Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Public meeting

Réunion publique

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Le 18 décembre 2014

Public Hearing Room
14th floor
280 Slater Street
Ottawa, Ontario

Salle des audiences publiques
14e étage
280, rue Slater
Ottawa (Ontario)

Commission Members present

Dr. Michael Binder
Mr. Dan Tolgyesi
Dr. Sandy McEwan
Ms Rumina Velshi
Mr. André Harvey

Commissaires présents

M. Michael Binder
M. Dan Tolgyesi
Dr Sandy McEwan
Mme Rumina Velshi
M. André Harvey

Secretary:

Mr. Marc Leblanc

Secrétaire:

M. Marc Leblanc

General Counsel:

Ms Lisa Thiele

Avocate générale :

Me Lisa Thiele

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Ottawa, Ontario / Ottawa (Ontario)

--- Upon resuming on Thursday, December 18, 2014
at 9:01 a.m. / La réunion reprend le jeudi
18 décembre 2014 à 9 h 01

Opening Remarks

M. LEBLANC : Bon matin, Mesdames et Messieurs. Bienvenue à la continuation de la réunion publique de la Commission canadienne de sûreté nucléaire.

We have simultaneous translation. Please keep the pace of speech relatively slow so that the translators have a chance to keep up.

Des appareils de traduction sont disponibles à la réception. La version française est au poste 2 and the English version is on channel 1.

Please identify yourself before speaking so that the transcripts are as complete and clear as possible.

La transcription sera disponible sur le site Web de la Commission la semaine prochaine.

I would also like to note that this proceeding is being video webcast live and that archives of these proceedings will be available on our website for a three-month period after the closure of the proceedings.

I would also ask you to please silence your cell phones and other electronic devices.

Monsieur Binder, président et premier dirigeant de la CCSN, va présider la réunion publique d'aujourd'hui.

President Binder...?

THE PRESIDENT: Thank you, Marc.

Let me find my spot here.

--- Pause

THE PRESIDENT: Okay.

Good morning and welcome to the continuation of the meeting of the Canadian Nuclear Safety Commission.

Mon nom est Michael Binder. Je suis le président de la Commission canadienne de sûreté nucléaire.

Je vous souhaite la bienvenue and welcome to all of you joining us via our webcast.

I would like to introduce the Members of the Commission that are with us here today.

On my right is Monsieur Dan Tolgyesi.

On my left are Dr. Sandy McEwan, Ms Rumina Velshi and Monsieur André Harvey.

We already heard from our Secretary Marc Leblanc.

We also have with us here today Ms Lisa

Thiele, General Counsel to the Commission.

MR. LEBLANC: The *Nuclear Safety and Control Act* authorizes the Commission to hold meetings for the conduct of its business.

The agenda was approved yesterday. Please refer to the agenda 14-M76.B for the complete list of items to be presented today.

CMD 14-M79/14-M79.A

Oral presentation by CNSC staff

THE PRESIDENT: The first item for today is the Annual Performance Report, CNL's (formerly AECL) -- get used to this nomenclature -- Nuclear Sites and Projects: 2013, as outlined under CMDs 14-M79 and 14-M79.A.

I understand that we have CNL staff here and people who can help in explaining the annual performance, but first, I understand we are going to hear from CNSC.

Mr. Newland, the floor is yours.

MR. NEWLAND: Thank you.

Good morning, Mr. President, Members of the Commission.

My name is David Newland and I am the Acting Director General of the Directorate of Nuclear Cycle

and Facilities Regulation.

With me today are Mr. Christian Carrier, the Director of the Nuclear Laboratories and Research Reactor Division; Mr. Don Howard, the Director of the Waste and Decommissioning Division; and Ms Kim Campbell, who led the production of the Annual Performance Report.

Also with us today are licensing and compliance staff as well as subject matter experts to help answer any questions that the Commission may have.

We are here today to present Commission Member Document CMD 14-M79 entitled “Annual Performance Report for AECL’s Nuclear Sites and Projects: 2013.”

Before starting the presentation, I would like to note that while the report was being written, AECL completed a significant milestone in its restructuring and is now referred to as Canadian Nuclear Laboratories Ltd. We will continue to refer to Canadian Nuclear Laboratories or CNL for the duration of this presentation. That being said, we will probably from time to time accidentally lapse and use AECL but you will know what we mean.

Okay. Why are we on 8?

I will keep talking while the slides catch up.

Table of Contents. This slide shows the areas that will be covered in today's presentation.

Slide 3. I will now provide a brief introduction.

The CNSC regulates Canada's nuclear facilities to protect the health, safety and security of Canadians and the environment.

The CNSC achieves this mandate through licensing, reporting, compliance verification, and, when necessary, enforcement.

Slide 4. Safety performance is continually determined by staff using a risk-informed approach. That is, the compliance program is developed and planned commensurate with the risk associated with the facility, the complexity of the facility, and past performance of how well the licensee has managed its licensed facilities and activities associated with the risks.

CNSC staff also verify compliance through monitoring and desktop reviews of annual and quarterly compliance reports. The compliance program is supplemented with meetings with licensees to ensure clarity of CNSC expectations.

Finally --

THE PRESIDENT: Sorry to interrupt. Are you going to put the slide deck on or not?

--- Pause

THE PRESIDENT: Okay. Go ahead.

MR. NEWLAND: So on Slide 4, to complete. Finally, safety performance is also determined by inspection, using qualified inspectors supported by specialist subject matter experts.

Slide 5. CNSC staff assess the safety performance of licensees using a rating methodology that was established in 2010 and is based on multiple sources of inputs covering 14 safety and control areas. The 14 SCAs are illustrated on the right-hand side of this slide.

The inputs for the assessment include findings taken from inspections, follow-ups and desktop reviews. These findings come from the assessments conducted by CNSC staff at a topical area level within each of the safety and control areas.

In the past, the CNSC has produced a report on the performance of CNL's Chalk River Laboratories.

This year the scope of the report has been expanded to include an assessment of CNL's major Nuclear Sites and Projects. The report entitled "Annual Performance Report AECL's Nuclear Sites and Projects: 2013" summarizes CNSC staff's assessment of the safety performance of all CNL sites and projects where physical operations occurred in 2013.

These sites and projects include:

- Chalk River Laboratories;
- Whiteshell Laboratories;
- Port Hope Area Initiative, which includes the Port Hope Project and the Port Granby Project.

It should be noted that this is the first performance report for CNL's Nuclear Sites and Projects and in turn will be the last report for AECL.

The report highlights the regulatory requirements and expectations in selected areas and discusses significant events, licence changes, major developments and overall performance. It provides performance data on all 14 of the safety and control areas where applicable.

The report focuses on the year 2013 but also provides updates on key issues up to June 30, 2014.

I will now provide a brief overview.

CNSC inspectors are stationed in Ottawa at CNSC headquarters and are stationed at the Chalk River Laboratories site.

As you can see from this table, in 2013, CNSC inspectors conducted 28 site compliance inspections:

- 22 at Chalk River Laboratories;
- 3 at Whiteshell Laboratories;
- 3 for the Port Hope Area Initiative.

In addition to the inspections conducted, CNSC staff also performed desktop reviews to verify CNL's compliance with the regulatory requirements. A total of 109 desktop reviews were completed by CNSC staff in 2013. Note that the number of inspections and desktop reviews vary from site to site and reflect the risk-informed nature of CNSC staff's compliance verification program.

To keep communication lines open with CNL, CNSC staff also hold monthly and quarterly meetings with CNL to discuss the performance of various safety and control areas.

The table on this slide shows the performance ratings for Chalk River Laboratories, Whiteshell Laboratories, the Port Hope Project and the Port Granby Project.

You will note that for all sites, most safety and control areas are satisfactory, "SA". For the two projects under the Port Hope Area Initiative there are 3 safety and control areas rated as not applicable "NA".

One notable exception is the below expectation, shown as "BE", rating for the fitness for service safety and control area for Chalk River Laboratories.

The ratings presented in this table will be discussed in more detail within the site or project

specific sections of today's presentation.

In terms of overall performance, CNSC staff compliance activities during 2013 have confirmed that:

- no member of the public received a radiation dose that exceeded the regulatory limit;

- no worker at any CNL site received a radiation dose that exceeded the regulatory limits;

- the frequency and severity of non-radiological injuries to workers was minimal;

- no radiological releases to the environment from the sites and projects exceeded the licence limits;

- and finally, CNL complied with its licence obligations concerning Canada's international obligations.

I will now speak briefly to AECL's restructuring.

On February 28, 2013, the Minister of Natural Resources announced that Canada would undertake a competitive procurement for a contractor to manage the operations of AECL's nuclear laboratories using a government-owned, contractor-operated -- otherwise known as GOCO -- model.

As part of the procurement process,

Canadian Nuclear Laboratories was created in May 2014 as a wholly owned subsidiary of AECL.

The licences were transferred from AECL to CNL, and on November 3rd of this year CNL was fully operationalized.

In late 2015, the procurement process will conclude and a private contractor will take ownership of CNL.

I note further that CNL, AECL, NRCan and CNSC staff are due to come back to the Commission to give an update on the procurement and restructuring and that will occur in February 2015.

Turning to the Nuclear Legacy Liabilities Program (NLLP), it was established by the Government of Canada in 2006 to manage Canada's nuclear legacy liabilities at CNL sites. The main objective of the NLLP is to safely and cost-effectively reduce the nuclear legacy liabilities on CNL's sites and the associated risks based on sound waste management and environmental principles.

The nuclear legacy liabilities are associated with a number of CNL sites, as can be seen on this slide.

Currently, Douglas Point, NPD and Gentilly-1 are each in a safe storage state with no operational activities taking place during 2013 and

therefore were not included in this year's report. This may change in next year's report if decommissioning activities begin.

The Port Hope Area Initiative is shown in blue for completeness but it is noted that it is funded outside of the NLLP.

Chalk River and Whiteshell contain the majority of the nuclear legacy liabilities. At these sites, the inventory of legacy wastes includes used nuclear fuel and intermediate-level and low-level solid and liquid radioactive waste as well as contaminated lands, buildings, structures and tanks.

In January 2014, a series of meetings were held to discuss strategic initiatives associated with the NLLP activities. The objective of the meetings was to ensure a better-informed approach and alignment with international best practices in the development of waste solutions, executing selected projects and developing an acceptable disposal strategy, all to be considered in the context of the NLLP.

The NLLP projects and associated actions and milestones are also subject to the CNSC compliance activity. CNL submits semi-annual progress updates on key NLLP projects and matters of interest.

As previously mentioned, the Port Hope

Area Initiative is funded separately from the legacy program.

The Port Hope Area Initiative is defined by a legal agreement between the Government of Canada and the Municipalities of Port Hope and Clarington for the management of the historic low-level radioactive waste within each of their respective communities. The agreement came into effect in March 2001.

In a news release from January 13, 2012, Canada's Minister of Natural Resources announced that the Government of Canada is investing $1.28 billion over 10 years to clean up low-level radioactive waste in the Port Hope area.

More information on the Port Hope Area Initiative and the performance of its projects will be presented later in the presentation.

Since 2011, CNL has made significant progress in developing its Corporate Public Information Program and disclosure protocol and incorporating its activities among its various sites which meet the requirements of RD/GD-99.3 Public Information and Disclosure.

Key components of CNL's overall program include:

- the CNL CONTACT newsletter;

- CNL’s own website; and

- continued Aboriginal engagement.

There are also site-specific components to this program. These include:

- the CRL Environmental Stewardship Council;

- the Whiteshell Public Liaison Committee;

- the Port Hope Area Initiative Public Information Exchange; and finally,

- the Port Hope/Port Granby Citizen Liaison Groups.

Addressing the lessons learned from the nuclear accident at the Fukushima Daiichi nuclear power plant in Japan continues to be a focus area for CNSC staff in 2013 for both the Chalk River and the Whiteshell sites.

CNL has reviewed its existing safety cases and emergency management programs against the ability to withstand extreme external events.

By reviewing CNL’s reports, CNSC staff concur that the underlying defence-in-depth provisions are in place to deal with such natural disasters.

CNSC staff continue to track the open Fukushima actions as they move towards closure. Both CRL and Whiteshell have remaining open actions, as can be seen on this slide.

I will now pass the presentation to Mr. Christian Carrier to present CNSC staff assessment of the performance of CNL's Chalk River Laboratories. Thank you.

MR. CARRIER: Good Morning, Mr. President. My name is Christian Carrier and I am the Director of the Nuclear Laboratories and Research Reactor Division.

Next slide please.

As depicted on this slide, the Chalk River Laboratories, or CRL, are located on the south shore of the Ottawa River in the Province of Ontario, 160 kilometres northwest of Canada's national capital, Ottawa.

CRL is one of the most complex nuclear facilities in Canada. The CRL site is occupied by more than 150 buildings. Outside of the built-up area, there are several waste management areas for handling and storage of both nuclear and non-nuclear waste.

CNL employs approximately 3,000 people at the CRL site.

The CRL site provides for the production of medical isotopes, the delivery of various nuclear services and the conduct of a wide variety of research and development programs.

The CRL site licence was renewed in 2011. To support licence renewal and the continued operation of the NRU reactor, CNL implemented the NRU Integrated

Implementation Plan, otherwise referred to as the IIP. CNSC staff have and will continue to monitor the effective implementation of this improvement initiative.

As seen from this table, all performance ratings for CRL ranged from “below expectations” to “satisfactory” for the reporting period.

A notable rating change was issued for the SCA “management system” previously reported as “below expectations” in the 2012 report. CNL has completed several improvements, including the transition to CSA standard N286-05, which have resulted in this satisfactory rating.

Regarding the SCA “fitness for service”, CNSC staff continue to rate this SCA as “below expectations” due to the aging and legacy issues of structures, systems and components at CRL, particularly the NRU reactor.

The next two slides will provide more details on these two safety and control areas and their performance.

For the review period, CNSC staff rate the "management system" SCA at CRL as "satisfactory". This is primarily based on the progress related to AECL's transition to the CSA standard N286 Version 2005, the improvements made in safety culture and the further

implementation of the Operating Experience Program.

Safety culture at CRL has been the object of important strides for improvement, especially since the 2009 vessel leak event. In response to this event, CNL undertook significant effort to improve a wide range of programs and elements of safety culture and human performance.

CNSC staff have noted noticeable improvements to safety culture at CRL through their compliance activities.

For fitness for service, CNSC staff continued to rate SCA as "below expectations". This is primarily due to the aging and legacy issues of systems, structures and components, especially the NRU reactor.

Even though CNL continued to experience challenges due to equipment aging, in all instances CNL has taken actions to mitigate or correct deficiencies. Strategic programmatic improvements, as listed on the slide, are being implemented to increase the performance rating in this SCA. CNSC staff notes an improving trend in this SCA. CNSC staff will continue to monitor the progress of this SCA.

For the review period, CNSC staff continue to rate the radiation protection SCA at CRL as satisfactory. CNL has implemented and maintained a

Radiation Protection Program to control the radiological hazard present in its facilities and to ascertain doses for each person who performs duties in connection with their licensed activities.

No worker at the CRL site was exposed to a dose that exceeded regulatory limits. The doses that are presented in this figure is taken from CNL's annual safety report for the years 2011 through the year 2013. Please note that this figure uses a logarithmic scale.

The average effective dose to workers at CRL during the period is a low. It was approximately 0.4 mSv's per year, or 0.8 percent of the annual regulatory dose limit of 50 mSv. The maximum annual individual whole body dose for nuclear energy workers at CRL site was 8.89 mSv in 2013. The majority of the doses received by workers came from the operational activities within the NRU reactor and for the production of molybdenum 99.

The dose to the public from CRL is calculated by using environmental monitoring results. Airborne and liquid exposure pathways such as inhalation and ingestion are taken into account when determining public doses.

The table displayed here compares public doses for the years 2011 and 2013. As you can see, the doses to the public continue to be well below the

regulatory annual public dose limit of 1 mSv.

As shown in this slide, there were 18 recordable lost time incidents in 2013 at CRL. The severity rate of lost time incidents in 2013 are reduced below levels in the previous years. The reduction in severity rate is a direct result of increased management focus on the return to work program. This program supports the safe and early return to work within the abilities of the injured worker leading to fewer lost workdays.

In 2013, CNL provided more training to its employees, increasing awareness of occupational hazards and put further measures in place to reduce the exposure to conventional hazards. This included, for instance, improved machine guarding, protective equipment and clothing and the introduction of a safe lifting, hoisting and rigging procedure.

For the review period, CNSC staff continue to rate the conventional health and safety SCA at CRL as satisfactory. Overall, compliance verification activities conducted at CRL facilities confirmed that CNL continues to view conventional health and safety as a paramount consideration. CNL has demonstrated a satisfactory ability to keep its workers safe from occupational injuries. CNSC staff meet quarterly with CNL to discuss the performance of this SCA.

For the safety area environmental protection, CNL continues to implement and maintain an adequate Environmental Protection Program. This program controls and monitors releases of radioactive and hazardous substances and their effects on the environment. In 2013 there were no airborne or liquid exceedances of the effluent release limits. From its review, CNSC staff have assessed the safety area as satisfactory.

Like other programs, CNSC staff holds quarterly meetings with CNL to discuss the performance of this SCA. Airborne radiological emissions remain effectively controlled. The main contributor to public dose from the site is argon 41, resulting from the operation of the NRU reactor and the production of medical isotopes.

In 2013 there were 30 action level exceedances for airborne releases. It should be emphasized that the setting of these action levels is a small fraction of the regulatory or licensed limits. As such, these exceedances were a small contribution to the total releases from the corresponding monitoring period. The next slide will provide more detail on these exceedances.

CNL sets the action levels at CRL slightly above values normally encountered during normal operation to immediately identify the normal conditions. As can be

seen from the graph displayed, there were many action level exceedances in the late summer and fall of 2013. These exceedances were the subject of a common investigation by AECL and was the subject of a significant monitoring by CNSC staff. Again, incremental releases were negligible when compared to normal operational releases from the site. Those normally average between 5 and 6 microSieverts per month and this is doses to members of the public.

CNL determined that the cause of those exceedances was the processing of higher than usual irradiated targets for the production of molybdenum 99. Additional causal factors were identified as a reduction in the frequency of nuclear ventilation filters in the molybdenum 99 facility and the contamination of the molybdenum 99 waste flask.

CNL has implemented corrective measures that were effective in preventing recurrence. CNSC staff conclude that the setting of these action levels were effective in the early detection of potential problems at site and has allowed CNL to investigate and take prompt corrective actions.

Liquid radiological emissions are effectively controlled at CRL. In 2013 the annual average tritium concentration in drinking water at the town of Petawawa and the City of Pembroke was 2.5 Bq per litre.

This is well below all national and international limits for tritium in drinking water. Also, in 2013 there were no action level exceedances for liquid releases at CRL, including radioactive and nonradioactive releases.

Subsequent to the Fukushima accident CNL was requested to review initial lessons learned from the event for the CRL site and to reassess the safety cases for its facilities. CNSC staff concluded that the underlying defence in-depth provisions are in place to deal with natural disasters and accidents at the CRL. In addition to the reassessment of the safety cases, CNL developed an action plan to address the lessons learned from the Fukushima Daiichi accident, which includes short, medium and long-term actions. This action plan has been incorporated into the IIP, which is a condition of the license. CNL has completed the development of a severe accident management guideline and are on track with some limitations in the NRU for the year 2015.

CNSC staff will continue to monitor progress of these actions to ensure lessons learned from the Fukushima accident are implemented at the CRL.

In April 2010 the Government of Canada and the United States committed to work cooperatively to repatriate spent highly enriched uranium fuel currently stored at the Chalk River laboratories. In 2012 this

effort was expanded to the return of additional inventories of HEU material, including those in liquid form. All shipments of HEU will follow stringent transportation and security requirements.

In 2013, CNL repatriated two disassembled HEU SLOWPOKE reactor fuel cores to the U.S. These included cores from the École Polytechnique and the Kanata Reactor SLOWPOKEs.

This slide provides an update on the transportation package certification and the detail for HEU. The transport package for the repatriation of spent fuel rods from CRL research reactors has been certified in both Canada and in the U.S. The certification process for HEU in liquid form includes independent reviews by the U.S. Regulatory Commission, the U.S. Department of Transportation and the CNSC. The certification process is still ongoing in both countries.

CNSC staff's technical assessment of the design of the package is nearing completion. CNSC staff plans to post this technical assessment document on its public website for a period of public comments. This is likely to be done before the end of the calendar year.

CNSC's focus for the year 2014-2015 for Chalk River is summarized on this slide. As required under license condition, CNL will submit a plan before the end of

June 2015 for the end of the operation or the continued operation of the NRU reactor beyond October 31, 2016. As a result, the IIP will require an amendment to address the specific decision on this matter. CNSC staff will review this plan and continue monitoring implementation of the IIP. The government's decision to seize molybdenum 99 production will effectively result in cessation of the operation of molybdenum 99 production facility. This is after October 31, 2016. Regulatory focus will be on the orderly shutdown process of this facility and definition of a safe shutdown with surveillance state.

Finally, in preparation for the GoCo implementation implementation for the management of the CNL, CNSC staff will ensure that rigorous processes are in place to manage changes at sites, in particular changes that involve a change to the organization.

This concludes my presentation of the Chalk River laboratories. I will now pass the presentation over to Mr. Don Howard.

MR. HOWARD: Thank you and good morning. For the record, my name is Don Howard and I am the Director of the Waste and Decommissioning division.

This section of the presentation will summarize CNL's performance associated with the Whiteshell Laboratories.

CNL continues to operate the Whiteshell Laboratories in compliance with the *Nuclear Safety and Control Act* and its associated regulations and its license.

CNSC staff will continue to conduct compliance activities on an ongoing basis to verify CNL's continued safe operation of Whiteshell according to the authorizations and conditions of its license.

As shown on this slide, the Whiteshell Laboratories is located 100 kilometres northeast of Winnipeg Manitoba and operated from 1961 to 1997. This is where CNL pioneered the development of dry storage containment. The site is currently under decommissioning.

The Whiteshell site encompasses an area of 4375 hectares. The site comprises of a number of nuclear and non-nuclear facilities and activities, including the Whiteshell reactor, WR1, the shielded facilities, the liquid and solid radioactive waste management facilities and various research laboratories. CNL currently possesses the decommissioning license for Whiteshell expiring on December 31, 2018.

As shown on this slide, performance ratings for Whiteshell for the year 2013 were all satisfactory or fully satisfactory. These ratings remain unchanged from reports previously made to the Commission. For the review period, CNSC staff continued to rate the

radiation protection SCA as satisfactory.

CNL has implemented and maintains a Radiation Protection Program to control radiological hazards, ascertain doses to workers and estimate doses to the public. CNL continues to strive to maintain doses to workers ALARA by executing radiological work in the 2011 to 2013 period with minimal dose consequence, no internal intakes and no significant contamination or exposure events.

During the review period, no worker at the Whiteshell site received a dose that exceeded the regulatory limits. The dose data presented in this figure is taken from the CNL's annual safety reports for the years 2011 through 2013. The average effective dose to workers at Whiteshell during the period is low. It was approximately 0.03 mSv per year or 0.06 percent of the annual regulatory dose limit of 50 mSv. The maximum annual individual whole body dose for nuclear energy workers at the Whiteshell site was 0.8 mSv in 2013.

The dose to the public from Whiteshell is calculated by using environmental monitoring results. Airborne and liquid exposure pathways such as inhalation and ingestion are also taken into account when determining public dose. The table on this slide compares public doses for the years 2011 to 2013. As you can see, doses to the

public continue to be well below the regulatory annual public dose limits of 1 mSv.

A key performance measure for conventional health and safety SCA is the number of recordable lost time injuries that occur per year. As you can see from the table, for 2013 the number of lost time incidences and their frequency is relatively stable. However, the severity rate is increasing. This means a considerable number of injuries at Whiteshell are resulting in extended absences from the workplace. Although most of these injuries are minor, improvements to their return to work program are still required to minimize the number of days lost. CNL is currently in the process of implementing these improvement actions.

For the review period, CNSC staff continue to rate the conventional health and safety SCA at Whiteshell as satisfactory as CNL continues to view conventional health and safety is of paramount consideration in all decommissioning activities.

CNL continues to implement and maintain a comprehensive Industrial Health and Safety Program for the Whiteshell site. CNL has improved aspects of the program based on best industry practices and results from accident investigations and internal audits. CNSC staff will continue to monitor performance of this SCA.

For the review period, CNSC staff rate the environmental protection SCA at Whiteshell as satisfactory. CNL continues to implement and maintain an Environmental Protection Program to control and monitor liquid and air releases of radioactive and hazardous substances to the environment.

In 2013 there were no airborne or liquid exceedances of the effluent release limits or action levels at Whiteshell. In 2013 both airborne and liquid radiological emissions were effectively controlled. The maximum airborne emissions were less than 0.0005 percent of the derived release limits or DRLs. For liquid, the annual average tritium concentration in drinking water in the Winnipeg River was between 2.5 and 3.5 Bq per litre. This is well below all national and international limits for tritium in drinking water.

CNSC's regulatory focus for 2014-15 for Whiteshell is summarized on this slide. This includes an update to the Whiteshell Laboratories decommissioning and license to include standard license conditions and the license conditions handbook. Also, acceleration of the overall Whiteshell decommissioning schedule.

I will now switch the focus of the presentation to the Port Hope Area Initiative. The Port Hope Area Initiative comprises two distinct community-based

projects, the Port Hope Project and the Port Granby Project. This slide provides a summary of CNL's implementation of the public information program and its closure requirements.

CNL is currently implementing its Port Hope Area Communication Plan and is committed to disclosing information about the project with stakeholders in a timely, accurate and comprehensive manner. These activities include mailing out newsletters to the public, posting recent project news and updates to the website porthopeareainitiative.ca, launching citizen liaison groups for both the Port Hope Project and the Port Granby Project.

CNL also maintains the Port Hope Area Initiative Project Information Exchange where members of the public are welcome to drop in, meet with staff and learn more about the two projects. In 2013, CNL conducted public information activities for the Port Hope Area Initiative that met CNSC regulatory requirements.

Ratings for the Port Hope Project and the Port Granby Project for the year 2013 are presented on this slide. CNL was rated satisfactory for all SCA readings during the reporting period. These ratings remain unchanged since performance reporting at the onset of each license.

CNL has implemented the Port Hope Area

Initiative of Radioactive Material Transportation Plan to govern transport of radioactive material. The plan meets regulatory requirements. Once remedial activities begin, waste material will be transported to the long-term waste management facility via the prescribed transport routes. During the review period, no radioactive material was transported.

CNSC's regulatory focus for 2014-2015 is summarized on this slide. CNL has commenced resurveys of properties in the municipality of Port Hope and has commenced plans for cleanup activities. CNSC staff plan to conduct compliance verification activities during this period to verify that these activities are conducted in a safe and effective manner.

Construction of the wastewater treatment plant is completed and commissioning is underway and will continue into 2015. CNSC staff will conduct onsite inspections and reviews of performance data to ensure that design objectives have been met. Wastewater treatment plants commissioning performance data will be used to establish new effluent limits for each site.

The following eight slides summarize CNL's 2013 safety and control area performance ratings associated with the Port Hope Project and provides an update of activities presently underway. These slides indicate that

CNL continues to operate the Welcome Waste Management Facility and plan for construction and remedial activities in compliance with the *Nuclear Safety and Control Act* and its associated regulations and its license. CNSC staff will continue to conduct compliance activities on an ongoing basis to verify CNL's continued safe operation of the Welcome Waste Management Facility.

The slides for the Port Hope and the Port Granby Projects are very similar, but the Port Granby activities are further along so the info will differ as the project forward.

The Port Hope Project activities include the construction and operation of a new long-term low-level radioactive waste management facility, remediation of the existing Welcome Waste Management Facility and remediation of sites containing historic low level radioactive waste located within the Municipality of Port Hope. As noted on this slide, projected activities are being conducted by CNL in three phases. Phase II is underway and includes ongoing care and maintenance of the Welcome Waste Management Facility, off-site activities and the construction of the new Long-Term Waste Management Facility.

As part of the Phase II activities, CNL has constructed a new wastewater treatment plant adjacent to the existing water treatment facility and is currently

undergoing commissioning. With respect to the construction of the new Long-Term Waste Management facility and the remediation of the existing Welcome Waste Management Facility, CNL has begun construction of onsite infrastructure and support facilities, the excavation and temporary onsite stockpiling of soils and preparation for the construction of the long-term waste management facility containment mound. As was noted earlier, CNL has commenced resurveys of properties in the municipality of Port Hope.

As noted earlier, all safety and control areas have been rated satisfactory for the Port Hope A project. This slide represents the worker effective dose for 2012-2013. It should be noted that currently CNL does not monitor doses separately between the workers for the Port Hope and the Port Granby projects. Therefore, for both projects the average effective dose to workers during the review period is low. It was approximately 0.01 mSv per year or .02 percent of the annual regulatory dose limit of 50 mSv. The maximum annual individual whole body dose for a nuclear energy worker was 0.2 mSv in 2013.

CNL estimates doses to the public by using environmental TLDs posted on the perimeter fence of the Welcome Waste Management Facility. Monitoring results for the review period indicate that doses to the public are an order of magnitude below the regulatory limit of 1 mSv per

year.

For the review period, CNSC staff continue to rate the radiation protection SCA as satisfactory. CNL has implemented and maintains a Radiation Protection Program to control radiological hazards, ascertain doses to workers and estimate doses to the public. During the review period, no worker at the Port Hope Project Site resulted in a dose that exceeded the regulatory limits. CNSC staff rate the environmental protection SCA at the Port Hope Project as satisfactory. Oversight is a joint effort which is accomplished by the establishment of a joint regulatory group. The role of the joint regulatory group is to provide for a harmonized regulatory approach for the Port Hope Area Initiative. Other members of the joint regulatory group include, for example, Environment Canada and the Ontario Ministry of the Environment and Climate Change.

CNSC staff rated the conventional health and safety SCA as satisfactory as CNL continues to maintain an acceptable conventional health and safety program and has had no lost time injuries at the Port Hope Project during the review period.

Now, the following slides will summarize the 2013 SCA performance ratings and provide an update of the Port Granby Project activities. These slides indicate

that CNL continues to operate the Port Granby Waste Management Facility and plan for construction or remedial activities in a manner compliant with NSCA and its associated regulations and its license. CNSC staff continue to conduct compliance activities on an ongoing basis to verify CNL's compliance with authorizations and conditions of its place.

The Port Granby Project activities include the construction and operation of a new waste management facility and remediation of the existing Port Granby Waste Management Facility. As noted on this slide, project activities are being connected by CNL in three phases. Phase II is underway and includes ongoing care and maintenance of the Port Granby Waste Management Facility in addition to the construction of a new Long-Term Waste management facility.

As part of the Phase II activities, CNL has constructed a new wastewater treatment plant to the north of the existing water treatment facility. The tendering process for the remediation of the existing facility and the construction of the new Long-Term Waste Management Facility is currently underway. As noted earlier, all safety and control areas have been rated satisfactory for the Port Granby Project.

As previously shown on an earlier slide,

the average effective dose to workers at the Port Granby project is low, 0.01 mSvs, with the maximum effective dose of 0.2 mSvs per year or .02 percent of the annual regulatory dose limit of 50 mSvs. CNL estimates doses to the public by using environmental TLDs which are posted on the perimeter fence. Monitoring results for the review period indicate an estimated dose to the public well below the regulatory limit of 1 mSv. For the review period, CNSC staff continue to rate their radiation protection SCA as satisfactory.

CNL has implemented and maintains a Radiation Protection Program to control radiological hazards, ascertain doses to workers and estimate doses to the public. During the review period, no worker at the Port Granby Project site resulted in a dose that exceeded the regulatory limits.

CNL has implemented and maintains an Environmental Protection Program to monitor and control releases to the environment. As noted earlier, the CNSC staff established a Joint Regulatory group for the Port Hope Area Initiative.

CNSC staff rated conventional health and safety SCA as satisfactory as CNL continues to maintain an acceptable health and safety program and has had no lost time injuries at the Port Granby Project during the review

period.

This concludes this portion of the presentation, and I will now pass it back to Mr. Newland.

MR. NEWLAND: Thank you, Don.

I will now present CNSC staff's closing remarks.

Evaluations conducted by CNSC staff during the review period confirm that CNL has operated the nuclear sites and projects safely. These assessments confirm that no member of the public received a radiation dose that exceeded the regulatory limit; no worker received a radiation dose that exceeded the regulatory limits; the frequency and severity of injuries and accidents involving CNL workers was minimal; there were no radiological releases that exceeded the regulatory limits and; finally, CNL has complied with the *Nuclear Safety and Control Act*, the Regulations and their license conditions.

This concludes CNSC staff's presentation of the annual performance report for CNL's nuclear sites and projects 2013 and we are now prepared to answer any questions that the Commission may have.

Thank you.

THE PRESIDENT: Thank you.

I understand, Dr. Walker, that you have a short presentation for us. Please proceed.

DR. WALKER: Good morning, Mr. President and Members of the Commission. For the record, my name is Robert Walker and I am the President and Chief Executive Officer of Canadian Nuclear Laboratories, or CNL, which is a wholly owned subsidiary of Atomic Energy of Canada Limited. I am also the President and CEO of AECL.

Here with me today are Randy Lesco, CNL's Chief Nuclear Officer and Vice President of Operations; and Joan Miller, CNL's VP of Decommissioning and Waste Management. Joan and Randy are accountable to me for CNL performance against all our CNSC licenses.

J'ai l'intention de comparaître devant la Commission en février, avec des collègues provenant des Ressources naturelles du Canada et d'EACL, afin de vous fournir une mise à jour complète sur les progrès que nous réalisons sur notre démarche de restructuration.

Tandis que nous sommes ici pour examiner nos performances de 2013, j'aimerais aussi vous mettre au courant brièvement sur les activités de restructuration, afin de fournir l'avantage du contexte pour la réunion d'aujourd'hui.

This November we formally moved to a new legal entity and identity, Canadian Nuclear Laboratories, also known as CNL. This transition included the transfer of all AECL regulatory licenses to CNL and was the

culmination of many months of hard work and planning. It also represents a major milestone in the process which will conclude with the implementation of a government-owned contractor-operated management model anticipated to be completed in the fall of 2015.

We have one slide here. This slide illustrates our organizational relationships when restructuring reaches its intended end state. As you can see, ownership of CNL will be transferred to a private sector company. AECL will remain a crown corporation, albeit much smaller, and will retain ownership of site facilities, intellectual property and liabilities on behalf of the government, while overseeing the performance of the GoCo contractor in accordance with an oversight framework. The CNSC will continue its regulatory relationship with CNL, the licensee, monitoring its performance against the obligations expressed in its licenses and AECL will continue to report to Parliament through Natural Resources Canada in the same manner that it does today.

With the GoCo management model, the new CNL will have private sector management operation and business practices. This will help us to further improve and to better seize market opportunities in order to strengthen Canada's nuclear sector worldwide.

The employees of CNL are focused on three

mandates:

First, to manage Canada's radioactive waste and decommissioning responsibilities safely and effectively.

Second, to ensure that nuclear science and technology capabilities support the government's in matters of health protection, public safety, security and environmental protection.

Third, to provide industry with access to innovative nuclear science and technology expertise on a commercial basis. The government is the customer for the first two missions, industry for the third.

With the new name, corporate identity and focussed missions, CNL will operate with the same strategic outcome that articulates its role as Canada's premier nuclear science and technology organization. Our activities will help ensure that Canadians and the world receive energy, health, environmental and economic benefits through nuclear science and technology, with confidence that nuclear safety and security are assured and we will do so with the support of the Government of Canada which continues to invest in the revitalization and modernization of the Chalk River site infrastructure.

Construction of our new science and technology laboratory complex is well underway, which will

complement the many other facilities we have on site. The renovation of one of our existing buildings is nearing completion, which will create 12 new laboratories to enhance our hydrogen isotopes technology capabilities. Other improvements, including the supply of potable water to the site, updates to our IT infrastructure, enhancements to our Class IV power supply and improvements to NRU are all ongoing.

These investments are important to our future and to meeting our regulatory commitments. As the largest nuclear science and technology laboratory in Canada, we recognize the significance of the work we do on behalf of Canadians and the responsibilities we have in safely and securely conducting this work.

The launch of CNL was indeed a major accomplishment in the restructuring process. Our efforts remain the same, to advance science and technology for the benefit of Canada and are underpinned by the dedication of our employees to meet the conditions of the licenses granted to us by the CNSC. Nuclear science and technology is our overriding priority. Excuse me, nuclear safety is our overriding priority.

I believe our performance over the regulatory period illustrates this commitment. CNL operates four sites that are evaluated against 14 safety

and control areas and has achieved a satisfactory rating from the CNSC staff in all these SCAs with the exception of one.

Randy Lesco will now speak about the improvements we are making to achieve an acceptable rating for Chalk River Laboratories fitness for service SCA.

Merci de m'avoir donné l'occasion de prendre la parole aujourd'hui. Je serai heureux de répondre à vos questions une fois que monsieur Lesco aura conclu ses remarques.

MR. LESCO: Thank you, Dr. Walker.

Good morning, Mr. President and Members of the Commission. For the record, my name is Randy Lesco, I am CNL's Chief Nuclear Officer and Vice President of Operations.

Today I will provide you with a brief update on work to improve our fitness for service programs at the Chalk River laboratories. We have realized progress against this SCA in the past year that shows a clear trend towards improvement and a satisfactory rating. Investment is underway. As Dr. Walker has stated, CNL is addressing infrastructure and re-capitalization of the Chalk River Site.

Since 2011 over $200,000,000 has been spent invested in site infrastructure. Priority

improvements activities are continuing. During 2013 and 2014 maintenance inspections of equipment and upgrades were completed as scheduled. NRU's 2013 and 2014 annual 30-day extended outages were completed on schedule and without incident. Completion rates of these planned activities averaged at 94 percent. Inspection results confirmed that the NRU vessel remains fit for continued operation. Fitness of service of the NRU vessel is being enhanced. We are taking measures to improve environmental conditions in the vessel. This includes welding of ceiling plugs, ventilation changes to further reduce ingress of water and air.

We are continuing to improve our maintenance activities. In 2008-14, all regulatory and mandatory preventive maintenance activities for NRU systems were met. Through work management improvements we have reduced our elective maintenance backlog by 30 percent, our corrective maintenance backlog by 65 percent. Efforts to further reduce the backlog by enhancing work measure practices and scheduling of maintenance outages are underway.

We are investing in and enhancing safety and liability of the NRU. For example, we are now through the third year of our five year $83,000,000 Integrated Implementation Plan, or IIP.

At the end of 2013, 27 of 45 IIP high priority improvement activities have been subsequently closed. Since then we have completed an additional 11 activities, bringing the total to 38 high priority improvement activities completed to date. While 2 percent of our IIP actions are delayed, overall 68 percent are complete. Of these completed activities, 29 percent were completed ahead of schedule. The first phase of IIP remains on schedule for completion by October 2016.

Detailed plans are being developed to continuing our improvements after 2016. Our system health monitoring program is improving. As planned, over the past two years we have prepared initiatives on all 46 NRU priority system health reports. To further improve the program, we have benchmarked with industry to establish better performance indicators. These indicators are now in use and enable improvements to the overall system health program.

In 2013 CNSC staff performed a compliance inspection of our system health program and issued three recommendations and four action notices. To date, all the recommendations and three action notices have been implemented. The final action will be completed on schedule this month.

Through these activities and many others,

we have made clear progress in the improvement of our fitness to service performance at Chalk River Laboratories. We will continue to make improvements to ensure we meet CNSC expectations.

In closing, Mr. President and Members of the Commission, I would like to emphasize that we have operated in compliance with all the licenses with due regard for the safety of the environment, the public and CNL employees. We have complied with our license conditions and regulatory responsibilities and we will continue to do so.

My colleagues and I will be happy to answer any questions that you may have.

THE PRESIDENT: Thank you. I'm sure we have lots of questions, but before we do that we will now move, as per usual procedures, to our written interventions from the public.

We are slightly deviating from the order on the agenda. So I would like to start -- I would like to start with a written submission that was filed by Best Theratronics, as outlined in CMD 14-M79.3.

CMD 14-M79.3

Written submission from Best Theratronics

THE PRESIDENT: Any questions?

Maybe somebody, maybe AECL or staff, tell us a little bit -- bring us up to date about the cobalt production. I was in an announcement in Queensview Carleton Hospital about a new initiative to produce more cobalt by Bruce Power. I am just interested in knowing who is producing cobalt 60 in this country and is AECL or CNL will continue to do so.

DR. WALKER: For the record, Bob Walker.

Mr. President, I can advise that there are two types of cobalt that are of interest here. One is cobalt that is used for sterilization purposes in hospitals and the second is cobalt that is used for cancer therapy. In the case of sterilization there had been a long-standing contract with OPG through the Pickering reactors to produce the cobalt used for sterilization and with the coming shutdown of the Pickering site a new contract has been established to transfer that capability into the CANDU reactors at the Bruce site.

We continue at the NRU to produce what is called the high specific activity cobalt that is needed for cancer therapy around the world. Our business is going

well and we are increasing the output. There is many customers around the world.

THE PRESIDENT: So just out of curiosity, will that continue depending on what happens to NRU? If NRU continues beyond 2016, does that production continue with or without the isotope -- the molybdenum production?

DR. WALKER: For the record, Bob Walker.

Production of cobalt is independent from the production of moly-99. These are separate processes. The government has directed the end of the molybdenum mission, but the further production of other isotopes, including cobalt, would continue should we continue NRU beyond 2016, yes.

THE PRESIDENT: Thank you.

Any other questions?

Okay. Thank you.

The next submission is from Mr. William Tuer as outlined in CMD 14-M79.2.

CMD 14-M79.2

Written submission from William A. Tuer

THE PRESIDENT: Questions?

Ms Velshi.

MEMBER VELSHI: Thank you, Mr.

President.

A very interesting submission where the intervenor questions the benefit of the Port Hope area initiative given the risks associated with carrying it out.

One of the comments he makes on page 1 of his submission is that there is lack of public support for this project, and I'm hoping the Chalk River Laboratories folks can comment on that, and then I'll ask staff to comment around public support and for public outreach activities, what is it that you've been hearing from the public?

MS MILLER: Joan Miller, for the record.

I believe there's a two-part question.

In terms of carrying out the project safely, the project was undertaken following a very comprehensive environmental assessment, and the conclusion of that environmental assessment was that the project could be conducted safely. There is an environmental assessment follow-up program that is in place and that we continue to carry out and report on.

With respect to the particular comment in terms of the public support of the project, we carry out annual, maybe biannual surveys of the

communities, and in all cases there is very -- there is strong support for the project.

We have a very engaged public through our public information exchange program, through our newsletters, through our communications with the community. Right now, we are conducting radiological surveys and we have good results and participation from the public in proceeding with those surveys, indicating to us that they are also interested in the project proceeding.

MEMBER VELSHI: And what's the nature of concerns that you do hear from them?

MS MILLER: Joan Miller, for the record.

I'll ask Craig Hebert, the general manager of the Port Hope Area Initiative Management Office, to answer -- respond to your question.

MR. HEBERT: Thank you. For the record, Craig Hebert of the Port Hope Area Initiative.

The nature of the concerns we hear from -- most from the public is one of progress, when are we going to proceed with the remedial works in the various areas of the communities. They're very anxious for us to begin.

MEMBER VELSHI: Thank you.

THE PRESIDENT: Any other questions? Mr. Tolgyesi.

MEMBER TOLGYESI: When we're looking for time is the removing of radioactive waste. Eventually, when the project will fully progress, there will be lots of transportation and that kind of activities which will accommodate the population.

Is this something what the population is looking into it could happen, and what are the consequences of that? Because we are talking about thousands of truckloads, et cetera, et cetera for several years.

So usually, when you are looking in a community is that it's okay when we work on the street of the neighbours, but when it's on our street, it takes a long time, even if it's just a few months. So you know, the perception now of work and eventually when it comes will be maybe different.

So how have you make sure that it will be seen and expected from the population that it will happen?

MS MILLER: Joan Miller, for the record.

The transportation of the waste to the long-term waste management facility was an important

component of the environmental assessment, and it was assessed very thoroughly through that -- through the assessment process. It was concluded that it could be done safely.

There were identified traffic routes that were agreed to from the -- with the -- with public input.

Once we start the actual transportation of materials, we have a very comprehensive public communication program that would ensure that the public is well aware of where we're going to be transporting waste and when. That program would include not just general information on our web site, but also communicate -- almost door-to-door communication with the community or the streets that we would be conducting work in.

So there's a very comprehensive communication plan to ensure those affected are aware of our activities.

MEMBER TOLGYESI: And could the project, for any reason, be suspended, delayed or stopped, what will be the consequence?

MS MILLER: Joan Miller, for the record.

There is a legal agreement between the

Government of Canada, the Municipalities of Clarington and Port Hope. I actually am not familiar of -- with the detailed contents of the legal agreement that would arise to such a situation that you describe, but that all parties, I believe, are -- have agreed to execute the project as defined within the legal agreement.

So if there were only going to be any changes, it would need to be reviewed and agreed to by all parties.

THE PRESIDENT: Just still on the transportation, on page 3 this intervenor's argued there's going to be huge traffic, 120 to 200 trucks to be confined street or to the town 10 to 12 hours per day for six years. And his conclusion is that there's going to be diesel exhaust exposure of Chronic Obstructive Pulmonary Disease, COPD. And I think what he's saying is there's going to more injury done from that than from low level radiation.

Any comments about that observation?

MS MILLER: Joan Miller, for the record.

Again, the safety of the transportation was assessed through the environmental assessment. It had also been thoroughly reviewed as

part of the project approval and our licence to proceed with the project.

We continue to carry out transportation studies and have experts look at routes that we have chosen to ensure that they are safe. The data that we have as part of those studies is that the increase in traffic would be up to about a five to six percent increase, depending on the route.

Some of those routes would be much less with respect -- so an increase of only one to two percent compared to the current traffic on those routes.

As part of our independent transportation studies, we have also -- we're also looking to upgrade some of the intersections where those have been recommended to improve safety.

THE PRESIDENT: Okay. Thank you.

Anything else on this intervenor?

MEMBER VELSHI: I'd like to get staff's opinion on this intervention, and if you have any comments on it.

MR. NEWLAND: Dave Newland, for the record.

Well, certainly with respect to traffic, it was considered in the environmental

assessment. There was a mitigation plan put in as part of the environmental assessment follow-up, and that is one of the licence conditions.

And so it is something that we will provide regulatory oversight on.

I guess my other observation is that the intervenor contends that there is not a direct safety concern.

We recognize that this is not a safety concern. This is about something quite different, the stigma of the society with the waste that's been left there historically.

Thank you.

THE PRESIDENT: Okay. Thank you.

We'll move on to the last submission. It's from the Municipality of Port Hope as outlined in CMD 14-M79.1 and 79.1A.

CMD 14-M79.1/14-M79.1A
Written submission from the
Municipality of Port Hope

THE PRESIDENT: Questions?

Mr. Harvey?

MEMBER HARVEY: Merci, monsieur le

président.

The written submission from the Municipality of Port Hope gives the impression that there's a gap of communication or some miscomprehension of things between the municipality, the staff and LCM.

So I don't know who could explain that because the municipality being the centre of the activity, it's strange to see so many questions.

I do not perceive answers. They are not so complicated. So who would explain that, then? What is the problem?

MR. NEWLAND: Dave Newland, for the record.

I'll make a few introductory remarks and then I'll ask Mr. Thelen to provide some further details.

And so we did meet with the Mayor of Port Hope and the Mayor-Elect, and they did express a number of, I would say, concerns to us.

Now, many of these concerns are not regulatory concerns. They're concerns that are more related to the agreement between the municipality and the Government of Canada. So they're not really within our jurisdiction.

That being said, we do expect that CNL has an adequate program to engage stakeholders. And of course, the municipality, Port Hope-Clarington, are key.

So I'll ask Mr. Thelen to perhaps give a few examples of areas where the municipalities have sort of raised concerns.

MR. THELEN: John Thelen, CNSC project officer, for the record.

Just to summarize first, the municipality is seeing clarity on a number of issues that were raised in this written intervention. These concerns were also raised by the municipality in a meeting with CNSC staff in late November.

Many of the issues that the Municipality of Port Hope has been discussing to date or have issues with they've been raising primarily with NRCan and CNL to date, NRCan with respect to the legal agreement that the municipality has with the government. But more recently, Municipality of Port Hope has been looking for clarity from CNSC staff as to how the licence and its supporting Licence Condition Handbook will be used to verify that CNL meets all obligations of the licence and requirements set forth within conditions, also with the Act and its

associated Regulations.

We, at that meeting -- and we'll continue -- have confirmed and continue to provide clarification regarding both licence requirements and how these licence requirements may overlap with other aspects, including how they may overlap with the legal agreement.

As we left the meeting in late November, we did leave with an understanding of mutual agreement to work together collaboratively moving forward and committed to responding to all concerns of the municipality in the new year and working with them to ensure the clarity that they're looking for is reached pending satisfaction of all parties involved.

The Commission will be updated on this effort as this moves forward as well through ongoing reporting to the Commission.

THE PRESIDENT: CNL?

MS MILLER: Joan Miller, for the record.

We do have a number of engagements with the municipality at various levels, various levels of detail. As was mentioned, the scope of the project was defined in the legal agreement.

The devil is in the details, and I

think the legal agreement recognized that that could be a challenge as the project was implemented. There is provision for a dispute resolution process in the legal agreement and the outstanding issues -- so there are about five of them -- noting that the list was much longer. So we have worked with the municipality to reduce that list and obtain agreement on a number of issues that they have raised with us.

So of the outstanding ones, they are moving through the dispute resolution process that involves the municipality and the Government of Canada.

THE PRESIDENT: Just help me here. I remember distinctly that we all agreed there's going to be a liaison committee where all the parties will meet regularly. CNSC will be there. NRCan will be there, et cetera, to resolve such issues and, in fact, the most important issue as far as us was the cleaning criteria and how you're going to execute on this.

Has any of this been done? How often do you -- does this liaison committee meet, and do they actually, you know, have a regular agenda, et cetera?

We're going to be with you on an annual basis asking the same questions. I don’t know

if there was a formal structure being put in place to deal with this kind of issue, which we know are going to occur during the construction and execution of the contracts.

MS MILLER: Joan Miller, for the record.

I will, in a moment, turn it to Craig Hebert provide further details on how we meet with the municipalities, but there are a number of formal meetings. There is an agreement monitoring group where NRCan, CNL and the municipality meets on a regular basis. That's a structured process that's been in place since the legal agreement was signed.

We have met with the municipality on a series of meetings to address the issues, again, a very formal process put in place to address those. That has been ongoing.

And I don't know if -- whether or not all three parties are sitting down at the same meetings. I know we have on occasion, but I don't know if there's a structured process for that, so I'll turn it to Craig Hebert.

MR. HEBERT: Craig Hebert, for the record.

As Ms Miller indicated, we do have a

comprehensive municipal dialogue framework established with both municipalities. At issue here, obviously, is the Municipality of Port Hope.

There is an agreement monitoring group forum that meets on a quarterly basis. It involves NRCan, the municipalities individually for part of the session and collaboratively for other parts. All of the municipal issues are discussed at each meeting, the status of them, efforts that are ongoing to resolve them.

In addition to that, there's community liaison groups that CNSC does attend as observers where we provide two-way communication on the part of -- or between the project and the communities.

As Ms Miller indicated, there are -- we have reduced the list of concerns substantially. It started out with 26, grew a little bit, and we've now got it narrowed down to the few that you are aware of. And there's very active communication on a very regular basis with the municipalities together with NRCan in that regard.

THE PRESIDENT: So is the clean-up criteria now accepted by all parties?

MR. HEBERT: Craig Hebert, for the record.

The clean-up criteria is one of the active areas under dispute, but specifically, it's the application of what criteria to what properties as opposed to the criteria itself.

THE PRESIDENT: Staff?

MR. NEWLAND: Dave Newland, for the record. I'll ask Mr. Thelen to respond.

MR. THELEN: John Thelen, CNSC project officer, for the record.

Clean-up criteria for remediation are clearly listed in the project licence. Moving forward, staff continue to do compliance verification activities to verify that -- what remedial work will be done according to these licence requirements.

The licence also clearly identifies land use classifications, includes both residential and parkland land use classifications as well as commercial-industrial land use classifications.

Re-survey of Port Hope project, the properties, is currently under way right now and, as an outcome of that work, CNL is ascertaining which sites require clean-up and, specifically, where clean-up is required, how those clean-up criteria will be applied, including which land use classification is appropriate.

And again, as mentioned, we will be verifying that activity as it is carried out.

Some of the issues that were touched upon by CNL have interaction with the legal agreement on which properties need to be cleaned up according to these land use classifications. However, the licence is clear.

When a site has been identified under a select land use classification, the criteria are clear within the licence in order to meet licensing requirements and remove legacy waste.

THE PRESIDENT: Ms Velshi?

MEMBER VELSHI: I'm sorry, but I'm a little confused because from your description, it seems this is all fairly clear, that the criteria are clear, the classification in the licence is all clear.

So after your meeting with the municipality, did they walk away feeling reassured that this is all well spelled out and little area for debate?

MR. JAMMAL: It's Ramzi Jammal, for the record.

To answer your question, Ms Velshi, I personally met, with staff, with the municipality in late November. The clarity that's described in the

licence was presented to the municipality once more, and we had the discussion with respect to the indicators that are in the licence and the key indicators for the clean-up criteria.

The municipality fully accepted our explanation, but we made it very, very clear there is no safety element, what the Commission has approved on the basis of the safety case that the licence was issued.

So there are some -- I think staff is being diplomatic about it, but there is a friction on contractual elements between CNL and the municipality.

So what we're trying to do here is not mediate, but re-emphasize the fact that the licence was issued, based on the safety case. On our expectation, as Mr. Thelen mentioned, we will conduct our compliance activity according to the licence.

So every once in a while, we repeat the fact to the municipality, on what basis the licence was issued, and the indicators will be used according to the licence conditions and the Licence Condition Handbook.

If that didn't answer your question, I will elaborate a bit more, but I, personally, met with the municipality, with the outgoing Mayor and the new

elect Mayor, plus their contractual engineers and municipality group.

THE PRESIDENT: This will be a question with us on an annual basis at least as we go forward. Just to -- for all of us that still remember the hard discussion with the Ministry of Environment of Ontario and Natural Resources, we all agree on the criteria and I thought that, you know, the way ahead was very, very clear.

So now is the project now being delayed because of these discussions? Are we now behind schedule?

MS MILLER: Joan Miller, for the record.

As was indicated during the CNSC staff presentation, we are proceeding with Port Granby, so we are out on tender and expect to award the contract for the construction of the long-term waste management facility and the remediation activities.

To initiate the contract for the long-term waste management facility at Port Hope, we do need to resolve these issues because they do define the scope of work that would be undertaken with respect to the cleanup, how clean and the quantity -- the material that would need to go into the Long-Term Waste Management

Facility.

THE PRESIDENT: So they are not resolved as of now?

MS MILLER: They are not resolved as of now. As I mentioned earlier, they are in the -- there are various stages within the dispute resolution process and they are in the formal -- we are progressing them under that formal process defined in the legal agreement.

THE PRESIDENT: Is there kind of a time forecast on this?

MR. HEBERT: Craig Hebert, for the record.

We are working together with NRCan and the municipality with a view to expedite the resolution of these. As I'm sure is appreciated, formal processes such as this do take some time, legal involvement in those sorts of things, but all parties, the municipality included, are committed to resolving these as expeditiously as possible.

THE PRESIDENT: So my last question is on this. Staff, is our criteria not that clear that they can be disputed on interpretation?

MR. NEWLAND: Dave Newland, for the record.

The criteria in the license are very clear. I think there are some questions around how those criteria may be implemented once it comes to the field

work.

THE PRESIDENT: So who resolves those questions? I'm trying to understand, is that a financial issue, is that a regulatory issue? If the criteria is clear, than the cleanup, how you do it, should be clear. So what am I missing? What is the dispute about?

MS MILLER: Joan Miller, for the record.

Specifically with respect to the cleanup criteria and one of the sites that has been identified for cleanup, the issue fundamentally boils down to within the legal agreement it identifies that we would cleanup properties to a criteria for foreseeable use. So what is foreseeable use is what is really being negotiated.

For example, it is clear what applies to the Highland Drive Landfill with respect to the cleanup criteria. However, there is debate and discussion as to what could be the foreseeable use for a landfill, particularly when we are not going to clean up the complete landfill. We are only going to clean up the waste that is historic waste.

So it's those kinds of debates that we are getting into with the municipality and of course they will impact the project in a few ways. It will impact it in terms of cost, plus it will also impact it in terms of material that needs to be transported. We just had a

discussion about transportation of waste and whether or not it was safe. We would have to design a larger Long-Term Waste Management Facility. So it does have some significant impact on the project, so it is important that we resolve this and move forward. That is what we are trying to do and it is now in the process that is defined in the legal agreement to solve.

MR. JAMMAL: It's Ramzi Jammal, for the record.

Mr. President, Members of the Commission, when I mentioned there has been contractual friction that's what I'm talking about. The requirement in the license is very, very clear. It is not CNSC staff who are going to determine what foreseeable use of the land is going to be. It is going to be between the municipality in their own classification or even the province or according to the legal agreement. I am just giving hypothetical, potential elements.

From our perspective as CNSC oversight, depending on the classification of land, depending on the agreement that is being executed, we will ensure that the regulatory requirements have been met under the license, taking into consideration the key elements that they are using as an indicator with respect to the cleanup. As Dr. Miller mentioned, there is a debate or an issue between the

historical waste that existed prior or after, versus what is going to take place from a cleanup perspective. So my conclusion is, depending on what the municipality classification of land, we will make sure it will meet our requirements.

THE PRESIDENT: Okay. The last comment I would make on this, our concern has always been that the cleanup for the residential sector will be such that an owner can get a clean certificate. There is no lien on this particular house and residents.

The industrial, again, I remember clearly that our discussion with MOE led us to a particular criteria and that's it. I don't know what else is unclear about this. If somebody wants to ease up and go beyond those industrial things that's -- you and NRCan can negotiate it with the municipality, but it should not delay the project.

Lord knows that we are here after many, many years of debate and I am more concerned about the residential side of this equation the industrial side, with all respect to the municipality. So I really would like for staff to keep us informed as to how we are doing on this.

Does anybody else want to say anything about this intervention? Okay. Thank you. So this

concludes the written submission and I would like to proceed now for our question from the Commission Members on everything we have just heard until now, starting with Ms Velshi.

MEMBER VELSHI: Thank you, Mr. President.

Thank you to staff and CNL for their very informative submissions. My first question is around the nuclear legacy liabilities part of the report, or the part that wasn't in the report. I understand that for the old reactor facility since there was no operational activities you didn't include it in the report. But if you could please provide at a very high level what the decommissioning schedule is for those facilities, including for Whiteshell where you said they are looking at accelerated decommissioning, I think it would be very helpful what at least the indicative timelines are for them.

MR. NEWLAND: Dave Newland, for the record.

I will ask Mr. Howard to respond. Thank you.

MR. HOWARD: Don Howard, for the record.

The scheduling for decommissioning of some of the nuclear liabilities that CNL currently owns, with this new restructuring and this GoCo model that they are

proposing to implement in the very near future, we have been informed that there will be an acceleration of the Whiteshell and nuclear power development facility decommissioning. So we anticipate that will probably start in the next two to five years, let's say, to be optimistic. So we expect to see the plans and see progress on that.

Douglas Point and Gentilly-1 are not -- they will be followed later and my understanding is that that was more in the 2025 to 2030 timeframe as to possible timing of that, but I would suggest that CNL may want to confirm that.

DR. WALKER: Bob Walker, for the record.

The NLLP is backed up by a comprehensive assessment that is conducted by first AECL, now CNL, that is the entire cost estimate for just positioning all of the legacy liabilities and that ends up as the statement in our annual report and it's the basis for costing and putting that forecast inside the public accounts on the CNSC staff submission. There was the $10 billion undiscounted cost that's in the public accounts and in that is all of the various activities that lead to environmental remediation, to decommissioning and to ultimately waste disposition.

So we have a plan. We have updated that plan comprehensively in 2012-13 and every year we come back and refresh that plan.

When government has decided to implement the GoCo model it has identified two activities within the overall initiative that it's interested in having the contractors, the consortium that are interested in bidding on this contract submit what are called target cost proposals for, that is for Whiteshell and for nuclear power demonstration of the NPD reactor. So there would be an expectation that the government has that those particular activities would be accelerated.

I can turn now to Joan Miller to give some more details. Thank you.

MS MILLER: Joan Miller, for the record.

So I don't think I could say anything further with respect to Whiteshell and NPD. They would both be progressed on accelerated schedules. For Douglas Point and G-1, we are planning to advance any decommissioning and demolition of buildings that may be non-reactor, non-contaminated buildings that we feel aren't needed to support the decommissioning activities.

We are proceeding with reducing any health and safety risks with the continued storage of those facilities, however in our plan we don't actually show demolition of those reactors until about 2035 to coincide with the availability of a Long-Term Waste Management Facility for the low- and intermediate-level waste. We, of

course, though, have left in our plan that we would continue to have dialogue with both Hydro-Quebec and Bruce Power on which sites those two reactors sit to see if -- to ensure that our decommissioning plans are aligned with their site plans.

MEMBER VELSHI: Thank you.

My next question is for CNL and it is around your fitness for service for Chalk River. I appreciated the update you gave on all the extra effort you have made to bring about improvement in that with the additional investment and reduction in backlog. So when do you expect to get from beyond expectations to satisfactory?

DR. WALKER: For the record, Bob Walker.

We have a very extensively crafted improvement program through the Integrated Implementation Plan to enhance performance against a safety case. That program is a five year program. We are now in year three, on schedule, and it is front-end loaded. We are beginning to see the improvements in reliability as a result.

So we believe we are trending in the right direction. Of course I would not want to speak on behalf of the CNSC staff of where that assessment may go, but we are confident we are moving in the right direction. I will ask my CNO to make some additional comments.

MR. LESCO: Yes. Randy Lesco, for the

record.

As Dr. Walker indicated, I think we are moving in the right direction here in terms of how we are actually making physical improvements to the plant around NRU. I guess a critical component with respect to our systems components and structures is, it is right around delivering an IEP by 2016.

MEMBER VELSHI: So we shouldn't be surprised if even next year's report shows it as the event, because it is a long journey is what you are saying?

MR. LESCO: As Dr. Walker has indicated, most IIP activities are front-end loaded, so a lot of activities are included in 2013-2014 as an example. So I would just leave it up to staff to comment on that.

MR. NEWLAND: Dave Newland, for the record.

I don't want to pre-judge what the rating will be next year. I would like to say -- and I will have Mr. Carrier fill in some more details -- we do recognize that it's, as you have described it, a long journey and a difficult one. We do recognize that there has been substantial investment over the past three years and there is recapitalization on the site. We also recognize the amount of work that has gone into the IIP and that that will continue.

So I will ask Mr. Carrier to provide a little bit more detail.

MR. CARRIER: Just to complete the information, the fitness of service is about a number of programs, initiatives, measures, practices at the site that basically support fitness for service. These elements contributed to define what fitness for service is and provides for monitoring and provides for feedback basically to ensure that fitness for service is not only attained, but maintained. AECL, in the past and nowadays CNL, has always had several of those elements to ensure fitness for service. Through the IIP, AECL -- CNL, I'm sorry for that -- is integrating those systems and modernizing it and measuring themselves against best industry practice.

We have seen in the recent years AECL putting those new programs and initiatives in place, including an aging management plan, reliability program, fitness for service program, maintenance program. These programs are more and more dovetailing with one another. However, these programs are still being implemented and they have not reached full maturity. So I will say, and as I stated during my presentation, we are noticing an improving trend and, again, AECL's on a journey. We are seeing improvement in this area, but I don't think they are totally there yet.

THE PRESIDENT: I don't want to put you on the spot. I detect that you are now in a transition period where there is going to be a lot of unknowns coming at us with this GoCo model.

What can you share with us about what -- we know that the GoCo model is focused by and large on the whole site, but the emphasis was on the waste side. What can you tell us about what's likely to happen on the science side, on the investment in -- well, that there will be investment in NRU beyond 2016 or not, because that will colour the kind of laboratory you could have in the future?

DR. WALKER: Bob Walker, for the record. That's a comprehensive question, Mr. President. I will offer a few comments.

First, in my remarks I observed that the mandates for CNL going forward has three missions. One of those is decommissioning and waste management on behalf of the government and the other two are science and technology missions, one where the federal government is the customer and the second is where the commercial sector is a customer. Those are sizable parts of our business today.

The underpinning of this of course is also reinvestment and recapitalization, particularly in the Chalk River site, and as Mr. Lesco indicated, that is in full bloom with more coming. So this is about Canada's

premier nuclear science and technology organization with a go-forward mission.

The government also has to assure that we through it, through CNL, effectively deals with that $10 billion liability on the public accounts as efficiently and of course as safely as possible. So it is one of the objectives. This, however, is a diverse company with diverse mandates and the expectation is that under the GoCo contractor we will excel in all, including the opportunity to grow the business through our commercial streams, our S&T services domestically and internationally.

The issue of a neutron capability is certainly an area that will have to be explored. The NRU is an elegant machine. It served us well for decades. It is in our 58th year of operation. At some point the NRU will shut down, whether it is in 2021 as our current plans have or at the time earlier. We will come back and see, but it will shut down and some of the discussions that will take place in the coming period will be what comes next. That is a discussion I expect that the government would want to have with many parties to answer that question.

I would finally highlight that one of the innovations CNL over the past two years has been to introduce the concept of 10 virtual centres of excellence by which we bring together our technical expertise, our

people, our facilities, our intellectual property to offer our services and to maintain our leadership in nuclear science and technology. Many of our facilities are the backbone to those 10 centres of excellence. The NRU is the backbone to three of the 10.

So it's an absolutely central part of our reality, but there are many other parts of our program that go forward as well.

THE PRESIDENT: But the reason I'm raising it now is because we are talking about the below expectation on fitness for service. If the government decided to shut down the NRU in 2016, I don't see a lot of big investment into modernizing a facility that you are going to shut down.

DR. WALKER: Bob Walker, for the record.

We are expecting to receive government direction in the near future on that year and, as you indicate, when we have that direction we will have to come back and reassess our plans in going forward. Our plans remain to operate the reactor safely and reliably and continue to move to world-class performance regardless of the decision. However, once we have the specifics we will be going back and fine tuning our approach.

THE PRESIDENT: Okay, thank you.

Monsieur Tolgyesi...?

MEMBRE TOLGYESI : Merci, Monsieur le Président.

On your annual report regarding Chalk River the staff has expressed concerns with the current complement of certified health physicians. Is there now a sufficient staff and what do you do to make sure that you will have them?

MR. LESCO: Randy Lesco, for the record.

Currently we have now a full complement of health physicians for NRU, that is sitting at three individuals with a fourth to be certified early next year. We now have a comprehensive program to making sure that we have proper succession planning that comes through certified health physicians.

MEMBER TOLGYESI: I will go to Whiteshell. I'm looking at your recordable lost time injuries, frequency and severity. And over the three years lost time injuries dropped from eight to five to grow to seven, but the severity is increasing steadily, which means that there is about -- over 66 percent increase from last year and there is also about a 20 percent increase from 2011 to 2012. It's a sharp increase. And they were saying that a considerable number of injuries at Whiteshell are resulting in extended absences from workplace.

And on the other side most of these

injuries are minor, which means that there is -- usually when it happened, in general when it's happened, is that there is some kind of reluctance with the small injuries to stay outside of work and not come back. What are challenges to make sure that these employees will return? It's small. You are saying it's minor injuries. So what you have as challenges and what you have as a plan to make sure that it will improve?

MS MILLER: Joan Miller, for the record.

Of course our goal is to have zero lost time injuries. However, when we do have an unfortunate incident we do need to improve our return to work program and there has been some significant improvements in that program at Whiteshell over the past year. To have an effective return to work program you have to of course involve management workers, union leaders and the medical community. So there has been some significant improvements in that regard and we are starting to see the effects of that over the last number of months or in 2014 where in fact our trends are going -- we are trending in the right direction for 2014.

I would also say that an important part of our program is to ensure that we are not hurting people in the first place. So we have introduced a number of improvements in that regard as well. We have a much more

effective human performance program where we have human performance advocates that are part of the work plan, the details. We have management-union leadership, regular meetings where we review safety at the site. So much more engaged leadership to work towards our joint goal of zero lost time injuries.

MEMBER TOLGYESI: Staff, do you have any comments when we see that it is improving this year? Do you have any comments to that? Once the programs are implemented, are they satisfactory or there should be some improvement?

MR. HOWARD: Don Howard, for the record.

First, I would like to start off by saying that we look at all of the events that are reported to the CNSC and we look at them from the perspective of the injury, the severity of the injury and whether, you know, what caused it and how it can be prevented in the future. So that's our goal.

Basically when we looked at these particular injuries, decommissioning is unique because basically you are moving a lot of heavy equipment. You are, you know, doing a lot of physical work and sometimes when you get into injuries that are what I consider to be soft tissue injuries, sometimes they are very hard to pinpoint and to remediate. So basically when we looked at

the severity or the severity for 2013, even though there were only seven events, a lot of them were soft tissue injuries so a lot of times they take a long time to recover.

So the longer people are away, climbs the number. So now at CNL, Ms Joan Miller had pointed out they are working on a return to work program. It does require discussion with management employees unionized and things of that nature, so we see a positive trend going on there and we are following this closely for 2014 to make sure that programs are in places. Decommissioning, especially if it's going to Excel rate at Whiteshell -- so we want to make sure the program is robust and they do have -- to prevent the injuries to start off with is paramount and then if injuries do happen, how are the workers going to be treated and handled to ensure that they get back to work in a reasonable amount of time?

MEMBER TOLGYESI: Do you have contractors and are they included in the stats?

DR. WALKER: It's Bob walker, for the record.

Contractors are not included in that. However, we do track our contractor injuries and have been putting an increasing focus on our management and supervisory oversight for contractor safety. Perhaps,

Randy -- if Mr. Lesco could comment further on this?

MR. LESCO: Yes. So Randy Lesco, for the record.

When we have contractors on the site especially with respect to people who have what we refer to as "construction islands", we are making sure that we have supervision on the site making sure that all contractors are performing to their own safety program. We do that on a daily basis based on the size of the project.

MEMBER TOLGYESI: You know, when you don't include contractors it's not the complete image of the site, because eventually if you will contract all the work and you will stay just the president, two vice presidents and two managers, you will not have an accident as an entity. But those who are contracting, they will have, so it doesn't give a global picture of performance on health and safety.

My question is if there are contractors and if you know how they perform compared to your staff. Staff, do you have any stats about that also?

MR. NEWLAND: Dave Newland, for the record.

No, contractors are not included in the statistics. I would say we do monitor the performance of a licensee in their oversight of contractors and so we do

expect them to have a program of oversight and we would monitor that. If there are significant injuries to contractors and we have an EIR as an example coming up later today, then we do report them to the Commission.

MEMBER TOLGYESI: So because in general what the companies are doing now, large companies, they include in their performances also contractors. So probably it will be good to see, You know, you check the oversight. How do you measure the oversight if you don't know what's happened with contractors?

THE PRESIDENT: Mr. Jammal...?

MR. JAMMAL: It's Ramzi Jammal, for the record. There are a couple of elements I would like to highlight.

If I take you to page 61 of the annual report itself, I am going to read you a quotation, Mr. Tolgyesi:

> "AECL stated that its Decommissioning Quality Assurance program applies to all staff and contractors who participate in, or support, projects or activities. However, CNSC staff determined that the information included in the DDP does not provide a clear description of how AECL would

manage external contractors involved in this project."

So we will be keeping a close eye on this in order to ensure that there will be -- our requirements under the CSA N286 will be met.

In addition to what Dr. Newland mentioned, if there are events onsite it doesn't matter, contractor or not. The key point here under the license, the license holder and the licensee is obligated to ensure that the safety of the contractors onsite is maintained at all times. So in other words, they are responsible for the control of licensed activity and if there are events it will be reported to us accordingly.

But that is one of the elements that we will keep an eye on as we go forward with respect to the annual reporting to the Commission.

THE PRESIDENT: I think this is a good time to take a 10-minute break and we will come back in 10 minutes and resume the proceedings. Thank you.

--- Upon recessing at 11:08 a.m. /
Suspension à 11 h 08
--- Upon resuming at 11:22 a.m. /
Reprise à 11 h 22

THE PRESIDENT: Okay, we are back and we will continue with the Commissioners' questioning, avec monsieur Harvey, s'il vous plaît.

MEMBRE HARVEY : Merci, Monsieur le Président.

Ma première question... I'm sorry. My first question is about the follow-up of Fukushima. On page 7 and on page 26 you mentioned that it is in progress and just to go to Annex G to see that, and in Annex G we see the same thing, "in progress."

So I would like to -- if you go to Annex G, it's for the items medium term. There are some items completed, some others should be at the end of this year, but it's written in the table there "in progress," "in progress," "in progress" for four items. So I would like to --

THE PRESIDENT: You're on page 153?

MEMBER HARVEY: 153, yes, that's right.

So you mention "in progress" but what does that mean, it's supposed to be completed at the end of the year?

So who could answer that? Maybe the LCN or the staff?

MR. NEWLAND: Dave Newland for the record. We're just getting ourselves organized.

So could I clarify the question? Are you more --

MEMBRE HARVEY : C'est simplement je voudrais savoir... Étant donné que dans le texte vous marquez que l'avancement progresse, puis quand on va au tableau, c'est marqué « in progress », je voudrais voir c'est quoi le progrès.

MR. CARRIER: Yes. So regarding the note number 1, everything is in progress and is progressing well. I will say this. If I have to say something about one of CNL's activities that has been -- that CNL has taken seriously the follow-up to Fukushima. So it's just to set the tone on this one.

To give a general flavour of this, CNL has completed the development of this severe accident management structure, basically the analysis, development of procedures and implementing training programs. So we are foreseeing that CNL would be completed with the implementation of SAMP, which is very -- which is a great part of this whole table, by
September 2015, and that includes training of staff.

There has been some slippage on the medium term, on 2014, but some recovery on the long-term items. And that includes also identification or modification to facilities to facilitate basically implementation of the

Severe Accident Management Program.

So there's a series of specificities in this thing. So I could say, for instance, that for note number 1 the final stages of all the analyses that are incorporated in there, I expect it to be completed by February 2015. So we are meeting on a regular basis with CNL to discuss progress on those matters.

MEMBER HARVEY: Okay.

MR. CARRIER: And they do vary. So those were the original dates. I will say that CNL is pretty much on track on that project.

MEMBER HARVEY: Okay.

THE PRESIDENT: Okay. Just the methodology of reporting, the heading is "Medium term (2013-2014)." Is that fiscal year or calendar year? Because if it's calendar year, 2014 is gone. So "in progress" means what?

MR. CARRIER: I will be fair, I don't remember but I had assumed those were calendar dates.

THE PRESIDENT: If it's calendar days, then "in progress" in every place in December is a bit stretching the credibility.

MR. CARRIER: Yes. And again, those were target dates. Again, I will still insist on this one. AECL is pretty --

THE PRESIDENT: That's fine. Then you just define between target and where they are now.

MR. NEWLAND: Dave Newland.

Noted. Thank you.

THE PRESIDENT: Okay. Monsieur Harvey.

MEMBER HARVEY: On page 22 about the procedures. Here it's just because I read the French and the English and it's not the same in English and in French. The conclusion is the same, almost the same, but in French there is a sentence which makes the conclusion a little bit different.

If you go in French, because in French there is a remark -- just a moment. Sorry. It's not exactly the same page, for sure.

--- Pause

MEMBER HARVEY: Okay. That's on page 25.

There is a sentence that says:

> « Toutefois, l'échéancier pour compléter les documents à produire dans le cadre de ce projet a été retardé de plusieurs mois. En effet, pendant l'évaluation du plan de mise en œuvre intégré, le personnel de la CCSN a confirmé que plusieurs éléments de ce projet encourraient

> des retards de plus de six mois. Malgré ces délais, l’EACL s’attend toujours de compléter le projet en entier pour l’échéancier prévu du 31 mars... »

Ça fait que vous avez la même conclusion, mais vous avez quelque chose là qui n'est pas dans le texte anglais. C'est moins optimiste, disons.

M. CARRIER : Laissez-moi un petit 15 secondes pour lire les versions française et anglaise.

MEMBRE HARVEY : Mais ce n'est pas... J'ai juste...

--- Pause

LE PRÉSIDENT : Vas-y.

M. JAMMAL : C'est Ramzi Jammal pour l'enregistrement.

Monsieur Harvey, tu as demandé une bonne question concernant la traduction, mais malheureusement, je n'ai pas la version française auprès de moi. Mais je voudrais vous préciser que selon le programme d'amélioration, ou bien ce qu'on a référé, IIP program, il y a des sections qui sont tout à fait obligatoires que LCN doit être en exigence avec. Ça veut dire qu'ils n'ont pas le choix : Ils doivent mettre sur place ces améliorations.

Donc, c'est pourquoi potentiellement vous

allez avoir une différence. Alors, à la page 22, la version anglaise dit :

> "AECL continues to work toward the target end date of March 31, 2016, for this project."

Alors, ils doivent le compléter d'ici le 31 mars 2016. Alors, c'est... Si je t'ai confus de plus là, dis-le-moi, mais le point ici que...

MEMBRE HARVEY : La simple affaire, c'est qu'en français, il y avait un retard de six mois. Ça fait que ma question est juste : Malgré ça là -- je peux effacer la phrase en français -- est-ce que la date du 31 mars vaut toujours?

MR. CARRIER: I think I'll take this one.

MR. JAMMAL: Okay. Go ahead.

MR. CARRIER: The point here is that there were indeed delays in the production of those procedures, and yes, indeed, AECL still intends to recover those delays and have the same deadline.

And as was asserted by Mr. Jammal, they are matters in the IIP that we feel a lot stronger about and that we see as high priority matters that need to be addressed, and procedures and critical procedures are important.

MEMBRE HARVEY : O.K.

LE PRÉSIDENT : Alors, vous allez corriger cette... faire la concordance entre les deux versions?

MEMBRE HARVEY : L'effacer.

MR. CARRIER: Yes. And as stated, those are draft reports.

THE PRESIDENT: Okay.

MEMBER McEWAN: Thank you, Mr. President.

I would like to start with the radiation protection satisfactory rating and how you differentiate between a satisfactory and a below expectations, and I specifically want to review the two events that we have discussed during this reporting period, the lack of transition of reports to the national database and the lost tritium data for workers.

CNSC view the consequences of these two events as minimal perhaps but I would still argue that both of these display an underlying -- perhaps an underlying approach to the radiation protection framework and to sort of a global gestalt of trying to be compliant that failed, and therefore, I wonder why you have spent so little time on those two events because we certainly, I think, during our conversations about them felt that they were serious and that they reflected perhaps imperfectly on the culture of CNL.

MR. NEWLAND: Dave Newland for the record.

I will have Mr. Carrier speak initially to the events themselves and the rating and I will also ask my radiation protection colleagues to fill in further details.

MR. CARRIER: So this is Christian Carrier for the record.

Yes, it is -- I will just set a few clarifications on this one.

When we reported those events, I think it is first important to emphasize that the doses to the individuals were investigated and they were kept on record at Chalk River. The local radiation program, radiation protection program was aware of doses to those individuals, and any outstanding or abnormal values would have been addressed. So the people locally on the radiation protection program knew about those doses and were acting consistently with any findings that may have arisen from those dose estimates.

One of the issues was the transfer of those data to the National Dose Registry, which was the main issue in this case. Now, this is a different matter which deals with a different licence, which is separate from the Chalk River licence. It still is a CNL licence but it's a dosimetry licence that is basically subject to another reporting process.

So I may turn the question to Mr. Tristan

Barr if he wishes to elaborate on this matter.

MR. BARR: Tristan Barr for the record. I'm the Dosimetry Services Specialist.

So indeed, we did report on those EIRs and there is continuing follow-up going on for the dosimetry services licence but it is a separate licence, so it doesn't impact their SCA and their evaluation of the acceptability of the RP program.

From a dosimetry services perspective, we have an inspection planned that's for March of this next calendar year and we are following up on those EIRs.

MR. CARRIER: If I may, I just wish to complement on this one.

Following the issuance of those EIRs, it was recognized that dealing with two licences for the same site, and to some extent with the same people, creates a situation where some issues may fall between the cracks. So that is why the inspection that is currently planned in March is a combined inspection by inspectors of Mr. Barr's group and my division to ensure that basically we are looking at the same matters but with two different sets of eyes to avoid a situation where basically we may be missing something.

MR. JAMMAL: It's Ramzi Jammal for the record.

Dr. McEwan, your question is very pertinent and you have highlighted a deficiency in our reporting. Even though it's two licences, I take that accountability with respect to the improvement for the next year annual report, that we will make a reference even though it's a separate licence but it's global activity as we report it on the other sites.

So we will commit to the Commission that all licences -- with respect to an annual report at least -- there will be some reference to it. Because as my colleagues explained, there is a radiation protection program on site itself versus other licences. Just like we talk about transport, we will be highlighting any other licences pertaining to CNL.

MEMBER McEWAN: Thank you.

So I guess my second question is for CNL.

On page 32, Figure 3, I think when you presented you said that there has been an improvement in backlogs and that in particular there has been a significant improvement in the open elective backlogs, which would obviously be in contradistinction to the red graph on this figure.

MR. LESCO: Randy Lesco for the record.

What I was trying to do is provide in my opening remarks how we are trending downwards in terms of

our performance. So basically if you look at the open elective backlog on this graph, today we are down to below 600, so about a 30-percent reduction.

MEMBER McEWAN: Okay. So there has been a peak and it is now on its way down?

MR. LESCO: That is correct.

MEMBER McEWAN: Okay. Thank you.

THE PRESIDENT: Sorry, I'm slow. How do we get down when the red --

MR. LESCO: The red one only goes to May.

THE PRESIDENT: Yes.

MR. LESCO: Year end.

THE PRESIDENT: So from May, we don't have the data here? I mean I love this graph because it's very stark. So you're telling me between May and now it really went down?

MR. LESCO: Randy Lesco for the record.

That is correct, Dr. Binder.

THE PRESIDENT: And we will see this I guess in the next report?

MR. LESCO: That is correct.

THE PRESIDENT: Thank you.

Okay. Ms Velshi.

MEMBER VELSHI: A question for Port Hope.

On Slide 57 on the CNSC presentation, as

part of your Phase II activities, you are resurveying properties. Can you comment on how those resurveys compare to the original surveys and are the results consistent?

MS MILLER: Joan Miller for the record.

We are completing the resurveys in a number of campaigns. So the first campaign involved about 400 -- or maybe actually about 500 properties and what we had assumed going into this project would be that about 10 percent of the properties would need cleanup, and indeed, out of that first campaign those assumptions were confirmed. So through the more detailed radiological surveys, we confirmed that I think it was about 43 properties would need to be cleaned up under the criteria for the project.

And we are just initiating parts of campaign 2, where we do it in different -- actually, even in the phases we undertake different types of survey -- or obtain different types of survey information. So we have started some of the other campaigns but they are not yet concluded.

MEMBER VELSHI: So when you talk about resurvey, you revisit the same property; is that what the resurvey means?

MS MILLER: Joan Miller for the record.

No. In this case, the properties were all

surveyed earlier in the late 1970s, early 1980s, to define the scope of the cleanup that would be required and we are -- as part of this project, we are resurveying or surveying all of the properties in the various wards in the community and then determining or confirming those that require cleanup under the cleanup criteria that have been approved for the project.

MEMBER VELSHI: So just to make sure that I'm getting this correct, the first time in the seventies it was really just to get some kind of an indication of how big a problem it is and what the cleanup is, and now you are actually assessing what the scope of it is and doing some detailed --

MS MILLER: Joan Miller, for the record.

That is correct.

MEMBER VELSHI: Thank you.

The next question is for staff on Slide 35. This is on the highly enriched uranium packaging.

You mentioned you have completed your -- this is for the transport package certification -- that you have completed your assessment and now you are going to go and seek feedback on that.

So what do you see as the timing for getting the package certified?

MR. NEWLAND: David Newland for the

record.

I will ask Mr. Sylvain Faille to respond to that. Thank you.

MR. JAMMAL: It's Ramzi Jammal for the record. Mr. Faille just handed me the baton to provide the response. I will do that.

--- Laughter / Rires

MR. JAMMAL: With respect to the certification process of the package, it's an ongoing process. As a matter of fact, CNSC staff did complete the technical assessment and as we speak -- as a matter of fact this morning -- we signed off on going forth with respect to public input on the technical assessment itself, so that, as part of our consideration, the public will have input with respect to staff's action and evaluation of the package itself.

There is one thing I would like to highlight, though. I am taking this opportunity to inform the Commission that the certification of the package itself, or even the package itself, the exterior shell of the package is a type B package that has been in use internationally around the world in a very safe manner, transporting nuclear fuel in a solid form. In the certification itself, we considered all of the other elements to include the inner portions of the package

itself.

So in conclusion, we are very shortly -- if we can make the translation and posting and everything else, it will be in a matter of a few days that we will put out the technical assessment. But again, it's nothing new for the external part of the package itself. It has been used safely around the world for the transport of nuclear fuel.

MEMBER VELSHI: Thank you.

So my question really was how long do you expect, you know, getting the feedback, dispositioning, and I realize it will all be dependent on the kind of feedback you get but what kind of timeline are you working on?

MR. JAMMAL: It's Ramzi Jammal for the record.

Sorry, I misunderstood your question. We are aiming for at minimum 30 days to allow the public to provide feedback. When I say 30 days, we are going to take the holiday season into consideration and so on and so forth. So we will provide ample enough time for the public -- so it can be 30 days, and so on and so forth -- but that is where we are adjusting as we speak.

MEMBER VELSHI: And then based on the feedback, it will give you an indication of how long before you can actually get the whole package approved?

MR. JAMMAL: It's Ramzi Jammal for the record.

Correct.

On the Canadian side, if I may, Ms Velshi, this is unique that we are doing this, allowing the public to provide input on a technical assessment.

The other binding element is with respect to the international regulation and requirements. The country of origin, which is the U.S., will have to provide its approval first before Canada can endorse or issue a certificate. So the country of origin will be first out the door with respect to the certification and Canada to follow.

So taking all this into consideration, so one trigger is going to be first, even though if we get enough information and the public input and dispositioning of the public input -- I shouldn't say legally but the practice is, according to the IAEA international regulation, that the country of origin will have to go out first with the certification.

MEMBER VELSHI: Thank you.

THE PRESIDENT: Thank you.

Monsieur Tolgyesi.

MEMBRE TOLGYESI : Merci, Monsieur le Président.

Looking at page 79 -- this is regarding Whiteshell and waste management practices -- the reactor VR-1, I think it's in permanent stoppage and you expect that it will be decommissioned instead of -- dismantled, instead of 2024, in 2015.

Now, when I look at page 79, what is the status of waste storage buildings, years of storage, space remaining, how much waste is annually produced at Whiteshell?

MR. NEWLAND: Dave Newland for the record. Is that for staff or for CNL?

Don Howard, please.

MR. HOWARD: Don Howard for the record.

I think what you will find on this page is that right now there's two components to the waste management area.

One is the spent fuel dry storage facility, which basically is complete. It's been in that state since the early eighties. There's no spent fuel being added to that.

The waste management side of things for the intermediate- and the low-level radioactive material, basically there's been ongoing decommissioning at Whiteshell, especially with Building 300 that generates -- I can't give you an exact number as to cubic metres of

waste that's produced per year but they currently just finished building some what we call SMAGs, shielded modular above ground storage buildings, which accommodates for the waste that's being placed in there.

Now, if AECL accelerates the decommissioning of Whiteshell, then we have to re-examine the availability of the infrastructure for waste management at Whiteshell, whether it stays on site or if it's going to be moved off site, so all of that will have to be re-examined if things accelerate at Whiteshell.

MEMBER TOLGYESI: All right. Because my question is that why do we count that in years? If Whiteshell is not operating any more, it's dismantling, we should probably talk more about is it enough space to store everything that is radioactive on the site?

Do we have enough space, enough room depending on the classification, low-level or medium level, or not? Because giving a year he gives an impression that it still continues to operate and we have two or three years of operation, the rule, and the question is that we don't operate that anymore. The question is where do we start and do we have enough space to store all the radioactive material?

MS MILLER: Joan Miller, for the record.

That's an excellent observation because

the amount of waste that we actually produce in a year depends on our decommissioning activities.

And depending on the type of activities that we carry out, we have a very extensive waste characterization program. So a lot of our waste is determined to be clean. Therefore, it doesn't require storage in our waste management area.

So we should in fact be looking at this in terms of volume, because it is the volume of waste that will use up the space and that is in fact dictated by the decommissioning activities that you are carrying out. So it is a correct observation.

We of course recognize that in order for us to proceed with or accelerate decommissioning that we will need to have in place the appropriate waste storage facilities or a path for the waste that we would produce and, thus, if it's required that we need to construct a new shielded modular aboveground storage building, for example, that is what we would do. We constructed this first one for decommissioning activities. The others were already in place as part of the operation of the site.

MEMBER TOLGYESI: The second is to staff. On page 121, this is regarding Port Granby. "Bluffs, see page from south bluffs". And you are saying that the "bluffs, see page from south bluffs", there is no

unreasonable impact to the aquatic environment. What it means it's not unreasonable -- which means it's reasonable -- and what is the limit between reasonable and unreasonable? Is there a regulatory limit or is it perception?

MR. THELEN: John Thelen, CNSC Project Officer, for the record.

The bluffs seepage that you have mentioned has been identified as an untreated liquid stream source term to be monitored on a quarterly basis, which is a requirement of the licence and has been monitored since 2010 under the license. Concentrations in this bluffs seep were above provincial water to quality objectives which are conservative criteria. However, enhanced monitoring was done in surface water in the Lake Ontario along the shoreline's within sediment and surface water and indicated that that receiving environment remained below the conservative provincial water quality objectives and within the background level.

Again, these bluffs seepage will obviously be eliminated with the movement of the waste, which was a source term from this liquid through moving forward with the construction and emplacement of this waste in the Long-Term Waste Management Facility which is north of the current site as the project moves forward.

MEMBER TOLGYESI: So probably instead of saying there is no unreasonable impact we should say that it responds to request of provincial -- conservative provincial legislation or regulation or limits?

MR. NEWLAND: Dave Newland, for the record.

Yes, we can fix the wording so that it is more precise in the final report.

THE PRESIDENT: I thought we made a commitment not to use double negatives in sentences like this.

MR NEWLAND: Yes. It just crept through.

MEMBRE HARVEY : Merci, Monsieur le Président. On page 31 of the staff paper, in the third paragraph:

> "Finally ACL has also reported a number of failures or degradation at this CRL steam system which provides building heat to the majority of the CRL facilities and some process systems." (As read)

I hope -- I think that those failures have no direct impact on the security of the facilities because the response to that is strange:

> "CNSC staff are satisfied by AECL's

commitment to address the failure and degradation of the steam system which has exceeded its design life by repairing system components as they fail." (As read)

It's not a commitment. I think it's an obligation and I don't see any other solution but a replacement of all the system. So why?

MR. CARRIER: Okay. Well, I will initiate a response and then I may turn it over to AECL. Indeed, the steam produced by the powerhouse at Chalk River basically provides for heating for a large number of the majority of the buildings on the Chalk River site and is used also in a number of facilities for process. So the waste treatment centre uses it basically to evaporate waste and the molybdenum production facility uses it.

MEMBER HARVEY: But that's --

MR. CARRIER: So, however, for the processes usually the steam is not being needed on an urgent fashion. Those are the things that can be delayed. For heating and buildings it has been annoying to AECL in some areas where heating was required to remain within normal, you know, liveable conditions and also for some systems, basically maintaining an adequate temperature to maintain the system with an operating temperature. It has

been an annoyance at AECL and we have been monitoring. AECL has been putting locally electrical heaters to compensate.

The steam system is very much needed, but it has now been identified as a critical need for urgent operations. So AECL was capable of compensating in all cases that we became aware of. So it is something that AECL has been tackling for a number of years now and we understand that AECL has plans so it is not simply waiting for these things to burst and basically repair them.

AECL has a longer term plan basically regarding the steam system, which includes consideration of the life of certain buildings that may not be used in some future and the incorporation of the Chalk River site of basically natural gas that may be used. But, again, this is a vision that will depend on the future of the laboratories basically.

So AECL is just not fixing things as they go. They actually do this thing, but they have a longer term plan.

So I may turn the question over to AECL because I feel that they have an opportunity to expand on this one.

DR. WALKER: For the record, Bob Walker.

We do have a decade-long integrated site

master plan that looks at the development of the plan. It is about both fitness for service and fitness for purpose, the right facilities for the programs going forward and then the investments coming from the federal government, the orderly replacement of those facilities; prioritized of course first by health, safety, security and environment needs and; secondly, by the purpose for which those facilities are managed.

That is under the oversight of my VP for Operations and Mr. Lesco could comment further.

MR. LESCO: So Randy Lesco, for the record.

As Dr. Walker indicated, we have a long-term strategy in terms that we need to provide services to the site long term. So one of the examples Mr. Carrier talked about was natural gas. So we do have a project underway to move away from steam heating as an example and move to natural gas heating as an example.

With respect to how we are dealing with the current system is that we have two maintenance outages associated with our steam system. We are going to do proactive maintenance, making sure that we are properly maintaining the system as we go forward.

MEMBER HARVEY: On page -- on the same line on page 33, it's about structural integrity. CNSC

staff have reviewed the governing program documents and identified elements of the program that do not meet the CNSC standard. CNSC staff also identified other areas for improvement such as making programs, scheduling, implementing programs, et cetera, et cetera.

What is the importance of such noncompliance? And why is there no target, no obligation to comply at a certain date? It's right at the bottom of page 33.

MR. NEWLAND: Dave Newland, for the record.

I will ask our colleagues from structural integrity, Blair Carroll, to comment. Thank you.

MR. CARROLL: For the record, my name is Blair Carroll. I am a Specialist with the Operational Engineering Assessment Division.

This is more of a programmatic issue when it comes to the implementation of the periodic inspection programs for the different systems at the NRU facility. We do have, through the IIP, targets for the updates to these different periodic inspection program documents and we are hoping that when we get to that element in the IIP that these issues will be addressed.

And again, I would point out that there haven't been issues where these program implementation

issues have caused a safety concern for the CNSC, it is more of a management concern of the programs. The actual execution of the programs and the findings of the programs have all indicated that the systems are within safe operating limits.

THE PRESIDENT: Okay. Those are the kind of sentences that we would like to see.

In the previous conversation about steam we would like to see no safety implication, if that is your conclusion as an explanatory, and deal with some of our concern which is based on safety always.

MEMBER HARVEY: A short one. Last one, yes. Yeah, it's on page 34. I's about the NRU.

The information provided to date by CNL indicated that annual site corrosion of the vessel has not progressed at a rate at which will prevent current structural integrity of the vessel. What is the current rate and what rate could be problematic and the current rate -- will the current rate permit to operate until 2021, for example?

MR. NEWLAND: Dave Newland, for the record.

I will ask Mr. Carroll to respond.

MR. CARROLL: Blair Carroll, for the

record.

As of right now there hasn't been any detectable change in wall thickness through the NRU vessel, but there is a tolerance on the inspection, inspection tools for detecting wall thickness. So for example the maximum tolerance that we know of right now is about plus or minus 5 millimetres on the detection and we have not seen any wall thickness changes within that range. So it appears that the strategies that have been implemented to mitigate the annual side corrosion have been working.

There has been extensive wall thickness inspection of the vessel and we do not have data right now to be able to predict what the rate is. We just know that it has been quite low. It has been within that plus or minus 5 mm tolerance of the inspection tool.

MEMBER HARVEY: Is this to say there is no more corrosion in the analysis?

MR. CARROLL: We can't say that there is no more corrosion. We just can't say there has been no detectable change in corrosion.

THE PRESIDENT: Maybe it's a good time to get a quick update about the welding that was done inside. How are they holding out? This was an amazing piece of engineering that you guys did. Is there any way to monitor performance of the NRU, on the inside on those welds?

MR. LESCO: So Randy Lesco, for the record.

As part of our inspection program we also inspect the weld frequently to make sure that they are still maintaining their purpose for use.

THE PRESIDENT: And so far there is no area of concern?

MR. LESCO: Randy Lesco, for the record.

That is correct, Dr. Binder.

THE PRESIDENT: So presumably you can keep repaying this machine forever. You don't have to answer that.

--- Laughter / Rires

THE PRESIDENT: Okay. We have now -- Dr. McEwan...?

MEMBER MCEWAN: Thank you, Mr. President.

This is a question on pages 42 and 43 of the reports and Slide 31. It's really questioning some of the language in the report and trying to understand the data that are presented. So let me start with the data.

So 30 action level exceedances and the statement there are 15 iodine 131 exceedances. If I look at the graph you presented in the talk, there are either only four exceedances or there are cumulative data in those bar graphs. If they are cumulative data, then that implies

that around August or October, I'm guessing, 13 or 14 of those exceedances occurred.

So what happened at that time that led to that? Was that significant and was that related to a statement that you make in the paragraph on page 42:

> "AECL has identified corrective and remedial actions, including reinstating more frequent operating equipment maintenance." (As read)

So does that mean they abandoned operating equipment maintenance at that time and that led to those exceedances or this was just an unfortunate accumulation of events?

MR. NEWLAND: Dave Newland, for the record.

I will ask Mr. Carrier to respond.

MR. CARRIER: Christian Carrier, for the record.

So I will refer to Slide 31. I think most of your questions relate to that slide.

Just as a short explanation, the Chalk River site currently is about 50 different monitoring exhaust points where exhaust points are being monitored. Each of those have action levels and each exhaust point may have more than one parameter, so they may be monitoring for

iodine, normal gases, betas, gross betas, and what have you. So you have a large number of potential exceedances.

Now, the events that occurred in the late summer and fall of 2013 were such that they affected buildings with very low action levels. In other words, the same event triggered in the same facility sometimes three action levels which are counted as separate items and events in separate buildings that were basically triggered because of the same origin or the same cause. So yes, those are aggregate values that you are seeing in there.

And as I mentioned during my presentation, I do believe we said that in the report also, this indeed raised interest on the part of our side and on the AECL side. And AECL did a common -- instead of reviewing these things independently, tried to find a root cause basically of those events occurring at sites.

So we have been pretty close to AECL, meeting on a regular basis to identify what were the sources. those were identified basically in changes in the molybdenum 99 production where targets that were irradiated for longer periods of time and thus generate more mobile gases and iodines were processed during that period of time and also changes in some practices in the production of molybdenum 99, including the frequency of cleaning of the transportation flask for the waste that is being

transported in the waste management areas. Reducing the frequency of cleaning resulted in a situation where the contamination level increased.

Just the fact of storing those transportation containers in the neighbourhood of a building that usually does not use any iodine 131, basically the interpretation was that some of the iodine got captured in the air of those buildings and since the outlets of those buildings were being monitored, they measured basically iodine 131.

So the aggregate affect is resulting basically. So the same contamination of those flasks and increased releases from the facility from the lower frequency of replacement of filters triggered basically actual level exceedances in multiple locations on site. So, if I recall, it was about eight buildings and locations that basically were affected during that period.

Now, I don't know if AECL wants to complement that answer or if you want to refine your question.

MEMBER MCEWAN: I'm happy to refine the question. So I think I now understand which you were talking about in your presentation.

I think it would have been very helpful in the report to have a little more detail than you have put

in it because, as I read this, what you are effectively doing is saying, well, we noticed it and that was fine. I think something as complicated as this, particularly something which really is a change from the previous two years when there were no exceedances needs a little more explanation, a little more discussion and a little more overview so that somebody reading the report can understand it and not do what I did, which was go from graph to figure to graph to figure and just not see any correlation between the two.

MR. NEWLAND: Dave Newland, for the record.

Yes, that is a very good observation. We will change the report accordingly.

MEMBER MCEWAN: Thank you.

So my next question relates to the mobile gas emissions. Again, it is partly the wording in the report that leads to this question, it is partly trying to understand Figure 6. So in Figure 6 you have a slightly -- almost a tripling of mobile gas emissions from 2012 to 2013 and you actually have a factor of five increase in mobile gas emissions from 2011 to 2013, so there is no real discussion of that. Is that a significant increase? What caused it? Does it require further monitoring?

And then in the last sentence on page 42

you say emissions continue to be effectively controlled. Again, in an absence of understanding of what that fivefold increase means, I question the value of the word "effectively".

MR. JONES: Hello. I'm Mike Jones. I am a Program Officer for the record.

When you are looking at Figure 6 on page 43 of the report then there is the increase in mobile gas emissions from 2012 to 2013, basically it's for a couple of reasons.

First of all, the way we have presented the data since the implementation of new licenses that instead of using the dried release limits which are based upon 1 mSv we are using limits which are based on 0.3 mSv. So there is a bit of a difference when comparing the data towards the ones that are used to calculate those to the public. But specific to the 2013 year the information that we received is that the increase there is basically due to -- really to the increased production of the molybdenum 99 facility in 2013 and the corresponding numbers of submitted molybdenum flasks which are placed upon the tile hulls in the waste management area B.

So the emissions rates that are measured related to mobile gas, they are related to the ones that are from the molybdenum facility as well as the tile holes

in area B. So the combination is the reason for the increase.

THE PRESIDENT: CNL, do you want to add something about -- I hear changes in the isotope production causing some of these things here. Does somebody want to elaborate on that?

DR. WALKER: Bob Walker, for the record. Our volumes of molybdenum production depend on market and we had a period in late 2013-early 2014 where we were under contract to deliver quite a surge in production, about two and a half times our typical volumes for a period of, as I recall, four to six months. And these emissions tend to be a percentage of production, so more production, a bit more is released.

But perhaps I could ask Randy or Rick, some of our staff, for more detail.

MR. LESCO: Randy Lesco, for the record.

I'll call on George Dolinar to speak to the data.

MR. DOLINAR: George Dolinar, for the record.

So I would concur with the explanation that was provided by CNSC staff. There's two things in the figure that are of note. One is the

re-baselining compared to previous reports where it would have been against the one millisievert.

This graph is presented as against the .3 millisievert threshold.

There's two noble gases represented in that figure as well, so there's Argon-41, which is a noble gas from NRU, and it's probably worthwhile pointing out that there have been slight reductions in Argon-41 through, you know -- through efforts taken at the NRU facility to limit Argon-41 releases to the extent possible.

And the explanation provided against the mixed fission product noble gases, which is the second bar in that figure, which is the effluent from the Moly production facility. That is tied to production that was during the last seven weeks of 2013, as Dr. Walker indicated, that the facility was in increased production, and, as a result, had increased emissions during that time period.

MEMBER McEWAN: So again, it would be helpful to have a little more detail in the report just to understand that because it clearly is a rational explanation for data that just sit there otherwise.

MR. NEWLAND: Dave Newland, for the

record.

Yes, I agree. And we will add that level of detail for the final report.

THE PRESIDENT: Ms Velshi?

Mr. Tolgyesi?

MEMBER TOLGYESI: The last one is a comment. I'm not sure to what extent it will be useful to mention when you are using logarithmic scale to mention that at the bottom because in the public -- for public in general, who could read this report. It doesn't explain what's happened. It could be confusing.

My last question is to AECL. On page 19, for instance, there is a staff comment noting that AECL will benefit from periodical reviews and self assessments.

This is regarding -- it was in several places which was mentioned these self assessments.

What's the commitment of AECL and what you do in self assessment and how do you proceed?

MR. LESCO: Randy Lesco, for the record.

Perhaps I could ask Kathy Smith, our general manager responsible, to speak to your question.

MS SMITH: Kathy Smith, for the record.

As part of our annual plans that we prepare every year, comprehensive self-assessment plans are prepared by the line organizations. These are typically identified to address perhaps a gap in performance or an opportunity to seek some benchmarking information to lead to improvements in processes or procedures or something that the line organization has proposed.

All of these self assessments are assembled together, and those who lead our management system organization assemble those. They review them and, on an annual basis, we review the findings of those self assessments holistically for comprehensive action plans to address any systematic gaps.

MEMBER TOLGYESI: So staff, when you put this comment, what were your observations?

MR. NEWLAND: Dave Newland, for the record.

Could you repeat the question, please? I've lost the point.

MEMBER TOLGYESI: When you were talking about that AECL would benefit from self assessment, now when we listen to AECL, they are

saying that they are doing that.

So what is the -- do I understand that they are doing that, but for you it will be benefit to do them?

MR. NEWLAND: Dave Newland, for the record.

I'll initially ask Mr. Carrier to respond and then we'll transfer it to our human performance colleagues. Thank you.

MR. CARRIER: Christian Carrier, for the record.

So this absence or lack or delayed self assessment has been noted during a couple of our inspections, so that is the reason why we emphasize it in the report.

So the need to conduct self assessment is required by licence, and it's also required by the standard.

I will not develop -- I will just pass the microphone to Mr. Dan Constantinescu of our management system group.

MR. CONSTANTINESCU: Mr. President, Members of the Commission, for the record, my name is Dan Constantinescu. I'm a management systems specialist with the management system division of the

CNSC.

As Mr. Carrier indicated, there are regulatory requirements regarding the obligation of the licensee to conduct self assessments. And these regulatory requirements are captured in the Licence Condition Handbook as well as in the CSA Standard N26-5.

As far as we know, AECL -- CNL, excuse me, they have programs and procedure in place for conducting self assessment, and they may address -- they address requirements in a graded manner. Therefore, the self observation included in the report is about improving this graded manner. And we believe that there is room for improvement in this area.

So we are expecting CNL to conduct more self assessment and more rigorous self assessment as necessary.

THE PRESIDENT: Okay. Mr. Harvey?

MEMBER HARVEY: A quick, and the last one. It's on page 47.

Just to illustrate the difficulty we can have sometimes to have a good comprehension and to appreciate what is written, AECL's required under 10.5 on the CNL operating licence -- it's top of the page -- to report on the environment assessment

follow-up programs.

To date, AECL has submitted the annual reports as required and has completed many of the follow-up commitments.

I don't know what this meant. I don't know how many commitments there were.

In French, it's a little bit better because it's -- it's la plupart des engagements.

So reading the French and -- it's not too bad, but reading the English, we cannot understand. I cannot appreciate that.

MR. NEWLAND: Dave Newland, for the record.

Yes, I agree we could have been more precise, more specific with what is meant by that exact word.

MEMBER HARVEY: It would be easier for us.

THE PRESIDENT: Okay. So I'll bite.

So on page 46, just in front of that sentence, you're talking about groundwater monitoring. And you would know that some of us are always interested in the groundwater monitoring, and you keep giving us there are 32 different monitoring sites, all the wonderful -- you even tell us about the kind of

isotopes, but nobody's talking about the measurement itself.

You remember we're always interested about the plume and we're always interested whether the plume goes into the river, so you've got to finish the conversation here.

You do say it's stable. I have no idea what "stable" means. And by the way, is -- so let me ask you again.

Others have related drinking water. Is drinking water -- where do you get your -- let me start with a question.

Where do you get your drinking water from on site?

I know, Dr. Walker, you mentioned that there's going to be some investment about bringing potable water. Does that mean that no drinking water can be had from the site itself?

DR. WALKER: Bob Walker, for the record.

The previous sources of drinking water on site do not meet environmental standards. We are using bottled water that's imported to site for drinking purposes, and have a potable water project under way that will see us obtaining drinking water

from the Town of Deep River via an overland conduit that will then be distributed into the site.

That project is funded and is under way.

THE PRESIDENT: So if only 32 different monitoring sites, are you continuing to publish the actual levels?

At one time, you know, there is a posting of the actual results of those monitoring. Are they still on the web? That's what I want to know.

DR. WALKER: Bob Walker, for the record.

Perhaps I could ask George Dolinar to respond.

MR. DOLINAR: So AECL provides a monthly update on our web site for a number of performance parameters related to environmental releases. The groundwater monitoring concentrations are not part of that.

So this is -- this affects groundwater at the Chalk River site around operating and legacy facilities. It's not -- this water is not used for drinking water. It does not make its way off site as groundwater.

We provide an annual report to the CNSC regarding the groundwater monitoring program. The results are trended and the CNSC comment about stable indicates the trends are not changing significantly, so that's the "stable" comment.

The other point of interest here is the groundwater down gradient of NRU. And as you are aware, there was a significant project conducted where the rod bay water was removed. And what we've seen subsequent to that is that tritium concentrations in groundwater immediately down gradient of NRU have adopted the new lower concentration of tritium associated with the rod bays.

THE PRESIDENT: And some of us still remember this conversation, and we do remember that we committed to monitor the movement of the plume because there were concerns about whether this will eventually end up in the river. And I know that you did measurement of the river in your reported dose, but it would be nice -- again, when you give us the groundwater picture to complete and put some data, actual data as to the -- what is the tritium level in some of those monitoring wells.

Mr. Harvey?

Anything else?

Okay. I've got a couple of questions here.

First of all, on -- again, I don't want to put you on the spot, Dr. Walker. AECL staff, all AECL staff, how many of them are moving towards the CNL?

So we got two Vice-Presidents here. Are they going to be part of the AECL or the CNL?

DR. WALKER: Bob Walker, for the record.

They are already part of CNL. The effort to build the new small Crown corporation is under way. It's envisaged at peak to have somewhere on the order of 50 employees, and that is being staffed competitively through external competitions to which CNL employees are able to apply. So effectively, on 3 of November when we operationalized CNL as a wholly owned subsidiary, literally everybody moved from AECL to CNL.

There is a small handful of -- a small number of 10 to 20 people that are within AECL currently.

THE PRESIDENT: So you've done the staffing. We all saw the big ads for -- you know, for applications, so all of these were done now? You are

fully -- or you said 20?

DR. WALKER: Bob Walker, for the record.

That process is still under way, Mr. President. The target is to have -- of course, the objective is to have the new AECL able to function in its oversight mode by the time of the completion of the procurement contract and the transfer of the shares to the new owner. That's targeted for the fall of 2015.

THE PRESIDENT: My last question is about security.

Given the events of Ottawa, Quebec, Sydney, we are really concerned about security. Our attention as regulator has always been on the physical security. I'm now more and more interested in seeing what you're doing about inside security, staff monitoring.

Are you doing anything different as a result of events -- recent events?

DR. WALKER: Bob Walker, for the record.

We take security, nuclear security, extremely seriously. As circumstance would have it, in fact, on the day of the incidents in Ottawa on the

22nd of October, we were scheduled to do force-on-force exercises, which we have subsequently postponed in light of those circumstances, but to prove that we have our capability at the -- at top readiness and able to respond.

We have robust internal screening mechanisms to ensure that we're aware of the status of our employee base with observation and monitoring, training for trying to detect the early indicators of unusual behaviours in the workforce that could be signals of something coming.

But perhaps I could ask Kathy Smith, who these programs come under, to make some further comments.

Kathy?

MS SMITH: Kathy Smith, for the record.

As Dr. Walker indicated, we have several programs that support our site security roles. Of course, you're very aware of the highly robust nuclear response force that keep our sites safe, but also in terms of our nuclear security culture, we have several initiatives that are designed to increase awareness around matters of security.

For example, in 2013, we had a -- our

annual safety summit had a pretty -- high level focus on nuclear security where we engaged our 200 plus managers in several activities where we desk topped and workshopped through several scenarios to help them in their increased awareness around matters of nuclear security.

We also have recently rolled out four computer-based training modules that are required training for all staff this year, this fiscal year, again to increase our awareness around matters of nuclear security.

And another program that Dr. Walker mentioned was around our continuous behaviour observation program given to all managers, leaders, supervisors to help them identify areas of concern around individual behaviours. And this is supported by a comprehensive performance leadership program that we've implemented in the last couple of years, again around helping our leaders identify areas of concern around individual employee behaviours and address those in a timely manner.

THE PRESIDENT: Okay. Thank you.

Anything else?

So we are still keeping you here for the next item, which is event initial report

concerning a worker injured on B350 construction site as outlined in CMD 14-M86.

I'll turn the floor to CNSC, and I understand, Dr. Newland, you still have the floor.

CMD 14-M86
Oral presentation by CNSC staff

MR. NEWLAND: Thank you. For the record, Dave Newland.

We don't have an awful lot to say about this event initial report. The regulatory oversight of this particular event lies with the province, not directly with us.

Obviously, we like to understand how CNL has responded and understand its actions as the event unfolded, but we did think that it was important that we brought this to the Commission so that you were aware of it.

I -- in terms of describing the event, I would ask that CNL give you a small -- not presentation, but describe the basics of what happened.

THE PRESIDENT: Okay. Dr. Walker, over to you.

MR. LESCO: Randy Lesco, for the record.

We have a contractor who was building a new SNT laboratory in Building 350. It's currently under construction.

As part of that construction, they are doing some, quote unquote, concrete walls. And in this particular case, it was actually an elevator shaft for the building.

Their sub-contractor is responsible for carrying out those activities. They had committed -- they had completed their pour of the concrete and they were about to be -- basically, the concrete wooden form sits around the elevator shaft.

There were two individuals on manning what's referred to as a genie crane, which is, quote unquote, a scissor lift. They were elevated as they were moving the concrete form, so the concrete form that was supported by the crane above, it came back off the wall, basically, and knocked over the person on the scissor lift and he had fallen to the ground.

THE PRESIDENT: Okay. Thank you.

Questions?

I have a list here. Ms Velshi.

MEMBER VELSHI: Thank you.

So this is becoming a constant refrain of mine. On the event initial report, it's again scarce on details. It says it was a critical injury, so what was the nature of the injury of the worker? And I think it'd be helpful to include details like that in this.

So if staff doesn't know, maybe CNL can tell us.

MR. LESCO: Randy Lesco, for the record.

The report was based on the Minister of Labour initial investigation, and they have certain criteria by which they define, quote unquote, critical injury. In this particular case, the individual was unconscious when he had fallen, and that's defined as a critical injury in the MOL guidelines.

MEMBER VELSHI: So is there any long-term injury?

MR. LESCO: So Randy Lesco, for the record.

I do not know the details of the -- the nature of the injuries to the person. We do know that he was released from the hospital the following day and he continues to rest at home.

THE PRESIDENT: But again, to the

point, you know, critical, to me, could mean death, so I'm not familiar -- and I'm sure many, many people in the public are not familiar with the MOE definition. So for our staff, when you write something like this, it would be nice to say that "went to the hospital, was released" or whatever.

You can actually characterize what does critical mean, okay.

So not life threatening, some people now use. You hear this a lot.

Something that will actually explain a little bit what is an accident actually mean.

MR. NEWLAND: Dave Newland, for the record.

Yes, I think we could have been a bit more precise about the use of the word "critical".

One of the challenges, though, I think we have with the EIRs is we like to report promptly to the Commission. This one was quite late in the sense that it was very close to the Commission meeting, and therefore, we don't always have the level of detail that we would like to put in. And so we're constantly finding that balance point between reporting promptly and having enough detail to report, certainly.

MEMBER VELSHI: My next question's for

CNL, and I'm trying to understand your relationship with the contractor.

So is the contractor the constructor of the project and you're the owner? Is that it?

MR. LESCO: Randy Lesco.

That is correct.

MEMBER VELSHI: And --

MR. LESCO: Just a point of clarification is that the injury happened to a sub-contractor.

MEMBER VELSHI: And so what would be your long-term follow-up to this incident, then?

MR. LESCO: So Randy Lesco, for the record.

There are two things that we want to assure ourselves. One is that the constructor is taking appropriate action to make sure that we don't have a repeat event with respect to moving of concrete forms. Notwithstanding, we will also be following up with the investigation coming out from the findings of the MOL investigation.

The second piece is that we're having discussions with the constructor so it's an opportunity for AECL -- sorry, CNL to learn lessons and apply them to other construction projects going

forward.

MEMBER VELSHI: Thank you.

THE PRESIDENT: Mr. Tolgyesi.

MEMBER TOLGYESI: Merci, monsieur le président.

If you permit, I will come back a little bit to the stats. This is an example when I was saying that injuries on the site should be included in the stats what you are presenting.

Like this accident will be included in 2014 stats or not because according to what you are doing now, it will be not.

And it could be to the limit. It could be a fatal injury, okay, because it could happen. The employee, I think he was tied up on a rope to the scissor lift when this 18 by 23 feet, 5,900 pound wall -- I understood it hit the wall and it came back to the scissor lift.

Am I right?

MR. LESCO: So Randy Lesco, for the record.

So the form was released from the concrete wall, had come back and touched the scissor lift, which caused the scissor lift to fall over.

MEMBER TOLGYESI: So -- and the

employee was on the scissor lift. He was tied up on the safety rope to the scissor lift.

MR. LESCO: That's correct.

MEMBER TOLGYESI: Which means that probably saved his life to some extent. But if scissor lift tipped over, it could be a fatal accident.

So I'm coming back to these stats that it could be something which was quite serious. It is serious. And it will never be included in the Chalk River report.

This being said --

THE PRESIDENT: So just to close the loop on this, I know that in -- I'm told that in mines, the statistics on injury is including contractors. I don't know if NPPs do the same thing, but it -- I'd like -- if that's the industry practice, then I would like to understand why CNL would not do the same thing.

So this is something to observe.

Go ahead, Dr. Walker.

DR. WALKER: Bob Walker, for the record.

Let me be clear. We know the statistics. We monitor very carefully the

performance -- the safety performance of our contractors.

We screen -- as a criterion for winning contracts with us is our contractors must provide us with their safety performance. They must have programs in place that meet our expectations.

When failures occur, that enters our corrective performance measurement system, our impact system. We have the evidence. We have the data. We take this seriously.

And if there's a request that comes from the Commission staff to provide that information to the Commission, we will certainly comply.

THE PRESIDENT: No, we didn't imply that you don't keep it. What we mean is in the report, the annual reports, the industry reports back on accidents and loss of work, they include -- there's a benchmark that everybody's using. And if we're going to compare a safety case from facility to facility, we'd like everybody to use the same benchmark.

MR. NEWLAND: Dave Newland, for the record.

Yes, I really think that's a fair observation and we'll take that away and I'll work

with my other DG counterparts to figure out what is the best way forward and so that you do get consistency when we report to you.

MEMBER TOLGYESI: You were talking about contractors, it should be sub-contractors. I'm quite sure you keep that also.

Now, we would like to see that.

Regarding the root cause analysis, this is -- as you said, this is an accident which is -- which is reported or investigation by Minister of Labour. What kind of communication do you have?

You will have some feedback on the root cause analysis will be presented one, two -- I suppose you will have a root cause analysis as CNL? You will receive that from a contractor or sub-contractor?

MR. NEWLAND: Dave Newland, for the record.

We have Memorandum of Understanding with Labour Ontario Ministry, and so we have access -- we work with them where we have areas of mutual interest, and so we would have access to -- I don't think they're doing a root cause assessment as such, but they are undertaking an investigation, and we will get a copy of that report directly from the Ministry.

MEMBER TOLGYESI: While I think that even in construction they should have -- they should do a root cause analysis, so this is a contractor, I think, that they will do that.

And I suppose that CNL will request what's happened and what was the root cause analysis because it's difficult to talk about accident, you know, what we know, what was reported.

Now, what was the cause? It was an equipment failure.

At the beginning, I tell you I was thinking that this large panel is suspended in double cables, okay. I thought that one cable -- one rope broke or two ropes broke and that's why it was -- the scissor lift was hit.

And I was questioning what's the procedure, why you were so close. Are you manipulating the wall at the -- the form at the same time as it's coming up and down from -- with the crane or what's that. But I cannot ask those questions because you don't have -- we don't have any answers. It belongs to Minister of Labour.

So that's why I was asking what's the relation, how you could have this root cause analysis. And also, if not from Minister of Labour, probably

from CNL because they will -- I suppose they will request it.

So this is as a comment. I don't have more questions.

THE PRESIDENT: Thank you.

Mr. Harvey? Dr. McEwan?

Okay. I think that's it, so thank you very much for being here, and we'll see -- we'll look forward to your February presentation.

--- Upon recessing at 12:44 p.m. /
Suspension à 12 h 44
--- Upon resuming at 1:35 p.m. /
Reprise à 13 h 35

M. LEBLANC : Bonjour. Marc Leblanc ici, le secrétaire de la Commission.

Juste pour indiquer que toute personne peut utiliser la langue officielle de son choix, donc, l'anglais ou le français. Je sais qu'on a reçu des instructions de vos préférences, mais je voulais juste rassurer tout le monde que c'est à votre discrétion.

Merci.

LE PRÉSIDENT : Moi, je vais lire ce qui a été écrit pour moi.

The next item on the agenda is an update concerning the event involving the delivery of contaminated packages by Isologic Innovative Pharmaceuticals Ltd., as outlined in CMDs 14-M84 and 14-M84.A.

I understand CNSC staff has a presentation, and monsieur Régimbald va la faire.

CMD 14-M84/14-M84.A

Oral presentation by CNSC staff

MR. RÉGIMBALD: Merci, Monsieur le Président, et bonjour. Bonjour, membres de la Commission. Je m'appelle André Régimbald et je suis le directeur général de la Direction de la réglementation des substances nucléaires.

With me today are:

- Ms Kavita Murthy, Director of the Accelerators and Class 2 Facilities Division;

- Mr. Peter Fundarek, Director of the Nuclear Substance and Radiation Device Licensing Division;

- Mr. Henry Rabski, Director of the Operations Inspection Division;

- M. Sylvain Faille, directeur de la Division des autorisations de transport et du soutien stratégique;

- Ms Caroline Purvis, Director of the Radiation Protection Division; et

- M. André Bouchard, directeur de la Division du rendement humain et organisationnel.

Nous avons également plusieurs membres du personnel de nos directions et divisions respectives présents dans la salle.

Veuillez noter que je ferai ma présentation en anglais afin de faciliter l'échange d'information avec le titulaire de permis, mais nous pourrons ensuite répondre aux questions en anglais ou en français.

So this update relates to the incident involving contaminated packages containing Technetium-99m that were delivered by Isologic Innovative Radiopharmaceuticals Limited to three hospitals in Montreal, Quebec, over the period of August 12 to 14, 2014, in respect of which CNSC staff reported to the Commission at the November 5, 2014, Commission meeting.

This update presents information on the cause and circumstances of the events, and on the actions taken or proposed to be taken by Isologic and by CNSC staff.

And before I go any further, I would like to point out an error on Slide 6. So if you could please

turn to Slide 6. In the second bullet, the estimated skin dose of approximately 0.64 mSv is to the skin of the right hand of the driver and not to both hands.

I will start the presentation by providing you some context information on the matter.

Isologic is a private company located in Lachine, Quebec, who is licensed by the CNSC to process and distribute medical isotopes, including Technetium-99m, used in diagnostic and therapeutic nuclear medicine to various clinics and hospitals located in Central and Eastern Canada.

Technetium-99m is a short-lived medical isotope and must be received at the clinic or hospital on a daily basis. It has a physical half-life of 6 hours, which means that 50 percent of it decays after 6 hours, and cannot be stored for a very long time before it is no longer useful.

The incident happened over the course of three days from August 12 to August 14, 2014, when Isologic delivered Type A packages containing unit doses of Technetium-99m, such as the package shown on this slide, to the Royal Victoria Hospital, the Montreal General Hospital and the Montreal Children’s Hospital, all three operating under the CNSC licence issued to the McGill University Health Centre (or MUHC) in Montreal. Contamination was

detected on the exterior of packages after their delivery.

In summary, on August 12, 2014, Isologic made two delivery runs of Type A packages containing Technetium-99m for medical use at the three Montreal hospitals previously mentioned. Within approximately one hour of receiving the packages from the first delivery on that day, one of the hospital technologists, who is a Nuclear Energy Worker, from the Royal Victoria Hospital noted she had contamination on her left hand after manipulating the packages and reported this to the onsite Radiation Safety Officer at the hospital.

The RSO immediately informed Isologic of the contamination reported by the technologist.

On that same day, August 12, the hospital onsite RSO again reported contamination on the exterior of the packages to Isologic following the second delivery run.

Isologic either did not take immediate corrective actions or the actions taken by Isologic were ineffective following the first report of contamination because these packages delivered to the hospital later the same day had external contamination.

Isologic did not report these incidents to the CNSC until August 14, that is, two days after the first notification by the Royal Victoria Hospital. These should have been reported immediately to the CNSC by Isologic and

by the hospital, as required by the CNSC *Packaging and Transport of Nuclear Substances Regulations*.

Over the three-day period of August 12 to August 14, the Montreal General Hospital and the Montreal Children's Hospital also received Type A packages from Isologic which were contaminated with Technetium-99m on their outside surfaces. The hospital staff also reported these contaminated packages to Isologic.

Yet again, Isologic appears to not have addressed the problem because on those same days several other packages delivered by Isologic to the Montreal Children's Hospital were found contaminated with Technetium-99m.

So, in total, over the three-day period of August 12 to 14, of the 33 packages delivered by Isologic to the three Montreal hospitals mentioned previously, there were 10 packages that were reported to Isologic as having Technetium-99m contamination on their outside surfaces.

And as mentioned previously, Isologic reported these incidents to the CNSC two days after receiving the first notification by the Royal Victoria Hospital of a contaminated package.

There was a failure by Isologic to immediately report the initial event on August 12 to the CSNC, as required by the *Packaging and Transport of Nuclear*

Substances Regulations.

There was also a failure by the three MUHC hospitals that received the contaminated packages to also report the contamination immediately to the CNSC, as also required by these regulations.

CNSC staff followed up with both Isologic and MUHC hospitals on this issue and reminded them of their regulatory obligations.

CNSC staff met with Isologic management on October 9, 2014, to discuss the events. At that time, CNSC staff requested Isologic to undertake a more complete investigation of the events and submit a report to the CNSC describing the causes and circumstances of the events, including their root cause analysis and the proposed corrective actions to prevent recurrence of similar events. Isologic submitted the requested report to the CNSC on October 17.

Isologic conducted a root cause analysis of the August 12-14 events and determined that these were caused by:

- Workload issues in respect of the packaging and delivery of the medical isotopes, and the duties of the Radiation Safety Officer who was not fully dedicated to implementing the radiation safety program.

- Deficiencies in the application of

Isologic’s operating procedures in respect of contamination control and monitoring. The operating procedures which form an integral part of Isologic’s radiation protection program under the CNSC licence were not followed or not effectively being applied by Isologic staff.

- Inadequate training of workers, as workers were not sure of the requirements to follow.

- Inadequate management oversight of the radiation safety program and the operating procedures derived from the program.

- Deficiencies in the application by Isologic staff of emergency response procedures, as these were not properly followed.

CNSC staff reviewed information on dose estimates provided by the Royal Victoria Hospital and Isologic. Staff have determined that the skin dose to the left hand of the hospital technologist was approximately 0.03 mSv and the skin dose to the right hand of the Isologic driver was approximately 0.64 mSv.

It should be noted that there is a very high degree of uncertainty in the dose calculation to the skin of the driver’s hand since it is based on only one measurement of the hand provided by Isologic which was taken roughly five hours after the contamination was first reported to them. Therefore, a number of assumptions have

to be made about the exposure conditions and the dose to the hand of the driver, which could be in the range of 0.1 mSv to 150 mSv. Having a wide range in potential doses to the skin of the hand is normal due to the many factors involved in calculating the dose and the uncertainties identified in this situation.

CNSC staff have determined that the skin dose of 0.64 mSv is the most reasonable estimate, based on the initial contamination measurement provided by Isologic and the assumption that nearly all the contamination that was initially transferred to the driver's hand remained there for the entire five hours up until the point of measurement.

These skin doses to the hospital technologist and the Isologic driver are well below the CNSC regulatory dose limit to extremities of 500 mSv per year for Nuclear Energy Workers.

Also, according to information received from Isologic, the ring dosimeter, which would measure an external exposure to the hands due to routine handling of packages, and the whole body dosimeter, both worn by the driver during the period of July to August 2014, showed no result above reportable limits.

In addition, the information available to date indicates that it is unlikely that a member of the

public could have been exposed to a radiation dose in excess of the CNSC public dose limit of 1 mSv per year. CNSC staff consider this to be a reasonable determination.

Again, as requested by CNSC staff during the October 9 meeting with Isologic, in response to the August event Isologic took the following corrective actions to address the cause and circumstances of the event, with the objective to prevent its reoccurrence:

- Regarding workload, the packaging and delivery are now separate functions conducted by separate groups of staff at Isologic. The delivery driver had been doing both functions in the past.

- The Radiation Safety Officer position is now separate from management and is responsible for all radiation safety activities at Isologic. In the past, the same individual was occupying a management position while assuming the functions of RSO.

Isologic responded to CNSC staff requests by implementing improved measures of contamination control and monitoring in their radiopharmacy, through:

- performing additional surface contamination checks prior to delivery and post-delivery of packages and on all incoming and returned packages at Isologic;

- improving personnel contamination

monitoring; and

- shielding their contamination control instrumentation so as to increase its sensitivity.

Isologic also trained their staff to the revised radiation safety and operating procedures.

Isologic put in place measures to improve its management oversight of the activities authorized under their CNSC licence. The Applicant Authority at Isologic now better understands the CNSC regulatory obligations and, as mentioned previously, the RSO function is now separate from management and a new person has been appointed to this position. Isologic management supports the work of the RSO and ensures that there is effective oversight of the radiation protection program.

Isologic has improved its emergency response procedures such that communication with the CNSC will be immediate when a situation needs to be reported to the CNSC. Also, the RSO is now dispatched to the client location for assistance if contamination is reported by the client.

In the medium term, Isologic committed to complete the revision of its radiation safety documentation to ensure that it adequately documents the updated radiation safety and operating procedures put in place as a result of the August event.

Furthermore, CNSC staff completed a human factors review of Isologic's root cause analysis of the event and the proposed corrective actions described in the above. The staff review concluded that the management oversight and organizational issues were not completely addressed from a human factors perspective in the corrective actions proposed by Isologic. In addition, staff commented on issues with respect to communication, workload, procedural clarity and training of workers.

The CNSC staff review report was provided to Isologic on December 4, 2014, along with staff expectations for Isologic to address the issues identified in the review to the satisfaction of the CNSC.

In summary, CNSC staff expects that Isologic will:

- evaluate its organizational structure in relation to the roles, responsibilities and accountabilities during normal and emergency operations;

- develop and implement a management self-assessment process to review its programs and processes on a quarterly and annual basis; and

- establish more robust incident communication practices between Isologic and other stakeholders, including the CNSC.

CNSC staff will continue to follow up with

Isologic on these issues as part of our continued regulatory focus on Isologic.

In summary, at the direction of the CNSC, Isologic took short-term corrective actions to address the findings from the August 12 to 14 events having regard to Isologic's workload issues, contamination control and monitoring, training of workers, management oversight and emergency response.

CNSC staff is satisfied with these corrective measures and Isologic made a strong commitment to update its radiation safety documentation to reflect the improvements in place and to address all of the issues that have been identified as a result of the CNSC staff review of human factors elements of the corrective measures in place.

The following slides will outline other key actions taken by CNSC staff in relation to this matter.

On November 18 and again on November 25, 2014, the McGill University Health Centre reported contamination on packages received from Isologic. In response to those reports, CNSC inspectors conducted two unannounced inspections at the Isologic location on each of November 19 and 26.

During these inspections, CNSC inspectors conducted contamination checks in the package preparation

areas at the Isologic location, on Isologic's personnel and in the vehicles used by Isologic. The outcome of those inspections indicated that no contamination was present in the package preparation areas, the packages and the delivery vehicle of Isologic, and on personnel on both days, November 19 and 26. Swipe samples taken by CNSC inspectors on those dates were independently analyzed by the CNSC Laboratory, which confirmed no contamination present.

The CNSC inspectors also verified on both occasions that Isologic had implemented their corrective measures in response to the August event and that these improvements remain in place. Therefore, on November 19 and 26, CNSC inspectors noted no areas of regulatory concern with contamination control at Isologic in relation to the packaging and delivery of unsealed medical radioisotopes.

On the same days, November 19 and 26, the CNSC inspectors also inspected the McGill University Health Centre to determine the reason for their reports to the CNSC of contaminated packages received from Isologic on November 18 and 25. The inspectors identified some procedural problems with contamination control protocols and instrumentation accuracy at the MUHC as the reason for the over-estimation of the contamination. CNSC staff are

following up with MUHC to have these problems corrected.

Later, on December 3 and 4, a CNSC inspection team conducted an enhanced inspection of the Isologic processing location and of the three hospitals operating under the McGill University Health Centre. The purpose of this enhanced inspection was twofold:

- first, to evaluate the effective implementation of the corrective measures taken by Isologic, as directed by CNSC staff, in response to the August event; and

- second, to evaluate radiation safety with respect to package receiving and handling at the three hospitals.

The CNSC team reviewed the procedures for contamination control, the training program, the equipment suitability, use and accuracy, and reviewed management oversight of the work practices at all of these locations.

Overall, the CNSC team reported that Isologic effectively implemented their corrective measures, as directed by CNSC staff in response to the August event, to ensure that contamination is properly controlled and that there is adequate management control over package preparation and delivery work practices at Isologic.

Although the team identified no areas of regulatory concern at the Isologic location on December 3

with respect to contamination control, they made some recommendations to Isologic for improvements in terms of good practices to adopt.

With respect to the MUHC, the CNSC team noted important issues related to radiation safety, contamination control procedures and instrumentation, and management oversight of work practices.

On December 4, the CNSC team met with the MUHC Applicant Authority, who is taking these issues very seriously and has made a strong commitment to take corrective actions to resolve these issues.

CNSC staff is also maintaining increased regulatory focus on the MUHC to ensure that appropriate corrective measures are implemented in a timely fashion and to the satisfaction of the CNSC.

The CNSC will conduct further compliance inspections in 2015 to verify that the corrective measures put in place at the MUHC are effective.

As a result of the August event involving Isologic and the subsequent problems found at the MUHC, CNSC staff took the precautionary measure of issuing a safety notice on November 25 by email to all CNSC licensees who receive packages of unsealed nuclear substances. The CNSC safety notice emphasizes to licensees the need to check incoming packages for contamination in accordance

with CNSC regulatory requirements and as per industry best practices.

The safety notice also instructed licensees to ensure, in accordance with CNSC regulatory requirements, that:

- contaminated packages are segregated and clearly identified;

- the consignor is immediately informed of the presence of surface contamination on the package and the level of contamination found;

- decontamination of the package is carried out in accordance with procedures authorized under their CNSC licence; and

- an immediate report of the contamination is made to the CNSC through the 24/7 CNSC Duty Officer telephone line.

In addition, CNSC inspectors conducted inspections at the two other suppliers of medical isotopes in the Montreal area on December 10 and at the Isologic location in Ottawa on December 17.

The CNSC inspectors were satisfied with the measures in place at those locations regarding radiation safety, contamination control and management oversight of licensed activities related to the packaging and transfer of medical radioisotopes.

Only one procedural non-compliance item was observed at the Isologic Ottawa location, in respect of which the licensee committed to fix the problem right away.

In conclusion, in relation to the August 12 to August 14, 2014 event, CNSC staff is satisfied that Isologic has taken appropriate corrective actions to prevent reoccurrence of similar events in the future and that Isologic has made a strong commitment to complete any remaining actions, such as those identified in the CNSC staff review of human factors elements of Isologic's corrective actions.

As a way forward, CNSC staff will maintain regulatory focus on Isologic to measure the effective implementation of the corrective measures taken by Isologic and evaluate the progress made by Isologic in addressing the remaining issues and implementing any further corrective actions that may be required as a result.

Furthermore, as part of its ongoing compliance verification program, beginning in January 2015 and continuing throughout the year, the CNSC will conduct compliance inspections at radio-pharmacy licensees throughout Canada where unsealed nuclear substances are received and prepared for use by

medical diagnostic, therapeutic, and research licensees.

These inspections will put special emphasis on the preparation, handling and receipt of packages containing unsealed nuclear substances in order to determine if similar issues to those related to the Isologic August event, and issues identified at MUHC are present at those other locations.

Additional regulatory action may be taken by the CNSC, as needed, based on the results of our continued regulatory focus on Isologic, including the results of the inspections to be conducted in 2015. Once this round of inspections is completed and the results show satisfactory implementation by Isologic of all the corrective measures, CNSC staff will re-evaluate the frequency of compliance inspections for Isologic.

CNSC staff has taken additional measures to address actions arising out of the November 5 Commission meeting having regard to staff response to the Isologic August event.

Specifically, out-of-office messages by staff both on their phone and email now clearly instruct licensees to contact the duty officer of the CNSC to report events. The duty officer at the CNSC

is seen as a valuable resource for receiving initial calls of events and ensuring that information is shared quickly.

Safety significance and potential impact on all reported events are discussed on a weekly basis. Events are reviewed and response is coordinated so that any event that requires an escalation of regulatory actions is identified and dealt with in a timely manner.

Safety notices are used as a means of alerting licensees to events as they unfold. Safety notices have been shown to be an effective means of alerting licensees to issues that have broad impact.

Furthermore, staff now have a better understanding of the Commission's expectations with respect to event initial reports and the weekly review of events includes an evaluation of the need to bring the issue to the Commission's attention in a timely manner.

These are the short-term actions. In the longer term, we have initiated a review of the event management process and procedures to identify areas where further improvements can be made.

The measures we put in place seem to be working as we received a few notifications recently

regarding packages delivered to hospitals that showed contamination on their outside surfaces. This demonstrates that the licensees are paying more attention to verifying contamination on incoming packages and reporting contamination quickly to the CNSC.

I believe we have addressed the actions that the Commission put on CNSC staff with respect to this matter at the November 5 Commission meeting, and therefore we do not plan to update the Commission any further on the matter except in the case of any significant development in the future.

Thank you very much. Staff are available to answer questions in English or French.

Merci.

THE PRESIDENT: I would like to turn now to the floor to Isologic Innovative Pharmaceuticals Ltd. for their presentation. And I understand Mr. Gagnon will make this presentation.

CMD 14-M84.1

Oral presentation by

Isologic Innovative Pharmaceuticals Ltd.

MR. GAGNON: Thank you, Mr. President, Members of the Commission.

My name is André Gagnon, I am President of Isologic Innovative Radiopharmaceuticals. Joining me today I have Jerry Strugala which is VP of our Business Development Special Projects and Global RSO. And to my right Mr. Kevin Roland, which is the new Site RSO, newly-named Site RSO at Lachine, Montreal, the site at which we had the incident.

I would like to go through the process of what we do at Isologic so you better understand the relationship between delivering packages and what type of obstacles we have and what kind of a challenges we have on a day to day basis. And I want you to understand so we can better understand the actual incident that occurred on the 12th of August.

We provide the nuclear medicine community with PET and SPECT radiopharmaceuticals in unit dose and multi-dose formats primarily for diagnostic imagine; meaning that most of the injections we are giving are for diagnostic purposes,

very low dosages that we are giving to patients.

The Canadian company was established in March of this year. This was created from the merger of a company called Pharmalogic P.E.T. Services of Montréal and the Canadian Radiopharmacies of Cardinal Health.

We currently have four sites; one in Lachine, one in Ottawa, one in Toronto; and one in Burlington.

Our core business is the production and Canadian distribution of diagnostic and therapeutic SPECT pharmaceuticals and diagnostic PET to the nuclear medicine and molecular imaging community.

The business model was implemented in 2006 in Canada and is the first and only site where you have a cyclotron and a radiopharmacy at the same site. This has been successfully operational through the Canadian provinces over the past eight years. We opened our first Canadian SPECT and PET radiopharmaceutical manufacturing and distribution facility in Lachine eight years ago.

A second cyclotron and PERs manufacturing facility is scheduled to open in the fourth quarter of this year at the Sunnybrook Health

Science Centre in Toronto also.

We also operate, like I said before, two radiopharmacies; one in Ottawa and one in Burlington.

This is the organizational chart of Isologic, me as President and, as you can see, there is four sites, four different sites with different site managers. And every single site has a local RSO and we have our Corporate RSO, which is Mr. Strugala.

We are a small company, 72 employees in total; 39 of them are we call CSA or drivers that drives the products to customers. So when you look at in terms of the actual employees that do production, we are small group of individuals working at Isologic.

Mainly, it is staff that are certified and experienced in radiopharmacy, cyclotron engineering, nuclear medicine technology, chemistry, microbiology and medical physics.

The company has two types of businesses that we're operating on; we have a radiopharmacy service and we have manufacturing services.

We prepare and distribute more than 1,300 patient doses per day over three sites; Ottawa, Burlington, and Lachine.

Over 325,000 patient doses a year are received by hospitals from us. We ship an average of 200 containers a day or 50,000 containers a year and we service over 160 hospitals and clinics, and mostly in central Canada.

We also have a manufacturing in Lachine presently that prepares and distributes more than 100 patient doses per day or 25,000 patients per year at one site. We ship an average of 25 containers or 6,000 containers per year. We ship from New Brunswick all the way to B.C. and the majority of our doses are in Quebec.

This manufacturing of FDG and NaF are done on an agent that only has 2-hour half-life. You can imagine the limitations that we have to do logistics that involve distributing a 2-hour half-life product to a cancer centre around Canada.

We service as backup whenever people -- now, we are the only private entity, so whenever people are down, whenever it is Sherbrooke, whenever it is Edmonton, Ottawa, people call on us to try to be a backup for them, it is delivered to those places, to those hospitals.

So we service in total about 23 hospitals and clinics for the FDG distribution. This

will give you an idea of the distribution map that we have. Mainly the green area shows you the areas that we service by car from our radiopharmacies, and you can see the red dotted line that we service throughout Canada by plane.

We hold the three different licences. We have a Class II licence to operate a cyclotron, which is an accelerator facility, and we also have a Class II licence to service by us to the same equipment. And we have licences -- an 847 licence to process a total unsealed source possession for the radiopharmacy that we have.

I don't want to go too much into detail, but nuclear medicine in general involves the use of small amounts of radioactivity material, what you call tracer, to help diagnose and treat a variety of diseases. Radiopharmaceutical helps to create images of organs studied by the functions and analyze biological specimens.

For organ imaging procedures, radiopharmaceutically administered to patients intravenously, orally or by inhalation, and materials will concentrate on different organs in your system. So if a product goes into your brain, I will be able to see your metabolic pathway of your brain. If I see

something in your liver, I will be able to see the liver.

So different organs have different pharmaceuticals that we prepare for hospitals.

We use instruments called scintillation cameras to detect those radiations emitted by the radiopharmaceutical and that concentrates in the organs and we are able to make images out of that.

As a result, physicians can make a more informed decision on patient management through the detection, diagnosis, prognosis stage and extent and location of the disease. We can assess the therapeutic target, monitor therapy, and evaluate response to therapy.

To give you an idea, we talked about molybdenum early this morning. Molybdenum comes to us in a little generator. The generator's about 18 inches high, there is a little device that you see, in blue it says "TechneLite" on it. On the end there there is a small column that is around with -- we have lead. So with that, what we do, we generate or we elute the generator, we then capture that activity.

On any given day we can, in a site, capture 25-35 curies of activity everyday that we

prepare medication with. On the left side you have an idea of what type of medication we prepare everyday. Also there is a slew of medication we prepare, radiopharmaceuticals, we prepare for different hospitals.

To give you an idea, these are different types of images you can get; FDG PET scan for cancer, you have brain imaging, you have heart imaging that shows you the microprofusion imaging, you have NaF study that shows bone metastasis. So the different molecules are used to diagnose different types of conditions in patients.

The other ordering process at our place, we only fabricate in these radiopharmaceuticals to an order from an authorized physicians. Not everybody can order products obviously from us. These people are a licensee, they are restricted to authorized nuclear medicine physicians, perform nuclear medicine imaging and determine the patient needs for that exam.

Isologic has its own fleet of drivers or customers assistants that are trained and certified to deliver those goods to the hospital.

I would like to go just a few images to show you the process in which our employees go

through before we start the day, preproduction/production, so you have an idea what is involved in producing those medications and involved in the conditioning or the evaluation of wipe testing and so on.

We are heavily regulated by CNSC, but also by Health Canada. Obviously, we have to be GMP compliant. Before we even start the day we have to evaluate air, samples in the air, we have to look at microbes in the air, we have to look for surface microbes, we have to do a lot of different things in our lab.

So before we even start the day there is a lot of environmental evaluation we have to do before we even start the day. We have to sterilize our hoods, people have to obviously wear body and extremity dosimeters. And some of our zones have to be evaluated and tested for radioactivity within the hood that we prepare the medication in. They have to be sterilized before we even start.

This is all done in a clean-room type of environment when we prepare those medications. So every critical equipment before we even start the day needs to be validated or QC. That means that the machine I use to look at my contamination needs to be

tested to see if it works properly, if the efficiency is there. So it's done on a daily basis on every piece of equipment that we have.

Then when it's all done we're ready to process. This is the decision -- or the actual decision we have to go when we start the day with a production flow, we do it when we start the day.

I'll try to go quickly through every single part of this flowchart.

Products, when they are received at our site need to be tested like the customers are doing on their site. We evaluate for contamination on surfaces. We look inside, do wipe tests and evaluate if everything's good. It's all logged in, so every single piece of radioactive material that comes to our department are tested and logged in, so you can check that out and verify that in our logs.

Before we can start the day, first of all, we are using a very powerful management system that requires bar coding of every single item that we put in our hood or preparation. If I use a vial for the heart, then we scan this with a bar code. If somebody makes a mistake, the system will tell them this is not for heart, this is for something else.

So everything is bar coded, even the

casing that we're sending to the Royal Vic, it's scanned to say, this is not Royal Vic or this is Royal Vic. So there's a lot of protection built in the system that tells us what we're doing is good or not good. So the system is very good to tell us about our mistakes if we have mistakes.

To give you an idea, people work behind obviously a lead glass who have been preparing these materials, work with forceps, work at a distance to protect themselves for radiation safety. This takes a long time.

When we hire people it takes at least six months to a year before they become acquainted and good enough to be working alone in our lab. So this is not an easy task that people can just pickup like that. We don't pick people off the street in doing that job. It takes a long time before they can actually do processes and do doses every day.

So for people that are looking on the images, what you're seeing is two drawing stations. We have a physical limit that people prepare doses. Once the doses are prepared they're thrown on a counter, on a side, and physically there's the processing or the preparation or compounding side and there's the packaging side where it's on the other

side of the counter. So these are two separate sides.

So when the products leave the drawing station there's a good chance that they might be contaminated because our staff are working with open sources. These are liquids they are putting in vials to another vial and so on. So there's a risk that you're going to have radioactivity on vials, on Pigs and so on.

So that's where we have to be very careful. Our employees then on the other side will take the package or the Pigs or the material that's drawn to them and they're going to do a wipe test to ensure that that product, if contaminated, not go any further than that.

Once the container is wiped, calculated in a counter, then it's going to be released. There's a prescription on it, there's stickers on the vial again with bar codes. It's put into a container, that container again is going to be wiped to verify contamination.

It's going to be surveyed also, and this is all included and put into a system, our BioRx system, that will know who did that at what time of the day and who's the person with the initial and so on. So we have a very very solid way to track

everything that's being done. Obviously our survey's all done on all sides of the packages, as regulations require.

Then these packages, once they leave our offices, are delivered on different sites. I put pictures there to show you mostly delivered in hot labs in hospitals. These are small environments where people draw doses or measure the doses before they can inject it to patients. So drivers put that in their trucks, deliver to customers, and that's what you're seeing there.

This is performed by our dedicated drivers. This is important to us because it goes from our controlled environment to a controlled environment from the hospital. So there's no in between, there's no Purolator, there's no -- so it's always in control of our driver.

If we call our driver back, we have the driver's phone number, call them back, so we have direct access and quick access to our employees that way.

To give you an idea, as you work you have to do other verifications. People, as soon as they leave a station, they need to verify their hands with a Geiger counter to make sure that they're not

transferring the activity throughout the lab. So every time they move from one place to the other, they have to verify their station, they have to verify their hands.

If they leave the lab, they also have to verify their hands and feet before they can leave.

As I mentioned before, everything is entered in our radiopharmacy management system, everything is bar coded, so from the order and to the processing of the compounding that we're going to be doing to the shipping of the product we have that on file.

On top of that is the system will tell us if we go over our limit, it's going to ring a bell saying, listen, this is not passing, your trigger limit is met. So even if you try to put the human error there, it would be difficult to do so.

Regulatory framework that we work around. I mean, we have internal audits, we have business level audits, distribution audits with some of our suppliers, we have cGMP audits, EHS and radiation safety audits. And most audits result in categorizing and severity of the findings when we do our own audits.

Canadian Regulatory Agencies that come

to Isologic are Health Canada and CNSC.

Our QA program is in force and makes sure that there's the right dose to the right hospital at the right time. The tracking is done through all the stages of the production, the reception, the compounding, the dispensing, the shipping, and the waste that comes back when they do.

Every compounded radiopharmaceutical is tested for nuclidic and radiochemical purity prior to release. Sterility analyses are performed routinely to monitor adherence to aseptic processes. Our staff are trained for QC and production. We do a systematic reassessment procedure on our staff.

It's good to say, you know what, we train our people, we put them in a room, we show them slides. But this often does not result in a lot of retainment of the information. We like to do, is reassess people on the fly at the time they work. We have a questionnaire and a sheet that we look at people working and say, okay, he's drawing the dose, check. He's using his gloves, he's using proper techniques and so on.

So these reassessment procedures for us are much more beneficial than their only courses or simple courses that we do on a daily basis, or annual

basis I would say.

We do aseptic garbing as per Health Canada requirements. We, like I said before, environmental monitoring and sanitation procedures everyday. We have an emphasis on staff training, hindrance to CGMP and radiation safety, and all deviations that we might have are documented and tracked to closure.

We have over -- a lot of documents, the procedures, the SOPs that we have to follow. They are all control documents. We have over 41 documents for administrative SOPs, 38 documents for manufacturing SOPs, 48 documents for quality control SOPs, and about 24 SOPs for radiation safety. And these are the lists of the radiation safety procedures that we have.

Now for the event. On the day, on the 12th of August, our production manager at that time, now which is a QC Manager today, Josie Mancuso, received a call from the CUSM department to tell us that around 8:45 on August 12th that Isologic radiopharmaceutical delivery container was contaminated and showing external radiation contamination after a technologist detected a left hand radioactive contamination on her bare hand.

She initiated an investigation. She verified with the driver on what might be the cause of single contamination, on a single box of one of the hospitals.

That hospital only had one driver driving to the three sites of the hospital. So there's a dedicated driver for that hospital on the three sites.

So she says the situation as it is, a wipe test, probably the wipe test failed, that happened on a box. Maybe in the course of our wipe testing -- obviously we don't wipe the whole box -- maybe there was an activity on that box.

The Isologic CSA driver at that time completed a second delivery to the hospital later in the morning and the container was found again to be contaminated. The site called us again much later in the day. When they called us, if I can recall, it's around 12:00 that day that that driver -- we start at 3:00 in the morning, 2:00 in the morning. So by 10:00-11:00 in the morning the day's over.

So by 12:00 they knew that something else had happened, that some of the contamination had occurred on the second packages.

So at that time she verified the

driver's hand and that's when she saw that he was contaminated on his hand. The customer also reported the next day another contamination on the handle to the CNSC, but not to us. We never got any report from the hospital on the second, third, and fourth day after this incident.

So to us, when we met in October with the CNSC, it was news to us that we had more than one container or more than two containers that happened on that day.

So the event obviously resulted in unnecessary radiation exposure to both Isologic CSA driver and the CUSM technologist. Unfortunately, Ms Mancuso wrongly ultimately concluded that the incident was caused by the Isologic driver that failed to properly identify the contamination.

But the failure was more or less the way we handled the investigation. That was not done in a proper, in a more in-depth way. This contamination was then transferred to the SPECT radiopharmaceutical container delivered to the Royal Victoria at the CUSM. Without any more deliveries on that day, no further action was initiated. She did inform the RSO the next day because at that time I was in Toronto and I was her RSO at that time.

When you look at the direct cause of the incident, this is where it gets a little difficult for us because obviously not having done a proper or an in-depth investigation it became more difficult for us. The initial report concluded that -- conducted that the cause was a failure of Mr. Bernard's driver responsible for wrong packaging to wear gloves, to further identify a contamination on his right hand coming from the manipulation of a lead peg used to for shipping technical product. He presumably contaminated the container on run one and later on run two.

The difficulty with this scenario we have proposed there is the fact is, the driver prepares over 30 other boxes for other hospitals on that same day. So he had to somehow wear a glove at one point and not wear a glove at another point when he left to deliver to the other customers. On that day, every single box that left our shipping area showed no contamination on the box, on the inside container. None of the boxes showed any contamination.

So it was difficult for us to figure out at what time did these boxes get contaminated. So since the initial report investigation of October 17, new information has surfaced as to the direct cause of the contamination. The initial presumption that the driver

failed to properly monitor his hand and failing to wear gloves at all times during the packaging period has become less credible. The premise for that conclusion was that the site did not have activity. It could not have themselves contaminated box. We said, "You know what? The hospital does not have activity in the morning. We are here. We are the first guy coming in. How can they contaminate the box that's there?"

After we had more incidents reported to us we understood some other things, because then we were ready to do an in-depth analysis and in-depth investigation. We realized that, first of all, the customer is receiving other boxes from other vendors to start with, and the customer often starts using the box, opens the box and starts working on the box between 7 o'clock and 8:30.

So there is a remote chance that it could have happened. So we don't know, but the fact is, without any evidence on my part on that 12th of August, there was no way for us to say by any stretch of imagination that we know where it's coming from. It's the contamination that we couldn't say.

So the only possible scenario we have to come up with is he left Isologic with a contamination. We failed to measure his hand at the time when he left the door and we failed to measure a box that might have been

contaminated at that time also. So that's where we are sitting now with this investigation.

The failure to respond adequately with systemic collection of evidence resulted in less than optimal investigation and could have resulted in more contamination. No other containers delivered to all customers showed the presence of contamination on that day. To give you an idea, these are small vials that we are wiping. Not only are we wiping the vials. We wipe the entire vial. We don't just do a wipe test on a couple of surfaces. We wipe the entire vial.

Now you can see what these people are wearing, sleeves. They are wearing gloves, sometimes double gloves when they work to make sure that we don't contaminate anywhere.

So the possibility of radioactive contamination from manipulation of unsealed radioactive sources is well understood by production employees. Verification of a possible contamination before and after packaging is the responsibility of our driver. Failure to wear gloves and properly maintained for hand contamination is the root cause of this incident.

In addition, the system does not allow for identification of the employee shortcomings and deviation from radiation safety office procedures.

Inadequate removal of contamination wipe test procedures that does not include the shipping container handle as a potential source for radioactive contamination.

We do contamination evaluation, a wipe test. Nothing says in our book that it needs to be done on the handle, on the locks or he needs to do a 300 cm square. So it's done anywhere -- it was not identified properly. So now we have our driver knowingly that they have to do it on a handle. They have to do it on a lock. They do six surfaces so we make sure that that could not happen or very badly that it's not possible that it could happen.

So the inadequate and slow response of the initial incident allowed for the container to return to the same customer and repeat contamination and verification failure.

The deficiency, the corrective measure: We have modified SOPs. We have identified that our supervisor failed to really capture employee's negligence. the driver failed to identify hand contamination; driver trained inadequate; not clear enough, as I just mentioned. Our response was inadequate also. So we had multiple things that we have done.

We took the managers -- supervisors to make sure that from now on any -- whatever we find, it's

small, big; an incident is an incident. We better have the CNSC duty officers as well, if it's not a reportable incident, then having to come here and say, "Well, we failed again". Obviously, now we are reporting anything that remotely resembles an incident when we work. These are all the 11 items that we think.

I think the one thing that really helped to safeguard this process is the fact that we separated our driver from our packagers. The fact is that a driver is working in a packaging area where we load the boxes and it might not be the wisest thing. Having them separately, meaning somebody packages, sends the box outside to the shipping area, the chance, the risk is minimized that way and mitigated in a way where we feel very confident that something like that could not happen again.

The impact of our measures, obviously it could clarify the contamination evaluation process. It improves incident recognition on our hands, enhances emergency response from our staff, increases awareness and reporting to CNSC, improving incident documentation and evidence collection.

We had -- since this incident we had two more incidents of false reports that people say, listen, this is contaminated again. Within an hour we knew if the driver's hands was contamination -- the wipe surface. We

knew that the car, the driver's car, steering wheel, everything around our driver and our site was already wiped and we knew within an hour there was no activity on our end. So this is quick. Our response is far different than it was on the 12 of August.

We also have improved communication with other licensing customers. Obviously, we see there is a gap in communication between the RSO, the hospital, ourselves. The fact that they didn't call us. We say that they haven't called us on the second or third day. You know what? Maybe on the other hand we should have called them and make sure that there was nothing, everything on those days, make sure that when we call them that there was nothing.

To say that they called, they didn't call, the RSO wasn't called, we have put in place where our RSO now are. Our system have all the RSO's phone numbers that we can call them directly. So there is a site of an incident or may be an incident, we are able to call the RSO directly and make sure that we have a proper investigation, a proper person to talk to when we have an incident to report.

I might not repeat what has been said before about the dosimetry. I's very low, lower than the actual limit for a nuclear generator worker. The effect on

the health of both individuals obviously is negligible. The estimate, the contamination on the hands of the driver was 38 microcurie, at worst, and the average dose that we inject on patients, just to give you an idea, is 25,000 microcurie.

At the moment we -- some of the recommendations we took from that also is the fact that there is going to have to be -- we have to be very proactive with our customers. That where we have seen that there is two deficiencies and at the sites we have deficiencies now, that things are counted in light of the wipe testing. So the calculation process, we have to work with our customers to make sure that the way it's delivered, the way it is reported that it is done in a proper way.

So I think we have to work with our customers to make sure that we all see eye to eye with the things that are done. We are seen as a resource. Well, we need to act as a resource and make sure that everybody understands the system and that we are doing it the proper way.

Thank you for your attention.

THE PRESIDENT: Okay. Thank you. Let's start with the questions and let me start with Monsieur Tolgyesi.

MEMBRE TOLGYESI : Merci, Monsieur le Président.

It's a very short question to Isologic.

Est-ce que la vérification des boîtes qui sortent de l'usine est faite avec wipe test, manuellement ou il y a un appareil que vous passez la boîte et qui détermine c'est quoi?

MR. GAGNON: André Gagnon for the record.

Présentement, l'ensemble des boîtes, il y a un wipe test, ce qu'on appelle un swipe, qui est fait sur l'ensemble de la boîte, sur l'ensemble de la poignée, du lock, et ensuite le Geiger.

On fait une évaluation avec un Geiger, un contamination survey. Le problème avec le Geiger, c'est que les activités qui sont en cause sont tellement basses qu'on ne peut pas les détecter; 4 becquerels n'est pas détectable avec un Geiger.

Donc, le fait est qu'il faut faire attention. Il faut que les wipe qu'on fait soient très bien faits, de façon à ce qu'on aller chercher ces activités-là. Même si la régulation est très basse, nous, on doit essayer d'aller chercher ces activités-là sur les boîtes.

MEMBRE TOLGYESI : Alors, si vous ne détectez pas ça avec Geiger, comment vous pouvez le

détecter?

M. GAGNON : Le wipe test, comme je l'ai indiqué dans une couple d'images, est fait avec ce qu'on appelle un CSA or SCA or MCA, a multichannel analyzer, où on place les wipe... On prend un coton ouaté ou une pièce avec de l'alcool, on frotte la boîte, ce qu'on appelle un wipe test, et on le met dans un compteur à scintillation qui est très sensible. Puis, à ce moment-là, lui est capable de détecter des CPS, des comptes très bas là, pour pouvoir faire la détection de ces activités-là sur la casing comme telle.

MEMBRE TOLGYESI : C'est un petit peu... Vous avez parlé que vous faites les livraisons à partir de 3 h 00, 4 h 00 le matin jusqu'à 11 h 00. La journée est finie à 11 h 00 parce que, normalement, les hôpitaux travaillent à partir de 7 h 00, 8 h 00 pour faire le test.

Ça ici, c'est arrivé à 8 h 45, je pense que vous avez parlé, que l'hôpital vous a appelé. Vous avez parlé aussi que vous avez une communication continue avec le conducteur ou chauffeur qui fait la livraison. À 8 h 45 quand l'hôpital vous a appelé qu'il y a un problème, est-ce que vous avez une procédure qui dit, bien, je rappelle tout de suite le chauffeur et on vérifie?

MR. GAGNON: André Gagnon for the record.

Le chauffeur était déjà de retour, parce

que nous, évidemment, on livre très tôt le matin, 6 h 30, 7 h 00. À 8 h 45, 8 h 30, le chauffeur est déjà revenu chez nous.

Lors du questionnement, le premier élément de notre problématique, c'est qu'on n'a pas vérifié ses mains, en pensant... Le manager a pensé que la contamination est une boîte unique dans un client et non pas la main du chauffeur qui est contaminée. Donc, on n'a pas fait de vérification de mains.

Si on avait fait la vérification de mains à ce moment-là, ça aurait été beaucoup plus simple d'identifier à quel moment cette boîte-là a été contaminée comme telle.

MEMBRE TOLGYESI : Ça veut dire que vous avez inclus maintenant cet item dans vos procédures, que vous vérifiez les mains du chauffeur... je ne sais pas si c'est avant de partir pour la livraison, je suppose, ou quand il revient ou quand il y a une plainte?

MR. GAGNON: André Gagnon for the record.

Le chauffeur ne rentre jamais dans notre endroit, où est-ce que c'est chaud, dans la production area. Donc, il n'y a pas lieu pour lui. Il prend des paquets qui sont froids et les amène chez le client. Ils sont supposés être froids encore.

Présentement, on va installer un Geiger de

sortie -- mais encore là, comme je vous ai dit, dépendamment de ce qu'on peut capter avec le Geiger -- pour faire une vérification supplémentaire pour ça.

Présentement, ce qu'on a institué pour les prochains six, sept mois, huit mois, c'est que notre chauffeur fait des frottis au site aussi pour s'assurer que lui-même, quand il arrive là-bas, il n'y a pas de contamination. Ça fait que s'il y a une contamination qui se produit, bien, elle n'aurait pas été reliée à lui.

Mais présentement, vous avez raison, nous avons un système qui fait en sorte qu'à la minute près, aussitôt qu'on a une annonce de contamination, nos gens sont prêts à répondre, à avoir les wipe tests faits sur leurs mains, leurs véhicules, l'ensemble de notre matériel qui est chez Isologic.

MEMBRE TOLGYESI : Parce que de la même façon, dans ce cas-ci, c'était le chauffeur qui empaquetait, après qui livrait. Ça veut dire qu'il a touché les boîtes avec ses gants probablement, et il a contaminé la boîte qu'il a manipulé après avec la main nue.

MR. GAGNON: André Gagnon for the record.

C'est là qui est la difficulté dans la compréhension de notre problème. On a proposé un scénario qu'on disait plausible, sauf que le technicien, si c'était le cas, s'il avait contaminé une boîte, si sa main est

contaminée avec son gant, parce qu'il travaille avec des gants, il aurait contaminé un paquet de boîtes, il aurait contaminé 20-30 boîtes, ce qui n'a pas été le cas ce matin-là. Toutes les boîtes qui sont parties n'avaient pas de contamination.

Donc, on a parti sur la prémisse qu'il devait avoir une contamination sur sa main nue, en dessous de son gant, et lors de sa livraison -- parce qu'il doit enlever ses gants lors du départ de chez nous -- à ce moment-là, il aurait pu mettre ça sur le contenant du CUSM et non pas sur les autres contenants. C'est comme ça qu'on a sorti avec un scénario plausible pour la contamination.

MEMBRE TOLGYESI : Bon.

THE PRESIDENT: Okay. Ms Velshi...?

MEMBER VELSHI: Thank you. So the 10 of the 33 packages that the CNSC staff have in their slide deck you said you were not notified of those, just the two on the first day.

So who was notified? Was CNSC notified of those or was this something you then found out once you started your investigation?

MR. RÉGIMBALD: André Régimbald here.

I believe the information I have is the hospital told the driver of Isologic when the contamination was found to report, you know, the contamination on the

13-14.

Mais j'aimerais demander à madame Simoneau si elle voudrait ajouter des détails là-dessus, s'il vous plaît.

MME SIMONEAU : Oui. Lucie Simoneau for the record.

La première journée, les colis contaminés ont été rapportés directement à Isologic par le Royal Victoria.

Les deux jours subséquents, le chauffeur a été avisé par la technologue à l'Hôpital pour Enfants que ses colis étaient contaminés. À ce qu'elle nous a dit, elle n'a pas contacté directement Isologic ni son responsable de la radioprotection, mais elle a informé le chauffeur que les colis qu'il livrait étaient contaminés.

MEMBER VELSHI: And so, Isologic, when you spoke to the driver -- or he never told you or you never found out from him. So I totally agree with you, two incidences versus ten, the scope changes dramatically, so right now we are just speculating on what the cause of that contamination is.

M. GAGNON : Si je peux rajouter. If I can add to this. Obviously to us it's very concerning that we have 10 boxes, but the problem we did have after the second and third incident that was reported in November we

realized that the calculation that these people were doing on the box was wrong. So chances are, for them to find 5 Becquerel activity on a box probably was wrong at that time because the calculation was done wrong.

I speculate today that chances are there was never 10 boxes contaminated. It was just the fact that they were doing kind of a verification and those verifications were not done properly, because the two subsequent incidents they were not doing the calculation right.

MEMBER VELSHI: So I guess we will never find out whether those 10 were real contamination. We do know for a fact that the driver's hand was contaminated because you verified that. Did you check the steering wheel and other parts of the car at that time to see if contamination had spread on that first day?

MR. GAGNON: André Gagnon, for the record.

Unfortunately it's exactly what our failure goes in. We did not address these issues properly with the steering wheel. We had 10 other spots, the floors, doors and a lot of other places in our facility, but not the driver's hands and not the actual drivers' cars, and so on.

MEMBER VELSHI: Staff, you said that since all this has happened in November there have been

additional contamination incidents reported and on the plus side, at least, the reporting is happening, but what's causing the contamination in the first place? I'm presuming these aren't containers from Isologic but from elsewhere.

MR. RÉGIMBALD: André Régimbald, for the record.

We received notification at least three times from hospitals receiving packages from different suppliers. I will ask Mr. Rabski or Mrs. Simoneau to explain because the inspectors went on site on November 19 and November 26 and also on December 3 and 4. We also visited the places where -- the hospital that reported and perhaps if they can add information to your questions.

Thank you.

MR. RABSKI: Henry Rabski, for the record.

The incidents that reported subsequently in November by hospitals were verified by CNSC staff. What was determined was that the packages were not contaminated as per the reporting requirements, but there was some indication on those packages below the reported requirements. So there was something indicated on the packages, but not reportable quantities. These are active areas, but they were not contaminated packages.

MEMBER VELSHI: So the question, there is

contamination just at low levels. Those were not packages from Isologic, the two or three that you are referring to?

MR. RABSKI: Henry Rabski, for the record.

The packages that were reported by other licensees, several came from Isologic and we determined that they were not contaminated packages after investigation. There was one other report from another radio pharmacy supplier in the area and that one as well was verified as not being contaminated.

MEMBER VELSHI: So I'm confused. I thought you said they were actually contaminated, but just below reported level.

MR. RABSKI: Yes. For the record, yes, they were. They were below the reportable.

There was contamination indicated on the containers, but below reportable levels. What our work has found out is some inconsistencies with respect to calculating the actual dose or contamination level on packages and we are following up with the hospitals on that issue.

MEMBER VELSHI: I guess what I'm getting at then is if some of those packages were coming from Isologic and they have put all these controls in place, that in spite of all the swiping and cleaning and whatever else, maybe low levels of contamination is inevitable. Is

that what we have been concluding?

MS SIMONEAU: Lucie Simoneau for the record.

Le problème avec les contaminations de frottis est souvent là quand l'échantillon a été prélevé. Les valises sont livrées dans les laboratoires chauds, dans les laboratoires de médecine nucléaire. Donc, c'est un environnement où il y a une grande quantité de substance nucléaire qui est manipulée. Si le frottis est fait immédiatement à la réception, on peut dire à ce moment-là que oui, la valise est arrivée contaminée. Comme dans le cas du Royal Victoria le 12 août, on peut dire qu'il y a des très, très fortes possibilités que la valise est arrivée contaminée.

Par contre, dans certaines autres situations, les frottis sont faits plus tard dans la journée. Donc, les technologues ont le temps de travailler dans la pièce où ils sont, en manipulant les radio-isotopes, et il y a un potentiel de légère contamination sur les colis. Et s'ils font le frottis un peu plus tard que juste à la réception, il est possible que cette légère contamination-là trouvée sur les colis provienne de leurs activités durant la journée et non directement de la livraison.

THE PRESIDENT: So my problem with the

report is, the staff report, there is nothing about the source, the possible source, the theory of a possible source, just acknowledgement there was contamination. There was no indication of where it might have come.

I now heard from both of you two scenarios, the driver or the actual technician that was actually using the equipment contaminating the driver. Why is that not a plausible scenario? And I can't understand, even on the second time you went in, why is there no description as to what you now suspect was the cause of contamination?

MR. RÉGIMBALD: It's André Régimbald, for the record.

It's very difficult at this time with the information that we have to draw any conclusion very evidently to determine exactly how come the contamination happened. We are still following up with McGill University Health Centre to review their procedures, their radiation safety operations, but as Madame Simoneau pointed out, it is possible that there could have been cross-contamination from the activities conducted at the hospital.

THE PRESIDENT: But studying more procedures will not get you a retroactive view about what happened. So I don't understand why we are not afraid to put in a hypothetical situation and say that we don't know

what actual situation happened but at least get some idea as to a scenario that is equally likely, even though the more I hear, the more I think it's more likely onsite contamination. So that's number one.

Number two, I'm mostly hearing about measurement problems, but how do you measure whether the swiping is the right thing to do, et cetera? So all of this is not discussed in the report.

So I'm trying to understand. You should have an opinion about what is it that you found and I don't think that you can actually say there was something wrong but we don't know what it is.

MR. RÉGIMBALD: André Régimbald for the record.

All the evidence regarding August, the August event which we focused on the report, points to Isologic and this has been recognized by their investigation and also the corrective actions that were put in place.

The reports that we had following the safety notice we put out indicate that there are difficulties with measurement, contamination, instrumentation and all that. In one instance, the licensee who reported the contamination acknowledged later on that they had made a mistake in calculating the values.

THE PRESIDENT: This is the hospital?

MR. RÉGIMBALD: Yes, one of the hospitals, around December or something like that, who reported to us.

But, as Mr. Gagnon indicated, there are many, many thousands of packages delivered all day, and following our safety notice, we received three reports from hospitals or licensees who received unsealed sources and in all instances there is no evidence that contamination is widespread or coming from Isologic. It points to the difficulty they have in calculating the contamination and we are following up with those licensees to make sure that they do the calculation correctly.

THE PRESIDENT: Ms Velshi.

MEMBER VELSHI: When the hospitals receive these packages, are the technicians wearing gloves? Should they just treat these as there could be lower levels of contamination and take precautions accordingly?

MME SIMONEAU : Lucie Simoneau.

Oui, les technologues portent des gants lorsqu'ils reçoivent les contenants, les colis. Ils portent aussi les gants lorsqu'ils manipulent les seringues.

La technologue pourrait avoir eu sa main contaminée la journée du 12, parce que lorsqu'elle est arrivée dans le département ce matin-là, elle avait deux

portes à ouvrir. Donc, elle a ouvert les deux portes pour rentrer dans son département de médecine nucléaire. Par la suite, elle a mis ses gants et elle a fait les frottis sur les valises.

Personne d'autre n'a à toucher ces portes-là durant la journée parce qu'elles demeurent continuellement ouvertes, et personne d'autre n'a eu ses mains contaminées, à l'exception de cette personne-là. C'est pour ça qu'on pense qu'elle a contaminé ses mains sur les portes en arrivant le matin, parce que par la suite elle a toujours porté des gants.

MEMBER VELSHI: So I'm even more confused. Contamination was from the handle of the door or the handle of the container if she was wearing gloves when she was handling the container?

MME SIMONEAU : Les deux, parce que la porte... la poignée de la porte devait avoir été contaminée par les mains du chauffeur. Donc, elle est arrivée pour travailler, avec ses mains nues parce qu'elle arrivait pour travailler. Elle a manipulé les deux poignées de porte qui étaient contaminées. Donc, de ce fait, quand ils ont fait les frottis, elle avait à peu près 3000 CPM sur ses mains.

Par contre, quand elle a fait le frottis sur la valise, ils ont trouvé des comptes d'à peu près 133 000 CPM juste sur la poignée de la valise, et elle, elle

avait ses mains qui étaient juste à 3000. De là le fait qu'on conclut qu'elle a contaminé sa main nue en manipulant les poignées de porte pour rentrer dans son département.

Puis, par la suite, ils ont détecté la contamination sur les frottis, mais elle portait des gants à ce moment-là. Donc, elle n'a pas surcontaminé ses mains, si on peut dire.

THE PRESIDENT: Okay. Dr. McEwan.

MEMBER McEWAN: Thank you, Mr. President.

So just to finally put to rest the idea that the contamination could have occurred at the hospital, how often has this hospital had positive lab tests in their routine testing?

MS SIMONEAU: Lucie Simoneau for the record.

Ils font une vérification de la contamination de leurs pièces où ils travaillent et les salles une fois par semaine, selon leur procédure.

Par contre, les colis qui sont repris par Isologic doivent être frottés avant chaque départ, ce qu'ils ne faisaient pas. On s'est rendu compte qu'ils le faisaient plus avant dans la journée.

Mais les colis sont vérifiés chaque jour et les espaces de travail une fois par semaine.

MEMBER McEWAN: But I would guess that the

work spaces would be rarely positive.

MME SIMONEAU : Oui, c'est... Bien, c'est rarement contaminé, mais ça arrive que c'est contaminé. Lorsqu'ils sont contaminés, leur procédure est de nettoyer, de refaire le frottis pour s'assurer que c'est propre, et par la suite, c'est fini.

THE PRESIDENT: But just following up on this, you yourself did an inspection of the hospitals and you found some irregularities. You keep saying you found some improvements required. What were those improvements required?

MS SIMONEAU: At the hospital? We recommended that the RSO be more involved in the management of the radiation -- en français.

LE PRÉSIDENT : En français, s'il vous plaît.

MME SIMONEAU : Oui, c'est vrai.

On a recommandé que le responsable de la radioprotection soit beaucoup plus impliqué dans la gestion du programme de radioprotection au niveau des différents départements de médecine nucléaire.

Bien que les médecines... Il y a trois départements de médecine nucléaire différents sous le CUSM. Chacun d'eux fonctionne un peu en silo. Chacun a ses procédures. Chacun a de très bonnes procédures qu'il

applique, sauf que les trois départements fonctionnent différemment et les instrumentations qu'ils utilisent sont différents ou ont des réponses différentes dans les trois départements.

Donc, on a demandé à ce qu'il y ait une uniformité et une amélioration des méthodes de calcul utilisées et la vérification de ces dernières.

THE PRESIDENT: Dr. McEwan.

MEMBER McEWAN: So, to go to Isologic, very simplistically, your process, in the morning you elute the generator, you label the products with the eluted pertechnetate, you then dispense the products from a bulk vial into the unit doses, and then -- so that is done -- if I look at Slide 16, that is done in the drawing station.

So to go from the drawing station -- so you go from the drawing station with the unit doses in a lead pig?

MR. GAGNON: André Gagnon for the record.

To make it a little more complicated than it needs to be, we also deliver in bulk. In Montreal we have this profile where we want to reduce radiation dosimetry for the fingers and so on, so we deliver to customers in bulk where we send both unit doses and bulk. So both small vials and unit dose vials are sent out to the --

MEMBER McEWAN: Okay. So the unit dose is drawn up in the drawing station and the bulk doses will have a final assay in the drawing station?

MR. GAGNON: André Gagnon for the record. Yes. As a matter of fact, we do on-the-fly labelling. Our labels are done -- as the dose calibrator spits out the label, then we put it on the vial at that time, so the exact dose for the exact patient at that time.

MEMBER McEWAN: Okay. So the last time you're manipulating is actually in the drawing station?

MR. GAGNON: André Gagnon for the record. Yes.

MEMBER McEWAN: So it's then carried from the drawing station into the packaging area by the tech or somebody comes in and collects it?

MR. GAGNON: André Gagnon for the record. We have a tray. Vials are put in a tray and pushed on the counter towards the other side of the counter.

MEMBER McEWAN: Okay. So in this drawing, you're showing -- so the tray would be on the other side that we can't see in this photograph?

MR. GAGNON: André Gagnon for the record. Again, yes. The tray -- it's a plastic

tray -- is about a foot by eight inches, has slots in it. All these vials are put in there. It just slides onto the other side.

MEMBER McEWAN: Okay. So that would be the last time, because of the manipulation, that contamination could occur on the outside of the pig?

MR. GAGNON: André Gagnon for the record.

Exactly. If there was contamination on that pig, that pig would have been sent on the other side. The driver would have wiped the pig. If the pig was contaminated, it would have been sent back.

We hypothesize that he did the wipe, didn't find anything on it, contaminated his hand, that probably he wasn't wearing gloves at that time, and he put that in the casing and that is him being contaminated. He put his glove after the fact and when he left the premises then contaminated the case.

MEMBER McEWAN: So realistically, that is the most likely place for the contamination to have occurred?

MR. GAGNON: André Gagnon for the record.

Exactly.

THE PRESIDENT: Okay, but if that's the case, were there other deliverables that day or that period to other hospitals -- not the McGill Hospital, to other

hospitals?

MR. GAGNON: André Gagnon, for the record.

There are about 70 other containers that were delivered on that day without any contamination.

THE PRESIDENT: Well, that's why -- so something doesn't compute in my mind here. If the driver was the source of contamination, why are the other hospitals not phoning CNSC?

Please, somebody, try to explain this to me.

MR. GAGNON: André Gagnon again, for the record.

That's where the difficulty of the investigation for either us or the CNSC. We are walking in the dark here.

The fact is that we stipulated that the driver must have come inside the laboratory at one point before he put his gloves on to start working, would have taken a vial, put it in front of him, put his gloves on and started doing the actual wipe. He would then have the contamination under his glove while he was working, so not contaminate any other vial or containers around. At the time when he left for his three deliveries -- he takes off his gloves -- it might at that time have contaminated one container. That's the Royal Vic.

THE PRESIDENT: But not just one. He would have to do it -- there were 10 events here we are talking about. No, no, but not all at the same time. So there is another event coming in. Something doesn't jive here.

MR. RABSKI: Henry Rabski, for the record.

We could surmise, too, that since there were five packages of the six that were sent to the Royal Vic it was the driver, once he had it on his hand took his glove off, had it on his hand, began to deliver to those three hospitals. In his manipulation of the packages, taking them from the truck into the hospitals for placement, he would have touched the other packages, hands on the handles as moving them to the truck and to the hospital, transferring potentially contamination to the other five of six.

THE PRESIDENT: Okay, I will accept that there were other hospitals. If it's on the same day delivery is already contaminated, right?

MR. RABSKI: He only delivered to -- the one driver that was involved in this case is the only delivered to those three hospitals.

THE PRESIDENT: I was just told to more than just those three, that's why I asked.

MS SIMONEAU: No. Lucie Simoneau, for the

record.

Les colis, les autres colis, les 70 autres colis qui ont été livrés ont été aussi livrés par d'autres chauffeurs. Il n'y a pas juste un seul chauffeur. Le chauffeur qui a eu sa main contaminée a livré les colis aux hôpitaux qui sont reliés à McGill, alors que les autres colis ont été livrés par d'autres chauffeurs qui avaient les mains propres.

LE PRÉSIDENT: O.K. Alors, c'était ma question.

MME SIMONEAU : Oui.

LE PRÉSIDENT : O.K. Merci.

MEMBER McEWAN: So again, coming back to the President's point, again, when I read the report I was frustrated that there was no attempt to build a chain of events that could have happened.

I mean it seems that it is not improbable, to use a double negative, that the event occurred early in the morning, that it was related to one of the trays that was put out on this driver. That I think at least is a working hypothesis that you can go back and test.

I think to suggest, you know, as we have heard, that it could have been the other hospital, I mean there are a lot more checks I would think in a hospital that are likely to show some anomalies is something like

this happen. So I mean, I guess my concern is, I get the impression now you have changed all your processes anyway. Why would you be having a driver do a relatively sensitive job such as doing wipe testing on both packages and on pigs? That's the bit that I don't understand about your old processes, why you would even have thought that was acceptable.

MR. GAGNON: André Gagnon, for the record.

This process was on for eight years without a single incident. Obviously today we are looking at this. It may not make more sense. That's why we did actually change our method.

THE PRESIDENT: Okay.

Monsieur Harvey...?

MEMBRE HARVEY : Je viens d'avoir la réponse. C'était pour demander si vous aviez eu, durant ces huit années, des problèmes. Est-ce que le personnel, vous avez reçu pendant ces années, des plaintes des hôpitaux ou des...

MME SIMONEAU : Pas à ce qu'on sache. On n'a pas eu de plainte de réception de colis contaminé qui était reliée à Isologic ou à d'autres radiopharmacies.

MEMBRE HARVEY : La personne qui fait l'emballage et tout ça, est-ce que ça arrive fréquemment que ses mains sont contaminées?

MR. GAGNON: André Gagnon for the record.

Définitivement. Le processus qu'on doit mettre en place, aussitôt que les vials sortent... Quand on dit « contaminé », il faut s'entendre là, on parle de 3000-4000 compte, 300 compte. Nous, on s'attarde de façon à avoir du background sur nos vials.

Donc, aussitôt que le chauffeur prend le vial avec ses gants, parce qu'il a toujours des gants, il va avoir à ce moment-là de l'activité sur ses gants. La première option qu'il a à ce moment-là, c'est d'enlever ses gants, de pousser le vial vers l'opérateur, de changer de gants et de recommencer de nouveau. Le processus est en place pour vraiment éviter que les mains soient contaminées, évidemment.

THE PRESIDENT: Mr. Tolgyesi...?

MEMBRE TOLGYESI: Oui.

On your CMD on page 4 you are saying that:

> "New procedural concerns were identified at the McGill University Hospital Centre as a result of these evaluations." (As read)

There is nothing more said about this new procedural concerns. That means there are some old ones also and you have some additional ones? It's at page 4, the second paragraph before the last line at the end.

"New procedural concerns were identified at McGill University Hospital. As a result of these evaluations..." (As read)

That was after 18, 19 and 26.

MME SIMONEAU : Lucie Simoneau.

Oui. On a été, un groupe d'inspecteurs, visité Isologic et McGill University Health Centre, et ce qu'on a vraiment trouvé en conclusion, avec les différentes vérifications qu'on a eues, c'est qu'il n'y avait pas vraiment de responsable de la radioprotection sur site qui était activement à gérer chacun des différents départements. Chacun des trois différents départements était géré individuellement par une assistante chef technologiste, qui était d'ailleurs très compétente. Donc, on n'a pas vraiment de difficulté avec la façon dont chacun des programmes de radioprotection est géré à l'interne.

Ce qu'on a eu comme difficulté, c'est vraiment le peu d'implication du responsable de la radioprotection corporative et aussi dans son implication via la vérification des instrumentations qui sont utilisées pour mesurer les frottis, donc, de la vérification de la contamination.

Donc, on a demandé à la responsable de la demande -- on a discuté avec la responsable du permis -- de

faire des modifications au niveau de sa gestion et de s'assurer qu'ils vont avoir une implication directe du responsable de la radioprotection dans les différents départements de façon à les uniformiser.

MEMBRE TOLGYESI : Vous savez, l'événement était les 12, 13 et 14 août, et la CNSC a rencontré the licensee le 9 octobre, et c'est là que vous avez demandé the root cause analysis.

Ma question : Is there a procedure or event definition or severity which will trigger a request for a root cause analysis as soon as you receive early notice?

M. RÉGIMBALD : Je vais demander à monsieur André Bouchard, s'il vous plaît, de répondre. Merci.

MR. BOUCHARD: André Bouchard, Director of Human and Organizational Performance Division.

Triggers to cause analysis would actually be linked with severity of events. In this case of contamination a single event may not require this kind of extreme measures of a root cause analysis. The repetition of events obviously would then be the trigger for that. So it's a bit subtle into what would require root cause analysis to be performed.

MEMBER TOLGYESI: So if it was a high contamination instead of -- I don't know how much it was,

point something -- if it was very high contamination, that will trigger the request for a root analysis right away?

MR. BOUCHARD: It actually is addressed into CNSC's Regulation that analysis to identify the causes of events have to be done. It's staff now to interpret and require a licensee to actually apply this requirement which is prorated to obviously the severity, yes, of the event.

So a single exposure important to a person would then trigger such things, but several repeated offences of the same things could also trigger the same kind of request from CNSC staff.

MR. RÉGIMBALD: If I can add, please. André Régimbald here.

Also if there is any exceedance of a regulatory requirement, for example, a dose rate or a surface contamination limit or any kind of regulatory limit would trigger such an analysis.

MEMBER TOLGYESI: And my last question, Monsieur le Président, c'est à Isologic.

Sur votre charte, la slide numéro 4, vous avez l'organisation. Vous parlez de quatre divisions. Vous parlez de site managers sur chacune des divisions; il y en a quatre. Dans votre prochaine slide, vous parlez seulement de trois, mais je suppose que c'est une typing error.

Mais je veux vous parler de celui de Toronto. Monsieur Habib Bhatti, the Site Manager, is the Site Manager who is reporting to the President. At the same time, he is reporting to the Quality Management, to the Global Manager and the Vice President, Business Development Special Projects.

Vous avez séparé maintenant les rôles. Par exemple, le chauffeur ne peut plus emballer, empaqueter, mais il doit faire d'autres choses. On avait la question des responsables qui étaient plus alignés.

Est-ce que deux responsabilités remplies par la même personne ne causent pas des problèmes? Parce que le Site Manager jusqu'à un certain point est responsable aussi, si je vois bien, de ce qui se passe en dessous de lui, et en même temps, la même personne répond à quelqu'un d'autre ailleurs.

MR. GAGNON: André Gagnon for the record.

Je ne sais pas si j'ai bien saisi la question, sauf que juste pour ajouter, c'est que le Site Manager manage le site, ça, c'est évident, mais le fait est que chaque RSO sur le site a le pouvoir ultime là d'arrêter la production, de faire des actions pour arrêter la production s'il y a cas de problématiques sur les sites comme tels.

MEMBRE TOLGYESI : Parce qu'en général,

dans les structures organisationnelles, on essaie d'éviter que tu es responsable pour ces choses-là et, en même temps, t'es ici et tu réponds à quelqu'un d'autre qui peut te donner un ordre ou une directive qui est tout à fait différente de la tienne.

MR. GAGNON: André Gagnon for the record.

Juste pour essayer de donner un peu plus d'informations, c'est évident que c'est difficile de faire un organization chart.

Monsieur Caldwell, il ne travaille pas pour nous. Il a été consultant. Il est à Sunnybrook. Il est déjà RSO pour un autre permis et il devient... Étant donné qu'on est sur le site de Sunnybrook, il est aussi notre... Donc, il ne se rapporte pas à monsieur Habib Bhatti. Tout simplement, c'est le fait qu'il faut le mettre quelque part. On aurait peut-être dû le mettre au dessus des managers pour refléter un peu plus vraiment leurs liens fonctionnels.

MEMBER TOLGYESI: (Off microphone) and the production flow, when you are going to 2.1.7, with the dose area packages in a case for transportation, and the following step is 2.1.9, bills of lading, and at the same time you have a parallel going to 2.1.8.

Is there a choice that somebody could do one or could do other things because, as it is in the chart

now, there is an option?

MR. GAGNON: André Gagnon, for the record.

I'm going to answer in English. The reason what you were seeing there, the bill of lading is printed at the same time as -- not at the same time, as soon as the data is entered. You can't actually do a bill of lading if you haven't done the actual test.

If you do a wipe test on the box in needs to be on the paper -- transportation paper. It needs to be in there. The reason the box is there, if there is a positive, then it has to go back to be repackaged again.

But the bill of lading has to be printed out after this process is done in order to be able to send the package out. So there is no way. It cannot be done where the package would go out without having the result put in the system, because the system wouldn't allow you to even close the box.

MEMBRE TOLGYESI : Okay. Merci.

THE PRESIDENT: On the same kind of a line, I'm always interested in governance model. So from the McGill Health Centre it's one licensee that holds the license for all the three hospitals? Is that the way it works? Are we happy with this kind of governance model? You know, we have in other provinces challenges with this kind of a model.

MR. FUNDAREK: Peter Fundarek, for the record.

Yes, the model as you described it is correct. There is one licensee, the Montreal University Health Centre -- sorry, McGill University Health Centre -- and they do hold the license for the three hospitals, the Royal Victoria, the Children and the General. There is a corporate Radiation Safety Officer and then there are site personnel responsible for radiation safety at each of the locations.

We have accepted that model in other locations and it does seem to work quite well. We haven't faced any challenges in the majority of the locations where that has been used.

THE PRESIDENT: These are huge institutions. I don't know if you have visited them. They are huge. I am just not a fan of one headquarters RSO overseeing all the local RSOs.

MR. FUNDAREK: Peter Fundarek, for the record. The reason why we have the site RSOs, they have the full authority at each location to effect the Radiation Protection Program as necessary and that's exactly why we have the Radiation Safety Officers at each location.

THE PRESIDENT: Yes, so why do we need the corporate one?

MR. FUNDAREK: The corporate one is to provide overall control and to ensure consistency between the various sites and to function as a liaison, the ultimate liaison with the organization between the organization and the CNSC.

THE PRESIDENT: Okay. On a different topic, maybe it's a bit off-topic, Isologic, where do you get your technetium from?

MR. GAGNON: André Gagnon, for the record. We are buying from multiple vendors. We are an independent pharmacy so we buy from both Mallinckrodt and Lantheus.

THE PRESIDENT: So are there any other -- are you worried about isotope production with AECL? That's not on your --

MR. GAGNON: André Gagnon, for the record. As a matter of fact it is a concern for us, but the fact is there has been indicated plans on both Mallinckrodt and Lantheus that have other suppliers in the world that are providing in case of problems. So we have seen issues at one point where the NRU was closed and they ended up being able to get some suppliers from other regions.

THE PRESIDENT: So your cyclotron, is your cyclotron able to produce technetium?

MR. GAGNON: Are you asking me if we can

do technetium with cyclotron?

THE PRESIDENT: You have a cyclotron you said, don't you?

MR. GAGNON: André Gagnon for the record.

I mean I am not an expert. I can just tell you what the marketplace is. I mean obviously I have a very different vision than Dr. McEwan would have on technetium produced by cyclotron. Our cyclotron is a very fragile machine. It is broken every day or every other day. When you work with the machine like that in nuclear medicine, if I told my customer that tomorrow you you may or may not have your product, that's not going to work. I'm not going to be in business for long.

So as a hybrid system it might work to produce cyclotron technetium, but there are a lot of challenges that would come with producing cyclotron. I know that we are on different views with Dr. McEwan on that.

THE PRESIDENT: No, I just want to know if you now produce any technetium with the cyclotron.

MR. GAGNON: It's not possible for now to produce technetium with cyclotron, in our cyclotron at least.

THE PRESIDENT: Okay. Thank you.

Anybody else? Any other questions? Okay,

thank you. Thank you very much.

We have scheduled an important presentation on waste management, but Commissioners have to catch a plane here and we are not going to be able to give you the time that is needed to give this presentation justice. So we will reschedule it to sometime in the new year.

So this concludes the public meeting of the Commission. Thank you, and I wish you season's greetings and safe, secure 2015.

Merci beaucoup.

--- Whereupon the meeting concluded at 3:21 p.m. /
La réunion s'est terminée à 15 h 21