Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Public meeting

Réunion publique

November 5th, 2020

Le 5 novembre 2020

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

via videoconference

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

par vidéoconférence

Commission Members present

Ms. Rumina Velshi
Dr. Sandor Demeter
Dr. Timothy Berube
Dr. Marcel Lacroix
Dr. Stephen McKinnon

Commissaires présents

Mme Rumina Velshi
Dr Sandor Demeter
M. Timothy Berube
M. Marcel Lacroix
M. Stephen McKinnon

Secretary:

Mr. Marc Leblanc

Secrétaire:

Me Marc Leblanc

Senior General Counsel:

Ms. Lisa Thiele

Avocate-générale principale :

Me Lisa Thiele

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Ottawa, Ontario / Ottawa (Ontario)

--- Upon commencing on Thursday, November 5, 2020
at 9:00 a.m. / La réunion débute le jeudi
5 novembre 2020 à 9 h 00

Opening Remarks

THE PRESIDENT: Good morning and welcome to the virtual meeting of the Canadian Nuclear Safety Commission.

Mon nom et Rumina Velshi, je suis la Presidente de la Commission Canadienne de Sûreté Nucléaire.

I would like to begin by recognizing that our participants today are located in many different parts of the country. I will pose for a few seconds in silence so that each of us can acknowledge the treaty and/or traditional territory for our locations.

Please take this time to provide your gratitude and acknowledgement for the land.

Je vous souhaite la bienvenue and welcome to all those joining us via Zoom or webcast.

I would like to introduce the Members of the Commission that are with us today remotely: Dr. Sandor

Demeter; Dr. Stephen McKinnon; Dr. Marcel Lacroix; and, Dr. Timothy Berube.

Ms. Lisa Thiele, Senior General Counsel to the Commission and Marc Leblanc, Commission Secretary are also joining us remotely.

As always, I'd like to begin today's Commission meeting with a safety moment to talk about fire prevention.

We moved the clock back on hour last weekend. Across the country fire departments use this occasion to remind us all to check our smoke and carbon monoxide detectors and to replace the batteries. Of equal importance is to also replace detectors that are past their expiry date.

Because of the COVID-19 pandemic, many of us are working from home. It has been reported that house fires have increased by as much as 30 per cent since March 2020. So more so than ever before please make checking your detectors a priority today. Thank you.

I'll now turn the floor to Mr. Leblanc for a few opening remarks. Mark.

MR. LEBLANC: Merci, Madame la présidente.

Bonjour, Mesdames et Messieurs.

J'aimerais aborder certains aspects touchant le déroulement de la réunion aujourd'hui.

For this Commission meeting we have simultaneous interpretation. Please keep the pace of your speech relatively slow so that the interpreters are able to keep up.

To make the transcripts as complete and clear as possible, please identify yourself each time before you speak. The transcript should be available on the CNSC website within one to two weeks.

I would also like to you know that this proceeding is being vide-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.

As usual, the President will be coordinating the questions to avoid having two people talking at the same time. During the question period, if you wish to provide an answer or add a comment, please use the raising hand function.

The *Nuclear Safety and Control Act* authorizes the Commission to hold meetings for the conduct of its business. Please refer to the agenda published on October 22nd for the complete list of items to be presented

today. I wish you to know that all the Commission Member documents, also referred to as CMDs, listed on the agenda are available on the CNSC website.

In addition to the written documents reviewed by the Commission for this meeting, CNSC Staff and other registered participants will have an opportunity to make verbal comments and Commission Members will be afforded an opportunity to ask questions on the items before us today.

Madame Velshi, présidente et première dirigeante de la CCSN, va présider la réunion publique d'aujourd'hui.

President Velshi.

CMD 20-M32

Adoption of Agenda

THE PRESIDENT: Thank you. With this information, I would now like to call for the adoption of the agenda by the Commission Members as outlined in Commission Member Document CMD 20-M32.

Do we have concurrence?

For the record, the agenda is adopted.

CMD 20-M33

Approval of the Minutes of Commission Meeting held on September 16, 2020

THE PRESIDENT: I will now call for the approval of the minutes of the Commission Meeting held on September 16th, 2020 as outlined in CMD 20-M33.

Are there any comments, additions or deletions that the Commission Members wish to make to the draft minutes?

Okay. I note that there are no changes, therefore I would ask the Commission Members to approve the minutes.

Do we have concurrence?

And with the show of nods, yes, thank you. For the record, the minutes of the September 16th Commission meeting are approved.

CMD 20-M37

Written submission from CNSC staff

THE PRESIDENT: The first item on the

agenda was to be an update provided by CNSC Staff on an overexposure to a member of the public at CancerCare Manitoba as outlined in Commission Member Document CMD 20-M38.

This was an action item from the September 16th Commission meeting. Consideration of this matter is being rescheduled to the December 8th to the 10th, 2020 Commission proceedings so that additional information recently requested by the Commission can be addressed.

So let's move to our next agenda item, which is an update pertaining to Mississauga Metals & Alloys, or MM&A, as outlined in CMD 20-M37. I note the representatives from MM&A are joining us remotely to be available for questions.

Before opening the floor for questions, I will turn to CNSC Staff.

Ms. Murthy, the floor is yours.

MS. MURTHY: Good morning, President Velshi and Members of the Commission. My name is Kavita Murthy, and I'm the Director General of the Directorate of Nuclear Cycle and Facilities regulation.

With me are Dr. Caroline Ducros, the Director of Nuclear Processing Facilities Division and CNSC

Staff from her division and other CSCC divisions ready to respond to your questions.

Mississauga Metals & Alloys holds a waste nuclear substance licence issued by a CNSC-designated officer for the management and storage of nuclear substance waste at its site in Brantford, Ontario.

In April 2019 the Commission issued an exemption to MM&A from the application of paragraph 24(2)(c) of the *Nuclear Safety and Control Act* and Part 2 of the Cost Recovery Fees Regulations in respect of the requirement for MM&A to be in good financial standing at the time of licensing.

This exception allowed a licensing decision to be made by the designated officer. This licence expires on April 30th, 2021.

In issuing the decision, the Commission directed Staff to take specific actions which are captured in the record of decision. To this memo we are providing an update to the Commission on those actions. This memo also provides an update on additional matters of relevance to the Commission.

No action or decision is being requested of the Commission associated with this update today.

We are available to answer any questions that the Commission may have. Thank you.

THE PRESIDENT: Thank you. I'll turn to the floor to Mississauga Metals & Alloys. Mr. Sharpe, do you wish to add anything of make a statement?

MR. SHARPE: No. I'd just like to stay good morning and I'm here to answer any questions you may have regarding this.

THE PRESIDENT: Thank you. Well, we'll open the floor to the Commission Members for questions, and we'll start with Dr. Demeter.

MEMBER DEMETER: Thank you very much. I have a two-part question. Well, first, is just to clarify. I'm looking at the financial guarantee component of the CMD and it says, "Staff is of the opinion the amount of $200,000 may be insufficient to fund a complete clean-up, including the removal of all contaminated waste. So, for that, I wanted to confirm that that $200,000 is actually sort of in the bank, like that $200,000 is there should it be needed? Because all the other stuff talks about the RAP fees.

And then for Mississauga Metals, they're looking at an alternate way of processing that may cost

less and they have to provide a detailed decommissioning plan. Until this is done, the cost of waste removal cannot be estimated.

So to CNSC, is that $200,000 in financial guarantee available should the company abandon the site, leave, go bankrupt?

And for Mississauga Metals, the alternate process, what's the timelines for the decommissioning plan to be forwarded?

MS. MURTHY: Kavita Murthy, for the record. The short answer to your first question, that is the money in the bank, it is a letter of credit that Mississauga Metals & Alloys has provided. So that answer is yes.

For the details on the rest of the questions you have related to the decommissioning, I'll ask Ms. Nancy Greencorn, the Director of Waste and Decommissioning Division to respond.

MS. GREENCORN: For the record, my name is Nancy Greencorn, I'm the Acting Director of the Wastes and Decommissioning Division.

To answer your question, yes, a financial guarantee includes both the financial instrument as well as

the cost estimate. So as Ms. Murthy indicated, the type of instrument provided by MM&A is a letter of credit, and this type of instrument is acceptable to the CNSC.

The other component, as you asked in your question, is the cost estimate for decommissioning. MM&A is currently expected to provide a revised decommissioning plan this fiscal year. Once this is received, Staff will review the decommissioning plan and associated cost estimate against our regulatory expectations to determine if the cost estimate is sufficient.

For details on the status of the decommissioning plan, as you requested, I would have MM&A provide that response.

THE PRESIDENT: Mr. Sharpe, did you wish to add anything to that?

MR. SHARPE: Yes. The only thing I would like to say is, yes, it was absolutely correct, we plan to have that information available once we start the process of the decommissioning plan and we obtain those costs, and then we can provide those results to everyone.

THE PRESIDENT: Thank you. Dr. McKinnon.

MEMBER MCKINNON: Yes, I also have a question about the financial aspects. There were some

numbers given in the memorandum about quarterly costs for the fees for CNSC and, from that, you can estimate that the annual fee is around $130,000 just to round up.

It was also mentioned that, in CNSC's opinion, the cost for the clean-up, if it would have to be done, would be over the $200,000 bond limit, but a number wasn't given.

And it was also in the memorandum mentioned that, you know, the plan was for Mississauga Metals & Alloys to come up with a plan to finalize clean-up by March 2024. So that, in terms of fees alone, would be close to $400,000.

So my question to MM&A is it would seem, just on the face of it, that it would be, you know, advantageous financially to clean-up as soon as possible. So I was curious why is there delay given the apparent financial advantage in doing so?

MR. SHARPE: David Sharpe, for the record. So our limitations have been on the site. We've had to do some reconstruction, we've got a Phase 1 that has -- Phase 1 of our new building has been erected. We are into this property, but we are waiting for the second phase to be completed, which should be done approximately June of 2021.

In there and part of our decommissioning plan will be like a process we'd like to propose to get the waste into a form that's suitable to go to a waste handling facility. And we need the -- and hence the additional time to be able to do that. That's what's taking so long.

We did not anticipate, as you probably read in the reports we had a fire back in 2017, and the whole reconstruction process of our facility and everything we do has taken much longer than anticipated. And, yes, you are right, it's in our interest to try clean this up as quickly as possible and that's what we'd like to do as well.

MEMBER MCKINNON: Okay, thank you very much.

THE PRESIDENT: Dr. Lacroix.

MEMBER LACROIX: Yes, thank you. I was wondering is it an unusual situation for CNSC to deal with MM&A in the sense that it's been going on for a number of years now?

The second question is that what happens if MM&A goes bankrupt? Who inherits from the waste and who will pay for the clean-up?

MS. MURTHY: Kavita Murthy, for the

record. This is a most unusual file for us to be dealing with. We have someone from finance online today who can probably give you how many times in our history we have had a situation similar to this. So it isn't a common situation for us at all.

With respect to MM&A going bankrupt, the purpose of the financial guarantee, to a certain extent, is to allow us to recover the cost of decommissioning and to enable us to decommission the site, if needed.

I'll ask Ms. Sonia Racine perhaps to give a little bit of history about financial arrears by licensees.

MS. RACINE: Sonia Racine, for the record. No, it's really an unusual situation. I've been at the CNSC for 11 years and I'm aware of two files where we had issues on the financial side. One of them was everything was paid out and, unfortunately, one of them closed the company and CNSC lost some money.

THE PRESIDENT: Maybe a follow-up to Dr. Lacroix's question.

So when MM&A changed its process, which resulted in the need for greater financial guarantee, what does that trigger for the CNSC to say we need to revisit

this financial guarantee? At that point, is the $200,000 adequate or not? And do we have a similar situation with other licensees where perhaps the financial guarantees that we have are not sufficient, and how do we make sure that's not the case?

MS. MURTHY: Kavita Murthy, for the record. Before handing off to Ms. Nancy Greencorn, the sentence in the memo that says the financial guarantee changed from $25,000 -- around $25,000 to $200,000, so that transition really happened around our institution of a more rigorous review of financial guarantees for various nuclear substance licences.

Because this is a nuclear substance licence, it does not have that -- did not have the programs necessary for the level of financial guarantee that you are used to seeing for larger nuclear facilities.

I'll ask Ms. Nancy Greencorn to perhaps explain in a little bit more detail the financial guarantee situation for this licensee.

Nancy, over to you.

MS. GREENCORN: Nancy Greencorn, for the record. So, yes, the original financial guarantee of $25K was for monitoring and maintenance. CNSC currently expects

the financial guarantee to be sufficient to cover all the decommissioning costs associated with the site, including the waste management activities.

So in determining those costs or determining the adequacy of the costs, we look at the decommissioning plans, and in the decommissioning plans we would look at how the waste is going to be dispositioned. So, for example, different processing costs, depending on the technology that is used for processing the waste or the different characteristics of the waste will impact the waste management cost.

So in determining how adequate the financial guarantee and the costs associated with it, we really need to have a holistic view of the decommissioning plan that is set forth.

So again, CNSC are anticipating receiving this decommissioning plan within this licence period and will review it, and then look at the costs to see if those seem adequate to cover the planned decommissioning activities.

THE PRESIDENT: But I think we're circling around the same issue. I understand the $25,000 to $200,000, there's a clear statement in the CMD that Staff

do not believe that the $200,000 is sufficient to completely clean-up the site if that was so required.

Thus the question, what triggers, and Ms. Murthy mentioned that for the larger facilities we do have a systematic way of ensuring there's a review on a regular basis on the adequacy of financial guarantees, that we don't have other licensees in a similar situation where the financial guarantee is not adequate.

How can the Commission get reassurance that that's not the case?

MS. GREENCORN: Nancy Greencorn, for the record. Typically, you would see in a licence that we ask that a licensee have a decommissioning plan and that decommissioning plan be revised every five years. Similarly, we expect the cost estimate to be -- or the financial guarantee to be revised on a five-year basis. So CNSC continue to review the documents.

There's also expectations if a licensee changes the activities that would affect the decommissioning plan, they would update the decommissioning plan at that time as well.

In the new regulatory documents that were put forth for the Commission in June, we have provided more

stringent requirements with respect to the revision of decommissioning plans and financial guarantees. So there will be an implementation phase for licensees to incorporate those decommissioning expectations into their licenses.

THE PRESIDENT: Thank you. Dr. Berube.

MEMBER BERUBE: Yes, good morning everyone. To continue on on this idea of financial guarantee I just want to expand a little bit on this topic.

Specifically, the financial guarantees here that we're talking about are the primary instruments basically for securing clean-up of sites should the operator fail to be able to do that on their own.

This question is for CNSC Finance. Are there any secondary or tertiary instruments or methodologies we can use to get additional cost recovery should the financial guarantees prove to be insufficient with private operators such as this company?

MS. MURTHY: Sonia, over to you.

MS. RACINE: Sonia Racine, for the record. At this time, to help us recover the funds of the unpaid fees the file was also transferred to CRA to the Refund Set-Off program.

If MM&A is submitting any claim to get a refund for tax or GST, CNSC would receive these funds.

Regarding the financial guarantee aspect, I'm going to transfer the file back to Kavita.

MS. MURTHY: Kavita Murthy, for the record. So the question I think was related to whether if the $200,000 is not sufficient, what other means exist for us to get access to additional funds?

Did I understand that correctly? That is the question?

MEMBER BERUBE: That is correct. And actually not just for this operator but all operators in general, specifically in the private sector where it is very, very difficult to get access to additional funds should a bankruptcy occur.

Are there secondary or tertiary methods by which we can actually achieve enough funds to cover the cost of remediating all this material?

MS. MURTHY: I would like to -- I know there is a history and there is a licensee for whom we had to make a Treasury Board submission to get access to additional funds some time ago when we had to access additional funds.

I will request if Mr. Ramzi Jammal is on, for him to please provide some of that information because I want to make sure that the information we provide is accurate.

If we can't, then we will get back to you on this question.

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

A couple of things I would like to say with respect to the operational requirements and the financial guarantees, as my colleagues mentioned, we will be matching the operation and changes in the operation.

Dr. Berube, with respect to your question on what happens if there is inadequate funds and how we can recover, we will go into different phases with the cost to recover. And if everything fails in the end, we are going to have to go to Treasury Board in order that the Crown will become liable -- I shouldn't say liable, the financial request that we will be going to Treasury Board requesting the funds for decommissioning.

We have done this before to one licensee in Alberta, where the CNSC hired and did the work via consultant and we were able to get the funds from Treasury

Board.

There is one thing I would like to reiterate; the fact that we are before you giving an update because the licensee has not been a good performer at multiple levels. So that's why we are bringing up to you where we are in dealing with this licensee. And especially right now we are coming towards a licence renewal and the financial guarantee, as we've done with other licensees, matching the operations.

So it's up to the licensee right now to reduce and mitigate their operations to match the financial guarantee. And staff will be taking that regulatory oversight to ensure that the licensee will be meeting all our requirements as we come towards the licence renewal.

This is not the licensing here now. I just wanted to provide you with an update. Staff, my colleagues, wanted to provide you with an update in accordance with the Record of Decision that was given by the Commission.

I would like to put the fact that the licensee has not been a good performer and that's why we are coming with an update on the challenges we are facing. We will continue updating the Commission according to what

has been provided by staff to make sure that the licensee understands the seriousness of the issue and their obligations to meet all of our requirements.

THE PRESIDENT: Thank you, Mr. Jammal.

I don't see any hands up.

Ms. Murthy, could you review again with us what additional information will be available in February when you appear in front of the Commission and when the Commission may have to make a decision on granting of exemptions or not?

MS. MURTHY: So we have in getting to the point in February, we will have to receive an application from this licensee for a licence renewal, and this licensee will have to apply to the Commission for an exemption from the application of the *Cost Recovery Fees Regulations*.

So between now and then we are monitoring the compliance of the licensee. They have given us some very specific milestones that we are monitoring.

So at the time when we are at the February point in time where the Commission will be contemplating on the licensee's request, we will be able to provide you with additional information on the licensee's compliance and meetings its commitments that they have made to the CNSC.

THE PRESIDENT: Thank you. Would you have the revised detailed decommissioning plan and updated financial guarantees at that time as well?

MS. MURTHY: Kavita Murthy, for the record.

It will depend on what MM&A would like to do in the next licence period. Should they choose to remain status quo, then it will be looked at differently. Should they propose to continue with processing or to resume processing and start decommissioning or decontaminating the site, then yes, we will be looking at that as well as the detailed decommissioning plan for them.

THE PRESIDENT: Thank you.

Dr. Berube.

MEMBER BERUBE: Just one question for MM&A while we have them on the line here.

I appreciate that basically you have been having a number of problems here with operations due to unforeseen circumstances, and of course COVID hasn't helped.

Given the timelines that you provided here to the CNSC staff, are you comfortable that you can actually bring your operations back up and get into a good

financial position here with the timelines you have stated at this point?

MR. SHARPE: David Sharpe, for the record.

Yes, I do. I have firm plans to do this business. It was a difficult year from COVID but we have new contracts in place. We have business improving. Things are looking better. We expect to finalize construction and we would like to propose a decommissioning plan and how we can finish processing the remainder of the waste. And we do hope that this will be our last licence renewal and that we can dispose of the waste and finish and close out our licence.

THE PRESIDENT: Thank you very much.

I don't see any more questions.

So, staff, first of all thank you for giving the Commission a heads-up on what may be coming in the next few months our way.

And to MM&A and Mr. Sharpe, again we wish you well and hope that you can deliver on your plans and we don't have MM&A and a bad licensee in the same sentence anymore and can proceed with the clean-up and compliance with the CNSC's expectations moving forward.

So again, thank you all for participating

in this agenda item.

We will take a two-minute break before we move into our next item. Thank you.

--- Upon recessing at 9:30 a.m. /
Suspension à 09 h 30
--- Upon resuming at 9:35 a.m. /
Reprise à 09 h 35

THE PRESIDENT: We are ready to resume.

Our next item is the Regulatory Oversight Report on the Use of Nuclear Substances in Canada: 2019 and Class 1B Accelerators in Canada for 2018 and 2019, as outlined in CMDs 20-M23 and 20-M23.A.

The public was invited to comment in writing. The Commission received two submissions.

We will hear a presentation from CNSC staff and then take a short break before the submissions from intervenors and rounds of questions from Commission Members.

I note that two licensees, TRIUMF and Canadian Light Source, are joining us to be available for questions.

So I will turn the floor over to Ms. Owen-Whitred.

CMD 20-M23/20-M23.A

Oral presentation by CNSC staff

MS. OWEN-WHITRED: Bonjour, Madame le Président, membres de la Commission.

Je suis Karen Owen-Whitred, Directrice Général de la Direction de la réglementation de substances nucléares. J'ai avec moi aujourd'hui Sylvain Faille, Director de la division des permits de substances nucléares et d'appareils a rayonnement; Claire Pike, Director of the Operations Inspection Division; Eric Lemoine, Director of the Transport Licensing and Strategic Support Division; Mark Broeders, Director of the Accelerators and Class II Facilities Division; Michael Davey, Licensing Specialist and lead for Part I of this report; Yani Picard, Senior Project Officer and lead for Part II of this report; along with many other CNSC staff involved in the regulation of nuclear substances.

We are here today to present our two-part regulatory oversight report on the Use of Nuclear

Substances in Canada: 2019 and Class 1B Accelerators in Canada: 2018 to 2019.

As we will discuss later in our presentation we continue to mature and modernize our regulatory program, increasingly leveraging our systems and technologies to explore new and innovative ways to regulate the sector and ensuring readiness for new applications of nuclear technology.

With the benefits of our systems and analytics, we are now better able to monitor, adapt and target our regulatory interventions, which can take various forms including communications, licensing and certification, compliance or enforcement in areas that will have the biggest impact and deliver the best results for Canadians.

This year, as with the 2018 report, we concentrated on providing useful information to stakeholders on notable performance trends and opportunities for improvement, as well as referencing rather than duplicating information already on the CNSC website.

This has helped build a more streamlined report without any substantive changes to the specific

performance information included in the report.

In addition, we have highlighted case studies from the commercial sector intended to demonstrate lessons learned from a regulatory oversight perspective.

Today's report is the first of a series of regulatory oversight reports that together present a comprehensive overview of the performance of the nuclear industry in Canada and outline our rigorous and extensive regulatory oversight programs that collectively ensure across all activities and facilities that the CNSC regulates that Canadians and our environment are protected.

This slide presents an overview of today's presentation, which will begin with a brief COVID-19 update.

Before beginning the presentation I will take the next two slides to provide a high level overview of the modified regulatory oversight plans put in place by the Directorate of Nuclear Substances Regulation as a result of the COVID-19 pandemic.

This is not part of the ROR which covers the previous calendar year, but due to the importance of this issue we felt it would be helpful to briefly describe the current situation before proceeding with the report.

As a result of the COVID-19 pandemic and to ensure the health and safety of CNSC staff, the CNSC activated its Business Continuity Plan on March 15, 2020 and CNSC staff were directed to work from home.

As a result, all non-critical oversight activities including routine on-site inspections, were suspended. In addition, access to CNSC systems were limited, which affected licensing and certification related activities.

CNSC staff adapted to these limitations by exploring and implementing alternative regulatory strategies to ensure that its regulatory objectives continued to be met.

For instance, CNSC staff immediately arranged for critical staff to be equipped and ready to respond to any unplanned events or situations.

In addition, CNSC staff ensured that critical services such as licensing and certification activities continued to be performed by effectively reallocating staff resources to ensure program delivery.

In the early stages of the pandemic CNSC staff conducted outreach activities to ascertain the operating environment of its licensees and to verify that

all licensees had maintained measures for the safety and security of their nuclear substances.

Between engagement with the licensees and the monitoring of reported events we are confident that we mitigated the effects of the temporary suspension of inspections during the early phase of the pandemic to ensure there was no impact on safety.

CNSC staff continues to improve by ensuring that its capability to perform regulatory functions in the pandemic environment is not compromised and remains effective. This includes developing a strategy for performing compliance verification activities during exceptional circumstances such as the COVID-19 pandemic.

As part of this strategy CNSC staff developed processes for alternate compliance verification activities such as remote inspections and modified its inspection plans to leverage the use of these alternate activities.

In addition, the CNSC developed relevant health and safety protocols for CNSC staff in order to have appropriate measures and controls in place for travelling and performing on-site inspections safely.

In this slide I will provide a brief

overview of DNSR's revised regulatory oversight plans as a result of the COVID-19 pandemic. The revised plans for fiscal year 2020-21 were developed based on the following three principles.

The first, as previously mentioned, is to adapt to the pandemic environment by leveraging the use of alternate performance verification activities such as remote inspections.

The second is to prioritize the health and safety of CNSC staff, licensees, inspectees and the public when making decisions related to the type of compliance verification activity to be performed, such as conducting inspections on-site or remotely. The type of compliance activity is determined on a monthly basis and is chosen based on the current climate of the pandemic.

The third principle is to ensure that high priority inspections continue to be completed as planned. This includes reducing the total planned number of lower priority inspections to focus on completing the inspections identified as high priority this fiscal year.

There are no expected impacts on safety due to cancelled or deferred inspections and due to revising the regulatory oversight plans.

CNSC staff believes that a mix of remote and on-site inspections is sufficient to maintain regulatory oversight and could, furthermore, enhance the overall efficiency of its regulatory oversight program.

Additional information related to our revised regulatory oversight plans for this sector will be covered in the 2020 Regulatory Oversight Report on the Use of Nuclear Substances in Canada.

I will now turn the presentation over to Michael Davey.

MR. DAVEY: For the record, Michael Davey, Licensing Specialist in the Directorate of Nuclear Substance Regulation.

I will start with a brief introduction of our work.

Nuclear substances and prescribed equipment are used in a broad range of applications. These are regulated under the *Nuclear Substances and Radiation Devices Regulations* and the *Class II Nuclear Facilities Regulations*.

The nuclear substances industry in Canada continues to operate safely in 2019. CNSC oversight activities, including licence reviews, technical

assessments and inspections confirm that licensees in the sector have appropriate safety programs in place in order to protect the health, safety and security of Canadians and the environment.

Further, CNSC staff verified that licensees continue to maintain adequate measures to implement Canada's international obligations. Despite the generally strong performance in the industry in 2019, there was one instance where a worker exceeded the regulatory dose limit for effective dose for NEWs and one instance where a worker exceeded the regulatory dose limit for effective dose for non-NEWs.

These events were reported to the Commission and are discussed in more detail later in this presentation.

I will now provide an overview of the oversight activities performed by the CNSC in 2019.

The medical sector accounted for approximately 21 per cent of the licences held for the activities covered by this report. The medical sector covers the use of nuclear substances and prescribed equipment for diagnostic and therapeutic purposes. The sub-sectors included are nuclear medicine, radiation

therapy and veterinary nuclear medicine.

The industrial sector accounted for approximately 59 per cent of the activities covered in this report. The industrial sector covers uses of nuclear substances and prescribed equipment in industrial facilities or as part of field work or construction. The sub-sectors included are portable gauges, fixed gauges, industrial radiography and oil well logging.

The academic and research sector accounts for 9 per cent of the activities covered in this report. The academic and research sector covers uses of nuclear substances and prescribed equipment in universities, colleges and research laboratories for research and teaching purposes. The sub-sectors included are laboratory studies and consolidated use of nuclear substances.

The commercial sector accounts for approximately 11 per cent of the activities covered in this report. This sector covers the production, processing, storage and distribution of nuclear substances, radiation devices and prescribed equipment, as well as the servicing and calibration of radiation devices and prescribed equipment.

In addition, this sector covers the

management, handling, storage and processing of Low-Level Radioactive Waste generated from nuclear facilities and activities. The sub-sectors included are isotope production, waste nuclear substances, processing of nuclear substances, distribution of nuclear substances, servicing radiation devices and prescribed equipment and calibration of radiation devices to prescribed equipment.

In 2019 there were 2,042 licences held across the country as well as 48 licensees that are based outside of Canada that perform licensed activities within Canada. This represents a slight decrease from last year where a total of 2,135 licences were reported, including those located outside of Canada.

The same requirements and expectations apply to these licensees as to those based in Canada. Inspections of these licensees may be conducted at locations in Canada when they are performing servicing work, or at their headquarters offices abroad.

The subsectors covered by this report are risk ranked. The risk ranking of the activities is part of the Risk Informed Regulatory Program. The Risk Informed Regulatory Program provides a relative risk ranking of activities that recognizes the potential safety impact of

the licensed activity and the likelihood of an incident occurring while conducting the activity.

The performance of the individual licensee is also a consideration for risk ranking.

As a whole, the program provides effective, transparent, consistent and comprehensive regulatory oversight of the use of nuclear substances and prescribed equipment.

When an application for licensing or certification is submitted to the CNSC, the CNSC staff review the application and conduct a technical assessment to determine if all regulatory requirements are met and that adequate measures are in place to protect health, safety, security and the environment.

A peer review of the assessment is conducted. Once the peer review is complete the designated officer makes a decision on each request for licensing or certification based on the evaluation and recommendation made by CNSC staff. A license or certificate will only be issued if the designated officer is confident the applicant has met all requirements and has the necessary programs in place.

The CNSC publishes application guides as

part of its REGDOC series to assist applicants. The REGDOC listed here are the main three application guides applicable to manufacturers of prescribed equipment and licensees in the industry sectors covered in this report.

Compliance activities conducted by CNSC staff include field inspections and desktop reviews. The reviews of compliance activities are documented and non-compliances are tracked until they are addressed by the licensee to the satisfaction of CNSC staff. In 2019 a total of 863 inspections were conducted for licensees covered under this report.

Annually, the CNSC staff uses a risk informed approach to develop inspection plans to focus on high-risk licenses and prioritize inspections based on a number of factors, including past performance, increased event trends, significant program changes, for example a new RSO, and other factors. This ensures that CNSC staff focus compliance effort on risk significant activities.

In 2019 CNSC staff developed a new approach to manage the performance verification program and how the CNSC applies to the risk informed decision making in its regulatory oversight. The risk informed regulatory approach is used to assess factors such as the licensee,

industry sector performance, and resources available for the implementation of the Performance Verification Program to determine priorities and set objectives for each year.

Historically, the primary focus was on high risk licensees, while medium risk licensees were not hitting the objectives for the expected frequency of inspections. It was also found that performance of high risk licensees continued to be strong, whereas performance of medium risk licensees were declining. As a result, CNSC staff undertook a review of the CNSC compliance strategy for these licensees. CNSC staff modified their approach to planning and prioritizing inspections for the fiscal year 2019-2020 where, as part of the Risk Informed Regulatory Program, a risk informed decision was made to change the focus from high risk licensees to prioritizing inspections of medium risk licensees due to the declining performance of licensees in the medium risk category.

The Risk Informed Regulatory Program and the associated Inspection Frequency Guidelines for NSRD licenses were revised in 2019 to ensure that they provide effective risk-informed oversight of regulated activities. This re-balance of priorities of the inspections to increase the frequency of inspections for medium risk

licensees and reduce the frequency of inspections for high risk, high performing licensees and industries.

CNSC staff continue to focus performance-based inspections as opposed to records-based inspections since conducting performance-based inspections has improved our effectiveness in detecting common areas of non-compliance.

This slide and the following slide look at enforcement actions. When CNSC staff find a licensee in non-compliance, they use the graduated approach to bring the licensee back into compliance and to deter future non-compliances.

CNSC staff select the most appropriate enforcement action based on risk-informed decision making. Orders and AMPs are highlighted in the report and are in the representation, but they are just two of the many tools available.

In 2019 thirteen escalated enforcement actions or Orders and AMPs were taken for reason of safety and/or security. All were orders of 2019. Any high risk or immediate health and safety findings were immediately addressed. In three cases licensees that received orders have yet to comply with the terms and conditions of the

orders. And the orders remain open. The CNSC is actively working with the licensees and these orders to ensure that the order requirements are addressed.

Most of the enforcement actions were taken against licensees in the industrial sector consistent with trends from previous years.

In the following section, I will speak to the overall safety performance of licensees covered by this report. The information presented here is at a high level. More detailed information is available in the Regulatory Oversight Report itself.

The performance of licensees is presented according to three key metrics:

Doses to workers;

Safety and control area performance results from inspections; and,

Reported events.

I will go through each metric in turn, starting with doses to workers.

Licensees are required to implement radiation protection programs that ensure radiation doses to workers are below regulatory limits and are kept as low as reasonably achievable. Looking at doses to workers is

an indication of how successful licensees are as a group in accomplishing this.

On this slide you see the distribution of workers across the four sectors covered in the report. Licensees are required to monitor occupational radiation doses for workers. In 2019 over 63,000 workers in the industrial, medical, academic and research and commercial sectors were monitored.

Workers who may, in the course of their job, receive more than one mSv per year must be identified as nuclear energy workers. In 2019 forty-two percent of all workers were nuclear energy workers or NEWs. All other workers are referred to as non-NEWs in this report and in the presentation.

This slide shows doses to workers over the last five years. Doses to workers remained low in 2019. Most workers received less than 0.5 mSv per year. There was one instance in which a NEW had a dosimeter result above the effective dose limit of 50 mSv per year. There was one instance in which a non-NEW received a dose above one mSv limit per persons not identified as a NEW. Again, these events will be discussed later in the presentation.

Now, moving on to look at licensee

performance in select safety and control areas. Results are shown at the sector level only. The Regulatory Oversight Report itself has performance results on the sub-sectors.

The presentation will give performance results and trends in four safety and control areas. These safety and control areas, management systems, operating performance, radiation protection and security were selected as being representative for the licensees covered by this Regulatory Oversight Report.

While the performance in a sub-set of safety and control areas are included in the presentation, and the Oversight Report, it is important to note that all relevant safety and control areas are evaluated during the assessments and compliance verification activities. These four safety and control areas have also been selected for ease of communication. Presenting all SCAs would require additional time and every SCA is not necessarily applicable to all licensees, for example, the package and transport SCA.

Reported events are a meaningful indicator for packaging and transport SCA and a list of events are included in the Oversight Report.

On the next series of slides, I'll present the performance ratings in each of the four safety and control areas, starting with management systems. In the management system safety and control area, performance across all sectors was strong. 97 percent of inspections met expectations in the safety and control area. There were three unacceptable results for management systems SCA. Additional details on the unacceptable ratings will be provided on the next slides.

Items of non-compliance were addressed by the licensees.

As mentioned on the previous slide, three licensees received an unacceptable rating in the management system safety and control area during an inspection. One licensee was a nuclear medicine licensee from the medical sector.

The reasons for the unacceptable rating was that the licensee did not have adequate management oversight of the radiation safety program, and the licensee did not have a sufficient number of qualified workers to carry on the licensed activity safety.

CNSC staff are monitoring the licensee's progress for correcting the findings from the inspection.

The second licensee was an X-ray fluorescence device from the industrial sector. The licensee received an unacceptable rating due to inadequate management control over the Radiation Protection Program. An order was issued to the licensee and is currently open.

The CNSC is actively working with the licensee to ensure that order requirements are addressed. CNSC staff are monitoring the licensee's progress for implementing corrective measures to meet the terms and conditions of the order.

The third licensee was an Isotope Production Accelerator Facility licensee from the commercial sector. The reasons for the unacceptable rating was that the licensee had insufficient support from senior management. The inspection results also concluded that there was inadequate follow-up on items of non-compliances from internal audits, and there was insufficient resources provided by management for the safe operations of the facility.

The licensee has addressed all items of non-compliance and CNSC staff will further evaluate responses during the inspection scheduled in 2021.

Moving on to operating performance. The

performance in the safety and control area slightly improved in 2019 compared to 2018. In 2019, 86 percent of inspections met the expectations in the safety and control area.

Two licensees received an unacceptable rating in operating performance. Additional details on the unacceptable ratings will be provided on the next slides.

Licensees addressed items of non-compliance.

Looking at trends in operating performance, the medical sector performance improved from the 2018 results. Both nuclear medicine and radiation therapy licensees improved in performance in the safety and control area.

The first licensee to receive an unacceptable rating was a fixed-gauge licensee from the industrial sector. The reason for the unacceptable rating was that the licensee was conducting vessel entries contrary to the stipulations of the licence condition. The licensee has since implemented corrective measures that were reviewed by CNSC staff and were determined to be satisfactory.

In response to the inspection findings,

CNSC staff issued an order. The licensee met the terms and conditions of the order, and the order was closed.

The second licensee was a research particle accelerator licensee from the academic and research sector. The reasons for the unacceptable rating was a combination of multiple issues related to the safety systems:

Some safety systems were not clearly identified;

Testing of the safety systems had not been performed; and,

Some areas did not have all the required systems; and,

User authorizations were not documented appropriately.

The CNSC issued multiple action notices and this licensee has since implemented corrective measures that were reviewed by CNSC staff and were determined to be satisfactory.

Next is the radiation protection safety and control area. In 2019, 80 percent of inspections met expectations in the radiation protection safety and control area. Where performance did not meet expectations,

licensees implemented corrective measures.

One licensee received an unacceptable rating in radiation protection. Details about this are provided on the next slide.

In 2019 most sectors experienced what appears to be a slight decline in the performance in the safety and control area. CNSC staff will continue to monitor performance in these sectors and will take action where appropriate.

As with the operating performance SCA, the increase in the number of licensees with below expectation ratings in the radiation production SCA may be due to prioritizing medium risk licensees, particularly within the medical sector and the industrial sector, especially portable gauge licensees.

The focus was on licensees that had not been inspected in the last five years; licensees with a poor compliance history; and, new licenses that had not been inspected. This focus provides a possible rationale for the observed decline in performance across this SCA.

Licensees are given a below expectation rating in an SCA if they are non-compliant in at least one item of the SCA regardless of the risk.

In addition, there was an increased focus for the CNSC inspectors to look at licensee's implementation of the Radiation Protection Program and management oversight of their operational activities, especially for licensees that have not been inspected for some time. This may also have contributed to the increased number of non-compliances in that area and, therefore, contributed to the overall decline in performance across this SCA.

Both the medical licensees and the portable gauge licensees were highlighted in the case studies provided in the 2018 ROR.

The regulatory strategy described in those case studies was to target these licensees using a performance-based inspection, observing workers performing their duties. This inspection approach has a proved detection of common areas of non-compliance which is another possible explanation for the perceived decline in performance in this SCA.

The performance of the radiation protection SCA will continue to be monitored in order to determine if additional actions are required. The inspection frequency for medium risk licensees is every two

to five years, so it may take a few years before improvement is noticed on subsequent inspections.

As mentioned on the previous slide, one licensee received unacceptable ratings for the radiation protection. Details of this case are shown in this slide. The licensee with an unacceptable rating was a portable gauge licensee.

CNSC staff issues an unacceptable rating due to the insufficient management oversight of the Radiation Protection Program. CNSC staff issued an order to prohibit work until the problems identified during the inspection were corrected.

The licensee addressed the items of non-compliance and put in place corrective measures to the satisfaction of CNSC staff, and the order was closed.

And now we move on to the final safety and control area covered in this part. Overall performance in the security, safety and control area was strong. In 2019 95 percent of inspections met expectations for the safety and control area. Items of non-compliance were addressed by licensees to the satisfaction of CNSC staff.

None of the licensees received an unacceptable rating in the security, safety and control

area. However, on licensee received significantly below average in security and this licensee was issued an order. The order was still open and the details cannot be provided since the security details are protected information.

Currently, there is no immediate risk due to the security of the nuclear substances.

The next performance measure we'll look at is reported events. Licensees are required to have programs in place for the management of unplanned events and accidents. The *Nuclear Safety and Control Act*, regulations made pursuant to the *Act* and license conditions set out when licensees and other users of nuclear substances and prescribed equipment must report unplanned events to the CNSC.

When a licensee or other user reports an event to the CNSC, the CNSC staff review the information in the report and assess the proposed corrective measures. All reported events are tracked by CNSC staff.

The CNSC staff assign a ranking to each event based on the *International Nuclear and Radiological Events Scale* or INES. INES is a seven-point tool used for communicating the safety significance of events to the public. Note that the rankings provided in this report and

in the presentation are those of CNSC staff. This slide gives a short description for the three lowest INES levels, and for INES Level-0 or below the scale.

The events reported to the CNSC by licensees covered by this report typically fall in Level-0, 1 or 2.

In 2019, 188 events related to the use of nuclear substances and prescribed equipment were reported to the CNSC. Most of these were ranked as INES Level-0, having no safety significance.

One event ranked at Level-1, anomaly.

And one event ranked at Level-2 incident.

I will provide additional details on this event in subsequent slides. Short descriptions of all events are provided in the report itself.

This slide gives information about the INES Level-1 event. A non-NEW worker had a dose of 1.85 mSv. The licensee was unable to determine the cause of the dose. The employee could not come up with a reasonable explanation for the exceedance.

The license dosimetry service provider did not find any anomaly with the dosimeter. The Event Initial Report, or EIR, was presented to the Commission in November

2019. The licensee implemented corrective actions including increased monitoring with a direct reading dosimeter. All doses recorded during the six-month period and after the event were normal. The individual has shown no health consequences and none are expected, and the event is closed.

Next, we'll move on to the Level-2 event. The INES Level-2 event involved a nuclear energy worker who exceeded the whole-body dose limit of 50 mSv. The licensee's investigation did not reveal a specific event that could account for the elevated dose result. However, the investigation did indicate that the dosimeter reading was likely due to local contamination on a badge and that the majority of the dose recorded on the badge was non-personal.

The CNSC issued a return to work authorization for this worker on December 20th, 2019.

A dose change request form as not been submitted for this worker to this day. The individual has shown no health consequences and none are expected.

CNSC staff presented this event to the Commission in the form of an EIR in June 2020.

In contrast to other sectors regulated by

the CNSC who have similar licensee types, the nuclear substance and prescribed equipment sector is diverse and dispersed across the country. That is why we must recognize the importance of regular broad, as well as targeted communications within the regulated industry.

Stakeholder engagement and outreach are critical elements of the CNSC's regulatory approach. Given the breadth of licences regulated in the area of nuclear substances particular focus is on reaching and engaging with the licensee communities, which leads to increased awareness and better understanding of the regulatory process and requirements. This, in turn, can lead to improved workplace safety.

CNSC staff leverage a variety of fora to engage with licensees to promote the use of tools that are developed to support the compliance with regulatory expectations.

Inspections are a particularly valuable opportunity to engage directly with licensees.

In 2019 CNSC staff participated with stakeholders through industry working groups like the Industrial Radiography and Canadian Radiation Protection Association working groups. Other events included

presentations to a school and participation in outreach with indigenous groups from Transport staff in Ontario and New Brunswick.

CNSC staff also held a virtual townhall meeting for accelerator and Class D Facilities Division licensees to discuss regulatory changes.

In 2018 case studies were added to the ROR. This was done to provide examples of the regulatory activities that may be of interest. In 2018 we presented case studies for the nuclear medicine and portable gauge subsectors.

For this year, two case studies on licensees for the commercial sector are presented in the ROR. The first is a case study on Iodine-131 processing licensee, Isologic Innovative Radiopharmaceuticals Ltd. And the second is on a Positron Emission Tomography, or PET isotope cyclotron and associating processing laboratories, Montreal Neurological Institute and Hospital.

The case studies are not intended to be punitive; they are intended to demonstrate lessons learned from the Regulatory Oversight perspective and actions taken by the licensee that resulted in improvements to their programs. These lessons could be implemented by other

licensees.

I would now like to introduce Jonathan Schmidt who will be presenting the first case study.

MR. SCHMIDT: For the record, my name is Jonathan Schmidt, and I'm the Special Advisor to the Director General of the Directorate of Nuclear Substance Regulation.

In the next three slides I will be providing information on the regulatory strategy that was developed and implemented by CNSC staff to address a decline in performance at one of our Iodine-131 radioisotope production licensees.

As a brief introduction, Iodine-131 is a radiopharmaceutical that is used in the nuclear medicine industry for diagnostic and therapeutic applications which include diagnosis and treatment of thyroid disease, and diagnosis of neuroendocrine tumors.

Due to the high-risk nature of Iodine-131 production, there are only a small number of commercial facilities that are in production in Canada. These few facilities supply all of Canada and much of the United States. One of these facilities is operated by Isologic Innovative Radiopharmaceuticals Ltd., and was the licensee

involved in this case study.

In 2018, Isologic reported a worker extremity dose which exceeded regulatory dose limits at their Iodine-131 processing facility in Burlington, Ontario. This occurrence triggered a non-routine inspection of their production facility and a number of non-compliances were noted, which included, workers routinely not following the procedures relevant to Iodine-131 processing, and personnel monitoring.

In addition, CNSC staff concluded that the responsibilities for implementation and oversight of the Radiation Protection Program were not clearly understood and executed by licensee staff.

One month later, the licensee also reported an environmental release of Iodine-131 which exceeded their CNSC approved action level. In order to address the decline in performance and risk to the safety of the members of the public, workers and the environment, a designated officer issued an order to this licensee in December 2018.

In general, the order required the licensee to immediately cease all processing of iodine-131 until actions are taken to address the deficiencies in the

licensee's radiation protection program that were identified during the recent events in non-routine CNSC inspection. In addition, the order required the company to immediately make provisions to ensure an adequate supply of iodine-131 radiopharmaceutical products to Canadian patients throughout the time period of ceased operations.

Due to the potential impact of the order on the supply chain of I-131 radiopharmaceuticals in Canada, the CNSC took a collaborative approach in working with the licensee to return to compliance. This collaboration also included a diverse team of specialists from radiation protection, environmental protection, licensing, and compliance inspectors who performed detailed reviews of the monthly updates and standard operating procedures submitted by the licensee.

The licensee requested a two-phase approach to restart commercial activities involving iodine-131. Lower risk, diagnostic production was allowed to resume first in the current production area, while high-risk therapeutic production operations were transferred to a newly designed and constructed hotcell facility.

As a result of the construction of the new

facility, the terms and conditions of the order for therapeutic production were met in January of 2020, 13 months after the order was issued.

Once the licensee met all terms and conditions of the order, commissioning of the new I-131 production facility could begin. This commissioning was conducted in a phased approach and was very closely monitored by the CNSC. The authorization for routine operation of the new therapeutic production facility was granted in April 2020.

At present, the licensee now has a clear understanding of the CNSC regulatory requirements and has improved its worker training and management oversight practices. Rather than placing blame on workers for not following procedures, the licensee showed a questioning attitude to find corrective actions to address the deficiencies in the radiation protection program.

In this case, they involved production workers in the development and validation of operating procedures for the new I-131 production facility, including commissioning of the new hotcell with improved environmental monitoring systems.

The licensee has also demonstrated a

strong commitment to improving the safety of their I-131 production activities through increasing resources, such as hiring an additional on-site radiation safety officer so that all production hours are covered.

As observed by CNSC staff during the two compliance inspections conducted in 2019, the presence of radiation protection staff on the production floor has created a partnership with workers with the goal of continued safe operations. In addition, the licensee has worked to achieve fully compliant I-131 operations at this time and the reported monthly releases of I-131 to the environment remain low at less that 0.3 per cent of the licence limit.

Finally, the licensee has multiple sites spread across Canada. These operations also cover radiopharmaceutical production outside of I-131. The licensee is motivated to continuing best practice and is looking to implement improvements identified over the last year in other aspects of their operations.

This slide shares the regulatory lessons learned by CNSC staff from this case study. The CNSC uses a standard approach to regulatory oversight for similar nuclear substance activities across multiple licensees.

Based on the reported events and non-routine inspection findings, CNSC staff recognize that the licensed activities being carried out by Isologic Innovative Radiopharmaceuticals Limited did not fit well into the CNSC's standard approach to regulatory oversight for this type of licensed activity. As a result, CNSC staff developed a tailored regulatory oversight strategy using a facility assessment and compliance team to ensure that appropriate specialist support was included in the review of submitted documentation in the on-site compliance verification activities.

In addition, throughout the order closure process, the CNSC monitored the licensee's compliance performance very closely through monthly meetings with the licensee to review progress and discuss document submissions, including those related to the commissioning activities and licensing hold point for the new I-131 therapeutic facility.

The licensee has requested that regular meetings continue to occur, as they feel that there is value in maintaining their relationship with the regulator as it helps them to continuously improve.

In conclusion, CNSC staff's use of the

collaborative regulatory approach with a cooperative licensee has resulted in fully compliant operations at this time.

I would now like to pass the presentation to Mr. Abdul Alwani, who will present the second case study in this report.

MR. ALWANI: Hi, I'm Abdul Alwani, senior project officer in the Directorate of Nuclear Substance Regulation.

In the next three slides, I will be providing information on the regulatory strategy that was developed and implemented by CNSC staff to address a decline in performance at a medical isotope production cyclotron facility.

This case study is about one of the two dozen facilities around the country for producing medical isotopes from cyclotrons. This facility produces positron emission tomography isotopes. The produced radioisotopes -- usually carbon-11, nitrogen-13, oxygen-15, or fluorine-18 -- are processed in associated in laboratories to make conventional or new radiopharmaceuticals.

The production of fludeoxyglucose,

commonly abbreviated as FDG, a clinically approved product, is done fully using an automated process. However, research and development work on new radiotracers involves some direct handling of radio isotopes. Most but not all the processing is automated.

This particular facility is the oldest processing facility in the country. The hotcells used for the synthesis are not equipped with manipulators. The operator may need to access vials or syringes in the hotcell during certain steps in the process. It's important to note that manipulators, although not mandatory, are nowadays an industry standard.

In 2017, the licensee reported two instances of monthly extremity action-level exceedance for radiochemistry technicians working in the research isotope processing lab. Two other action-level exceedances for extremity doses were reported in 2018 too.

This coincided with the CNSC staff comparative study of compliance performance of the Class II radioisotope licensees with similar operation. The latter was eventually published as radioisotope production accelerator report card, the study showed that this facility has the highest extremity dose per produced

activity among similar licensees.

The reported decline in the licensee dose performance triggered an intensified CNSC compliance monitoring and enforcement using a variety of tools. CNSC staff increased the inspection frequency from the standard of once every four years to once every two years. The scope of the CNSC staff compliance inspections has been extended to cover more details of the licensee operation, including interviewing a large number of the workers in addition to the licensee representatives, or in other words, five-point inspection instead of Type II.

CNSC staff requested the licensee to conduct a comprehensive ALARA study and review all its operations involving handling radioactive materials. Furthermore, CNSC staff requested monthly progress reports from the licensee covering not only the maximum individual doses but collective doses and production grades. As the licensee reported working on initiatives to improve their handling techniques and processing procedures, CNSC staff followed up, encouraged, and discussed progress and plans with the licensee.

When all these steps didn't lead to a significant and persistent improvement, CNSC staff

exercised their power under the Act and issued an order pursuant to the act. The order imposed a temporary limit on maximum activity the licensee workers could handle under any circumstances. The cap would be lifted following the licensee providing convincing ALARA justification and dose reduction. However, instead of submitted a revised ALARA review to justify lifting the temporary limit, the licensee decided to incorporate the imposed limit as part of its permanent revised work procedure. Hence, the order limits became permanent and part of the licensee operation limits.

Since the order has been issued, there has been no new action limit exceedances from this licensee. In addition, the most recent annual compliance report shows a clear decrease in doses. However, CNSC staff continue to apply enhanced oversight until satisfied that the licensee's program has improved and the improvement is sustained.

It's also important to note that under 13 comparative studies of groups of licensees, such as the radioisotope production accelerator report card mentioned before, can help CNSC staff identify licensees with performance below industry standard. This leads CNSC staff to increase compliance monitoring focus and then take any

necessary regulatory actions.

I would like now to pass the presentation to Mr. Yani Picard, who will present part two of the report.

MR. PICARD: Hi, I'm Yani Picard, senior project officer in the Directorate of Nuclear Substance Regulation.

I will now provide an overview of CNSC's oversight activities for Class IB accelerators in Canada for 2018 and 2019.

There are currently two Class IB accelerator facilities in Canada, TRIUMF, located in Vancouver, British Columbia, and CLSI, located in Saskatoon, Saskatchewan.

TRIUMF is Canada's national laboratory for nuclear and particle physics research as well as a producer of radioisotopes. TRIUMF operates one 520-megaelectron volt cyclotron and diverse smaller accelerators under an operating licence issued by the Commission in 2012 for a period of 10 years. TRIUMF has been in operation since 1975.

CLSI operates a 2.9 gigaelectron volt cyclotron which produces synchrotron radiation that is used

as a light source for experiments in diverse scientific fields under an operating licence issued by the Commission also in 2012 for a period of 10 years. CLSI has been in operation since 2005.

CNSC staff monitor these facilities to provide assurance to Canadians of their continuing compliance and safety performance. This table presents CNSC staff's licensing and compliance effort for Class IB accelerator facilities in 2018 and 2019. CNSC staff spent a total of 23 person days on licensing activities related to Class IB accelerators. The total of 445 person days were dedicated to compliance activities, which included inspection of these facilities, licence activities, and processes, as well as desktop reviews of licensee reports.

An increase in compliance activities can be observed in 2019 due to the implementation in both facilities of CSA Standard N286-12 Management System Requirements for Nuclear Facilities. This increase in compliance is notable for CLSI, which had a management system inspection in 2019. More details on the implementation of CSA Standard N286-12 will be provided later in this presentation.

CNSC staff performed a total of six

compliance inspections at the Class IB accelerator facilities in 2018 and 2019. CNSC staff provided all the inspection findings to the licensees in detailed inspection reports. CNSC staff conducted consistent and risk-informed regulatory oversights at the Class IB particular accelerator facilities.

CNSC staff used the SCA framework in evaluating each Class IB accelerator facility's safety performance level. Each SCA is rated through compliance inspection, desktop reviews of events and incidents, and in all compliance reviews. These ratings serve as performance indicators and identify potential areas requiring attention from the licensee and CNSC staff.

CNSC staff develop compliance oversight plans by taking into consideration a number of factors including these ratings. CNSC staff will plan escalated enforcement on any SCA rated below expectation or less until the situation is remedied.

This table provides the performance rating for TRIUMF for 2018 and 2019. For this period, all individual SCAs were either satisfactory or fully satisfactory, with the exception of management system SCA, which was rated below expectation for both years. More

details regarding the management system SCA as well as the radiation protection and conventional health and safety SCAs will be provided later in this presentation. Overall, these ratings indicate adequate management in safety and control measures at TRIUMF.

This table provides the performance ratings for CLSI for 2018 and 2019. For this period, all individual SCAs were either satisfactory or fully satisfactory with the exception of management system SCA, which was rated below expectation for 2019. More details regarding the management system SCA as well as for the radiation protection and conventional health and safety SCAs will be provided later in this presentation. Overall, these ratings indicate adequate management and safety and control measures at CLSI.

Part Two of the DNSR ROR focuses on the following three SCAs: management system, radiation protection, and conventional health and safety. These SCAs provide important key performance indicators of the safety of these facilities.

The management system SCA was also selected due to below-expectation ratings that both TRIUMF and CLSI received for the period covered by this report due

to the implementation of CSA Standard N286-12 at both facilities. More details will be provided in the next slide.

The other two SCAs, radiation protection and conventional health and safety, were selected since the main hazards associated with Class IB accelerator facilities are radiological exposure and conventional industrial hazards. Nuclear substances are present as a result of deliberate irradiation of targets designed to produce desired isotopes or as an unavoidable by-product generated in irradiated air or accelerator components.

Furthermore, CNSC staff established and maintains a risk-informed analysis for each SCA for both TRIUMF and CLSI. This risk is based on estimating the probability of occurrence of an incident, either low, medium, or high, and the impact of the accident, either low, medium, or high. Although some SCAs are graded high for either the probability of occurrence or the impact, the conventional health and safety SCA is the only SCA rated high for both.

Highlights of these three SCAs for both TRIUMF and CLSI will be presented in the next three slides.

The management system SCA covers the

framework which establishes the processes and programs required to ensure an organization continuously monitors its performance against its safety objectives and fosters a healthy safety culture.

For years, both facilities have been operating their facilities safely under a management system which CNSC staff rated satisfactory except for one below-expectation rating in 2016 for CLSI.

In 2016, both TRIUMF and CLSI agreed to comply to CSA Standard N286-12 Management System Requirements for Nuclear Facilities by January 2018. With this agreement, CSA Standard N286-12 became part of CNSC staff expectations for the management system SCA in 2018.

As shown in this slide, both facilities had difficulties demonstrating compliance to N286-12, and this is the reason behind rating TRIUMF below expectation for both 2018 and 2019 and rating CLSI below expectation for 2019.

The below-expectation ratings do not introduce additional safety concerns; however, compliance to N286-12 may result in opportunities for improvements that will increase the difference in depth, resulting in an increased safety. The delay does not pose an immediate

risk to health and safety.

The radiation protection SCA covers the implementation of a radiation protection program in accordance with the radiation protection regulations. The program ensured that contamination levels and radiation doses received by individuals are monitored, controlled, and maintain ALARA. The rating for the radiation protection SCA for both Class IB accelerator facilities was satisfactory or better, which is unchanged from the previous three years.

These graphs provide the maximum and mean effective doses to nuclear energy workers for both Class IB accelerator facilities for 2018 and 2019. During this period, CNSC staff determined that all Class IB accelerator facilities implemented effective measures to keep radiation exposures and doses to persons ALARA. This has consistently resulted in dose to persons well below CNSC regulatory dose limits of 50 millisieverts per year.

Both TRIUMF and CLSI have put in place those action levels that, if reached, may indicate the loss of control of part of their radiation protection program. TRIUMF action level is 15 millisieverts per year, and CLSI action level is two millisieverts per quarter. In 2018 and

2019, there were no occurrences of those exceeding action levels at either facility.

CNSC staff conclude that for 2018 and 2019 the Class IB accelerator facilities effectively maintained their radiation protection programs to ensure the health and safety of nuclear energy workers and their facilities.

The conventional health and safety SCA covers the implementation of a program to manage workplace safety hazards and to protect personnel and equipment.

CNSC staff verified conventional health and safety at TRIUMF during the April 2018 inspection and again during the April 2019 inspection. CLSI's last conventional health and safety inspection was in 2017.

The rating for the conventional health and safety SCA was satisfactory or better for both Class IB accelerator facilities in 2018 and 2019.

A key performance indicator for the conventional health and safety SCA is the lost-time injury rate, which is presented in this slide for both TRIUMF and CLSI. A lost-time injury is an injury or an illness resulting in lost days beyond the date of the injury as a direct result of an unconventional injury or illness incident. The ultimate target is to have a lost-time

injury rate of zero.

In 2018, TRIUMF had one lost-time injury resulting in a rate of 0.15 lost-time injuries per 100 person-years. In 2019, there was an increase to four lost time injuries resulting in a rate of 0.6 lost time injuries per 100 person years. This is a factor of two more than TRIUMF's target key performance indicator of 0.3 lost time injuries per 100 person years.

To put the injury rate in context, WorkSafeBC, the provincial agency with a mandate to oversee a non-fault insurance system for the work place in British Columbia, has assigned trials in the advanced research classification unit along with similar businesses in British Columbia, such as institutions which provide post-secondary education including university, college, business and computer programs.

For both 2018 and 2019 the average lost time injury rate for the advanced research classification unit was 0.6 lost time injuries for 100 person years. Therefore, TRIUMF lost time injury rate was well below the average rate for the advanced research classification unit in 2018 and was on par with the average rate for 2019.

It is important to note that none of the

injuries were directly related to the licence activities. Nevertheless, to address the increase in lost time injuries in 2019 TRIUMF's Occupational Health & Safety Staff updated the pre-job hazard analysis and briefing form to provide more clarity to the workers on potential hazards.

In 2018 and 2019 there was no lost time injuries at CLSI.

CNSC Staff conclude that for 2018 and 2019 the Class 1B accelerator facilities effectively maintain their conventional health and safety programs to ensure the health and safety of persons present in their facilities.

In August 2018 when CNSC Staff presented the previous ROR for Class 1B accelerators the Commission expressed concern with the number of lost time injuries at TRIUMF. The minutes of the meeting contain an action item to CNSC staff to provide additional details regarding lost time injuries in future RORs. To address this action, CNSC Staff provided a description of TRIUMF's five lost time injuries in Table 25 of the written CMD.

The CNSC uses a graduated approach to enforcement to encourage compliance. When non-compliances are identified CNSC Staff assess the significance of the non-compliances and determine he appropriate enforcement

actions.

In 2018 and 2019 neither TRIUMF nor CLSI had enforcement actions beyond normal inspection follow-ups.

Similar to the licensees of Part 1 of this presentation, Class 1B accelerator facilities are required to have programs in place for the management of unplanned events and accidents.

The *Nuclear Safety and Control Act*, Regulations made pursuant to the *Act*, and licence conditions set out when licensees must report unplanned events to the CNSC.

For 2018 and 2019 TRIUMF had 11 events and CLSI had six events. None of the events resulted in injuries. For each event reported the licensees performed an internal investigation and implemented corrective actions to prevent reoccurrences. Both facilities reported these events to CNSC as required by the Regulations or the licence conditions. In each case, CNSC Staff reviewed the report and corrective actions and found them to be satisfactory.

Out of the 11 events at TRIUMF six were accidental releases of short-lived radioisotopes which

resulted in a combined estimated maximum dose impact to the public of 120 nanosieverts or 1/8000th off the regulatory dose release limit.

Class 1B accelerator facilities have a responsibility to inform the public about their nuclear facilities and activities.

CNSC Staff recognize that Class 1B accelerators are low-risk facilities and that a full-scale public information program, as undertaken by larger nuclear facilities, is not warranted.

However, the CNSC requires these licensees to provide open and transparent information to the public. The objective is to ensure that timely information about the health, safety, and security of persons and the environment and other issues associated with the with the nuclear facility are effectively communicated.

The public information and disclosure program was established in December 2018 for TRIUMF and in September 2018 for CLSI. CNSC Staff verified through annual compliance reporting that public information and disclosure programs were maintained satisfactorily during 2018/2019.

The CNSC has provided feedback on TRIUMF's

and CLSI's communications programs, including recommendations for improvement to ensure that the program remains effective at communicating useful information to the public.

I will now turn to Karen Owen-Whitred who will deliver the rest of the presentation.

MS. OWEN-WHITRED: As per our standard process, the CNSC posted the draft ROR for comments prior to presenting the report to the Commission in order to provide the regulated industry, civil society organizations, Indigenous communities, and the Canadian public time to review and provide insights on the information covered in this report.

The draft report was published for a 41-day comment period and participant funding was made available and awarded to the Canadian Environmental Law Association, or CELA.

Following the comment period, the CNSC received two interventions, one from CELA and one from the Canadian Radiation Protection Association, or CRPA.

We welcome the intervenors' suggestions for potential improvements to the report, which we will consider for inclusion in future editions as we work to

continuously improve our program reporting.

Following this Commission meeting, CNSC Staff will finalize and publish the report, making it available publicly along with previous editions of the report.

We have included full details of CNSC Staff responses to the interventions in an annex to this presentation. While I won't go through these one by one, I will take the next few slides to summarize some of the themes from the interventions along with the responses from CNSC Staff.

Beginning with the positive comments, the CRPA indicated that the ability of the public to watch Commission meetings and hearings via webcast remains helpful to licensee staff, both for gaining an increased appreciation of CNSC expectations as well as in gathering operating experience.

In addition, they wish to acknowledge their appreciation for CNSC Staff involvement with stakeholder engagement generally, but specifically for the ongoing participation in CRPA's annual conference and involvement with CNSC industry working groups.

In terms of recommendations for

improvement, we identified three broad themes. First of all, the intervenors noted a few factual errors in the ROR, some examples of which are listed on this slide. All of these errors identified by the intervenors will be corrected in the final version of the ROR.

Second, one common suggestion from the intervenors was to include other safety and control areas in the ROR. In particular, CELA suggested including more information related to the environmental protection SCA, while the CRPA pointed out the relevance of the packaging and transport SCA to the industry.

The CNSC response to this suggestion comes back to balance. We want to provide sufficient meaningful information in the ROR without overwhelming the reader with data. The ROR is a focused regulatory oversight summary that conveys the annual status of various industry sectors at a relatively high level and is not intended to provide detailed information on every SCA.

The SCAs used in the ROR are selected because they are the most indicative of overall safety.

Presenting all SCAs would significantly increase the size of the ROR, which risks making it less accessible. While the performance in a subset of safety

and control areas are included in the ROR, it is important to note that all relevant SCAs are evaluated during assessments and compliance verification activities.

In addition, any unacceptable rating in any SCA would be included in the ROR.

All this being said, as they pointed out in their interventions, this is not the first time these intervenors have made similar comments in the past with the CNSC providing the same response.

This indicates that a more in-depth discussion is required to better understand these different positions.

This brings me to plans for an upcoming CNSC discussion paper on the subject of RORs, which I'll cover in more detail in the next slide. The final theme that we identified within the interventions covers a variety of suggestions for improvement in the scope or content of the ROR. A few examples of these suggestions are listed on the slide.

This is a common theme raised by intervenors for essentially every ROR presented by CNSC Staff. Since their inception, the nature of these reports has evolved somewhat over the years, and we've heard

different requests from different stakeholders for what they would like to see. In reaction to this, the CNSC is planning to publish a discussion paper on the RORs in late 2020 or early 2021. The purpose of the discussion paper would be to solicit feedback from all interested parties in the ROR process.

The publication of the discussion paper would be followed by a comment period to allow submissions on potential changes to the RORs. We are recommending that all suggestions related to changing the content of scope of the ROR be raised in the context of this discussion paper. This will allow for a more fulsome discussion of stakeholder feedback as well as a more holistic consideration of these suggestions.

I will now turn to some closing remarks for this presentation.

Part 1 of this regulatory oversight report highlighted the CNSC's oversight activities for 2019 as related to nuclear substances and radiation devices. Based on the indicators covered in the report, as well as the results of all other relevant regulatory activities, CNSC Staff conclude that the use of nuclear substances and prescribed equipment in Canada continues to be safe.

Part 2 of the report covered the CNSC's regulatory oversight activities in 2018 and 2019 for the Class 1B accelerators.

CNSC Staff conclude that for the reporting period both TRIUMF and CLSI made adequate provision for the health and safety of workers, the protection of the public and the environment, as well as Canada's international obligations.

In closing this presentation, I would like to highlight the conclusion that was recently drawn by an international team of experts as related to the sectors covered by this regulatory oversight report.

In September 2019 an international team of senior nuclear and radiation safety experts met with the CNSC and other Government of Canada Staff to conduct an Integrated Regulatory Review Service, or IRRS, mission. The purpose of the IRRS mission was to perform a peer review of Canada's regulatory framework for nuclear and radiation safety against IAEA Safety Standards.

The mission was also used to exchange information and experience between the IRRS team members and Canadian counterparts.

The IRRS team carried out the review in

the following areas: responsibilities and functions of the government; the global safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities of the regulatory body, including authorization, review and assessment, inspection and enforcement, regulations, guides, nuclear safety and security interface.

The IRRS team conducted interviews and discussions with the Staff of CNSC and observed regulatory inspection activities. The IRRS mission found that Canada has a comprehensive and robust regulatory framework for nuclear and radiation safety covering current facilities and activities.

The CNSC strives to continuously upgrade its regulatory framework to address new challenges and upcoming technologies.

The full report is available on the CNSC website.

This conclusion is a mark of pride for the CNSC and exemplifies the hard work and dedication of CNSC Staff in conducting the activities that we have summarized for the Commission here today.

This concludes our presentation. Thank

you for your attention, and we are available to answer any questions the Commission may have.

THE PRESIDENT: Okay, thank you very much for the presentation.

Thank you again for the presentation and especially the case studies.

We'll now take a break and get back at 11:10 to start with the written submissions. So we'll see you then, thank you.

--- Upon recessing at 10:52 a.m. /
Suspension à 10 h 52
--- Upon resuming at 11:10 a.m. /
Reprise à 11 h 10

THE PRESIDENT: Welcome back, everyone.

We will now proceed with the written submissions filed by the two intervenors.

Marc, I will turn this over to you for us to lead us through the questions on this, please.

MR. LEBLANC: Thank you, Madam President.

I have two written interventions. I just want to remind the Members that those were written

interventions; that the intervenors are not available to answer questions. So your questions can be asked directly to staff or to Canadian Light Source or the TRIUMF representatives that are with us today.

The first submission is from the Canadian Environmental Law Association, as outlined in CMD 20-M23.1.

CMD 20-M23.1
Written submission from the
Canadian Environmental Law Association

MR. LEBLANC: I anticipate there are questions for Commission Members so we will start with Dr. Berube.

MEMBER BERUBE: Actually, I have no questions on this particular submission and I am satisfied with the staff dispositions at this point.

MR. LEBLANC: Thank you, Dr. Berube.

Dr. Demeter?

MEMBER DEMETER: Yes, I'm happy with staff's disposition of the matters. I have no specific questions.

I do have some environmental questions but

they are not included in the intervenor right now. So I'm happy.

MR. LEBLANC: We will have a round of questions after for those general questions. Thank you.

Dr. McKinnon.

MEMBER McKINNON: Yes, thank you. Just a comment to start with.

I was very pleased in the last presentations to hear that there will be an upcoming discussion paper on the RORs. I think that is a very good idea and it will capture a lot of the questions that commonly come up.

I do have one minor question for CNSC staff. It was something brought up by the CELA intervention.

It was in connection with announced versus unannounced inspections.

I'm just curious. They probably each have different demands on the licensee. So could you describe the differences in how the inspections are carried out and how extensive each type would be?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

To provide a little bit more information on unannounced versus announced inspections, I will turn first to Mr. André Bouchard and there might be some additional information that could be provided by staff in that division as well.

So beginning with Mr. Bouchard, please.

MR. BOUCHARD: Thank you. André Bouchard, for the record. I am the former OID Inspector Director for the calendar period of that report.

Basically the criteria for inspections are already predetermined, whether they are unannounced or announced. What is the difference at the core of it is whether we give a heads-up to the licensee before going or we simply make arrangements through alternative means to be able to perform inspections. And that's what we consider to be announced versus unannounced.

Our experience, though, in nuclear substances and radiation devices is that we have done some unannounced and announced inspections, and the outcome of the inspection is not really affected whether the inspections are done announced or unannounced. We find ways to find what we need to find and address the issues.

MEMBER McKINNON: Okay, thank you very

much. That's all my questions.

MR. LEBLANC: Thank you.

Dr. Lacroix, any questions?

So while we try to get Dr. Lacroix back online, I will ask if President Velshi if she has any questions.

THE PRESIDENT: Maybe a couple of minor ones.

One was CELA's overall comment around making these reports more accessible and with greater detail to address the needs.

Can you maybe comment on how many people really access this report and what is the level of interest and in what quarters?

I'm simply trying to understand whose audience needs are we trying to meet besides those of the Commission.

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I will provide a high level answer. I will just be consulting virtually with my colleagues to see if we have actual numbers that we can provide you, because we do have those numbers. I'm just not sure if we have

them at our fingertips right now.

While we are looking into that, I can say that for this particular -- well, for both parts of this report that we presented today, in general the interest as judged by the number of hits we have accessing the report online are quite low.

For Part 1 in particular, the majority of comments or interest that we tend to get are from industry itself, so from the licensees, and CRPA, which effectively as an industry association is representative of what it is that licensees are looking for, the content of the RORs for them. It would be more along the lines of operating experience and lessons learned.

So we don't tend to get a lot of interest or comments from audiences outside of that sector essentially.

THE PRESIDENT: Thank you. And I suspect when you do your ROR review you will get a better handle on exactly what the needs are.

Maybe I will turn to TRIUMF and CLSI. Maybe you folks can comment on what do you do with this report once it's issued?

MR. BAGGER: This is Jonathan Bagger, from

TRIUMF.

Can you hear me?

MR. LEBLANC: Yes, thank you.

MR. BAGGER: So we circulate this report among our safety teams and our quality teams so that we're aware of the findings and the recommendations that are in this report. We use it to provide context. We use it to -- well, frankly, to motivate ourselves to continue to keep our improvement process cranking along.

Then any particular highlights we also communicate to staff further down the line.

THE PRESIDENT: Thank you.

And maybe before we move to CLSI, as far as CELA's particular comments that there should be other SCAs included, like environmental protection and so on, what are your thoughts on that? Or are the high level ones, the critical ones that staff have assessed, do those meet your needs well?

MR. BAGGER: So from TRIUMF's point of view, the critical assessments I believe are the most important because they are the ones where we need to place our focus and improve for the next reporting period. If there were an appendix with all of the SCAs, that would be

fine because it would be captured for the record.

But we need to focus on the most important issues and it helps to have you work with us to identify what those are.

THE PRESIDENT: Okay, thank you.

CLSI?

MR. CUBBON: It's Grant Cubbon here, for the record.

Yeah, I would say we have a similar approach. We share the preliminary report with our executive at CLS, managers and actually our board as well. Then once the final report comes out, we will share that with our staff as appropriate and again use that as a means to assess what issues we have and what we need to do to improve.

THE PRESIDENT: All right, thank you.

Marc, if I may, I have one more question on the CELA intervention and this is to do around medium -- I'm not quite sure if it's medium priority or medium risk inspections.

Given what you said, there were a couple of things in your presentation. One was that you would increase the frequency of the medium risk licensees because

there was a downward trend in performance in certain areas and inspections seemed to help on the trend.

But you also said that during COVID the priority has been on the high risk ones.

I'm just wondering if we were to fast forward to next year, what's the likely impact of that even though today you have said there has been no safety impact or you don't expect any?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I will provide a high level view but then I will also leave it open for my colleagues within the inspection group if they want to provide a little bit more detail.

So as you've noted, this year with the challenges that we've encountered in performing inspections, particularly on-site inspections, the total number of planned inspections has gone down. As you said, within that decreased number our focus is specifically on those high risk licensees.

So what we would expect to see next year is an increased number of planned inspections for those medium risk licensees which we had intended to inspect this

year and weren't able to. So it is possible that we will see those numbers go up next year.

What I would do is I will ask either Mr. André Bouchard or Mr. Mathieu Laflamme who could provide a little bit more information on what we anticipate for next year at this point.

MR. BOUCHARD: André Bouchard, for the record.

So basically from this year we will review the amount and the inspections we were able to do, taking into account our capability of doing remote inspections as well as on-site.

In addition to that we will also factor in annual compliance report as well as event reports and other performance data that we have in order to determine and refocus our priorities and resources in light with our commitment to really dive into the medium risks and some of their performances as well.

This is how we are reshuffling and adapting to a continuously evolving situation of COVID.

MR. LEBLANC: Thank you.

Any other questions from the Members? I don't see any raised hands.

Dr. Lacroix is having some technical difficulties but was able to come back to us.

So, Dr. Lacroix, we are still with the interventions from CELA and we are wondering if you have any questions you want to ask.

MEMBER LACROIX: Concerning CELA, no. Most of the questions have already been answered by CNSC staff. So I am satisfied with that.

MR. LEBLANC: Okay, thank you very much.

So we can move to the next submission, which is from the Canadian Radiation Protection Association, as outlined in CMD 20-M23.2.

CMD 20-M23.2
Written submission from the
Canadian Radiation Protection Association

MR. LEBLANC: Are there any questions from the Members on this submission?

And I will start by asking you Dr. Lacroix, since --

MEMBER LACROIX: Yes, since I'm connected. That's great.

Yes, I do have a question.

While CRPA notes that the radiation protection safety and control area for nuclear medicine has been declining in the past five years and CNSC provides an explanation for this situation. But on the other hand CNSC staff points out that the corrective actions implemented by the poor performing licensees were not effective in solving the issues.

I was wondering why? Is it a question of lacking the training or the lack of desire to comply to regulations? Is it complacency by management? What is the reason for that?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I will turn once again to Mr. Bouchard to see if this is the type of information we have available at this time.

We do also have -- it speaks less to motivation perhaps but can still provide some information on the typical non-compliances that we see in this sector.

So I will start just to see if Mr. Bouchard can speak to the kind of intention or the cause behind some of those non-compliances as you

mentioned, and then perhaps we can provide further detail.

MR. BOUCHARD: André Bouchard, for the record.

So the areas of poor performance within the two radiation protection that we've observed in the medical sector are mainly focused around the conduct of thyroid monitoring, sampling and counting methods for contamination and monitoring as well as detection of loose contamination in their facilities and the management oversight of the RP program.

Those are the core areas that we are observing.

When we are discussing about focusing on the right measures, the key element behind that is whether we are focusing on the symptoms or trying to attack the disease here.

It is our observation that we need to focus the measures on how the licensees, the management of the licensees make sure that they are correcting their core issues rather than symptoms of the issues. And we are doing a shift on that.

MR. LEBLANC: Thank you.

Any follow-up question, Dr. Lacroix?

MEMBER LACROIX: No, I'm satisfied. Thank you.

MR. LEBLANC: Thank you very much.

Dr. Berube, any questions?

MEMBER BERUBE: No questions, thank you.

MR. LEBLANC: Thank you.

Dr. Demeter?

MEMBER DEMETER: Thank you.

Thank you for the report as well. I forgot the first time.

I'm looking at slide 32 of the staff slide deck, and I just want to reiterate the observation that was made, Dr. Lacroix, by CRPA about the decline in RP for medical licensees. It was always below the pack and in the last five years it's gone down 10 per cent.

Some hypotheses have been put forward on why that is. It's still disconcerting and I think it needs a way of being turned around

The question I ask for CNSC is have you noticed that our current kind of fiscal situations in hospitals and healthcare, this continuous look at austerity measures and reducing costs, has that had an impact on the operation of radiation detection program? Is that one of,

as you called it, the symptoms of the disease or cause and effects? Is that one of the causes, do you think?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

Before attempting to answer the specifics of your question, I would just point out that this is a trend that we are also of course very much aware of and of course keeping an eye on.

We did spend a lot of time in last year's report discussing this in particular and talking about the regulatory response that we have initiated in order to address this declining trend.

That is still in place and there is still an expectation on behalf of the CNSC that these trends take some time for us to see the impact of our regulatory action. So we are still expecting to see some improvements with respect to the changes that we have already instituted within our approach to compliance.

I will start then, just to come back to your specific question about the impact of the fiscal situation of these institutions, I'll start again with Mr. Bouchard and then we might be able to pass it on to somebody else for some more detail.

MR. BOUCHARD: André Bouchard, for the record.

I will pass it to Mr. Mathieu Laflamme for the details. But from a high level we are observing from province to province some differences in the performance in the way the medical, especially the provincially operated medical facilities are performing. And we are observing that as a trend, depending on the province.

Further study of the data would be needed to be able to really focus and target on whether it's a resource issue or whether it's a training issue. And sometimes it's simply a human performance issue.

So I'll let Mr. Mathieu Laflamme give more details.

MR. LAFLAMME: Mathieu Laflamme, for the record. I'm a Project Officer in the Operations Inspection Division.

It is difficult to determine the actual cause of all these increase in trends over the past years. But what I can say is that the majority of the non-compliances being observed are towards the thyroid monitoring requirement which is a licence condition that requires thyroid screening to be performed within a period

of more than 24 hours and less than five days after handling a radioiodine in the amount set out in the licence condition.

What we are finding is that in a majority of cases for nuclear medicine licensees they are conducting thyroid monitoring, but we are observing that they haven't done it in one or some occasions over the past few years. That would result in a non-compliance and that would directly result in a below expectation in the SCA regardless of the risk of that actual non-compliance.

MEMBER DEMETER: Thank you very much.

MR. LEBLANC: Thank you.

Dr. McKinnon?

MEMBER McKINNON: No further questions, thank you.

MR. LEBLANC: Yes, President Velshi.

THE PRESIDENT: Maybe a follow-up on slide 32 again.

While we focused on the medical licensees, that downward trend is for all of them, other than the academic sector. Maybe you can refresh my memory, because I thought what I heard as far as what the CNSC was doing with this, it was going to be monitoring the situation.

Are there other interventions that the CNSC is doing when it comes to this particular SCA?

Again, if you look over the last four or five years, yes, it is generally a downward trend.

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

Again I think a couple of points just to clarify off the top.

First is that with our switch to more of a performance based inspection approach and particularly focusing on lower performers, we do expect to see some impact in a positive direction from that regulatory approach.

The issue is that it certainly does take time between the cause and effect. So while the trend does continue to be downward, we do anticipate that that will turn around within the coming years.

The other point I want to reiterate is what Mathieu just shared with us, which is that even one non-compliance in one specific area related to the safety and control area can result in this below expectations rating.

So what I think is important to remember

is that although the trends are going down, and we can all see that and it is absolutely important and something that we are keeping a close eye on, the risk significance is not as high as perhaps the graph makes it appear.

I think what I will do, as well, is refer to Ms. Caroline Purvis who might be able to provide a little bit more insight into the specific safety and control area.

MS. PURVIS: For the record, it is Caroline Purvis. I'm the Director of the Radiation Protection Division.

I think what I would like to add to this is radiation protection should be the focus of all in sections, and certainly it is for this type of licensee.

What the CNSC is doing to hopefully communicate better our expectations in the safety and control area is we are in the process of finalizing regulatory documents for radiation protection. They are expected to be before the Commission for approval in the spring of 2021.

What those documents will do is provide comprehensive guidance on CNSC expectations, touching on some of the areas where, for example, in the nuclear

medicine domain where they have had some troubles meeting expectations.

It is anticipated that this new guidance will assist licensees in this regard.

Further, CNSC staff are in discussions with the CRPA to have a workshop with their members on the contents of those regulatory documents and allow them the opportunity to ask questions.

So we are looking forward to that and hopefully we will see some improvements.

THE PRESIDENT: Thank you very much.

MR. LEBLANC: So I cannot see at the moment if there are any raised hands.

So do any of the Members have additional questions on this matter?

If not, Madame Le Président, we can proceed to open the floor to Commission Members for other questions on the Regulatory Oversight Report.

THE PRESIDENT: Okay. Why don't we start with Dr. Demeter?

MEMBER DEMETER: Sure, thank you.

The question I have relates to TRIUMF, and both maybe TRIUMF and CNSC staff may answer different

parts.

There are comments on C-11 gas releases and they talked about a number of them, and they talked about overall radiation impact on the public was negligible.

I was curious from CNSC staff, because they have to have a public info and disclosure program, do they have to notify the public of each of these releases? And if they do, from TRIUMF, what do you do? What information do you release to the public when you have an untoward C-11 gas release?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I suspect, as you said, part of this answer will come from the licensees as well.

For our part, I will go to Mr. Mark Broeders to provide an answer from the perspective of the CNSC staff.

MR. BROEDERS: Good morning. Mark Broeders, for the record. I'm the Director of Accelerators and Class II Facilities Division.

In general, the public information disclosure program is designed to meet the needs of the

stakeholders for each licensee. So by its very nature it's customed for each licensee, for the stakeholders in that vicinity or people who have an interest in the operations of that facility.

I'll perhaps leave it to Mr. Yani Picard to provide details of what information is actually posted.

MR. PICARD: Yani Picard, for the record.

Yes, every single release that TRIUMF has would contact the duty officer first, so that CNSC is informed. But they also have their public information and disclosure program and they have to post it on their website within a certain period of time. I can't remember if it's 24 hours or 48 hours. And they stay there -- like you get a history of releases, so you can consult in any time since they put the public information and disclosure program starting in -- I believe it's April 2018. So if you go on their website you'll be able to see all the releases.

MEMBER DEMETER: And TRIUMF, do you get a sense of how many hits you have on that? When you post this, do you get feedback, do you get data that tells you the metrics of how you're reaching people?

MR. BAGGER: So that's a very good

question.

So first of all, you should know that TRIUMF takes every single release very seriously and we do investigate them and try to implement corrective actions, both engineering and process controls.

We do communicate frequently -- well, relatively frequently with our community. We reach out to them annually for a meeting of -- with their -- with the community board to explain what we do so that they have comfort with what's going on at TRIUMF.

And we also then post every one of these releases on our website, as Yani mentioned.

This was a Board decision to have a zero threshold, so these are tiny releases that we're posting to the public, but the threshold is set at zero so that people have confidence that we're not hiding anything.

Now, that's a discussion that we should continue to have with CNSC as to whether that is the appropriate approach because it does lead to some very small releases being put on our website.

I do not have statistics for how often we have hits on that page. I can try to get them for you.

We certainly do not have people calling us

out of concern. There's no feedback at all, actually, from the community except through this annual meeting we have with the community association.

MEMBER DEMETER: Thank you. That answers my questions.

THE PRESIDENT: Thank you.

Dr. McKinnon.

MEMBER McKINNON: Yes, thank you.

I was very pleased to see the case studies in the report. I was very interested to read those.

But in connection with the I131 processing facility, there was a statement that said the goal of CNSC Staff was to assist the licensee to significantly improve their programs to prevent reoccurrences of similar events moving forward.

Now, this could actually be taken as a definition of how a consultant might work with a client, so my question is, really, where is your boundary? How do you define that boundary between being an advisor and a -- or a consultant and, on the other hand, being a regulator, you know, and defining the roles and responsibilities of the regulator versus an advisor?

If you could discuss that, please. That's

for CNSC Staff.

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

In a moment I'll go to Mr. Jonathan Schmidt, who is very well familiar with this particular case, but with respect to the particular phrase that you read out, it's perhaps unfortunate wording that led to that interpretation, and I can understand how you would get that interpretation.

The intent was to say that of course the responsibility for safety lies with the licensee and then it is CNSC Staff's responsibility to assess compliance against our expectations.

That being said, we do take our role of compliance promotion to be an important role as well and, in this case, as you saw in the case study and as Mr. Schmidt can provide some more details, we did work with the licensee perhaps more actively than in other cases with other licensees.

But we understand the boundary that you were just referring to and that there is certainly a difference between a regulator and a consultant, and compliance promotion is not the same as providing that

level of assistance or support to a licensee that you would see from a consultant.

So just from that higher level response, I'll ask -- I'll turn it over to Mr. Schmidt to provide a little bit more information on this case.

MR. SCHMIDT: Jonathan Schmidt, for the record.

So in this case, I think one of the major things that CNSC Staff did is we increased our interactions with the licensee. So because of the -- we found out because of the reactive inspection and the events that were reported that it would be very complex, the solutions that the licensee would have to put in place, to come back into compliance.

And to facilitate that compliance because we're talking about an industry that provides unit doses radiopharmaceuticals to a wide portion of the country in Canada, we wanted to ensure that it would have limited impact on patients, so we started a monthly meeting with Isologic Innovative Radiopharmaceuticals to discuss with them, well, here's the order, here are the requirements in the order, what work are you doing. Is it moving in the right direction?

And we were -- provided that promotion or kind of guidance was in our operational guidance. We've experience with other processing facilities in the country and we were able to share that experience with them so that the licensee could come to a solution that would meet our requirements.

So I think overall, it was just increased interactions with the licensee but, in the end, it was up to the licensee to meet the expectations in order to bring themselves back into compliance and ensure safety and protection of the environment.

MEMBER McKINNON: Okay, thank you.

I agree it's very important for the regulator to be approachable and there will always be certain grey areas, but it's important to keep that boundary in mind, so thank you for the discussion on that.

THE PRESIDENT: Thank you for that question, Dr. McKinnon.

Dr. Lacroix.

MEMBER LACROIX: Thank you. Yes, I do have a question.

On page 4 of the ROR, it is mentioned that most of the enforcement actions and, as a result, the

non-compliance are taken against licensees in the industrial sector, but I've also noticed that 59 percent of all the licensees are in the industrial sector.

So my question is that would you reach the same conclusion if you present the results as the number of non-compliances per licensee would it be comparable to the medical sector, for instance?

So that's the fist part of my question.

And the second part of my question is that I've noticed that most of the non-compliances in the industrial sector are related to the portable and fixed gauges. Is it due to the fact that most of the activities in the industrial sectors with respect to nuclear substances are related to gauges or, again, is it a question of training or what is it?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I just want to make sure that I've correctly understood the first part of your question.

So as you point out, the majority of enforcement actions were within that industrial sector, but you're asking whether if we reframed the number of licensees if we would still see the industrial sector as

being the highest --

MEMBER LACROIX: Right, exactly

MS. OWEN-WHITRED: -- results?

Okay. So if you'll give me just -- if you'll bear with me just a moment while I confer virtually with my colleagues.

Okay. Thank you.

I don't know that we have the statistics in front of us today that would be able to provide that answer that you're looking for, so that might be something that we'll need to come back to.

But if we can set aside the first part of your question, then, and look to the second part, which was --

MEMBER LACROIX: Right.

MS. OWEN-WHITRED: -- related to portable versus fixed gauges.

So for that, I think I'll start with Mr. Andre Bouchard to see if we can get you an answer to that part of your question.

MEMBER LACROIX: Okay.

MR. BOUCHARD: Thank you. Andre Bouchard, for the record.

It's really important to understand that the report currently discusses enforcement and then what you see permanently is orders.

CNSC Staff has several tools for enforcements that are being used regularly in order to bring licensees back into compliance, and it is a very important discretion that the inspector must take in order to determine the right tool for the right solution.

One of the -- one of these observations that we realized over time is that it depends on the situation you are. As an example, often a portable gauge user is alone in the field performing some unsafe -- unsafely, right, and our inspectors are there and they must make it safe at the very moment, so the choice often is an order at the very moment.

Back into a medical environment in a nuclear medical lab where there are several people around, there's handling going on, there's less high hazard immediate risks and there are other means that an inspector could determine or use to be able to bring the situation back to safety and compliance.

And this is what makes the difference between the number of orders for portable gauge in

industrial versus the medical sector. It doesn't mean that we don't take actions, but they're different actions tracked differently.

MEMBER LACROIX: Great. Thank you.

THE PRESIDENT: Dr. Berube.

MR. LEBLANC: Before, Madam la présidente, Ramzi would like to add to this item.

THE PRESIDENT: Okay.

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

I would like to complement Mr. Bouchard's answer. Dr. Lacroix, the question that you asked is what is the extent of condition or root cause for such activities, and you mentioned training.

I'd like to explain the fact that, as was mentioned by Mr. Bouchard, our inspectors are in the field. If you look at the portable gauge or industrial application for radiography portable gauge versus fixed gauge or other type of practices or nuclear substances, portable gauge industrial radiography, there are no physical barrier between the operator and the machine, so in other words, the training and the implementation of the administrative protocols to expose the source, to remove the source and

following those -- to be followed by the worker are key, so hence you see our inspector oversight in accordance to our prescribed requirement that there are established by the radiation protection program.

So the question and what you're looking at is, there are no physical barrier. For example, fixed gauge, there is a shutter that opens and closes, whereas when you're doing a radiography, you are manually exposing and extracting the same thing with the portable gauge.

THE PRESIDENT: You okay, Dr. Lacroix?

Okay. Dr. Berube.

MEMBER BERUBE: Yeah, my question has to do with both accelerator sites, and particularly looking at the management systems below expectations. Looking at adoptation of the CSA N286-12, I was looking at the CMD20-M23, page 11 where basically -- you highlight basically the issues with implementation at both of the nuclear facilities.

And my curiosity -- it's not curiosity, but what I find is your statements here are a little bit vague, and I'm trying to understand particularly what the problem with the implementation of 286-12 is, if you could give me some definition on that in terms of the management

systems.

And I believe also there was some communication about management engagement in one of the sites, too. Could you highlight what that might be as well?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I'll turn to -- Mr. Mark Broeders can give you some more information on the specifics of the licensee and their interactions on this safety and control area, and I'll also ask Mr. Pierre Lahaie to provide some more details on that actual CSA standard.

So we'll start with Mr. Broeders, please.

MR. BROEDERS: Mark Broeders, for the record.

As Ms. Owen-Whitred explained, the five-year trend that we provided in the report demonstrates that the licensee previously had satisfactory or better grading in the management system CSA, and that's because they complied with the expectations at that time. So this is more of a case of the licensee not responding quickly enough to a change in expectation, increased expectations, that is, N286-12.

There is different reasons in both cases as to why there was a delay, but that delay led to this below expectation grade because, in our opinion, there wasn't sufficient progress in the time allotted for -- to meet the new and agreed-to requirements in N286-12.

For the specifics of that kind of delta between the old and new expectations, I would ask Mr. Lahaie to speak in more details about that.

MR. LAHAIE: Good morning. Pierre Lahaie, for the record.

I think to answer the question, the first thing I would say is we need to understand what the previous requirement was for these licensees. And it wasn't actually a standard; it was a set of high level quality assurance principles that applied to safety-related activities and items, so it was very focused on a few key activities.

The N286 standard that was issued in 2012 was expanded to apply to a larger base of licensees and licence activities and it required, based on its nature as being a standard and its focus being safety, its -- excuse me.

It requires a little more discipline in

terms of understanding all the requirements and applying them across all activities and essentially all safety control areas.

So to give you an example, you're not only interested in quality through your management system, you're interested in performance in all SCAs. So having the core management processes of documentation, corrective action, all of these things applying to the various SCAs brings higher performance, so when you ask an organization to go from what they understood to be a quality assurance requirement for safety only and now a management system requirement that applies to all areas, then that makes it a little more complicated and takes a little more understanding.

MS. OWEN-WHITRED: Karen Owen-Whitred.

Just I'd like to kind of wrap up what we've heard so far just by saying that this is an extremely important safety and control area, as Mr. Lahaie has just said. Of course, it underpins essentially all of the other safety and control areas.

So while the below expectation rating is certainly something that we want to monitor and ensure that we see improvement, the nature of the below expectations in

this particular case does not lead us to have any concerns with respect to safety. And I think it's important to have that framing in mind when we discuss this particular result.

THE PRESIDENT: Thank you.

And Mr. Bagger, before I turn to you on this, maybe I can add my other part of the question on the management system, which is I think we've said that full implementation is not expected until end of this year for TRIUMF, and I can't remember what it was for CLSR, but does that mean that the ROR for next year would still show them as below expectations or is it because they're working towards an accepted implementation plan that that doesn't make it below expectations?

Staff, can you comment on that first, and then we'll turn to you, Mr. Bagger.

MR. BROEDERS: Mark Broeders, for the record.

So as part of the implementation plan, the project officer works closely with the licensee to develop milestones to meet. As long as the licensee's progressing toward those agreed-to milestones, that would be a satisfactory response.

That's exactly the reason why we're in a below expectation scenario right now because we did not meet the milestones that we mutually agreed upon. But as Ms. Owen-Whitred correctly pointed out, we're not concerned if there's any, you know, immediate risk to health and safety but it's something that we wanted to be addressed in a timely fashion.

THE PRESIDENT: Thank you.

Over to you, Dr. Bagger.

MR. BAGGER: So I would just like to add that TRIUMF takes this SCA very seriously. Frankly, we deserve the ranking of below expectation. It's below our expectations as well as yours.

It took us too long to realize that we did not have the proper personnel in place to move us towards full compliance with N286-12.

We hired a new head of quality management last year, approximately a year ago. When he first came in, he immediately conducted a gap analysis that was finished in March, and we have been working since March to address the gaps that were proposed.

We will be inspected either at the end of this year or early next year by CNSC and I hope to have a

very positive report out of that inspection.

Thank you.

THE PRESIDENT: Okay. Thank you. Thank you for that.

Let's see if Commission Members have additional questions.

Dr. Demeter.

MEMBER DEMETER: Thank you.

Just a short question. So with the Montreal Neurological Institute study and it showed the extremity overdose, hand dose, it talked about an action level of 450 millisieverts where the dose limit is actually 500 millisieverts, and most times I've seen action levels that are quite a bit lower than dose limits.

And is there sort of rhyme or reason or how is this -- how that was decided? Because that's really close to the margin versus usually one order of magnitude below or at least half. That seemed unusual.

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I'd like to go to Mr. Abdul Alwani for this one to provide an answer to this question.

MEMBER DEMETER: Okay.

MR. ALWANI: Abdul Alwani, for the record.

Yes, that's true. That's the number of 450 millisievert per year is very high for action level, but the detail of the action level is a monthly action level extrapolated for the year, so it's a formula that is calculating that is if the licensee continues to operate at the same fashion for the rest of the year, that means that the action level has been exceeded.

So it's never going to be 450 and they never touch the 450. When you talk about the action level, it's the action level monthly that is 450.

MEMBER DEMETER: Okay. So it's one-twelfth the 450 would trigger it because you'd extrapolate to 12 times that.

MR. ALWANI: Abdul Alwani, for the record.

It's the formula that is agreed on the licence and it's something that is also -- it can be modified is that the licensee will have the -- for the first month of the year, it's that one over 12, but for the second month, there will be a little bit --

MEMBER DEMETER: Yeah.

MR. ALWANI: -- less because it's -- if it

continues. So there is -- and it's something we are considering changing so that it is -- basically it's -- that it don't take credit for good performance in the end of the year by relaxing the action level.

MEMBER DEMETER: Okay. Thank you very much.

THE PRESIDENT: Thank you.

Dr. McKinnon.

MEMBER McKINNON: Yes, thank you.

My question is related to the interpretation of the performance charts that we looked at earlier and the design of the inspection program.

So I noticed in the report it was mentioned in the operating performance SCA, for example, it prioritized overdue medium risk licensees over well-performing high risk licensees and then, in the radiation protection SCA, the focus is on licensees that had not been inspected in the last five years and some other factors.

And it was also mentioned that these changes in the inspection strategy caused changes in performance, so this seems like a very complex process if you have the same thing across all of the SCAs, especially

if it influences the performance metrics.

So my question is, is it possible to standardize the strategy or is each year sufficiently fluid that you always require a yearly tuning of your inspection program?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

My short answer to that is it is sufficiently complicated that there is an annual tuning, as you've said, required. We do -- and in a moment I'll turn to my colleagues who are responsible for this planning that can provide you more detail. But I just wanted to say off the top that there's a certain baseline rating or risk ranking, depending on the nature of the licensee, that would lead to our assessment of those different, you know, high, medium, low risk and, therefore, an associated inspection frequency.

We would never go -- you know, we don't go lower than that inspection frequency, but we can go higher, and that's what you're seeing, kind of the movement between the medium and high risk and the number of inspections carried out in any given year. And it is something that we do take into account the results, including the performance

results of the preceding year, does feed in as a continuous feedback loop for the coming year.

So I'll just stop just to see if that answered your question or, if you'd like a little bit more detail on the actual process, I can certainly turn to our experts on that.

MEMBER McKINNON: I was more interested in the higher level because it is -- certainly is -- does sound like very complicated and I suspect that that would be, you know, what the response would be.

But given that, my follow-up question is, based on the earlier discussion when we were looking at the performance metric charts and we noticed, you know, there was a certain trend of five to ten percent drop over a couple of years, given that your inspections change in their manner each year, what do you think the variability of -- like, how finely can we interpret those, you know? Is it plus or minus five percent or are we trying to over-interpret here because of that -- those factors that vary every year?

MS. OWEN-WHITRED: Karen Owen-Whitred.

MEMBER McKINNON: What's your impression of that?

MS. OWEN-WHITRED: Thank you. Karen Owen-Whitred.

I think for this I will go to the -- the experts in the different licensing areas who could provide a little bit more about precision that you're looking for. So, I'd actually like to start with Caroline Ducros in terms of the -- the inspection planning process for the waste nuclear substances which -- which have one approach as opposed to -- then, I'll turn to our -- the planning process for the nuclear substance licensees.

So, if we can start with Ms. Ducros, please.

MEMBER McKINNON: Yeah. And just one comment as context, this is really all about identifying trends and our ability to do that given these inherent uncertainties. Yeah.

DR. DUCROS: Caroline Ducros, for the record.

So, in terms of the waste nuclear substance licences, the Directorate of Nuclear Cycle Facilities Regulations has developed a risk ranking for all the facilities for which it regulates. And the waste nuclear substance licences are classified as low risk

activities.

So these are -- we have a ten-year baseline plan for inspections. And for the low risk activities we would do an inspection three times in that ten-year rolling plan. But, as you mentioned, annually we will also advise and review to see if there's any reason why we would need to augment that. So, the reasons could include past performance, or events that happened last year. We may want to go back and do a focussed inspection on a particular safety control area.

So the plans, as I said, are reviewed every year just to see that we are still -- it's still adequate oversight. And, that is how it is done for the waste nuclear substances licences.

MS. OWEN-WHITRED: Thank you for that. And now I'd like to go to Mr. Broeders to speak about the inspection process in his particular area.

And then after that, we'll go to M. Mathieu Laflamme that can speak about that inspection process.

Of course, there's a variety of licensees covered in these reports, so I think it's worthwhile talking a little bit about each of the different areas.

So, please, Mr. Broeders is first.

MR. BROEDERS: Mark Broeders, for the record.

So just to complement what my colleagues have already said, at a high level we use a risk index method to risk rank or licensees based on use type. So, use type is a collection of like licensed activities. You can think of it as a class approach, if you will.

That risk index method yields a relative risk ranking based on all fourteen SCAs where applicable. And, then that informs our choice of how we are going to prioritize our inspections. So, that relative ranking tells us, okay, this one is more important than that. And we take that whole cluster or constellation of inspections, look at the available resources, and that forms our baseline inspection plan.

From the baseline inspection plan, we use other signals to inform where we need to change focus to fine-tune from year to year.

In the context of Class-2, all inspections are peer reviewed after every inspection, and one of the outcomes of that discussion is, does this licensee still warrant the baseline inspection, or do we need to escalate?

And just to add a bit of flavour for COVID one of the things we're also considering is, was our mode of inspection sensitive enough to give us the comfort that this licensee is performing as well as we think, and if not, they'll be top of the list for when we can return to physical inspections.

To complement all of that, we did experiment with finding other ways to augment our sort of field experience to inform our planning for inspections. We did two things. One, is, we tried benchmarking, so we looked at the French regulators, the equivalent of their ROR, and looked to see if we can use it as a benchmark for our subsectors to see if our licensees are performing as well as our peers. That proved difficult because they don't quite segment their data the same way.

The other thing we did was experiment with something called statistical process charts, which is kind of like a moving average. It's meant to be a more sensitive way to detect trends. So, in Class-2 many of our licensees have very low dose. The risk there is more of an acute dose because of a failure in the safety system rather than a chronic low dose, so we -- we obviously -- or, we see routinely and expect to see very low doses in

radiotherapy, and so we experimented with statistical process control charts to do -- increase the sensitivity of -- of that signal, to give us an early warning that something actually is trending the wrong way, and it's not just a random variation.

That proved problematic, as well, because of the data that we receive is aggregate and it's binned into ranges. It's not the raw data. So, that wasn't as sensitive as we would like, so we are reliant on what we're learning in the field and from other compliance verification inputs such as annual compliance reports to inform our planning year to year.

MR. LAFLAMME: Mathieu Laflamme, for the record.

I can speak to the planning process for the nuclear substance and radiation device licensees. For the -- and the way the inspection plan works, we do have a five-year baseline plan which looks at all licensees and their locations, and each have an inspection frequency depending on their respective inherent risk. However, their inspection frequencies can be increased based on the performance of those licensees.

And every year we come up with a -- what

we call our high priority inspection plan for the year. And the way -- in order to determine what licensees we would target, or prioritize, we would look specifically at the performance of all licensees based on the inspections, based on doses received, based on events, and any enforcement actions that were taken.

We also look at during the previous year inspectors and the regional site supervisors, we look at the feedback that they give us, and we add some licensees that were identified to need additional oversight, and that allows us to adapt our inspection plan, depending on any emergent situations or any required follow-ups.

With respect to our inspection practises, we look at trends and we adapt to those trends and we focus our inspections or the way we conduct inspections accordingly, to respond to performance.

THE PRESIDENT: Well thank you for that.

Dr. McKinnon, did you have any follow-up comments or questions on that?

MEMBER McKINNON: That was most helpful. Thank you for that.

The only -- the only point which hasn't really been resolved is, you know, the impact on the trends

and the sensitivity of you know how we can assess the -- the data that is reported in the RORs. It was mentioned that we may need multiple years to see things unfold. That's one part. But, you know, within any year again is it a plus or minus five percent, or what are we looking at? Or, is it even possible to -- do we have enough to make any statements on that?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

Again, I think the short answer to that is we don't have that level of precision, it sounds like, that you're looking for at this time. As you've noted, the cause and effects cycle that we tend to see is over a matter of years, as opposed to in a year, certainly.

I think it's possible that we are able to draw some conclusions in each ROR because we're looking back one year already, and of course we have trending information in those reports. But, the particular level of precision that you're referring to in your question, I'm not sure that we have the data to provide that, or at least not at our fingertips right now.

MEMBER McKINNON: Okay, that's all. Thank you very much for that; it's very, very helpful. Thank

you.

THE PRESIDENT: Okay. Dr. Berube.

MEMBER BERUBE: So my question has to do with actually technology implementation that you referred to, the hot cell matter that we spoke about, in terms of actually some hot cells are still using mechanical manipulation versus automated manipulator arms. And my question to CNSC staff is, how do you actually get technology to move forward to a higher standard from an existing standard?

I understand fundamentally that we have regulatory limits which are usually non-prescriptive in nature. That being said, what moves the curve in terms of technology adaptation within operators because simply they might be using antiquated technology and that means more dose to individuals?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

I'm going to start with Mr. Broeders, who can perhaps speak to that issue of technology and moving the bar at a relatively higher level.

And then if you did have questions that were a little bit more specific to the hot cells and the

manipulators, we can certainly go into that level of detail, as well.

But I'll start with Mark from that generic piece of moving the bar with respect to technology.

MR. BROEDERS: Mark Broeders, for the record.

So, there's kind of two parts to your answer. The first is, when a new facility is constructed, the expectations tend to be higher. We expect them to meet the current best practices for similar licensees and emphasize constructed.

Where the challenge comes is perhaps older facilities where at the time they were constructed that was -- I wouldn't say state-of-the-art, but you know normal practise. And then when we started asking questions of licensees about, you know, we think we can do better here, or do you not think you can do better here, you know that's when the whole discussion about ALARA comes in and a second part of that, social and economic factors taken into account. So, if the licensee stays consistently below the regulatory limit then it really becomes a case of us as a regulator saying, 'I'm requiring some evidence to say you know this isn't as good as you could do.' And that's where

this -- this sort of comparative study that we did really came in helpful as Mr. Alwani discussed, and that we looked at similar licensees who had similar production and -- and objectives in terms of research versus commercial, and we were able to show them that, 'Look, you're not in the same league as similar licensees.'

That really gave us the -- the tools to influence a licensee to do what we want. I used the terms "influence" because, again, as long as they are below the regulatory limit, our options are more limited than if they go over our limit, in which case we have more tools available to insist on different approaches.

So maybe I'll ask Mr. Alwani if he wants to complement my answer?

MR. ALWANI: Abdul Awani, for the record.

The current requirements that we have for licensees is a standard requirement. It doesn't have the details with regard to the hot cell manipulators.

The activity that is handled in a hot cell, if the activity is high, or if the frequency is higher, the consequences then will be a higher extremity dose for the individuals. But what happened with this particular licensee, that there is an increase of use of

the hot cells much more than before, and that's also with the new technique, with the new experiments that they did, and that goes to higher exposure to the extremities.

The -- another constraint for this particular licensee is the space limitation, because the -- a number of hot cells located in that small lab and the licensee's argument is that this will not give enough room for people to go inside and outside, so there are some difficulties with retrofitting an existing hot cell.

But what we did is that we send the licensee a recommended a lot, the international reference and standard for the IAEA is that's providing information about the hot cell -- what's the best practise for hot cell design and it becomes really an industry standard having the hot cell.

In this particular case, also, when we found that the dose -- the dose rates are high, we have to -- we have to impose some restrictions on the operation to deal with that.

THE PRESIDENT: Okay. I don't see any hands up.

I've got a few small questions. Well, the first one isn't a question, it's more -- and it's again for

you, Dr. Bagger. It's probably a repeat of the discussion we had in August of 2018, and this is around the conventional health and safety performance, because what we've seen today it looks almost like what we saw a couple of years ago. And given the interventions that you have had in this last year, what does 2020 look like, just to see how effective those have been? From a standpoint of injuries.

MR. BAGGER: Yes, my expectation is that 2020 will be -- we will be hitting our -- our KPIs on the conventional health and safety.

The formalized pre-job briefing and job hazard analysis that is being rolled out as we speak, site-wide, should be having an impact by then. So there definitely is an increased focus on conventional health and safety at TRIUMF quite appropriately.

As you know, Anne Trudel retired as our Chief Safety Officer. We are now finalizing the search for a new Chief Safety Officer, and experience in the realm of conventional health and safety was also an integral part of that search.

THE PRESIDENT: Okay.

MR. BAGGER: So I think we'll be in a good

position going forward.

THE PRESIDENT: Thank you. I'm happy to hear that.

And then, Staff, a quick corrections and a couple of fine-tunes. On the INES Level-2 event for the nuclear substances licensees, very similar to what we discussed at the last Commission meeting, what's Staff's role in encouraging the licensee to submit to dose change requests?

And, if you were to receive a dose change request, say in a couple of months' time do we then retroactively change the results of this -- you know, this ROR, if it's, you know, the determination is that it is a non-personal dose, or there was not an exceedance?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

Just, I will just take the second part of your question first, and then I'll turn it over to Ms. Caroline Purvis to talk a little bit more about the theory of dose change requests and how CNSC staff manage or process those.

So if we did have a retroactive change in effect, it's something that we would just look at what is

the best way to communicate that. I'm not sure if going back and editing a previous ROR, as opposed to recording it as an item of interest in next year's ROR, or the following year's ROR. But that's just an off-the-top-of-my-head hypothetically how we would handle that.

So for a little more about those change requests and how we handle those, I'll go to Ms. Purvis, please

MS. PURVIS: Caroline Purvis, for the record.

So, we've talked about this certainly before and in the -- the instance you're talking about, we had a lengthy discussion in June about the circumstances around this. And from all indications the majority of the -- the dose recorded on the dosimeter is non-personal in nature.

And based on the Commission's recommendation to the licensee they should be positioned to provide an estimate -- a replacement estimate for the exposures of that worker over that quarter.

To date, it is my understanding that the licensee has not come forward with a dose change request.

If we just take a step back and look at

the process, more often than not, if the -- the investigation reveals a specific cause that could have led to let's say a non-personal exposure to the dosimeter, in the recommendation from the designated officer for the return to work, we would include text to compel the licensee to -- to pursue that dose change request.

In this particular circumstance, there was a fairly complex investigation and some assumptions had to be made in terms of what the cause was. Again, through the discussion that we had in June, I think it's the licensee is well positioned to move forward with that dose change request, and from -- from my point of view, our licensing folks which are the single point of contact with that licensee should continue that discussion with them to -- to move that forward.

THE PRESIDENT: Okay. So once again from the Commission to Staff, licensees should be encouraged to change the dose record because that is the official record that we want to make sure is accurate. And if licensees need some encouragement then we need to do that.

MR. DAVEY: If I could just add one additional comment to that? Michael Davey, for the record.

We did actually speak with the licensee

just a few months ago. I had asked the licensing specialist responsible for that, so they got in contact with them and they went over the dose change request issue again, and the licensee is looking at now applying for a dose change request and we're expecting that shortly.

THE PRESIDENT: Okay.

MR. DAVEY: But before the -- before our presentation was done, we still hadn't received it yet.

THE PRESIDENT: Okay.

MR. DAVEY: But we're hoping -- it should come shortly.

THE PRESIDENT: Okay, I'm very happy to hear that. Thanks very much, Mr. Davey, for that.

And my last question was, for the Class-IB accelerators where we have had, I think it was 11 at TRIUMF and 6 at CLSI, events, but we didn't see any INES level rating for those seventeen. So, is that something that's just done for the other licensees, the nuclear substances licensees, and we wouldn't do it for them, or were these all, you know, kind of Level-0?

MS. OWEN-WHITRED: Karen Owen-Whitred, for the record.

First of all, just with respect to your

question with INES generally, it is applied across the board, so there's not a difference between the different licensees applied here.

And I can confirm, as well, that they would all be considered zero, those events.

And INES, in particular, is specific to radiological events and a number of the events in question, as Mr. Picard said during the presentation, were other -- related to other issues, not to the radiological aspect of that facility -- of those facilities.

THE PRESIDENT: Okay, thank you. Thanks for that clarification.

Okay, I don't see hands up from any Commission members, so that concludes this particular agenda item.

Thank you all very much for the presentations, for responding well to all the questions that we have, to TRIUMF and CLSI for being here with us.

To the two interveners, as well, thank you very much for that.

We'll now take a break and come back at 1:30 p.m. for our next agenda item which is on the status report on power reactors.

So we'll see you then. Thank you.

--- Upon recessing at 12:21 p.m. /
Suspension à 12 h 21
--- Upon resuming at 1:30 p.m. /
Reprise à 13 h 30

THE PRESIDENT: Welcome back everyone. So let's move on.

On our agenda the next item on the agenda is the Status Report on Power Reactors as outlined in CMD 20-M34.

I note that we have representatives from the nuclear power industry and CNSC Staff joining us for this item, they can identify themselves later before speaking.

I wish to note that Mr. Gerry Frappier is joining us today for the last time before his retirement.

Mr. Frappier, I would like to take this opportunity to wish you a happy retirement and to thank you on behalf of the Commission for your dedication, professionalism and hard work. I learned a lot from you. We wish you all the best in this new chapter of your life.

I turn the floor to Dr. Alexandre Viktorov, the new Director General for the Directorate of Power Reactor Regulation. Dr. Viktorov, over to you.

CMD 20-M34

Oral presentation by CNSC staff

DR. VIKTOROV: Thank you. Good afternoon, Madam President and Members of the Commission. For the record, my name is Alex Viktorov, I am the new Director General of Power Reactor Regulation taking over from Gerry Frappier. With me are the regulatory and technical CNSC Staff members and representatives from the industry also in attendance.

The status report on power reactors, CMD 20-M34 was finalized on October 28th. The following are updates reflecting changes since that date.

For Pickering, Unit 1 is currently operating at 91.5 per cent of full power. Power has been reduced due to fueling deficit. Unit 5 is operating at 94 per cent full power, also due to fueling deficit. Unit 8 of Pickering is currently operating at 85 per cent full power. The reason for power reduction are related to

troubleshooting of a turbine governor valve.

For Point Lepreau, New Brunswick Power completed the reactor outage. The unit is presently operating at 35 per cent power and generator synchronization load is expected soon.

This concludes the update on power reactors. We are available to take any questions the Commission may have for us.

THE PRESIDENT: Thank you, Dr. Viktorov. I'll open the floor for questions from Commission Members to both CNSC Staff and licensees. We'll start with Dr. Demeter.

MEMBER DEMETER: Thank you. I just wanted a bit of an update and maybe a reflection on where we were and where we are now. We started at the last Pickering hearing hearing a request from school boards to provide KI pills to school boards to distribute to children. That's quite a while ago.

And that sort of very focused question has been turned into this KI working group which may have a much better application, but it just seems like a long time to get there.

Maybe someone can give me some sense of

timelines or where we're going to go with this, what started out as an initial fairly simple question from school boards to a two or three-year project.

DR. VIKTOROV: Due to the pandemic, as you understand, the focus of health authorities has already shifted somewhat from this particular aspect. The KI pill working group has been quietly working in the background, slower than anticipated.

I will ask Lee Casterton to provide an up-to-date statement on where we are.

MEMBER DEMETER: Okay.

MR. CASTERTON: Lee Casterton, for the record. I'm the Chair of the KI Pill Working Group.

Yes, you are right, some time has passed. This pandemic has caused a bit of a delay on our Phase 1 report. The Phase 1 repot is focused on what currently is in place in terms of public education and KI distribution. Because of the school board's interest, we created an advisory committee and this advisory committee does include Toronto District School Board as well as the Toronto Catholic School Board, as well as some other NGOs and other municipal authorities.

The purpose of that group was to have a

group that we could share the results of Phase 1 and Phase 2 with and hear directly from those organizations.

So we had initially planned to actually have a meeting with that advisory committee on the Phase 1 report following the public consultation or during the public consultation. But because that has been delayed, that meeting has been delayed as well. We did actually meet this morning with a number of the members of the working group and we are getting very close to concurrence on the report.

So we are anticipating that we will be sending it to translation in the coming weeks and that will facilitate the public review. Once we have that report out for public review we will be meeting with the advisory committee.

So we haven't set up a date yet, but I would anticipate it would be early in the next year, calendar year, and we'll be meeting directly with the school boards as part of that advisory committee and we'll be able to seek their input on what we've prepared in that Phase 1 report.

MEMBER DEMETER: Okay. I know COVID has hit the last year, but you know the date of the Pickering

hearing, which predated that quite a few years. So I understand there's some -- I remember distinctly at the Pickering hearing the licensee said anyone who wants KI pills can get KI pills. That was the initial starting point. And the school board said, we want KI pills. So this has resulted in like a four-year project.

So I would love to see this move forward and actually figure out a way for distribution that works for everyone. But thank you for your answer.

THE PRESIDENT: Dr. McKinnon.

MEMBER MCKINNON: I have no questions, thank you.

THE PRESIDENT: Dr. Lacroix.

MEMBER LACROIX: Okay. Can you hear me?

THE PRESIDENT: Yes, we can.

MEMBER LACROIX: Okay, that's great. I just solved -- well, somebody solved my problem, connection problem.

I was wondering, Point Lepreau is presently in an outage state. And I was reading somewhere that 30 per cent of the electricity produced in New Brunswick comes from the power reactor at Point Lepreau.

So while it is down, where does the

electricity come from. And on the other hand, is there pressure on New Brunswick Power to -- well, to put the reactor back online?

MR. NOUWENS: Jason Nouwens, for the record. Can you hear me?

THE PRESIDENT: Yes, we can.

MR. NOUWENS: Great, thank you. Thank you for that question. So let's start with answering your final question. There is definitely no pressure for us to put the reactor back online quickly. You know, there is financial constraints but safety's always our number one priority, so we take the time we need to do every activity in the outage and make sure that we have quality in every aspect of the station prior to returning it to service.

So that being said, while we are out of service for the plant shutdown, we do have a combination of in-province generation which is from other power plants. We also have the Mactaquac Dam which provides some hydro electricity. And then we also us power purchase agreements from Quebec and outside the province to supplement our power requirements.

So before we embark on a planned outage, we have all of those various power sources available to us

and planned out well in advance so that we can make sure we have reliable power to the province while we're shutdown.

MEMBER LACROIX: Thank you very much, good answer. Thank you.

THE PRESIDENT: Thank you. And you're out of your outage now, right?

MR. NOUWENS: That is correct. So technically, we consider the outage complete when we reach 35 per cent power and synchronize to the grid, which we did today, so we are actually producing power and we will continue. We keep our outage team in place until we reach high power, but we are technically considering the outage complete at this point.

THE PRESIDENT: Thank you very much. Dr. Berube.

MEMBER BERUBE: Yeah, I have some questions for Pickering with regard to Unit 8. Obviously this is for Pickering operators themselves.

At this point I guess you're having some difficulty with both the turbine side and the reactor side. Looking at the reactor side of this, what the STS-2 regional overpower detector being out of service, can you just remind me how many other power detectors are actually

in the core itself and are they operating at an up level?

MR. GEOFROY: It's Richard Geofroy, I'm the Director of Operations and Maintenance for Pickering.

So in terms of number of detectors, we have in the order of about 20 detectors, all operational but the one. And we have operating procedures and safety analysis to demonstrate that we can operate safely with one detector unavailable. In fact, we have analysis that demonstrates we operate safely with more than one detector unavailable.

MEMBER BERUBE: SDS-2, that's the Gad(olinium) system, right?

MR. GEOFROY: That is correct.

MEMBER BERUBE: And CNSC, have you looked at the safety case and are you concurring with the safety analysis for returning the unit to full operation if it gets to a point that it's able to do that?

DR. VIKTOROV: Alex Viktorov, for the record. That's correct. The safety analysis routinely credits less than full compliment of detector sensors as a conservative measure, defence in depth. And again, the results are demonstrated to be acceptable, there's no safety limits or radiation limits being exceeded.

MEMBER BERUBE: And the other question I have too again is for Pickering with regard to fueling machine availability. Is this again a parts issue or an aging issue or a combination of both of them?

MR. GEOFROY: It's Richard Geofroy. So neither parts nor aging. So we do anticipate various components to breakdown throughout the course of fuelling activities, we have seen that, parts readily available. The troubleshooting and maintenance to date has confirmed that it is not age-related, so what I would I characterize as routine maintenance that we're addressing and machines are both fully available now and we're back fuelling those reactors.

MEMBER BERUBE: Thank you.

THE PRESIDENT: Thank you everyone. I don't see any hands up for any additional questions. So thank you very much for that.

Moving on the, Staff are going to take this opportunity to provide us with a verbal statement on the COVID-19 situation at CNL's Chalk River Laboratories and the impact on operations and radiation protection. Representatives from CNL are also available for questions.

So I'll turn the floor to Ms. Murthy.

MS. MURTHY: Thank you. Good day, President Velshi and Members of the Commission. My name is Kavita Murthy and I'm the Director General of the Directorate of Nuclear Cycle and Facilities Regulation.

The following is an update to the COVID-19 situation at Canadian Nuclear Laboratories, Chalk River Lab site.

On Monday, October 26th, CNSC Staff received notification of the first positive case of COVID-19 at the CRL campus. Since the first notification eight additional positive cases of COVID-19 have been confirmed, raising the total number of active cases to nine.

Contact tracing carried out by the Renfrew County and District Health Unit confirms that these new cases are the result of workplace transmission related to the initial isolated outbreak within CRL's waste characterization facility.

Public health authorities have classified this as an outbreak. All 25 persons working at CRL's waste characterization facility have been in self-isolation and have been tested for COVID-19.

In addition, a group of 55 workers in

adjacent or related buildings have also been asked to self-isolate at home and are also being tested by the Renfrew County District Health Unit.

Contact tracing and testing for all 80 persons and close contacts continues. Results are not available for all of the persons at this time, but I'm sure CNL will have more updated numbers.

CNL has conducted a full disinfection of the affected workspaces and as a further precautionary measure the remainder of the workplace occupants were sent home to self-isolate and self-monitor for symptoms.

CNL has provided timely notifications to CNSC Staff and has been responsive to Staff's information requests on the situation as it has evolved.

In response to the outbreak, CNL has mandated a 10 per cent reduction in the headcount authorizations for activities on the CRL site. A series of adjustments to COVID protocols have also been instituted including, but not limited to, the enhanced enforcement of mandatory use of face coverings, restrictions on carpooling, and the use of CNL vehicles on site and prohibition of in-country and international travel.

Additional protocols continue to be in

place to further protect the minimum shift compliment groups such as security and fire brigade so that the site security and safety are not impacted.

In the area of radiation protection, CRL has a sufficient number of qualified and trained persons in the radiation protection pool and does not anticipate any impact on its ability to manage the activities related to radiation protection. CNSC Staff agree with this assessment.

CNSC Staff are satisfied with the immediate actions and additional precautionary measures taken by CNL.

With respect to CNSC Staff's safety and compliance activities at the CRL site all planned inspections have been paused until further notice. Staff will continue to use remote inspections and desktop reviews to carryout compliance activities. We have successfully implemented remote inspections over the past several months.

CNSC Staff will continue to adhere to public health guidance and not access the site until public health officials have indicated it is safe to do so.

CNSC Staff are fully equipped to work from

home for the foreseeable future and Staff at the CNSC's CRL site office have been working from home since March 16th, as have staff from other CNSC offices.

In order to access the site, CNSC Inspectors must follow all the steps in CNSC COVID inspection protocol and the licensee's COVID protocol, including obtaining pre-travel approval from both the EVP of CNSC, Mr. Ramzi Jammal, and well as CNL's executive team.

Since the pandemic began CNL has enacted workplace measures to mitigate the risk of transmission of COVID-19 at its sites across Canada and to protect the health and safety of its workers, contractors, and visitors, including a mandatory daily screening process in order to be granted access to the site.

Given all of this, CNSC Staff are interested in understanding the reason for this outbreak and the lessons learned for CNL as well as the CNSC as we continue to monitor the situation and determine whether any improvements need to be made to our COVID protocol.

CNSC Staff are now available to answer any questions that the Commission might have. Thank you.

THE PRESIDENT: Thank you. From CNL, I

see we've got Mr. Wood with us. Would you like to provide a statement before I open the floor to questions?

MR. BOYLE: For the record, this is Phil Boyle, I'm the Vice-President of Operations and Chief Nuclear Officer at CNL. Dan Wood is in fact online. Dan is our Chief Operating Officer and is also serving as the Director of CNL's Crisis Management Team which was stood up to manage CNL's response to the pandemic, and he's the lead Senior Executive in charge of CNL's response to this outbreak.

Following Dan's remarks, I'll provide an update on nuclear radiological safety during the period, after which we will both be available for any questions the Commission may have.

So, Dan?

MR. WOOD: Good morning -- good afternoon, excuse me, Madam President and Members of the Commission.

For the record, my name is Dan Wood, CNL's Chief Operating Officer.

CNL last appeared in front of the Commission on June 17th of this year to provide an update on the measures we had taken to minimize the impact of COVID across all CNL sites.

The Commission will recall that CNL reduced operations at its sites in March. During the period of reduced operations a team of approximately 300 employees carried on the essential operational tasks critical to site safety and our mission.

At the same time over 2,000 employees worked remotely and the remaining staff members were placed on temporary administrative leave.

In April CNL developed a pandemic recovery plan and in May began a safe phased return to site work. Prior to any increase in our own site staff, CNL implemented a base set of COVID protocols to protect staff. These protocols extended to include daily site screening, pre-job briefings for employees returning to site, formal COVID hazard screenings and other controls previously briefed to the Commission.

CNL has also engaged Jevetti(ph), an independent epidemiology firm, to help us fully understand the pandemic risk in our communities where employees reside. These assessments, which continue today, have provided valuable input to the leadership team.

CNL transitioned to each recovery phase only when the predefined industry criteria had been met and

we have carefully controlled on-site head counts. CNL has provided regular updates to the CNSC staff on both our COVID protocols and the recovery progress.

Throughout the five-month period, from May through September, CNL incorporated lessons learned and adjusted controls as public health provided new guidance. In this period CNL experienced no workplace transmissions but had three isolated COVID positives among our 3300 employees.

During the month of September Renfrew County experienced an increase in cases attributed to several school-based transmissions. In response, CNL made a conservative decision and reduced the head count at our Chalk River site by 20 per cent.

More recently, on Saturday, October 24th, CNL was notified that an employee who works in our waste characterization facility tested positive for COVID-19. This employee had last been on site Wednesday the 21st.

Contact tracing was initiated in co-ordination with local public health officials. The initial tracing identified 12 staff members who were restricted from the site and a full disinfection of their workplaces was administered.

Further contact tracing continued on Monday, and on Tuesday a second positive case was confirmed in the same work group. Proactively CNL treated this case as a workplace transmission and sent all employees who worked in that affected facility, as well as two related facilities, home.

These measures affected a total of 80 workers. A full disinfection of all affected work areas was once again performed.

Since then CNL has been notified of seven confirmed workplace transmissions. We have found that one of the eight was actually a transmission outside of work. But it all affected this group of employees, raising the total number of active employee cases to nine.

That was as of 3:00 p.m. Tuesday, and as of noon today those numbers have not changed.

Twenty-two employees have tested negative and COVID testing continues for the remaining workers in the group of 80. The return to site of any of these workers will only occur after health experts deem it safe to do so.

CNL has issued three public disclosures notifying and updating the community of these positive

cases, and as you heard these disclosures have been shared with the CNSC staff.

On October 29th CNL held a virtual all staff meeting providing the workforce with an update on the outbreak and reinforcing the importance of our COVID safety measures. The next day the President and CEO, Mr. Joe McBrearty, conducted a virtual all managers meeting, stressing the important role that managers have in reinforcing our COVID safety measures.

CNL has put in place additional preventive measures to further reduce the risk of transmission at our sites. At Chalk River we implemented a 10 per cent reduction in on-site head count this Monday. Across all our sites we are restricting car-pooling, increasing the requirements for face coverings and surgical mask use and performing a COVID hazards and control review of our work.

Finally, we are completing another review of industry best practices and of the recent public health guidance to identify further opportunities for improvement.

In closing, I want to assure you, Madam President and the Members of the Commission, that CNL has taken the global pandemic and the current outbreak at our Chalk River site very seriously. We will continue to

review and update our COVID protocols to ensure the safety of our workers, the public and the environment.

Thank you for your time. I will pass it back to you, Phil.

MR. BOYLE: Thank you, Dan.

Before we move to questions, I would like to take a moment and reassure the Commission that nuclear safety has not been compromised as a result of this outbreak or the broader pandemic. We continue to meet our regulatory responsibilities with respect to nuclear safety and radiation protection.

This outbreak is isolated to a select group of waste processing personnel and facilities. These work areas have been put into a safe state and all the waste is being stored in accordance with necessary regulations.

Including our response to this incident, CNL continues to meet our licence requirements and under our modified COVID protocols in accordance with our pandemic recovery plan.

I will be honest. The pandemic has impacted our work in multiple ways. Our site work was reviewed to incorporate COVID safety measures without

losing attention to the other hazards involved. This identification of hazards and controls was and continues to be accomplished with the involvement of the workers who perform these tasks.

When key resources such as radiological protection personnel were not available, we have rescheduled the work. We have not altered any of our processes to reduce the required resources to perform work or tasks.

For especially essential resources such as emergency response and security, we have additional protocols in place to protect against the introduction and spread of the virus.

So as stated in our remarks, please be assured that protecting the health and safety of our staff, their families and our local communities remains CNL's top priority.

This concludes our prepared remarks and at this time Dan and I would be happy to answer any questions you may have. Thank you.

THE PRESIDENT: Thank you for your update.

Before I open it for questions, tell me what is the state of health of these nine employees?

MR. WOOD: Madam President, I am pleased to report that all of the employees are doing well. We had one that had relatively severe flu-like symptoms, not a respiratory problem, but his symptoms have now dropped to mild. So we have several employees with no more symptoms and the others just with mild symptoms. So we are thankful for that.

THE PRESIDENT: Thanks very much for that. That must be a great relief.

Let's start with Dr. Demeter.

MEMBER DEMETER: That's a very detailed plan that you've presented, especially since we're dealing with such a moving target and changing science and changing advice on a weekly, if not daily, basis. So I commend that as well.

I was curious if any of your up-front screening, whether it's just by the form looking at what signs and symptoms or the temperature, have you picked anyone up from that purpose or are they all self-declared in other ways?

MR. WOOD: Sir, during the five-month period, as well as even today, people are reporting mild symptoms as we described when the school outbreaks

occurred. It was the beginning of the fall weather. We had the typical colds among the children, which of course extended to some of their parents. So the screening process has caught quite a few people and kept them off site while they are symptomatic until such time as they are tested or the symptoms are resolved.

So the screening process has been effective in that regard.

The start of the particular outbreak of concern, again with an employee who was asymptomatic, and while we do not know exactly where the employee contracted the virus, we do know that they had been travelling outside the community. So we believed that it was outside the workplace.

MEMBER DEMETER: Okay, thank you.

MEMBER McKINNON: Thank you for the update. That is a very comprehensive program.

I have no specific questions; thank you.

THE PRESIDENT: Dr. Lacroix?

MEMBER LACROIX: I want to thank CNL and CNSC staff for keeping us informed. I really appreciate that.

So from what I understand, people at Chalk

River are not reluctant to be tested in the sense that they are not afraid of losing their job if they get tested positive.

Am I right?

MR. WOOD: You are very correct, sir. We have had in place an administrative leave program, that thankfully our government owner has supported, that allows employees who we send into isolation even just for symptoms that are negative to receive administrative pay. So that has removed any hesitancy in an employee reporting even the mildest symptom.

MEMBER LACROIX: Okay, thank you.

THE PRESIDENT: Dr. Berube.

MEMBER BERUBE: Thank you for that report. It's good to see that basically you are definitely focused on dealing with the pandemic. Unfortunately, it disguises itself as flu sometimes and sometimes it's a cold, so it's very difficult to pick that up, especially in indoor seasons.

Just to get a little more definition, obviously you have isolated key personnel, primaries and secondaries and back-up if you need to should you have a bigger problem, which you have right now. At what point do

you hit a threshold where you start shutting down operations totally?

Have you done assessments or an analysis on that particular?

MR. WOOD: So as we ramped up, we started operations slowly as we were confident in the controls. Unless something very dramatic happened, I believe that a fast ramp-down would not be our desire. So we would step back and measure, as we've done with the 10 per cent reduction at Chalk River. We would continue to drop back and of course deal with whatever affected facilities there were.

In this case we're building a contingency plan to bring our waste services area back into service. But that would be our approach.

So have I done an analytical sensitivity analysis? No, sir, we have not.

MEMBER BERUBE: So you've got a staged approach to this and that's basically your defence in-depth.

MR. WOOD: Yes, sir.

MEMBER BERUBE: Thank you.

THE PRESIDENT: Thank you.

I've got a couple of questions.

One is when you've had your town hall sessions with staff, has there been concern expressed by others? Have you had like work refusals or I need to get tested and I'm not going to work until I've got clearance?

MR. WOOD: I do not have a specific example of a work refusal. We have allowed employees with concerns, whether it be when their children were sick or other family members, we go through an accommodation process. So we have tried to take care of those situations on an individual basis.

You started your question with have they expressed any concerns, and I think the honest answer to that is yes, they have. It varies. I think the stress, both physical and mental in nature, is apparent somewhat. And everyone reacts a little differently to the situation.

We went for five months being a COVID-free workplace and to have that change, we certainly some concerns expressed. I think overall, though, the majority of the employees understand both their adherence to the protocols and our efforts to stay in line with public guidance are doing everything we can do to protect them.

THE PRESIDENT: Thank you. On that note,

as far as adherence to your protocols and public health guidelines, what has the compliance been? Were there issues even prior to these detections? Is there a level of complacency setting in? That's always something all of us worry about; that we kind of get used to it and let our guard down a bit.

MR. WOOD: Yes. The phrase COVID fatigue I think is a reality. Our performance is varied. We are humans. We were actually doing face mask use assessments while this event started, and those assessments found over 90 per cent adherence to the controls.

We did identify some weak points, such as walking outside on the sidewalks and letting your masks down and walking closer together than two metres. Also lunch and break areas seemed to be a weak point, not that people weren't allowed to remove their masks to eat but that they would linger and chat inside a closed area that is probably not advantageous.

So we are refreshing those protocols and stressing their use and continuing to communicate the seriousness of the potential disease.

THE PRESIDENT: Thank you.

Is yours a pretty mobile workforce? Like

do they move from one site to another?

MR. WOOD: No, ma'am, they are not mobile. We have ones, twos, that kind of thing.

Now in terms of where they live, we do have some personnel who live hours away and come in for their four-day week or five-day week. But the vast majority of the personnel at Chalk River are in the Petawawa-Pembroke-Deep River communities along the Ottawa Valley.

THE PRESIDENT: Thank you very much.

I don't see any other hands up.

So once again thank you for your further updates and I thank you for taking such prompt action in response. And hopefully you have nipped it, never to raise its head again.

Again thank you very much for that.

MR. WOOD: Thank you, ma'am.

MR. BOYLE: Thank you.

THE PRESIDENT: So before we move to our next agenda item, let's take a four-minute break to allow the room to clear and new guests to come in.

We will resume at ten after 2:00. Thank you.

--- Upon recessing at 2:06 p.m. /
Suspension à 14 h 06
--- Upon resuming at 2:11 p.m. /
Reprise à 14 h 11

THE PRESIDENT: We are starting again.

We have the Commission Members here.

So the next item on the Agenda is potential amendments to regulatory document REGDOC-2.2.4, *Fitness for Duty, Volume II: Managing Alcohol and Drug Use*.

Proposed version 3 is presented for approval to publish.

I note that representatives from industry and unions are joining us and will be available for questions.

Also available for any questions from the Commission is Professor Marilyn Huestis, a consultant engaged by the CNSC staff.

I will turn the floor to CNSC staff for their presentation.

Mr. Lamarre, the floor is yours.

CMD 20-M35/20-M35.A

Oral presentation by CNSC staff

MR. LAMARRE: Thank you very much.

Good afternoon, Madam Velshi, Members of the Commission. My name is Greg Lamarre. I'm the Director-General of the Directorate of Safety Management.

With me today are Mr. Jason Churchill, Senior Regulatory Framework Officer in the Regulatory Framework Division; Mr. Brian Torrie, Director-General of the Regulatory Policy Directorate; Mr. Ross Richardson, Director of the Human and Organizational Performance Division and Ms. Lynda Hunter, Human and Organizational Factor Specialist in the Human and Organizational Performance Division.

In addition to subject matter experts, as Ms. Velshi mentioned, we also have with us today Professor Marilyn Huestis. Professor Huestis was contracted by the CNSC to provide a scientific report on oral fluid testing and continues to advice the CNSC on this topic.

Professor Huestis is one of the world's leading toxicologists and researchers in this area.

CNSC staff and Professor Huestis will be

available for questions at the conclusion of this presentation.

I will now turn the presentation over to Mr. Jason Churchill.

MR. LEBLANC: You are muted.

Jason? Mr. Churchill?

MR. CHURCHILL: Okay, apologies. Thank you.

For the record, I am Jason Churchill, Senior Regulatory Framework Officer in the Regulatory Framework Division.

The purpose of this item is to ask the Commission to approve amendments to REGDOC-2.2.4, *Fitness for Duty, Volume II: Managing Alcohol and Drug Use*.

Today's presentation will follow the structure shown on this slide, starting with a timeline of events since the approval of REGDOC-2.2.4, Volume II, in the fall of 2017 until today.

This slide provides an overview of the timeline since the approval of the REGDOC in November of 2017. Many changes have occurred.

A version two of the initial document was published in December 2017 with a minor administrative

change.

Cannabis was legalized in Canada for recreational use in October of 2018. Around this time oral fluid testing was approved in Canada for recreational use.

Shortly afterwards, in November 2018, industry requested an amendment to the REGDOC to allow for oral fluid testing and point of collection testing for the detection of cannabis.

CNSC staff reviewed industry's proposal through the summer of 2019. Specifically meetings were held with industry to clarify their request. Where appropriate, industry was requested to provide additional substantiation.

In parallel, the CNSC contracted Professor Marilyn Huestis to provide a scientific report on the acceptability of oral fluid testing and to provide an independent analysis of industry's proposal.

In September 2019 a REGDOC amendment project was initiated. Around this time oral fluid guidelines were published in the United States. Public consultation was launched in March of 2020.

Dr. Huestis' report, Oral Fluid Testing Practices, was made available to the public upon request in

April of 2020.

The published version of REGDOC-2.2.4, Volume II, currently sets out a comprehensive set of requirements and guidance for managing fitness for duty of workers in relation to alcohol and drug use at all high security sites.

High security sites are defined in the *Nuclear Security Regulations* as: a nuclear power plant or a nuclear facility where Category I or II nuclear material is processed, used or stored.

With its publication the CNSC became the first regulator in Canada to require random alcohol and drug testing of workers in safety-critical positions.

The amendments before you today have no impact on the policy decisions associated with the current volume of the REGDOC, as approved by the Commission in 2017.

The proposed amendments reflect current advances since 2017 in science, technology and infrastructure associated with oral fluid and point of collection testing. The amendments also provide an increased flexibility with regards to testing methodologies.

In short, amendments to the REGDOC are reflective of the current state of understanding of oral fluid and of point of collection testing. The potential changes take into account legalization of cannabis for recreational use.

The document has gone through public consultations and has been revised as appropriate.

This slide is a quick view of the regulatory framework of the CNSC. It starts at the top with our enabling legislation, the *Nuclear Safety and Control Act*.

The second band consists of the CNSC's 13 regulations. Below that are licences and certificates that permit licensees to operate.

The largest segment, in red, represents the CNSC's regulatory documents, or REGDOCs, as well as accredited standards, such as those published by the CSA Group and ISO.

The Commission may choose to reference REGDOCs or accredited standards in whole or in part in a licensing basis.

The CNSC structure to regulatory documents according to the framework is shown here. There are three

categories of REGDOCs: Regulated Facilities and Activities; Safety and Control Areas, which have broad applicability; and Other, which includes reporting requirements and matters of Commission proceedings.

Highlighted in red is the Safety and Control Area, 2.2. Human Performance Management. This section has various components, including human factors, personnel training and personnel certification.

Sub-section 2.2.4 pertains to Fitness for Duty. As shown, REGDOC-2.2.4, Volume II, is one part of a multi-faceted subject area. Managing worker fatigue and various fitness for duty tests for nuclear security officers pertain to other aspects of ensuring workers are fit for duty.

The targeted amendment project for REGDOC-2.2.4, Volume II, followed the standard REGDOC development process, as illustrated on this side. Public consultations are an integral part of this process. The key difference for this project was that in lieu of seeking feedback on the entire draft document, comments were only solicited on specific changes to the published version. The remainder of the document remains as approved by the Commission in the fall of 2017.

We are currently at Step 7, seeking the Commission's approval.

This slide is meant to provide you with an overview of the content of the document. It applies to a subset of licensees defined in the *Nuclear Security Regulations* as high security sites. These include nuclear power plants with their associated spent fuel management facilities at Pointe Lepreau in New Brunswick, Gentilly-2 in Quebec and the Darlington, Pickering and Bruce sites in Ontario.

Also included are spent fuel management at Canadian Nuclear Laboratories Chalk River site, Whiteshell in Manitoba and the Douglas Point facility on the Bruce site.

The published REGDOC is meant to ensure that a comprehensive approach to ensuring the fitness for duty of workers is taken.

The document includes requirements and guidance regarding policy statements. For example, licensees are to establish policy statements that prohibit being at work under the influence of alcohol and illicit drugs.

The Regulatory Document also includes

program requirements that provide support to workers, such as employee assistance programs, access to training and awareness.

And the published document includes requirements for alcohol and drug testing for safety-sensitive and safety-critical positions but currently only allows for urine-based laboratory drug testing.

Safety-sensitive and safety-critical positions are the positions that have the most impact on safety and security and represent less than 10 per cent of the overall worker population.

Since its publication in 2017 licensees have been working towards implementation. Implementation has been paused pending the outcome of this amendment project. Once the Commission's decision is announced, implementation will resume.

This slide summarizes the scope of the amendments proposed for version 3. As mentioned the amendment project was initiated based on a request from affected licensees.

Oral fluid testing involves the collection of an oral fluid sample, which is sent to a laboratory for

analysis. The laboratory analysis involves two different tests: a screening test and a confirmation test.

Two benefits of oral fluid testing is that it is considered to be less intrusive and tests for more recent drug use than urine.

In contrast, point of collection testing is a screening test conducted in the field outside of a laboratory setting. The main benefit of this testing is that it provides immediate results.

Based on a review of licensee submission, recent technological and infrastructure advances, benchmarking, and input from Professor Huestis, the REGDOC was amended to allow oral fluid testing as an accepted methodology to test for all drugs rather than just cannabis; to allow for the use of both oral fluid and urine-based point of collection testing for all drugs; and, to add oral fluid cut-offs in addition to the urine cut-offs.

In addition, a few minor changes in response to the legalization of cannabis were also included.

In the currently published document cannabis is covered under statements regarding illicit

drugs. With the legalization of cannabis, it is no longer considered illicit and must be explicitly addressed similar to alcohol.

Next, we will discuss public consultation including key themes raised by the stakeholders.

As mentioned earlier, feedback was only solicited on the sections which have been amended. Key themes and CNSC responses are provided below.

The public consultation period for this document took place from March to May of 2020. During this time 57 comments from seven commenters were received.

The CNSC received an additional three comments during the feedback on comments phase. Commenters included licensees, unions, a drug testing device manufacturer, and a member of the public.

CNSC staff carefully considered all the comments received and this resulted in several changes to the document. Detailed responses were included in the materials submitted to the Commission.

There were three key themes that emerged from public consultation. The first theme concerned point of collection testing. Associated issues included clarity regarding the circumstances when point of collection

testing could be used, the reliability of the testing devices, and the training and competency of the collectors.

The second theme concerned a lack of laboratories in Canada with the required accreditations to conduct oral fluid testing.

The third key theme concerned overall oral fluid cut-offs for cannabis.

Each of these themes will be discussed in more detail in the next series of slides.

I will now turn the presentation over to Lynda Hunter, the technical lead on this project.

MS. HUNTER: Hello, Lynda Hunter, for the record.

I just want to make sure that I can be heard.

THE PRESIDENT: Yes, we can.

MS. HUNTER: Okay, fantastic. Thank you.

So my name is Lynda Hunter and I am a Human and Organizational Factors Specialist with the Human and Organizational Performance Division at the CNSC.

So stakeholders raised concerns regarding point of collection testing or POCT. Specifically, industry requested that POCT devices not be permitted for

reasonable grounds testing. Whereas, unions raised concerns that the regulatory document was not clear enough regarding when POCT could be used, the reliability of the devices, and training requirements for POCT collectors.

As a result of these concerns the regulatory document was amended to further clarify and restrict POCT use. POCT can now only be considered for use in random or post-incident testing circumstances, and is not to be used for reasonable grounds testing as requested by industry.

In addition, text was added to the document clarifying that training requirements listed in Section 6.2 titled *Drug Testing Process* apply to POCT. There are also training requirements listed under Section 3.8 of the regulatory document that apply to POCT collectors.

To address the union's concerns about the reliability of POCT devices, the regulatory document was modified to clarify the quality assurance provisions required to ensure the performance of the POCT devices and collection techniques of the collectors are assessed and monitored.

Licensees noted that there is currently no

laboratory in Canada that is accredited to analyse oral fluid tests, as required in the regulatory document. It is CNSC staff's position that laboratory accreditation is an essential element to ensure the quality assurance of laboratory results.

The draft regulatory document allows use of laboratory accredited by either the Substance Abuse and Mental Health Services Administration or SAMHSA, or ISO, the International Organization for Standardization, Standard 17025.

The Dynacare Laboratory in London, Ontario is currently accredited by SAMHSA to perform urine testing, and has confirmed that it is currently working towards accreditation for their oral fluid testing program. CNSC staff have requested an estimate from the laboratory as to when they anticipate applying for accreditation.

Both industry and unions raise concerns related to the proposed cut-offs for testing cannabis. The cut-offs proposed were 5 ng/mL for screening and two for the confirmation test.

Unions, notwithstanding their continued opposition to alcohol and drug testing proposed 25 or 15 ng/mL at the screening level to align with roadside testing

in Canada and with the Australian standard respectively. And, proposed a minimum of 5 ng/mL for the confirmation test.

Industry proposed 10 ng/mL for both screening and confirmation, which are the cut-off levels used by the Toronto Transit Commission.

CNSC staff carefully considered industry and union's proposals with due consideration of current science, benchmarking and expert advice derived from published drug administration studies. As a result, the cut-offs were revised to 10 ng/mL for screening, in line with licensees' proposal, and 5 ng/mL for the confirmation test, in line with the union's proposal.

These cut-offs identify recent drug use and risk of acute impairment at the time of testing.

The next two slides provide more information related to the cannabis cut-off. The over-arching issue in setting cut-offs for cannabis, for any drug, is having a good understanding of the drug's impairing effects. There is currently no consensus on the length of time a person remains impaired after cannabis use, also referred to as the impairment window.

The length of impairment varies by the

effect being measured, for example whether looking at cognitive impacts such as decision-making, or psychomotor impacts such as the ability to actuate controls. Impairment length also varies by frequency of use, so occasional versus frequent users; by route of administration, so whether it is smoking, vaping, or ingesting edibles; and, the doses used.

Acute impairment has been estimated between three and twelve hours. This is the time when the drug is having a direct impact on the brain, also referred to as intoxication, high, or inebriation.

For chronic frequent users, those using near daily, some longer-term impairments have been observed up to three weeks for psychomotor effects and up to 30 days for cognitive effects.

Oral fluid drug testing, similar to urine testing, identifies drug use. However, the window of oral fluid drug detection is much smaller and closer to the window of acute impairment in urine. So oral fluid detects use within hours. Urine detects use within days. The oral fluid cut-off selected directly relates to how recently someone consumed cannabis and the length of time someone would test positive.

For workplace settings, the screening cut-offs tend to be between 10 and 4 ng/mL. And the confirmation cut-offs are typically lower than the screening for technical reasons.

As can be seen in the shaded boxes, as the cut-off decrease, the detection time since last use increase. For example, at a screening cut-off of 25 used for roadside, most people would typically test positive for up to four hours, and negative thereafter. Whereas, as a cut-off of 2 ng/mL, a person may test positive up to 24-hours.

Please note that these data are very approximate as detection times may vary across studies.

This slide provides a comparison of the publicly available Canadian and International Cannabis Oral Fluid Cut-offs in use. As you can see, there's no consensus on the cut-off used. The screening cut-offs range from 25 used in roadside, down to four. Whereas, the confirmation cut-offs range from 10 to two.

Note that blood testing is used for confirmation by the criminal justice system, but is not used in workplace settings due to its high level of intrusiveness.

As previously mentioned, CNSC staff are proposing 10 ng/mL for screening and five for the confirmation cut-off. These cut-offs provide a high degree of confidence that those workers who test positive have used cannabis within a few hours and are likely acutely impaired.

These levels are based on current science, best practices, expert advice, and in due consideration of comments received during public consultation.

CNSC staff believe that these cut-offs are appropriate for ensuring nuclear safety while not unduly impeding human rights, including privacy rights.

As a reminder, drug testing is but one element of a comprehensive fitness for duty program. All measures included in the regulatory document are meant to work together to ensure the fitness for duty of workers is managed.

I will now turn the presentation over to Jason Churchill.

MR. CHURCHILL: Jason Churchill, for the record.

Should the Commission approve the amendments to REGDOC 2.2.4 Volume 2, the next step would be

to publish the REGDOC on the CNSC website. The REGDOC would then be added as guidance in the *Licence Conditions Handbook* of affected licensees.

The REGDOC would be moved to Compliance and Verification Section of the *Licence Conditions Handbook* once the implementation dates were reached.

Affected licensees have indicated that if approved they plan to implement the regulatory document within six months of publication for all but random testing. Random testing would be implemented 12 months after publication.

Staff acknowledged that there is a small risk that licensees may have to delay the oral fluid portion of their program in the event an accredited Canadian laboratory is not available.

So, in conclusion, the proposed amendments to REGDOC 2.2.4 Volume 2, provide additional flexibility related to alcohol and drug testing methodologies. It reflects the reality of legal use of cannabis in Canada. It is supported by sound research and expert advice, and was developed with meaningful stakeholder engagement.

Therefore, CNSC staff recommend that the Commission approve the amendments to REGDOC 2.2.4, *Fitness*

for Duty, Volume 2, Managing Alcohol and Drug Use.

Thank you for your time today. CNSC staff and Professor Huestis remain available to answer any questions you may have.

THE PRESIDENT: Excellent. Thank you very much for the presentation.

We'll open the floor for questions from Commission Members and start with Dr. Lacroix.

MEMBER LACROIX: Well thank you very much for this presentation. It's an eye-opener. I found it extremely interesting. And I read with great care the report published by Dr. Huestis. And thank you very much for this comprehensive report; you've answered many of my questions.

I must say that I'm a complete -- a complete neophyte in this field and so I had a hard time to understand some of the -- the terms, but then it's -- I've got a much better understanding right now.

One thing that Dr. Huestis -- and this is a question for you -- you made a distinction as far as the impairment window is concerned, with respect to the screening and confirmation levels. And I understand the impairment window, but what I have a hard time to grasp is

the impairment level in a sense that what is the difference is you consume cannabis, for instance -- what is the level of impairment between 2 ng/mL versus 10 ng/mL?

PROF. HUESTIS: So, Professor Huestis, for the record. It's nice to be with you all.

The entire issue is very complex, so I fully understand, and I've spent years and years since 1988, dealing with oral fluid testing and with cannabis for more than 23 years at the National Institute on Drug Abuse. So, it is not a simple topic.

Impairment, as Lynda Hunter showed you, is affected by many things. Certainly, the route of administration is one of the major areas that will affect it. So, if someone inhales the drug by smoking or vaporization, they are going to reach very high concentrations very quickly. Actually, while they are inhaling the drug, you have peak concentrations actually during the smoking process. And that's because people tend to titrate their dose.

If they take an edible, they are going to have a very slow increase in the concentration of Delta-9 tetrahydrocannabinol (THC) the active component. And it's going to increase slowly and it's going to peak much later.

So, instead of during the actual inhalation, if you take an edible you expect the peak effects may be two to four hours later, okay. And because you're eating it, you have no chance to titrate the dose, right, because it's going to take a long time for the effects to appear. So that's one of the biggest factors.

The other factor is the experience of the user. So, if you're an occasional user, you don't build up tolerance to the effects of cannabis. You take it in, the effects occur, they peak and then they dissipate over time.

If you are a chronic frequent user, which means generally daily use, the cannabis is a very fat-loving compound, a lipid loving compound, so it's completely different than alcohol.

Alcohol is water soluble, and it spreads throughout your body evenly.

Cannabis doesn't do that -- the THC -- because it will initially go to wherever you have the highest amount of blood flow, so to the brain, to the heart, to the liver, to the kidney, but then it will distribute into the fat tissues of the body. And if you use daily you don't excrete all of the drug you take in every day; you store a little bit. And people who use the

drug on a daily basis build up what we call a large body burden of THC, the active compound. And one of the fattiest tissues in our body is the brain. It has all that myelin on our nerves, and so a lot of THC is stored in the brain, and it's the active drug that's stored, and we have shown in our research on chronic frequent users -- we have shown psychomotor effects as long as three weeks after last use, where they were in my controlled environment, no access to drugs, under secure observation. So these are just two of the factors that affect the window of impairment.

Now, one of the reasons that oral fluid is better for cannabis testing than urine is that that window of impairment is more reflected in the window of drug detection in oral fluid than in urine.

So in urine, if you are an occasional user, less than daily user of the drug, the urine can still be positive at the 15 ng/mL that is the current cut-off for two to three days, whereas the window of impairment is shorter than that, and it does depend on these other factors, but it's shorter generally than that. And so oral fluid drug detection mirrors the window of impairment better than urine testing does.

So does that help? And if you want me to go further, I'm happy to do so?

MEMBER LACROIX: Well I would say yes, you could go on, it's extremely interesting -- but I'm not allowed to say that. But, thank you very much, it's -- it's an eye-opener. I really appreciate it.

PROF. HUESTIS: Thank you.

MEMBER LACROIX: Thank you very much.

THE PRESIDENT: Dr. Demeter.

MEMBER DEMETER: Thank you very much for the presentation and thank you, Dr. Huestis, for your explanation; it was very good.

I wanted to confirm one thing, I think I've got it right, but I'll just do this confirmation and then ask my question. The point of collection testing also has a confirmatory component; that's correct?

Okay, I see your head is nodding. That's good.

PROF. HUESTIS: Yes. I wasn't sure it was to me, but absolutely, yes.

MEMBER DEMETER: Okay. So I guess one of the questions I have from a more process point of view, is, if you go to lab or a controlled environment to be tested,

the collection of the specimen, the handling of specimen, the chain of specimen, or like the chain of evidence is fairly well laid out.

Once you go out to point of collection outside of that environment that chain of evidence gets a bit more complicated. So, maybe from CNSC's point of view, what advice -- how are you expecting a licensee to maintain a valid chain of the specimen to link it back to that individual if it's not in a regulated lab kind of setting?

MR. LAMARRE: So Greg Lamarre, for the record.

Perhaps I'll -- I'll hand this over to Lynda Hunter because I think those questions in terms of chain of custody of samples for point of collection testing is a very key one, and they are the issues that we've put some thought into with the licensees in terms of how that would happen.

But perhaps I'll turn it over to Lynda and she can sort of walk you though how that chain of collection of samples will occur.

And just to confirm, once again, that there is also laboratory confirmation that backs up the point of collection testing as well, which is another very

important part of this process.

But, Lynda, over to you. But perhaps you might ask Dr. Huestis also for some input.

MS. HUNTER: Thanks, Greg. Lynda Hunter, for the record.

As rightly mentioned, chain of custody is a very important element of any type of drug testing program. And for point of collection testing as well as laboratory testing, there are standard protocols that are typically in place. And the REGDOC's very clear that licensees do have to have competent collectors and maintain competent collectors or hire competent collectors through a third-party provider.

So processes have been very well-defined in this area. There's custody control forms, for example, that have very specific requirements. In terms of the very detailed level items, we don't necessarily go down to the real details in the regulatory document. Instead, what we will do is review licensees' programs during our compliance assessments.

But, as mentioned, competency and training of collectors is very important.

One clarification as well regarding point

of collection testing is that, as mentioned, the POCT testing is done onsite and typically, as mentioned in the REGDOC, there's actually two acceptable reasons why you would use the POCT device: 1) we are allowing licensees to use it as an initial screen. So, for example, they could use the POCT device, receive initial tests, and any non-negative results would have to be sent to the laboratory for the full laboratory process.

So once it goes to the laboratory it would actually go through another screening as well as the confirmation test to verify that in fact it is a true positive.

Then after that actually there's another process to verify that indeed it is a verified positive test, and that goes to a medical review officer who then reviews the results and provides the worker with an opportunity to discuss and provide a medical explanation for the positive. So, for example, if the person was taking a prescription medication.

So if this screening test is taken, if it's negative we are allowing licensees to not continue on with the laboratory confirmation, with the exception of the quality assurance measures which we're insisting on, which

would be a minimum of 5 percent of those negative POCT results would be sent for confirmation at the lab to confirm the performance of the POCT device and the actual collection as well is done appropriately.

So the second reason you would initiate a POCT as well would be in your decision making on whether a worker should be allowed to continue working in their safety-sensitive duties. And so this could happen, for example, if there was an event, they could -- licensees would choose to do a POCT test and that would provide them with some confidence on whether the worker should continue working, and then those results would always be sent to the laboratory for full confirmation.

MEMBER DEMETER: Thank you, that helps. And the minimum volume that you have to provide for the tests? Is it like 5ml, 10ml...? I know you've got some issues with people who have dry mouth and can't produce that much saliva.

MS. HUNTER: I believe it's 15ml, but I will defer to Professor Huestis just to confirm that.

PROF. HUESTIS: Professor Huestis, for the record. So for urine testing for POCT they would request 30ml of urine, but 15 would be a minimum and, of course,

it's usually a split specimen, so you have 30 in one and 15 in the other.

It is possible to test if you only have 15ml, that's possible as well, but then if the use the only specimen available and the individual requests a retest, that test might be cancelled at that point.

For oral fluid testing it's approximately 1 ml of oral fluid that is needed. There are some devices that use 3/4 of a ml, so it's not a very large amount for oral fluid.

I would like to add that all of the same safeguards that are in place for a regular laboratory test, the chain of custody can be done just the same for a POCT test. And then again, if it is positive of non-negative test, then you collect a second sample that goes to the laboratory for screening and confirmation.

As Lynda Hunter said, we definitely put into place the quality assurance because one of the problems is you want to have safeguards on the POCT having false negative results. So that's why 5 per cent of all the negatives will go to the laboratory and they will go to the laboratory anonymously, not tied to the employee. If you get a negative test result, that stands as a negative.

There would be 5 per cent which would include all sites and all collector to make sure the collector is performing the test correctly would be evaluated every quarter to make sure you don't have the false negative tests.

I do want to also bring up the fact the POCT tests, the oral fluid test, is actually observed, right, because it's collected right by the collector with the individual.

MEMBER DEMETER: Thank you very much.

THE PRESIDENT: Thank you. Dr. Berube.

MEMBER BERUBE: Well, thank you for that presentation. I really enjoyed all of them actually.

This is for Dr. Huestis. I have a question with regard to the differences between specificity and sensitivity between oral testing and the urine testing.

I know it's very difficult because it depends on the test and that you're looking at a lot of factors. But, in general, can you highlight, you know, are these things comparable in terms of results, in terms of false negatives, false positives? Potentially, could you just give us some high level?

Because we're being asked to add oral testing in this particular session, and so we need to

understand if these tests are actually really comparable in this way.

PROF. HUESTIS: Yes. Professor Huestis, for the record. That's a wonderful question. So in the laboratory there is identical safeguards, identical performance. What's interesting is you actually look for different compounds though in oral fluid compared to urine. So urine looks, in general, for the inactive metabolite.

And we use immunoassay to screen and we use a mass spectrometer for confirmation, that has the highest specificity.

In oral fluid we look for, in general, the parent compound, the actual compound that produces the impairment, but it's the same technology. We use immunology to screen for it and mass spectrometry to confirm it.

So in that regard, they really are equivalent as far as the laboratory performance.

Point of care testing is not quite as good as laboratory testing and it's primarily related both to sensitivity and specificity. It's a little bit hard to get the same sensitivity in a hand-held device, not in a laboratory with sophisticated equipment, and so that has to

do with sensitivity. And that's why you always go to the laboratory to confirm any positive POCT test.

And then we've put into place the quality assurance to evaluate the false negative rate, the sensitivity. So if we see a problem with the sensitivity, and I myself have done research on both devices that I discussed in my report. I've actually personally tested in my studies at the National Institute on Drug Abuse and we collected every sample and we determined sensitivity and specificity on all the devices at different cut-offs.

So it's not just my own data, but there's data from scientists around the world that we have. But it is clear that the POCT has less sensitivity, and specificity usually is not quite as good either, which is why we always use the laboratory to confirm. But they offer some real advantages to your licensees in their program.

THE PRESIDENT: Thank you. Dr. McKinnon.

MEMBER McKINNON: Thank you. I'm going to change my question from what I was going to ask to follow-on from this one. So my question is to Dr. Huestis.

There was a statement in the report in the comments sections and it was actually by Dräger Safety, but

it's to follow-on. And it said, it must be mentioned that drugs present in oral fluid are often a parent drug rather than a metabolite, and test kits reflect those differences.

Not knowing really what that means, my question is what is the significance of the metabolite rather than the parent drug being tested, and are there any implications for interpreting the tests?

PROF. HUESTIS: Very good question. Professor Huestis, for the record.

You're absolutely right, oral fluid in general -- and I will explain that in a moment -- tests for the active drug itself. So if we look at the issue of cannabis, oral fluid you are measuring THC, the active component that produced the psycho activity and the effects on cognitive and psychomotor function.

In urine you are measuring carboxy-THC, the inactive metabolite of THC.

And this is a beautiful question, the way you worded it, because now I think you can see why the window of drug detection is longer in urine than it is in oral fluid. Because the parent drug will decrease at a faster rate than the metabolite will decrease in the urine.

So, yes, it has differences in

interpretation. For instance, with urine, urine documents that an individual has been exposed to the drug. It doesn't say anything about impairment, it documents exposure to the drug. Whereas measuring the active drug tells you, yes, that there's been exposure to the drug, but it gives you a little better idea of impairment. Not the actual number itself, but the fact that that window of drug detection is closer to the window of drug impairment.

Does that help?

MEMBER McKINNON: Yes. That's fascinating, yes. So the levels, the cut-offs, have to be very carefully selected according to what you're testing?

PROF. HUESTIS: Not only the cut-offs, but also the actual analyte that you're measuring. So you try to measure carboxy THC in oral fluid, which unfortunately many people tried to do initially, the concentrations of the metabolite in oral fluid are a thousand-fold lower than the parent drug itself.

So selecting the proper analyte in the proper biological sample and the proper cut-off is very important.

MEMBER McKINNON: Thank you very much. That's fascinating and very helpful. Thank you.

THE PRESIDENT: Dr. Huestis, just to follow-up on that almost tangentially, what are your thoughts on the revision to the screening and confirmation cut-off levels from the original proposed 10/5 to 5/2?

Your thoughts on that?

PROF. HUESTIS: Professor Huestis, for the record. I have a lot of thoughts on that and I know we have limited time. You know, Canada is a special situation because cannabis is legal currently in Canada, and that has to be taken into account, and individuals' rights have to be taken into account.

There are lots of reasons that I recommended the 4 and the 2. I put into my report, I did research to get every single cut-off level used around the world that I could find, and you can see that, as was pointed out in the presentation, there's a range of values. But it's a pretty narrow range. I mean, for screening it's only going from 4 to 25, and for confirmation only 2 to 10.

So I do support the 10 and the 5. One of the reasons that I still supported 4 and 2 was the fact that honestly the workplace drug testing in the United States that's very large is going to drive what the immunoassay manufacturers produce. So they are going to

produce kits that screen at 4 and then the confirmation will be done by mass spec. The confirmation's not a problem, laboratories can set limits.

And I did want to add, it hasn't been brought up yet, that Dynacare in Canada has been doing oral fluid testing for more than two years. So that was not brought up. There was no certification program available. Now SAMHSA's is out and available and they do intend on obtaining that just like they have it for urine. But they have been doing it, and in Canada, many people are using it in Canada as they are in the United States.

So what happens with oral fluid is initially the concentrations are very high, really high, so it's sensitive for people who are taking it either by smoking, vaporization, or eating edibles like brownies and, you know, other food products, everything's available now as a cannabis thing, so they're very high.

And then they decrease over time, over approximately two to three hours in our research. And then at that point they parallel, they're not the same, but they parallel the concentrations in blood.

So, initially, whether you have a 4 or a 10 does not mean very much because the numbers are going to

be in the thousands of nanograms. But the further you get from the time of use the more they're going to be similar or at least parallel to the blood concentrations.

So I certainly can understand the need to carefully look at both the safety and security of the nuclear facilities as well as individuals' rights. So I'm not going to tell you there won't be a difference, there'll be a difference, whether you screen at 10 or 4 there'll be some samples that fall in there. But it's not a huge difference, it's not like 100.

Does that help?

THE PRESIDENT: Very much so, thank you. Thanks very much for that.

We'll do another round? Dr. Lacroix, any other questions?

MEMBER LACROIX: Yes, I do have another question for Dr. Huestis. Could you talk about the possibility, the potential, of adulteration of an oral fluid testing.

PROF. HUESTIS: Yes. Professor Huestis, for the record. So this is one of the real advantages, is we know that there is a lot of adulteration of urine samples, we know that. Remember when I told you that the

window of drug detection in urine is much larger than it is in oral fluid?

Well, in the Quest Diagnostics Testing Index in the United States that test millions of urine and oral fluid samples, you expect that the positivity rate would be higher in urine that oral fluid, just because of the fact that the window of drug detection is larger. Actually, they have a higher percent positive in oral fluid than they do in urine.

In discussing this with Dr. Barry Sample who is the person at Quest who oversees this, the only explanation is the fact that it's much more difficult to adulterate an oral fluid sample than a urine sample.

So remember, it is an observed specimen collection. So the individual comes in, they check their mouth to make sure they don't have something in the mouth that might interfere with the test, you have to wait a minimum of 10 minutes while the person's under observation, and then you directly collect it. So it's much less prone to any kind of adulteration.

Whereas with urine samples, very few urine samples are observed other than the U.S. Military and some occasional cases, mostly you prepare a bathroom and the

individual goes into the bathroom and provides the sample without direct observation.

And, unfortunately, there's a lot of different ways that you can adulterate or put a little bit of a substance in there that can adulterate the sample and come up with a negative test when drugs were present. The other issues is you simply drink a lot of water or fluid before you're going to give your sample, and that will dilute it out, and the individual hopes that it's diluted enough it'll be below the cut-off.

MEMBER LACROIX: Thank you very much.

THE PRESIDENT: Dr. Demeter.

MEMBER DEMETER: Thank you very much. So we heard earlier that accreditation is pending for the oral with Dynacare.

From the industry point of view, if there's only one player that can provide this test, is there any concern about economic barriers to taking it on, since it's a monopoly, and providing the test, and the regulator wants it? Or is that discussion already underway with Dynacare since they provide other testing kits potentially?

I don't know who in industry would like to

take that. Is there any anxiety in industry about a single player accredited lab and the economic impacts of that potentially from a market point of view?

MR. COTNAM: Can you hear me?

THE PRESIDENT: Yes, we can.

MR. COTNAM: It's Shaun Cotnam, for the record. I'm the Chief Regulatory Officer for CNL, but more importantly, Dr. Demeter, I am also the Chair of our industry steering committee, which we have stood up sometime ago to oversee this journey of preparing to implement this REGDOC.

So the point of your question, absolutely. We have -- each of the licensees has named a program administrator. We actually have on the line with us, if needed for detail, our lead for that team that reports to the steering committee and her name is Ms. Candice Kay, she works for OPG.

She has had personal discussion with both the selected tester. We've all aligned through our supply chain team to select the same tester as an industry, and she has had tremendous amount of conversation with them, with Dynacare. The punchline here is we are not overly concerned, we think this is managed. But she can certainly

expand on that if you need it.

MEMBER DEMETER: Okay, thank you very much.

THE PRESIDENT: Thank you.

Dr. Berube?

MEMBER BERUBE: Yes, this one is for CNSC staff and maybe the industry can pipe in too.

Should the Commission decide to approve this testing and that would set this process in motion, how long would it take to implement, roll out this program across all four licensees?

MR. COTNAM: Would you like industry to start, Dr. Berube?

MEMBER BERUBE: Yes, if you wish, you can start.

MR. COTNAM: Again on behalf of the four licensees, as the Chair of our industry Steering Committee, I can tell you that we have submitted letters last year to the CNSC staff, which they have accepted, and that binds us to implement the entire REGDOC within 12 months. In fact, it binds us to implement the entire REGDOC, with the exception of random testing, within six months. And the random testing to be one year after the Commission has made

its decision.

MEMBER BERUBE: And do you see any issues meeting that timeline if it were to be approved?

MR. COTNAM: Again, Shaun Cotnam, for the record.

Because we've had, as you can probably tell by the timeline chart, a head start on this and we've had these industry aligned sub-teams, like our supply chain sub-team, like our communication team, our legal relations team, we've had these teams working in advance, including the training team. So essentially we have most of us in our LCH version 2, which we implemented, and we have been waiting on the response to our submissions for us to go ahead and finalize the policy and go ahead with implementing version 3.

THE PRESIDENT: Thank you, Mr. Cotnam.

Dr. McKinnon?

MEMBER McKINNON: Thank you.

I have a question for CNSC staff and it's in relation to the link with testing and impairment.

So as I was reading through all the comments in the consultation section, there was a recurring theme, especially from the unions, about the effectiveness

or ineffectiveness of oral fluid testing and identifying impairment.

They had specialists who had stated that there was no effective relationship between oral fluid concentration and impairment.

CNSC staff also mentioned that impairment must be assessed through a form of standardized field assessment protocol.

So my question is: Is the issue here in one making the leap from oral fluid testing which really measures the drug concentration and not directly impairment? And secondly how strong is that correlation between the concentration and measured impairment?

MR. LAMARRE: So it's Greg Lamarre, for the record.

I'm going to make a couple of comments and then I will turn it over to Ms. Hunter and Ms. Hunter might want to turn it over to Professor Huestis.

So as we mentioned in the presentation and in the supported material, CNSC staff is very much of the opinion that oral does have a stronger link with acute impairment, given the shorter windows that Dr. Huestis talked about in some detail. As she mentioned, urinalysis

can detect cannabis out for many days into weeks, whereas oral fluid is a much more acute test.

But perhaps I will turn it over to Ms. Hunter and Dr. Huestis to go into a little bit more detail there.

Thank you.

MS. HUNTER: Thanks, Greg. Lynda Hunter, for the record.

As you mentioned, a reoccurring theme is that there currently does not exist a drug test that detects impairment unequivocally.

That being said, as presented in the presentation, we do have a lot of research that talks about the typical impairment window for, for example, cannabis and how long that impairment window is and the fact that oral fluid is actually testing current drug use and is testing a similar window to acute impairment.

So from that perspective staff are confident that the oral fluid test is providing a very good indication of the likelihood of acute impairment.

Standardized field assessments are another way of actually assessing impairment. That is typically conducted for roadside assessment and is not typically

conducted in the workplace setting.

And in terms of urine, as mentioned previously, the detection windows are much longer for urine with chronic users testing positive for several days, up to even 28 days if you are a chronic user.

MR. LAMARRE: Greg Lamarre, for the record.

Perhaps I could just provide a little bit more just to supplement that as well.

We have spent a lot of time, quite rightly so, talking about random testing and specifically the oral fluid testing. But we really do have to make sure that we keep in mind that that testing regime is part of a much bigger program that is outlined with REGDOC-2.2.4.

So on the specific question of impairment, just to put it into context, the other elements of the program that exist around supervisory awareness, the other elements that exist around shift turnover and the training that goes into that, is a very good supplemented measure of impairment as well.

So there are those other elements that are also going to be in play. Every time an individual in one of these safety-critical positions comes on to shift, there

is going to be that supervisory awareness. There's going to be that shift turnover there where there is a one-to-one dialogue that are also going to be other means of being able to assess impairment as well.

Thank you.

THE PRESIDENT: Thank you.

I have a question. I'll start with industry first and then to the unions.

Share with us your thoughts on staff's consultation process and the disposition of your comments. Are you comfortable with how that has been handled?

Maybe I'll start with you, Mr. Cotnam, and then maybe your colleagues may want to follow you, and then we will move to the unions.

MR. COTNAM: Yes, thank you for the question, President Velshi.

Again Shaun Cotnam, for the record.

We have honestly been impressed. I would say that staff have taken their time to analyze what was a fairly dense and as I've listened to the Q and A with Dr. Huestis, it's a very detailed subject. I think staff have taken the appropriate amount of time.

And when you take the appropriate amount

of time and you use logic and science, you tend to get a product that you want at the end of the day. And that product is I believe what we have before the Commission.

So we specifically as industry did note essentially four major things that we together had put in some opening remarks for today. Essentially they were about things like the oral fluid testing and cut-off level, which in consultation with our medical experts we believe is appropriate. It does show the likely correlation between cannabis and the impairment for fitness for duty.

So we have been impressed with that.

They have also made a lot offers here in the REGDOC about flexibility for the testing program that has been covered fairly well here.

Maybe the only point that we had asked previously and staff have said you can always ask to revisit the REGDOC again or you can do it in your LCHs. We had noted that we were quite certain that technology will change rapidly, and in order to accommodate that it would be best to have something with respect in the REGDOC that said can we take that right to the Commission for sake of expediency.

So to your point, those are kind of a

summary of my opening remarks. We are aligned with the -- I shouldn't say aligned. We support the amendments staff have proposed. They have taken time to analyze this very carefully and our medical experts are very much, I would say, in agreement when we've consulted them with where we've landed.

So perhaps Dr. Vecchiarelli from OPG or Mr. Burton from Bruce Power would like to supplement.

THE PRESIDENT: Mr. Vecchiarelli?

MR. VECCHIARELLI: I am Jack Vecchiarelli, for the record. I am Vice-President of Nuclear Regulatory Affairs and Stakeholder Relations for Ontario Power Generation.

I would just like to echo Mr. Cotnam's sentiments. We very much appreciate the opportunity to engage in the consultation process. We felt that our views had been heard. We saw some changes as a result of CNSC staff taking into account our comments.

So overall we are supportive of this proposed REGDOC.

There is one area that we do have some remaining concern about and if time permits, we could perhaps discuss that.

But other than that, overall we appreciate the opportunity to engage and no major concerns with the process itself. Thank you.

THE PRESIDENT: Thank you.

Well, you know, if you've got an area of concern, we would like to hear about that, Mr. Vecchiarelli.

MR. VECCHIARELLI: For the record, Jack Vecchiarelli.

And Shaun, feel free to add further.

The basic issue that we have with respect to the REGDOC the way it is currently worded, we had previously suggested that should technologies advance that perhaps CNSC staff within the REGDOC have the authority to allow for the adoption by licensees of these emerging technologies.

And understandably the CNSC disposition to that, CNSC staff has documented in their comment disposition table, it said they wanted to respect the transparency of the process and they offered alternatives around perhaps amending the REGDOC in future, or go through the licence condition handbooks. We understand that.

In response to that, our view here is that

that may not be the most expeditious way to try to introduce a newer, better technology for testing. So our alternative is to perhaps we be allowed to make a request to the Commission to allow for emerging technologies, and that would preserve some transparency and perhaps bring consistency across all licensees in terms of introducing new testing technologies.

I don't know, Shaun, if you wanted to add anything further to that?

MR. COTNAM: Yeah, I think there is more to say in the sense that we probably should make sure that the Commission is aware, very much aware that the licensees have had a long and robust fitness for duty program with respect to drugs and alcohol and other things for fitness for duty, like managing fatigue.

And through those we have relied on a variety of strategies to detect and minimize any risks that could negatively impact on human performance.

So we have issued broad communication to our staff, including on the legalization of cannabis with the emphasis on fitness for duty.

And really what I really had in the closing remarks was to say that we are supportive of CNSC

staff's recommendation. We believe implementation of this REGDOC would serve to enhance our fitness for duty programs and complement the effective measures that are already in place.

And frankly we look at this as adding an important tool to the fitness for duty toolbox. And at that point I think we are happy to take further questions.

THE PRESIDENT: Okay. Thank you very much for that.

Let me just make sure. Mr. Burton, did you have anything else to add?

We have made a note of your concerns around addressing any technology developments expeditiously.

Was there anything else you wanted to add?

MR. BURTON: Maury Burton, for the record, Bruce Power.

Nothing really to add from what Mr. Vecchiarelli and Mr. Cotnam have said so far.

Going back to your original question on the consultation process, I think it's been a very good, open and transparent process. And to be honest, the legalization of cannabis really threw a bit of a stick in

the spokes here and staff has reacted to that and our concerns surrounding that very well. So I think the process has been very well and we've landed in a reasonable spot.

Thank you.

THE PRESIDENT: Thank you.

And New Brunswick Power, Mr. Nouwens?

MR. NOUWENS: Thank you. Jason Nouwens, for the record.

I am certainly aligned with what my colleague has said; that the consultation has been transparent. And I don't have any other concerns other than the one that Mr. Vecchiarelli had raised about advancing technologies.

But overall I don't have any concerns at all about the process that we've gone through and where we've arrived at today.

THE PRESIDENT: Excellent. Thank you.

Let's turn over to the PWU and I know we have a few people from there.

Does someone want to take the lead there?

MR. STEPHENSON: I will. Good afternoon, Madam President and Commission.

My name is Richard Stephenson. I am counsel for the PWU. With me today is my colleague, Emily Lawrence, and also PWU's General Counsel, Mr. Christopher Dassios.

With respect to the narrow question of the perception of the process that has been engaged in by Commission staff, we certainly appreciate the opportunity that we have had for input and we appreciate Commission staff's time.

Our concerns are not so much with the process but rather with the recommendations, that more from an outcomes perspective. We do have a concern frankly that there is a predisposition to putting in place these outcomes.

I mean, one of the things that we are very concerned about is that we have heard today repeatedly an acknowledgement that the urine testing has essentially no probative value with respect to the critical question of current impairment, and yet that is the very process that CNSC staff recommended last time around.

It's somewhat concerning to me and to the PWU that there seems to have been a wholesale abandonment of really something which was defended up until today.

We understand that there is a view that the oral fluid testing methodology is better in some fashion, but the point is made that relative to something which was really wholly ineffective. So that's a concern to us.

We are also concerned that the use of the oral fluid testing, which is again acknowledged to be a little better, was the expression we heard today -- "a little better" -- is buttressed by the workplace observation and supervision. We are of course in favour of the workplace observation and supervision, but we note that the workplace consequences can arise in circumstances where there is a positive test notwithstanding the absence of any suggestion through workplace observation and supervision that there is any form of impairment at all.

The test, the positive test generates the outcome regardless of the absence of objective observation of workplace impairment.

So I am concerned about that outcome as well and about staff's use of that as essentially a buttress or backstop to the use of the oral fluid testing.

I appreciate that's in part about substance, but that is what drives our primary concern.

THE PRESIDENT: Thank you.

MR. STEPHENSON: Thank you.

THE PRESIDENT: I don't know if we've got anyone from the Society of United Professionals with us today?

Is Mr. Jackson here? I don't see that.

Okay. Well, let me go to staff to see if they have anything else they wish to add before we close this agenda item.

Mr. Lamarre?

MR. LAMARRE: Greg Lamarre, for the record.

Just perhaps in response to the last intervention. I'll caution us that many of the points that were raised have a lot more to do with the substance that was in the REGDOC that was approved by the Commission in 2017.

But I think what I did hear was that there is an acknowledgement that bringing in oral fluid testing with the higher link to risk of acute impairment is an overall positive step.

And with that and with the justification that's been provided by all of the material in front of the

Commission today, staff strongly stands behind the recommendations that are before you.

Thank you very much for your attention.

THE PRESIDENT: Thank you.

So a special thank you to Professor Huestis, to folks from industry, the unions and to staff for the presentation.

The Commission will deliberate on the proposed amendments of version 3 of REGDOC-2.2.4, and if we require additional information we will let you know.

If we are ready to proceed with a decision, you will be hearing about that accordingly.

So this concludes the Public Meeting of the Commission.

Again thank you all for your participation. Stay safe, stay well.

Bonne fin de journée, tout le monde. Au revoir.

--- Whereupon the hearing concluded at 3:32 p.m. /

L'audience s'est terminée à 15 h 32