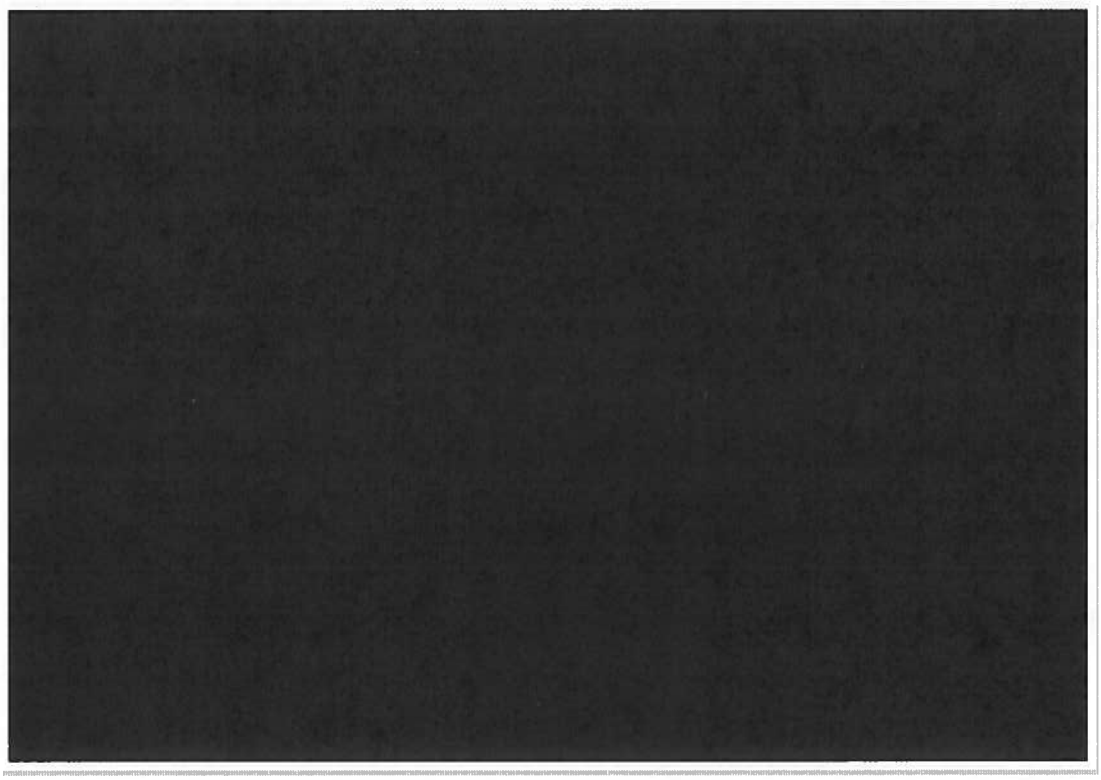


Figure 19 - Location of "Off Site" TLDs

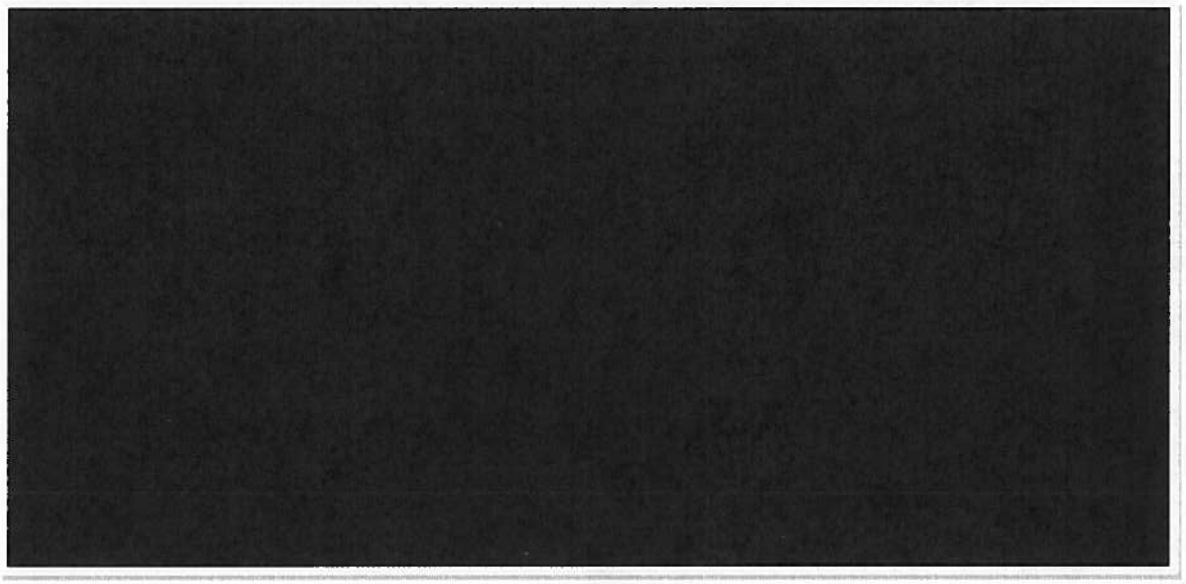


Figure 20 - Location of "On Site" TLDs

Appendix A
Table of Reportable Incidents

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Jan 7, 2011	11-01	[redacted] Package Damaged A damaged F513 Type A package was found during processing/sorting at the [redacted] in Memphis, TN. The package contained a [redacted] generator (~ 250 mCi total for this package). The package was found at the end of a conveyor / slider tray with the plastic lid separated from the body and some of the package contents outside of the package. There was no loss of containment of radioactivity. [redacted] personnel reassembled the package and notified Nordion. The package was re-sealed and sent to US DOE (disposal site for this product) for disposal. This is the first such incident with this package.	Non-compliance with Section 19 (1)(b) of the Packaging and Transport of Nuclear Substances Regulations (PTNSR)	• Unknown Likely occurred during internal transport and sorting operations at [redacted]	• Nordion followed up with the carrier.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Jan. 18, 2011	11-03	Additional Returned Ir-192 Sealed Sources not Reporting in 48 hours Four additional returned Ir-192 sealed sources with activities exceeding 21.6 Ci upon receipt were not reported to the CNSC SSTS within 48 hours as required by Nordion's site license NSPFOL-1A.04/2015. One source was previously not reported within 48 hours and investigated under report 10-22.	Non-compliance with Section 13 of Class 1B site license (Sealed Source Tracking)	• The HEGS Technicians were not following the procedure and completing all of the steps required for reporting to take place.	• The Production Manager reviewed with the HEGS Technicians the requirements of the Sealed Source Reporting procedure, he ensured that the backlog of sources pending receipt was cleared and he is to ensure moving forward that all incoming sealed sources are assessed as they arrive. Follow-up with Customer Service was also conducted to ensure that they are reminding customers to include the Returned Source List (RSL) with their shipments.
Jan. 12, 2011	11-04	Incorrect O-Ring in M10 An M10 exposure device had been returned to [redacted] due to problems initializing the exposure cycle. Upon investigation at [redacted], the problem was attributed to interference between the retaining screw o-ring and the source path in the collimator. Three other GammaMat M10 units were inspected at [redacted] using a boroscope. One of those units also exhibited an issue with the retaining screw o-ring.	Non-compliance with Section 30 (2)(a) of the Nuclear Substances and Radiation Devices Regulations (NSRDR)	• The retaining screw o-ring installed onto the device was incorrect.	• Nordion instituted a recall of all GammaMat M10 devices in Canada so that the retaining screw o-ring could be verified. • The two GammaMat M10 devices were returned to Nordion and have had the correct sized o-ring installed. All other devices in-house were inspected and repaired if required. • Nordion is implementing improvements to the inventory control process for GammaMat M10 replacement parts.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Jan. 17, 2011	11-05	TSI Source Holder Broken A TSI source holder was broken in the field. The source was in the secured position inside the TSI 5/1 device. The female connection end (which protrudes from the device) was broken during disconnection of the remote control.	Non-compliance with Section 38 (1)(b) of the NSRDR	• Unknown. There have been two other similar breakages (Investigation reports 09-02 and 10-03). The investigation is being led by the technical design authority in Belgium.	• The unit has been removed from the field. Assurances were made that the source was locked in position. The unit has been shipped to Belgium for investigation.
Jan. 18, 2011	11-06	Problems Loading TSI Source into Device A TSI source would not lock into the TSI 5/1 exposure device as expected. The source was returned to Nordion for inspection. Upon inspection it was noted that the pin used to secure the source cap was not in place.	Non-compliance with Section 38 (1)(b) of the NSRDR	• Operator error. It was confirmed that controls in place were not observed.	• The source assembly was returned to Nordion. A review of process controls was performed and deemed acceptable. Technicians involved were informed of the severity of the incident and were provided with addition training on the steps required to load a source into the TSI source holder.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Feb. 28, 2011	11-07	Environmental TLD in Room 2276 Receives 4.24 mSv An office monitoring dosimeter in Room 2276 of the KOB facility during the 2010 calendar year was processed and a dose of 4.24mSv DDE and 4.03 mSv SDE was recorded. This room is a record storage room located outside of the Active Area in the KOB and is accessed by non-NEWs. The regulatory limit for a non-NEW is 1 mSv/calendar year. If individuals occupied the room for ~25% of the year and the dose rate had been steady, then they may have exceeded the public does limit.	Non-compliance with Section 13 (1) of the Radiation Protection Regulations	• Human Performance. There is a limitation on the detection capability of the radiation survey equipment that was previously not understood.	• None. It was concluded that no Nordion employees using Room 2276 received a dose in excess of 1 mSv during 2010 and early 2011.
Mar. 20, 2011	11-08	[redacted] Truck Accident (F308) A truck carrying five empty Type A packages (F308s) was involved in an accident on Highway 17 near Dryden, Ontario. The F308 transport package is a large package (795 kg) and is used for waste shipments. This conveyance was headed to Nordion's Vancouver site.	Non-compliance with Section 19 (1)(a) of PTNSR	• N/A	• There was no visible damage to the package. Nordion will inspect and/or test the packages prior to re-use.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Jun 22, 2011	11-09	Earthquake June 2010 Report originally initiated as a drill summary report; however, at a later date decided it should be an investigation report. On the afternoon of June 23, 2010 a 5.0 magnitude earthquake struck the Ottawa area. As a result of the Earthquake, all the Nordion buildings were evacuated. There were no alarms as a result of the earthquake; however, the buildings were evacuated as a precaution.	N/A	• Naturally occurring event	• Numerous preventive actions were identified. Actions tracked through ERP Planning Committee.
Various	11-10	Non Conforming Shipments - Excepted Package Excepted package requirements not met for Cs-137 check source shipments.	Non-compliance with Section 19 (1)(c) of PTNSR	• Misunderstanding	• Training
Various	11-11	Non Conforming Shipments - F327/F113 1973 Regulation containers shipped into Mexico and Cuba without competent authority authorization.	Non-compliance with Section 19 (1)(c) of PTNSR	• Misunderstanding	• Controls put in place to send 1996 regulation container when competitor source return is scheduled.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Various	11-12	Non Conforming Shipments - F168 1973 regulation containers used for competitor source returns, even though the transport certificate does not authorize such contents.	Non-compliance with Section 19 (1)(c) of PTNSR	• Misunderstanding	• Controls put in place to send 1996 regulation container when competitor source return is scheduled.
Apr. 11, 2011	11-13	In-111 Shipment in Excess of Customer License Two shipments, shipped from Nordion's Vancouver site, were mixed up. The orders contained 50 mCi and 250 mCi of In-111 destined for Australia and Brazil respectively. Thus the 50 mCi order for [redacted] ended up at [redacted] and the 250 mCi order for Brazil ended up at Ludwig Institute. The Ludwig Institute is only authorized to possess 100 mCi of In-111. They have reported this as required in Australia.	Non-compliance with Class 1B site license	• The mix up occurred due to the similarity of the package numbers, 7112975-1 and 7112795-1. During packaging, the pots were matched up to the wrong dispensing worksheet and ended up in the incorrect box.	• The Shipping department in the Vancouver facility has added a second verification step during package loading. Previously there was a requirement to verify the shipment number on the lead pot against packaging documentation. They will now also verify the order quantity on the lead pot label to that on the package documentation.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Jan. 11, 2011	11-14	M10 Exceeded Maintenance Period On January 4, 2011, Nordion loaded a GammaMat M10 radiation device (with an Ir-192 source) and shipped it to [redacted]. The device was due for maintenance in June 2010. Nordion did not have the proper controls in place to determine the maintenance due date. The GammaMat User Manual specifies the requirement for annual maintenance prior to reloading.	Non-compliance with Class 1B site license	• The root cause was partially due to a new system for tracking Agiris product loading. The new system did not contain information from a previous loading since the source model (XC-234) was made redundant. Staff at Nordion assumed the maintenance due date was one year from the device loading in February of 2010.	• The XC-234 source information was not entered into the current management system. The XC-234 source is not longer used (or licensed) for the GammaMat M10. • Nordion has implemented controls into the manufacturing area requiring a check of the maintenance due date prior to device loading. • Nordion has divested in the Agiris business. It is now being run by [redacted]. Nordion continues to load sources for the Canadian market. Instructions and approvals for device loadings come from [redacted]
June 3, 2011	11-15	F458 Returned Mislabelled A F458 package was returned to Nordion's inactive warehouse and was found to be emitting a field.	Non-compliance with Section 19 (1)(c) of PTNSR	• A new Mo-99 customer returned the package as common goods rather than Class 7 Excepted Package.	• The package was moved to the active area and opened in the presence of a Surveyor. • Guidance was provided to the customer on how to return packages in a compliant manner.
Result from a December 2010 TLD	11-16	Non-Personal High TLD Result to Customer Service Representative	N/A	• Operator Error	• No corrective actions required.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
July 22, 2011	11-17	F458 Returned Mislabelled Nordion received returned F458 shipments from customers. The packages were not declared as Class 7 dangerous goods as per IAEA regulations.	Non-compliance with Section 19 (1)(c) of PTNSR	• Customers arranged for return shipments and were "unaware" of the compliance issue.	• Nordion has provided feedback to the customers. Nordion provided a routing for return shipments that would meet [redacted] concerns around regulatory issues in China and Canadian compliance requirements. • Nordion is reviewing the process for supporting customers with container return concerns. • Nordion has extended the agreement with Nordion's freight forwarder so that Nordion receives prior notification for any packages going through Toronto, as well as Montreal and Ottawa.
Aug. 2, 2011	11-18	Leaking In-111 Vial Customer identified that In-111 order (for 40 mCi) had leaked outside of the vial into the lead pot.	Non-compliance with Section 19 (1)(b) of PTNSR	• Issue due to an equipment malfunction in cell.	• Equipment has been replaced. • Customer is now using a crimped vial instead of a screw cap vial.
Aug. 12, 2011	11-19	UKI 4-135 Shipped with Expired Transport Certificate Shipments were made in Canada using an expired transport certificate.	Non-compliance with Section 19 (1)(c) of PTNSR	• Confusion between Nordion, [redacted] surrounding responsibility for transport certificate renewal.	• Transport certificate has been renewed.
Aug. 17, 2011	11-20	Return F458 Delivered by Non-Dangerous Goods Carrier Returned F458 transferred from NYC to Ottawa by a non dangerous goods carrier.	Non-compliance with Section 19 (1)(c) of PTNSR	• Issue relates to problems returning dangerous goods from China	• Nordion is working with customer and regulators in China to better understand compliant method for returns.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Sept. 13, 2011	11-21	Nuclear Medicine Shipper Not Wearing a TLD In reviewing the dosimetry reports forwarded from EHS, the Manager, Production Support noticed that one of his direct reports had impossibly low dose numbers recorded for 2011. The Direct Report was a Nuclear Medicine Shipper, who had a recorded dose of 0.01 mSv from January to May, 2011. The other Nuclear Medicine Shipper performing equivalent tasks had 0.96 mSv over the same time frame.	Reportable in accordance with license condition 6.1 (g) of Nordion's licence and as per section 16 of the *Radiation Protection Regulations*. In addition, there has been a violation of Section 17 (a) of the *General Nuclear Safety Regulations*.	• The current processes for follow-up on unreturned TLDs and for identification of issues with the dosimetry results are inadequate. • Performance would improve if instruction were provided on what to look for when conducting the review of dosimetry results. • The Manager should have been better trained to complete the review of dosimetry results. • The issue could have been prevented if the policy permitted wearing of TLDs attached to outer clothing (e.g. lab coats) • Performance would improve if there was a written procedure for management review.	• Nordion is to Implement processes for escalation and investigation of unreturned TLDs and for ensuring that dosimetry records are reviewed for any anomalous results (e.g. unusually high doses, unusually low doses) • Nordion is to prepare guidance for Managers on what they should be looking for when reviewing dosimetry reports. • Dosimetry records for the last 5 years are to be reviewed to ensure there are no additional similar issues. • Training of Managers on what they should be looking for when reviewing dosimetry reports will be improved. • Nordion's policy will be changed to require TLDs to be worn outside of lab coats and plant uniforms so that they are always visible. • A procedure for Management review of DRD records will be implemented.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Sept. 16, 2011	11-23	Broken [redacted] Vial Nordion received a customer complaint regarding a broken [redacted] vial (I-131 radiolabeled antibody). The [redacted] product is shipped in a Type A, F-461 box. It is shipped frozen and packed in dry ice for product stability reasons. The flash freezing process results in a certain percentage of product damaging the integrity of the vial (broken or cracked glass). For this reason, a step has been introduced prior to shipment in which the vial is inspected for integrity. This step along with changes to the product vial has greatly decreased the number of broken vials. The last complaint of this nature was in February 2010.	Non-compliance with Section 19 (1)(c) of PTNSR	• There is a known occurrence of broken vials in the [redacted] process. There is a well functioning pre-shipment inspection process. The specific cause as to why this vial was found broken in the field is unknown.	• No corrective action at this time as it is the only incident in the last 2 years. This will be monitored going forward.
Aug. 26, 2011	11-24	F318 Shipped Without Lid on Insert F327/F318 container was shipped from Kanata to [redacted] without a lid on the F368 shielding insert. The production technician forgot to replace the lid on the insert after loading. The lid was not observed in the hot cell until the next working day. Furthermore, the radiation field and TI measurement on the shipping container was not performed correctly. As a result of the latter, the package was mis-categorized as Yellow-II instead of Yellow-III.	Non-compliance with Section 19 (1)(c) of PTNSR	• There was a degree of technician error in both failure to replace the insert lid and failure to measure the package properly. • A training and documentation gap was also identified in the case of the insert lid not being replaced.	• Training of the technicians involved in the incident. • Revision of production technician training program to include preparation for shipment procedures.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Oct. 17, 2011	11-25	Damaged F325 Package A shipment of F325 packages were reported damaged in Montreal. There was no breach of the outer packaging.	Non-compliance with Section 19 (1)(c) of PTNSR	• The cause of the damage is unknown.	• The carrier was advised as to the damage.
Oct. 27, 2011	11-26	Ir-192 Sealed Source not Reported to CNSC SSTS within Required Timeframe One Ir-192 sealed source (serial number AB667 in M10 device #310) with an activity exceeding 21.6 Ci in an industrial radiography device received at Nordion was not reported to the CNSC SSTS within 48 hours. The subsequent transfer of this source to a Canadian customer was not reported to the CNSC SSTS on the day of shipment.	Non-compliance with Section 13 of Class 1B site license (Sealed Source Tracking).	• Advanced notification of the export of the re-directed camera with an existing shipment from [redacted] in Belgium was required for the scheduling of the required transfers from Nordion to occur properly. • The Production Manager and Production Technician did not make the connection that they were required to act. They believed that someone else was accountable for ensuring the necessary reporting to the CNSC was done. • The Production Manager did not use the procedure.	• Customer Service formally re-enforced with the customer that they are required to notify Nordion of any loaded cameras to be re-directed, minimize the frequency of re-directed shipments or eliminate them altogether, if possible. • Customer Service formalized communications between Customer Service and Operations with the Ir-192 Source Assembly Order Form. • EHS Compliance ensured the Production Manager and Production Technicians were made aware of their responsibilities. The Production Manager reminded the Production Technicians to inform him of any important information they receive or when they become aware of the arrival of sources/cameras that may require reporting. • EHS Compliance reminded the Customer Service Specialist to contact the Production Manager directly (preferably via email) to convey information.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Sept. 12, 2011	11-27	Purchase of CFC Containing Equipment Nordion purchased used equipment containing 2 lbs of R-502 (a CFC) from a US company. The unit was imported into Canada and delivered to Nordion.	N/A	• Appropriate EHS personnel were not consulted prior to ordering equipment. • Personnel ordering equipment did not know it contained a CFC. • Broker used for this equipment unintentionally classified equipment as laboratory equipment (lab oven) not temperature control equipment.	• Procedure IN/OP 0387 Z000 will be updated to include requirement for EHS to be consulted for any changes potentially affecting the environment, health or safety. • A checklist for key risks/watch-outs regarding the purchasing of equipment will be developed. • Nordion will work with/educate the Broker to ensure similar instances do not reoccur.
Nov. 17, 2011	11-28	In-111 Order Over-dispensed Customer advised that their 4mCi order of In-111 was measured closer to 8 mCi.	Non-compliance with Section 19 (1)(c) of PTNSR	• There was an issue during dispensing of this order. Improper tarring of the balance is suspected.	• The issue was discussed with the Operations team.
Nov. 28, 2011	11-29	I-125 / I-131 Orders Mixed Up An I-125 customer received an order of I-131 destined for another customer.	Non-compliance with Section 19 (1)(c) of PTNSR	• [redacted] applies the shipping paperwork to the package. The paperwork was mixed up for the two orders.	• [redacted] has been made aware of this issue.
Nov. 29, 2011	11-30	I-131 Order Over-dispensed Customer advised that their 50 mCi order of I-131 was measured closer to 150 mCi. The package was shipped as a 97 mCi order.	Non-compliance with Section 19 (1)(c) of PTNSR	• Low activity orders dispensed with high activity concentration stocks are at the limits of the process capability. Small errors in dispensed mass can lead to over dispensing of product.	• A more detailed investigation is underway. • The customer has been notified of this potential situation.

Date of Occurrence	Incident Number	Description	Reportability	Causes	Corrective Actions
Nov. 26, 2011	11-31	Small Motor Fire An exhaust fan motor on the dock behind the Security office failed creating smoke and a small fire.	N/A	• The direct cause of the fire is equipment failure.	• There were no corrective actions as a result of this incident; however, there was one preventive action (to have a new fire resistant container installed in the area).

NOTE: Report 11-02 involved an incident that occurred at another site which is not within the scope of this report.
NOTE: Report 11-22 was cancelled.

Appendix B
Non-Production Sealed and Unsealed Source Inventory

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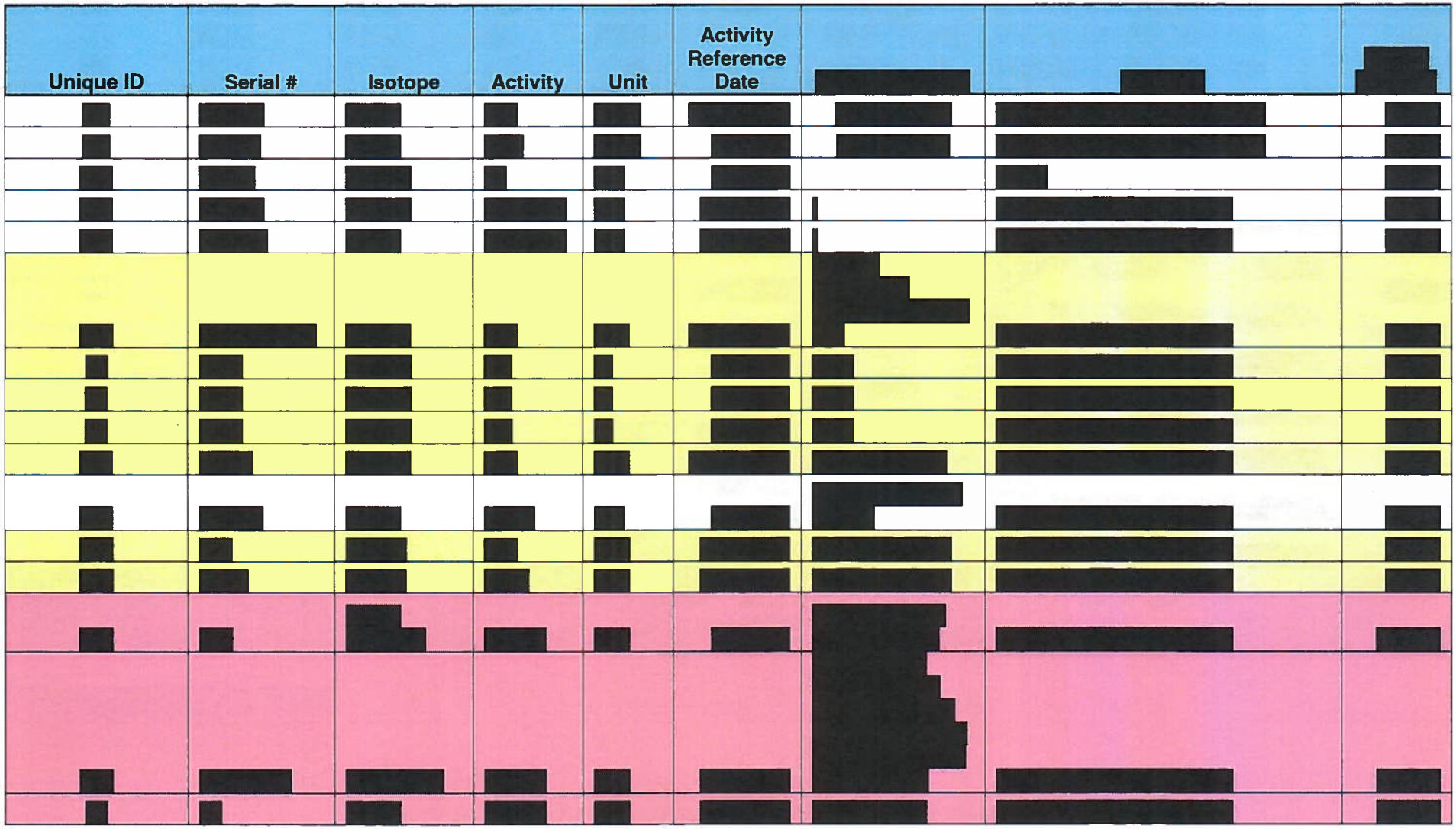
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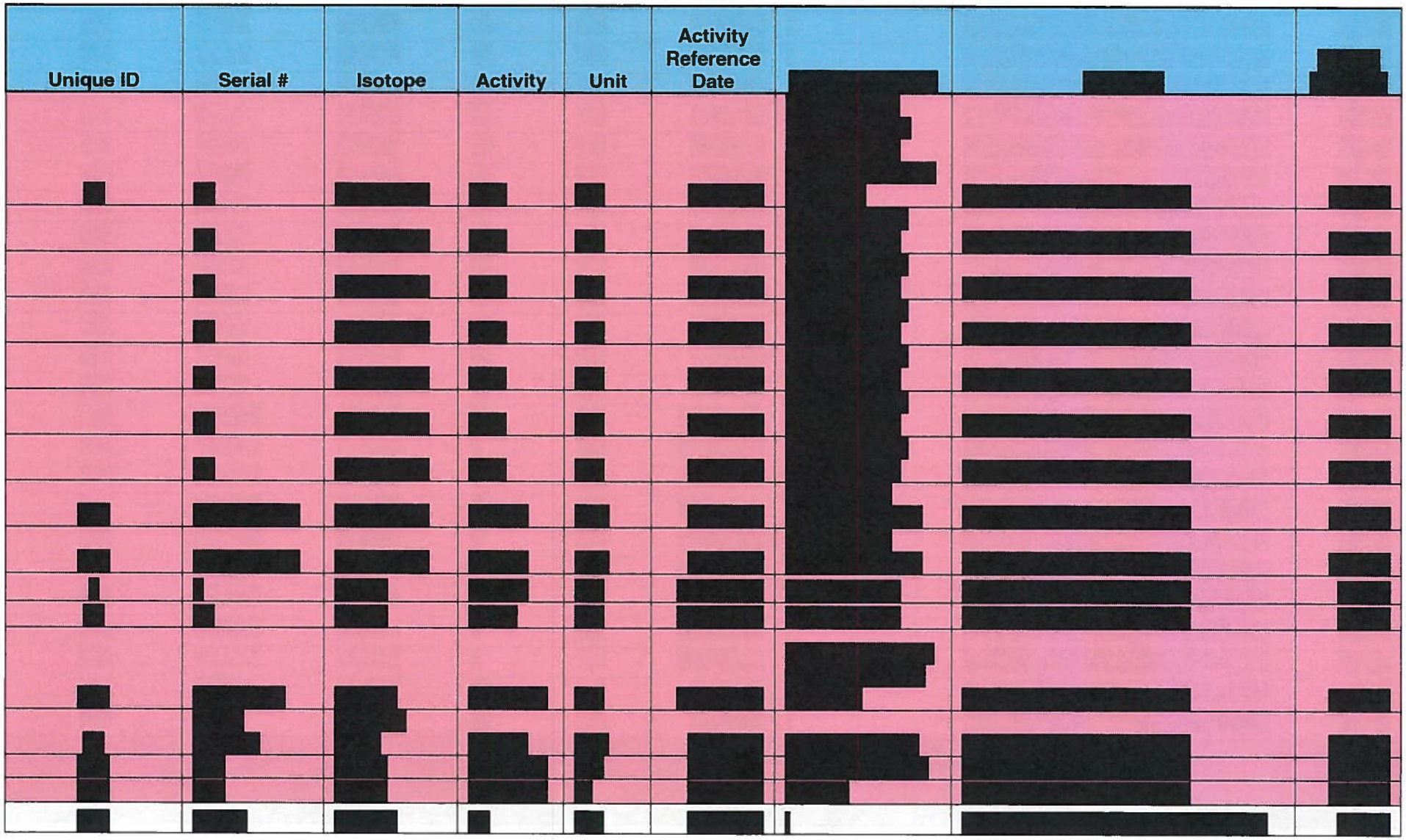
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2011 Annual Compliance and Operational Performance Report - Nordion Class 1B Facility

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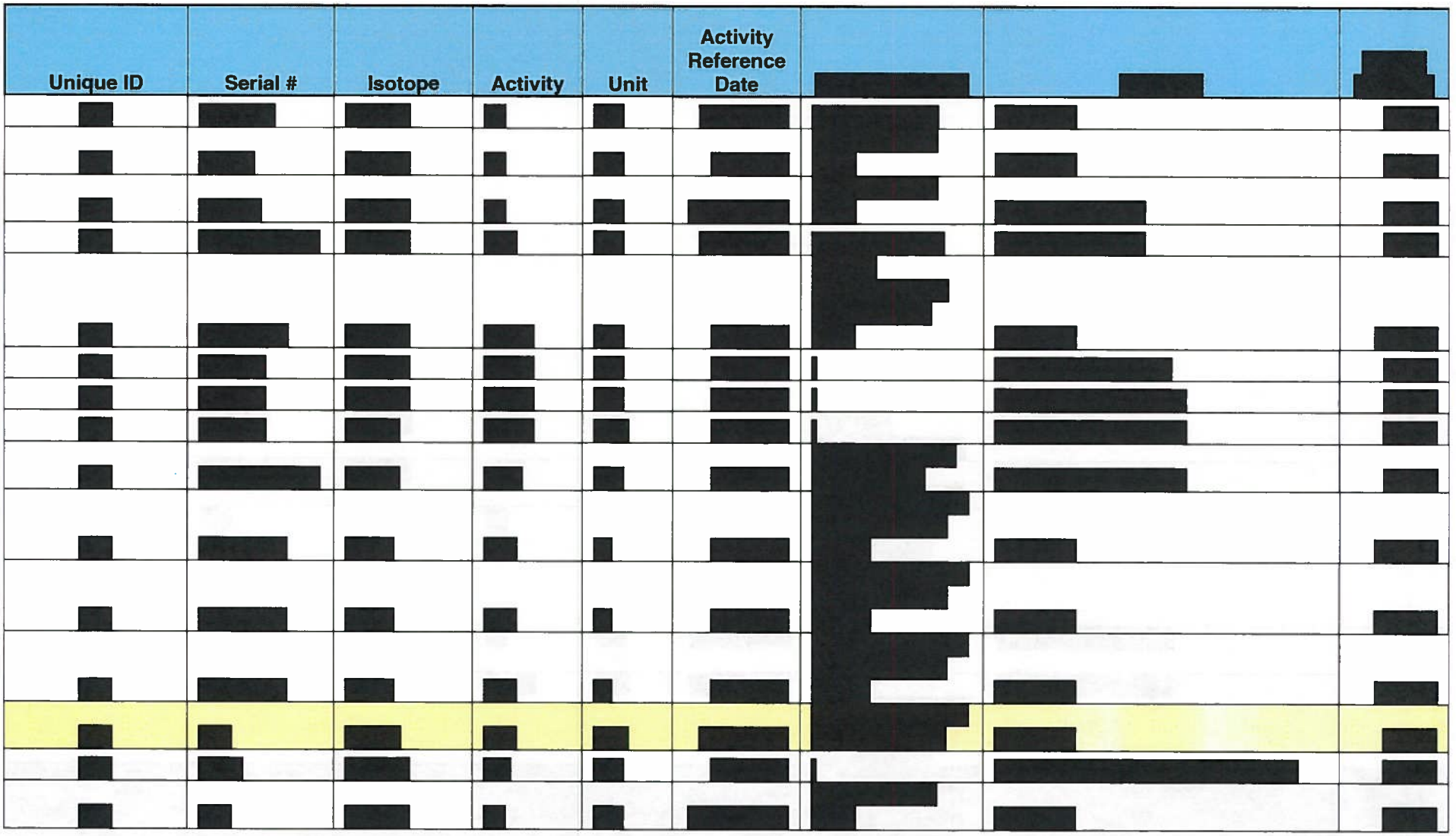
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