Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Public hearing

Audience publique

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Le 9 juin 2021

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Ottawa, Ontario

via videoconference

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14e étage
280, rue Slater
Ottawa (Ontario)

par vidéoconférence

Commission Members present

Ms. Rumina Velshi
Dr. Sandor Demeter
Ms. Indra Maharaj

Commissaires présents

Mme Rumina Velshi
Dr Sandor Demeter
Mme Indra Maharaj

Secretary:

Mr. Marc Leblanc

Secrétaire:

Me Marc Leblanc

Senior Counsel:

Mr. Denis Saumure

Avocat principal :

Me Denis Saumure

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by videoconference / par vidéoconférence

--- Upon commencing on Wednesday, June 8, 2021
at 9:30 a.m. / L'audience débute le mercredi
8 juin 2021 à 9 h 30

Opening Remarks

THE PRESIDENT: Good morning and welcome to the public hearing of the Canadian Nuclear Safety Commission.

Mon nom est Rumina Velshi. Je suis la présidente 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 pause for a few seconds in silence so that each of us can acknowledge the Treaty and/or traditional territory for our respective locations. Please take this time to provide your gratitude and acknowledgment for the land. As well, I would like to acknowledge that the BWXT Medical facility in Kanata is located in the unceded traditional territory of the Algonquin peoples.

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

Under my authority to do so pursuant to section 22 of the *Nuclear Safety and Control Act*, I have

established a three-member panel of the Commission to conduct this licence renewal hearing. I will preside over the hearing, and I have with me, on the panel Ms. Indra Maharaj and Dr. Sandor Demeter, who are, like me, participating remotely for this virtual hearing.

Mr. Denis Saumure, Senior Counsel to the Commission, and Marc Leblanc, Commission Secretary, are also joining us remotely.

I will now turn the floor to Mr. Leblanc for a few opening remarks.

Marc, over to you.

MR. LEBLANC: Merci, Madame la Présidente. Bonjour, Mesdames et Messieurs. Bienvenue à l'audience publique de la Commission canadienne de sûreté nucléaire.

The Canadian Nuclear Safety Commission is about to start the public hearing on the application by BWXT Medical Ltd. on the application for a Class 1B nuclear substance processing facility operating licence. The public hearing on Ontario Power Generation's application for the renewal of the site preparation licence for the Darlington New Nuclear Project is scheduled on June 10 and 11.

During today's business, we have simultaneous interpretation. Please keep the pace of your speech relatively slow so that the interpreters have a

chance to keep up.

L'audience est enregistrée et transcrite textuellement. The transcripts will be available in about one week.

To make the transcripts as meaningful as possible, we would ask everyone to identify themselves before speaking.

I'd also like to note that this proceeding is being video webcasted live and that the proceeding is also archived on our website for a three-month period after the closure of the hearing.

As a courtesy to others, please mute yourself if you are not presenting or answering a question.

As usual, the President will be coordinating the questions. During the question period, if you wish to provide an answer or add a comment, please use the Raise Hand function.

Madame la Présidente.

CMD 21-H3.C

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 21-H3.C.

Do I have concurrence? For the record, the agenda is adopted.

We will now proceed with the public hearing.

Marc, over to you for introductory remarks.

MR. LEBLANC: The first Notice of Public Hearing and Participant Funding on this matter was published on November 18, 2020. A revised version was published on February 12, 2021 to announce changes to the date for filing of Commission Member Documents.

The public was invited to participate in writing and by making oral presentations. May 3, 2021 was the deadline set for filing by intervenors. The Commission received 21 requests for intervention. Three requests to intervene were filed after the deadline and were refused.

May 26 was the deadline for filing of supplementary information. I note that supplementary submissions and presentations have been filed by CNSC Staff, BWXT Medical Ltd. and intervenors.

Participant funding was available to intervenors to prepare for and participate in this public hearing. Four groups and one individual are receiving funding. The funding decision is available on the CNSC Web

site.

Today, we will first hear the presentations by BWXT Medical and CNSC staff.

Ten intervenors are scheduled to present orally today. While the presentations are limited to 10 minutes, Commission Members will have the opportunity to ask questions after each presentation. There is no time limit ascribed for the question period.

The written submissions will be addressed during the rounds of questions at the end of the hearing.

President Velshi.

THE PRESIDENT: I would like to start the hearing by calling on the presentation from BWXT Medical Ltd., as outlined in CMDs 21-H5.1, 21-H5.1A and 21-H5.1B.

I will turn to Mr. Coombs for this presentation.

Mr. Coombs, the floor is yours.

CMD 21-H5.1/21-H5.1A/21-H5.1B

Oral presentation by BWXT Medical Ltd.

MR. COOMBS: Thank you. It's Martyn Coombs, for the record.

Good morning, President Velshi and Members of the Commission. As I just mentioned, my name's Martyn

Coombs, I'm the President of BWXT Medical and I'm please to have the opportunity to explain our company and our application today.

So let me start with our customers. This is actually an email we received just a month ago from one of our customers who's actually a patient suffering from liver cancer, Jan Louw. And this is what they said, and it was an unsolicited email:

> "I had TheraSphere treatment in December 2016 for HCC (liver cancer). I was expecting an extension of life of 13.8 months; we are now sitting at 53 months and still feeling strong."

So this is very heartwarming for our staff and employees here at BWXT Medical, because we're in the business of trying to get people better from illness. And it's very motivating, obviously, for us to receive such feedback.

This is a very good product that we manufacture here at Kanata, and it's a life-saving product.

Let me explain a little bit about our site here at Kanata. We acquired this business from Nordion back in 2018, so three years ago. And since then, we've been operating under Nordion's licence and Nordion's oversight.

So our application today covers the same products, processes and controls as existed previously under Nordion, it's just a fact that we bought the business.

We've got over 200 employees here with many many years experience producing medical isotopes and radiopharmaceuticals. And, historically, this has been a very important site in nuclear medicine. In fact, this site at one point produced over 60 per cent of the global supply of Molybdenum-99 which is a very important isotope in nuclear medicine.

So what we're talking about here is the same facility, the same products, and the same commitment to patient health as we've had over many years.

Just to explain a bit about what is nuclear medicine. It's obviously part of medicine and really consists of two parts; one is a radioactive isotope, and the other part is a drug. And the drug typically is engineered to go to a specific target within the body, typically cancer or some other disease.

And attached to that drug you can attach isotopes that are either suitable for imaging or for visualizing the body. And here, you can get fantastic visualizations of disease or the progress of disease.

Or, otherwise, a different sort of isotope

with higher energy can be connected to the drug for therapeutic purposes. And this will then travel like a heat-seeking missile right to the cancer or the problem, and kill the cancer. So this is quite an exciting growing field in the therapeutic section.

As we're and experience manufacturer, we work in nuclear medicine, we supply these products, they're used routinely. I think everybody on this call probably knows people who have had either these diagnostic or therapeutics. There's over 40 million diagnostic procedures a year to diagnose life-threatening conditions.

And our passion is to deliver these products safely and routinely around the world. And, in particular in Canada, you know, we need to make Canada self-sufficient, particularly at the moment, in the supply of these key products.

These are the particular products we make at the Kanata site. There's two products available commercially and one product in development.

The first product there is Indium oxine, and this is a diagnostic, it's used for inflammation. An example application is to diagnose diabetic foot.

The second product, and this was where got the testimonial, this is TheraSphere™, this is an implantable medical device used to treat liver cancer and

explore in different cancers that can be useful in the future as well. And we actually manufacture this under contract to Boston Scientific to supply this product. It's their product and we manufacture it for them.

I understand that Boston Scientific will be making an intervention later on today.

Our third product, and this is in development at the moment, this is Technetium-99m generator. This is really innovative, very new, dramatically new technology to produce Molybdenum-99. And this is really the lifeblood of nuclear medicine.

Our technology is very different to the technology existing on the market, and we believe it's far superior. And we've invested a lot in this new technology, as our plan is to submit it to the FDA by the end of this year, and shortly afterwards to Health Canada.

Just to explain a little bit about the market in general. On the left-hand side you can see this map of the world for nuclear medicine. About half of the market or the demand for these products is in Canada and the US, the other half spread around Europe and Asia.

At the bottom on the left-hand side you can see, this is for market research, independent market research, anticipated growth in this market. And you can see the anticipation is that it will grow dramatically over

the next 10 years, grow five times in 10 years.

So this is quite substantial growth. Here, it's measured in dollars, but you can think of this as numbers of procedures or numbers of patients it really helps.

On the right-hand side you can see this diagram and an excerpt from a press release. This is just from March, just from a couple of months ago. Novartis, one of the big pharmaceutical companies, I'm sure you know, in the world, issued results from a Phase III clinical trial that they have looking at this nuclear medicine product to treat metastatic prostate cancer, and the results were very very encouraging.

So at the top there you can see a patient on the left-hand side, in A, this gentleman has metastatic prostate cancer disease, and after four treatments spread over a year, you can see he's a good responder. And these were patients who have very little alternatives at the moment, regrettably.

So these products make a significant difference. And our aim is to be right at the heart of making these products, these sort of products, and delivering them to patients.

In terms of what activities are specifically carried out at the Kanata site, really we'd

split this into sort of a four-step process: there's receiving medical isotopes, these are typically produced offsite; then we process or purify the product; manufacture the final product; and, distribute to customers.

So you can see on the left the bit in green in the middle is what we do in Kanata. So for TheraSphere™ we receive Y-90, this is from University of Missouri and other sites. And then parts done in Kanata is basically to process and purify, dispense into unit doses and terminally sterilize, we autoclave for this. And then daily deliver to Canada, the US, and around the world.

Indium Oxine, similarly we get the Indium-111 actually from Vancouver and then at the site in Kanata we do some synthesis and then dispense into patient doses, and again terminally sterilize and then deliver to customers.

And with Technetium-99m generator it's in development, we'll receive Mo-99 from MURR or from OPG. Well, you have your hearing tomorrow. And then we immobilize, make this into powder and dispense into a generator and sterilize the product. Then we will deliver three times a week to Canada and the US.

It's well worth stressing, we don't use uranium as a starting material, unlike the competitive technologies around the world. I think this was perhaps a

misunderstanding in some of the interventions. But we don't use it in the process as a starter.

So just to stress, you know, in Kanata we are performing precision manufacturing. We're using radioactivity created elsewhere to create sophisticated products on site that are directly for patients, and then deliver them to patients.

A little about our audits. You know, we must be one of the most regulated industries I the world. We have nuclear regulations and then pharmaceutical regulations. So we get regularly audited. Last year we were audited by CNSC under Nordion's licence for work conducted by BWXT, and the CNSC found we were in full compliance with all criteria.

In 2019 we were audited by the FDA, Health Canada, by ISO, and we were compliant. So we've been compliant with the regulations and we are highly regulated.

So in terms of our application, as I mentioned before it's the same type of radioactive products as we've been doing previously under Nordion's licence. It'll be the same sort of levels or below in terms of quantities and levels of radioactivity. And we're not going to duplicate the products under Nordion's Cobalt-60 business, their sterilization business.

And any new products that we develop,

we're looking at new products, but they will fall within the scope of the current and the new licence we've applied for in terms of the type of products and the sort of radioactivity levels.

So I've got four or five slides just to explain how we manage the compliance and regulatory aspects. All of this is in detail in our application, but just to explain broadly.

Really our management system, you know, we were a part of Nordion on this site, so it's using Nordion's established safety and security programs. And they've been comprehensive and robust. We look carefully at the employees, contractors, the public, the environment. It covers all these aspects. And they are subject to regular review by the CNSC and being consistently assessed as satisfactory.

Next slide, please. Just some other areas, radiation protection. We measure radiation doses, you know, frequently for our employees for example, for our workers and what happens with the public, and the doses are far, far less that limits, a lot, lot less. So -- and in terms of conventional health and safety, we've got a very strong safety culture. We take it very seriously and we focus on continual improvement. And again, the incident rates we have on site here at Kanata are much lower than

that of comparable industries.

In terms of environmental protection, we don't expert to have any environmental or health impacts on the environment.

Next slide, please. We've done an environmental risk assessment. Again, that's available, but just to summarize here, we look at nuclear substances and hazardous substances. We look at airborne emissions and liquid emissions, and we measure these continuously, and they are all under limits and we're all in compliance. So we believe from this, is negligible risk to the environment.

Next slide, please. In terms of waste handling, all the radioactive waste on site is collected and then sent offsite to an approved radioactive waste management facility. Wastewater which might contain, or which potentially contains small amounts of contamination is collected onsite in holding tanks and then it's sampled and then released when it's below release limits. And in terms of solid waste, it is segregated here on site and screened, and then released through conventional methods when it's below accepted clearance levels from CNSC.

Next slide, please. The other part I should mention is decommissioning. As part of the application, we have -- we're required to have a

preliminary decommissioning plan, which we've got, and this meets the criteria of the CNSC and this is updated frequently. So the last time we did this was 2018 and we've -- we've got a financial guarantee in place, as required by the CNSC, for our cost estimate of just over 10, 10.5 million Canadian dollars.

Next slide, please. Other matters of interest, just in terms of public information, you know, we do try to be transparent and to engage with our communities. With Indigenous communities we're -- we've got a policy which in out parent company, which is on our website, and we're committed to long term proper engagement with Indigenous communities and we do active communications, and outreach, and discussions.

In communication methods, we have a website. We've got phone numbers and email addresses, as you saw from the testimonial we had earlier, and we do letters and electronic updates. Social media, we use. So we do try to communicate and engage with the community in which we work. We held a webinar, which is think was well attended on March the 31st. It's my colleague in the picture there, this is part of Chris Critch doing part of that presentation.

Next slide, please. Thank you for the opportunity to look at all the interventions, and we just

wanted to clarify a few statements in the interventions. At Kanata, we don't have a nuclear reactor or site.

--- Background noise / bruit de fond

MR. COOMBS: Excuse me? Okay. I think we had some off channel. Can everyone still hear me okay?

THE PRESIDENT: Yeah.

MR. COOMBS: Okay. I just wanted to.

THE PRESIDENT: Yes, we can. Sorry about that, yes.

MR. COOMBS: Yes. There's a bit of heckling, I think, or I'm not sure what that was. But anyway, I'll carry on.

So first of all, we don't have a nuclear reactor or cyclotron, we don't irradiate product here at Kanata. And the molybdenum associated with our new generator products, as I mentioned earlier, that would be produced and radiated offsite. It's the processes and manufacturing of the technetium generator that will be done at Kanata. And you know, it's bound by the same licence conditions as the current and new licence.

We don't use uranium as a starter material on our site, or at our partners' either. And our facility, in fact, has not only producing molybdenum, but produced technetium generators in the past, so we're very familiar with these sort of products.

And we, as part of the acquisition from Nordion, you know, we acquired all the personnel, which is perhaps the most important part, and these are well-experienced people who worked in the sector, in some cases for many, many years.

Next slide, please. Nordion -- this is our landlord and partner here on the site, and this is the company from which we bought what is now BWXT Medical. We've got a long-term lease agreement and, you know, they cover a lot to the building and building system modifications and maintenance. And we've got a framework to manage sitewide programs together, like, security, like environmental, health and safety we've got a joint committee, and environmental monitoring. So we do those sort of things together.

And Nordion is a strong partner of ours and we have a very good relationship and I understand they're also making an intervention later today.

Next slide, please. Just on -- one of the things I should say is, you know, we are -- we're investing in the future. We're investing for growth of this facility and we're making major investments in infrastructure and automation. On the right-hand side, this photo, this is our new packaging line for generators, and this is fully automated, that will be installed in Kanata. It's a very

impressive set up, I must say.

And we -- we're making frequent press releases. In March we announced a joint venture, we're setting up in Asia. In May we announced a long-term agreement with Boston Scientific to produce TheraSphere globally from our site in Kanta and that involved us investing in automation to the long-term partnership for growth and of this exciting product. And really, we committed to the site, and we committed to the long term, and we committed to investment and excellence on this site.

Next slide, please. So I should say as well, you know, we're trying to create many good jobs in the community. We've expanded our workforce since the acquisition from Nordion. We've got over 200 people working on our site here at Kanta. And these are skilled jobs, you know, these are jobs with degrees or further degrees, very accomplished, skilled, talented people that we're proud to have working with us and for us for the benefits of patients and customers and drawn from the local community.

So if anybody listening to this would like to apply, please apply. We are always looking for good people and we're trying to grow. And I think we're appreciated by the community and we in turn also appreciate the community here.

Next slide, please. So just to conclude, our licence application, you know, I think we've demonstrated that we are qualified to undertake these activities and that we make all adequate provisions for protection of the environment, employees, public, and the maintenance of national security, really and all the obligations to which Kanata has agreed. And we're proposing a 10-year licence and we'd request that that's effective from the first of November, later this year.

So I'd like to conclude then, and President Velshi, before I pass back to you, I should introduce the rest of my team who I hope will help me answer questions a little later as necessary. But on the line, we've got Bill Riddoch, who is Head of Research and Technology and Development here in BWXT Medical. Jackie Kavanagh, who runs Environmental Health and Safety, and Regulatory. Richard Decaire, who is our Radiation Safety Manager. Natalie Cutler, who is in charge of Communications and Government Relations at our parent company. Tammy Scantlebury is our Occupational Health Specialist. And then three people who are Environmental Health and Safety Compliance Specialists, Tim Mahilrajan, Shannon Lacasse, and Susan Lyles.

So I hope between us we are able to answer or respond to your points and questions from the Commission

and from the interventions too, that are satisfactory to you. And thank you for the opportunity, and I'd like to pass it back over to you, President Velshi.

THE PRESIDENT: All right. Thank you very much, Mr. Coombs, for your presentation.

Just a point of clarification in case there was any confusion, the hearing tomorrow and Friday for OPG is for the Darlington New Nuclear Project, not for their molybdenum 99 licence application. And a reminder to all participants, please do mute yourself unless you're presenting or answering any questions.

I'd now like to move to the presentation from CNSC Staff as outlined in CMDs 21-H5 and 21-H5.A. Ms. Murthy, the floor is yours.

CMD 21-H5/21-H5.A

Oral presentation by CNSC staff

MS. MURTHY: Thank you. Good morning, President Velshi and Members of the Commission.

For the record, my name is Kavita Murthy and I'm the Director General of the Directorate of Nuclear Cycle and Facilities Regulation at the CNSC. With me today are my colleagues, Mr. Andrew McAllister who is the Director of Nuclear Processing and Facilities Division, and

Mr. Jason Duhaime, a Project Officer from the same division.

We are here to present CNSC Staff's assessment of BWXT Medical's application for a Class 1B licence to operate a medical isotope processing facility.

Also in attendance are CNSC specialists who have been involved with the technical assessment and the compliance oversight of BWXT Medical. They are available to answer any questions that the Commission may have.

Our presentation, identified as CMD 21-H5.A provides a summary of CNSC staff's written submissions found in CMD 21-H5, as well as a high level overview of the things that we have identified in the interventions received from the public and Indigenous groups.

Next slide, please. Thank you.

We will start this presentation by providing an overview of BWXT Medical's licence application and the medical isotope facility in question. We will follow that with the summary of CNSC Staff's technical assessment of BWXT Medical's application and key safety and control areas. We will then cover off details of CNSC Staff's public and Indigenous engagement and the participant program -- participant funding program, excuse

me -- followed by the licence and *Licence Conditions Handbook*. We will end today's presentation with CNSC Staff's overall conclusion and recommendations to the Commission on the licence application request by BWXT Medical.

Next slide, please. And we can go next. Thank you.

BWXT Medical Limited submitted a licence application for a Class 1B licence in December 2018. The licence application requested a licence to operate a nuclear medicine production facility to process medical isotopes at 447 March Road in Kanata, Ontario. BWXT Medical also requested acceptance by the Commission of a financial guarantee through two new instruments, a surety bond and a letter of credit.

The activities proposed in the licence application are currently carried out under the Class 1B Nuclear Facility Licence by the -- issued by the Commission to Nordion Incorporated. Over the course of our presentation, when we speak to the historical performance of the licenced activities, we will often refer to activities carried out under the Nordion licence.

As I mentioned in the previous slide, the activities the BWXT Medical is proposing to carry out, if granted a licence, are activities that are currently

carried out by Nordion. This Class 1B nuclear facility site at 447 March Road comprises two distinct types of operations, the gamma technologies operations and the nuclear medicine operations, both located in the Kanata Operations Building.

The site has been under regulatory oversight, first under the Atomic Energy Control Board, and now the CNSC, and Nordion has operated the site safely since the 1980s. In 2018 Nordion leased the medical isotopes portion of the Kanata Operations Building to BWXT Medical for a 20-year period in a landlord/tenant agreement. The acquisition was completed in August 2018. Since that time, BWXT Medical employees have been working as subcontractors to Nordion in the nuclear medicine production facility. Nordion, as the licence holder, remains accountable for the operations.

In December 2018 BWXT submitted a request to obtain authorization to operate the nuclear medicine production facility under a separate licence. There are no substantive changes to the licenced activities for BWXT Medical in this request for a separate licence.

If granted a licence, BWXT Medical will be accountable and responsible for the nuclear medicine production facility. This completes the introductory portion of the presentation.

I will now pass it on to Mr. Andrew McAllister.

MR. McALLISTER: Thank you, Ms. Murthy. For the record, I am Andrew McAllister and I'm a Director of the Nuclear Processing Facilities Division.

Next slide, please. This slide helps situate where the facility is within the Ottawa area, as well as additional details on its location. If we look at the map on the right-hand side of the slide, you will see that the facility is located in the western part of Ottawa, in the suburb of Kanata. Looking at the aerial photo, in the top righthand corner is March Road, with the facility being located on the west side of that road in the Kanata Research Park. The building in the middle of the picture is Nordion's Kanata Operations Building. Within the building and highlighted by the red outline, is the Nuclear Medicine Production Facility.

Here are the typical steps in the production of medical isotopes. First off, the target material is irradiated in a reactor to produce a desired isotope. The irradiated target is then shipped to Nordion in compliance with regulatory requirements and brought to the Nuclear Medicine Produce Facility for processing.

As you can see in this picture, processing is typically done in a sterile environment, normally a

clean room, and the worker in the picture is fully gowned in a clean room suit, working with remoter manipulators in a shielded hot cell for protection against radiation. The final product is then labelled, packaged, and sent to user facilities, such as hospitals.

Currently, the Nuclear Medicine Production Facility produces Yttrium-90, which is a sterile active implantable medical device used to treat liver cancer; and Indium-11, a diagnostic radiopharmaceutical used for the assessment of inflammation and infection within the body. BWXT Medical proposes to continue to produce these two isotopes.

The Nuclear Medicine Production Facility has historically been used to process fission molybdenum-99, which is produced from the fission of highly enriched uranium targets in a reactor. However, production ceased in 2016 with the shutdown of the National Research Universal Reactor at Chalk River. BWXT Medical has proposed to produce molybdenum-99 using a natural molybdenum-98 target. The process involves the irradiation of molybdenum-98 target in reactors which would be located offsite. The daughter isotope technetium-99m will be extracted from the molybdenum-99 using a technetium generator, which will be loaded at the Nuclear Medicine Production Facility.

In support of the molybdenum-99 process, BWXT Medical intends to install electron beam sterilization equipment within the facility. This equipment would be classified as Class 2 prescribed equipment in accordance with the *Class 2 Nuclear Facilities and Prescribed Equipment Regulations*, and as such, a separate application is currently being assessed by CNSC staff in our accelerators and Class 2 facilities division. Finally, BWXT Medical plans to continue to develop new products within the licencing basis of the facility.

I will now pass the presentation to Mr. Jason Duhaime, Project Officer for the BWXT medical licence application and the Nordion Class 1B licence.

MR. DUHAIME: Thank you, Mr. McAllister. Good morning, President Velshi and Members of the Commission. For the record, my name is Jason Duhaime and I'm a Project Officer with the Nuclear Processing Facilities division of the CNSC.

I'm responsible for the licencing and compliance oversight of BWXT and the single point of contact for this facility and along with the technical specialists assigned to this facility, form the Facility Assessment and Compliance Team that conducted the various assessments related to BWXT Medical's licence application.

To begin this part of the presentation, I

will provide an overview of CNSC's regulatory framework. The CNSC has a robust regulatory framework in place to ensure licensees operate in a safe manner and in compliance with the requirements of the *Nuclear Safety Control Act*, associated regulations, as well as the licence and *Licence Condition Handbook*, regulatory documents including several CSA standards are prescribed as requirements for the licensees' operation to ensure safety. International Atomic Energy Agency Safety Standards are provided as guidance to ensure that the design and operation of facilities, like BWXT Medical, meets the nuclear safety control requirements and is consistent with international practices.

Safety control area framework is a set of 14 technical topics used by CNSC Staff across all regulated facilities and activities to assess, evaluate, review, verify, and report on regulatory requirements and performance of licensees and applicants. For a new applicant, information is obtained through CNSC Staff's reviews and assessments of the documents submitted as part of the application.

Through its technical assessment process, CNSC Staff also ensures that licensees -- licensee has submitted all the information required under the *Act* and the applicable regulations.

The table on the right shows all 14 safety and control areas that were assessed during the technical assessment. The bolded safety and control areas in the table will be discussed further in the presentation.

CNSC Staff's written submission CMD 21-H5 Section 3 contains a description of the safety and control areas and specific areas assessed. Appendix A1 of the CMD provides the regulatory basis of what the requirements are for a Class 1B nuclear processing facility. And Appendix A-3 of the CMD provides the technical basis of what standards and regulatory documents were used as references for the assessment itself.

I will now start with CNSC staff's assessment of the management system, safety and control area. BWXT Medical's proposed management system includes measures to understand and promote safety within the organization. They will conduct safety culture surveys every three years, with its first survey to be done in late 2021 or in 2022 as a means to assess its safety culture.

The proposed management system also includes measures to collect and share information with other licensees and follow operating experience and best industry practises.

CNSC staff also confirm that BWXT Medical's proposed management system includes measures to

assess performance and implement corrective plans.

The proposed management system includes an acceptable change in design control program and also ensures that records will be maintained in accordance with CNSC requirements.

BWXT Medical's management system meets CNSC requirements.

BWXT Medical's management system is adopted from Nordion as these documents form part of the licensing basis for the facility.

BWXT Medical employs over 150 employees that are trained to work in the nuclear medicine production facility. The employees continue to work at the facility as subcontractors to Nordion and continue to implement the programs and procedures that were in place before the acquisition. The programs and procedures were assessed during the technical assessment and found to be acceptable by CNSC staff.

BWXT Medical has committed to revising and updating these documents within a 12-month period following the issuance of a licence. The updates are administrative in nature such as updating the organization's name, logo and removing references to Nordion.

Next in the presentation is the safety analysis control area. BWXT Medical's application included

a safety analysis report for the nuclear medicine production facility. The safety analysis report included a description of the facility and the measures in place to protect the safety of the workers, the public, the environment on any environment under normal and abnormal operations and accident conditions.

Some of the measures include the processing of nuclear substances in hot cells, gloveboxes, fume hoods and transferring and storing nuclear substances with appropriate shielding.

Activity limits are also established and maintained for hot cells, gloveboxes and fume hoods.

BWXT Medical also submitted several related assessments that were conducted to ensure the safety of its operations. These assessments included earthquake risk analysis, aircraft impacts, and fire. To ensure the safety analysis reports remain valid and accurate the CNSC requires that safety analysis reports be reviewed a minimum of once every five years or whenever a facility undergoes significant changes, whichever is sooner.

Moving on from safety analysis, I will now discuss the physical design, safety and control area. BWXT Medical's facility design must comply with all applicable codes and standards as listed in the staff's CMD. These

codes and standards ensure that building structures, heating, ventilation and equipment are appropriately constructed, commissioned and operated.

BWXT Medical is required by its licence to notify the CNSC of significant changes to its fire protection program which mitigates fire hazards at this facility, and the licensee must submit accompanied third-party reviews for compliance with the applicable codes and standards.

CNSC staff confirm that all operational changes are assessed, managed and documented by BWXT Medical through implementing and maintaining a change control program and related procedures under its management system that ensures any major changes are within the licensing basis.

CNSC staff assessed that BWXT's physical design program meets the requirements under the *Nuclear Safety and Control Act*.

In the next few slides, I will discuss CNSC staff's assessment and conclusions regarding the radiation protection and environmental protection safety and control areas, beginning with the radiation safety -- radiation protection and safety control area.

BWXT Medical's application included an ALARA as low as reasonably achievable program based on the

existing programs in place at Nordion.

CNSC staff assessed BWXT Medical's ALARA program and determined that it contains the elements set out in Section 4(a) of the *Radiation Protection Regulations* and meets CNSC expectations. For example, action levels are set appropriately with multiple levels of control with quarterly and annual action levels based on the type of exposure.

The radiation protection program meets CNSC requirements and is protective of workers at the facility.

In this slide we see the occupational exposure to the nuclear medicine production facility, nuclear energy workers from 2015 to 2020. The last three columns that are bolded represent doses to BWXT Medical workers from the acquisition of the nuclear medicine production facility in 2018 to 2020.

As you can see in the Table occupational doses to workers are well below the annual regulatory limits for effective dose, skin dose and extremity dose.

As we can see in this Table, annual effective doses to the public are well below the regulatory limit of one mSv per year. There's no impact to public health and safety from BWXT Medical's operations in the nuclear medicine production facility.

Now, we'll turn our attention to the environmental protection, safety and control area. As part of its licence application BWXT Medical had submitted the Nordion environmental risk assessment that was deemed acceptable by CNSC staff and this was reflected in CNSC staff's CMD.

Subsequent to the approval of the CMD, BWXT Medical submitted an environmental risk assessment specific to the nuclear medicine production facility and its proposed activities that meets the requirements of the CSA standard for environmental risk assessments. This environmental risk assessment has been posted on BWXT Medical's website and it was submitted by BWXT Medical as supplementary information on May 17th, 2021.

In this slide I will speak to the environmental protection program highlights which include the following:

BWXT Medical submitted an acceptable environmental risk assessment that meets the requirements of the CSA standard for environmental risk assessments.

The proposed measures submitted by BWXT Medical to control and monitor airborne emissions and liquid effluent releases to the environment comply with the requirements of the CSA standard for effluent monitoring programs.

Environmental action levels were not developed as releases from the nuclear medicine production facility are below detectable levels as per the CSA standard for establishing and implementing action levels for releases to the environment from nuclear facilities. However, as part of the licence condition, in *Licence Condition Handbook,* BWXT Medical will be required to reassess the need for environmental action levels at least every five years or sooner by monitoring data, or if there is a change in operations that may result in an increase in releasants to the environment.

BWXT Medical's environmental protection program meets regulatory expectations.

The derived release limits established for the nuclear medicine production facility meet the requirements set out in the CSA standard for guidelines for calculating derive release limits for radioactive material in airborne and liquid effluents. The joint BWXT Medical-Nordion Environmental Health and Safety Committee will monitor and ensure that the joint releases are being kept below the derived release limits and regulatory public dose limits.

The derived release limits ensure that the joint releases of radio nuclides from the BWXT Medical and Nordion Class 1B nuclear facilities will not result in an

exceedance of the regulatory limit of 1 mSv per year for a member of the public.

The derived release limits assessment included radionuclides currently measured in the environmental protection program, known or anticipated radionuclides that will be released and radionuclides that may be introduced in future operations.

From a historical perspective, Nordion's environmental monitoring program was assessed by CNSC staff and found that it meets expectations. Historically, airborne emissions and liquid effluent releases have remained well below regulatory limits.

In 2016 and 2018 the CNSC performed independent environmental monitoring at the Nordion site as part of the CNSC's independent environmental monitoring program. Sampling focussed on radioactive substances. CNSC staff collected air, soil, sediment and water samples in publicly accessible areas outside the Nordion facility perimeter. The results indicated that the public, Indigenous communities, and the environment are safe and protected.

In the next slide I will discuss the emergency management and fire protection safety and control area.

BWXT Medical has proposed to continue,

follow and be integrated in the emergency preparedness program established by Nordion. The emergency preparedness program includes details on the management and maintenance of the program, plans and procedures for responding to all hazards and scenario-specific events and business continuity plans.

CNSC staff confirmed that BWXT Medical has worked on a formal service agreement with Ottawa Fire Services in order to meet the requirements of the CSA standard for fire protection for facilities that process, handle or store nuclear substances.

CNSC staff are satisfied with the measures proposed by BWXT Medical for the emergency management and fire protection, safety and control area.

Here, I will speak of the BWXT medical's preliminary decommissioning plan. The decommissioning of a nuclear facility is required to be considered in all phases of the facility's lifecycle and a decommissioning plan is required in the license application.

BWXT Medical's application included -- includes a preliminary decommissioning plan which includes a cost estimate for the Class 1B facility. CNSC staff determined the preliminary decommissioning plan meets the requirements for the CSA standard for decommissioning of facilities containing nuclear substances and CNSC

regulatory guide G-219 *Decommissioning Planning for Licence Activities.*

Information on BWXT Medical's proposed financial guarantee is covered in the next slide.

As part of its licence application, BWXT proposed the financial guarantee of $10.54 million through two proposed instruments: a letter of credit in the amount of $2.6 million for putting the facility in a safe shutdown state, and a surety bond in the amount of $7.94 million for the remainder of the decommissioning costs.

CNSC staff determined that the proposed financial guarantee is credible and that the financial instruments are acceptable.

I will now pass the presentation back to Mr. Andrew McAllister.

Thank you.

MR. McALLISTER: Thank you Mr. Duhaime.

In this section of the presentation, we will cover BWXT Medical's public information and disclosure program, CNSC staff's public outreach, and CNSC staff engagement and outreach with Indigenous groups.

CNSC staff have reviewed BWXT Medical's public information disclosure program and determined that it identifies clear goals and objectives in terms of dissemination of information to targeted audiences;

identifies that a public disclosure protocol will be available to the public and posted on their website; provides contact information for members of the public who want to obtain additional information; and, finally, identifies multiple targets in close proximity to the licensed facility such as elected and government representatives, local schools, local health units and first responders, community leaders and associations, and local Indigenous groups.

BWXT Medical's public information disclosure program meets CNSC requirements.

As part of the license application process, CNSC staff have conducted public outreach activities. The announcement for the Notice of Hearing was posted on CNSC's website on November 18th, 2020.

On March 31st, 2021, CNSC staff participated in BWXT Medical's public outreach session. And the following week CNSC staff held a Meet the Nuclear Regulator webinar. This webinar included information on BWXT Medical's license application, CNSC's licensing process, information on how to participate in the hearing, and Indigenous engagement and consultation.

As an example, of CNSC staff outreach as can be seen on the right-hand side of this slide, our Notice of Public Hearing for BWXT Medical's license

application was mailed to residents who live within a 10-kilometer radius of the facility in March 2021.

With respect to Indigenous engagement, CNSC staff identified different Indigenous groups who previously expressed interest in being kept informed of CNSC license activities occurring in proximity to their tradition and/or treaty territories.

CNSC staff were also satisfied that BWXT Medical engage with appropriate Indigenous groups regarding their planned licensed activities.

CNSC staff regularly engage with Indigenous groups in a number of ways and in our current pandemic environment it has largely been through email, letters, telephone calls, and video calls.

This slide lists engagement activities undertaken, starting with the notification letters sent in July 2019.

In November 2020, CNSC staff sent follow-up letters to each Indigenous group with updated information regarding the Commission's public hearing process and the availability of participant funding.

Some Indigenous groups were awarded funding through the participant funding program in February 2021 which will discussed in greater detail in the next slide.

In March 2021 identified groups were provided a copy of the Commission Member documents and invited to meet with CNSC staff to discuss any concerns.

CNSC continues to engage with Indigenous peoples to build trust and foster relationships.

The CNSC participant funding program has been implemented to assist members of the public, Indigenous groups, and other stakeholders in providing value-added information to the Commission through informed and topic-specific interventions.

The CNSC awarded $68,200 to the five funding recipients listed on this slide to participate in the BWXT licence application regulatory process. The recipients are: the Algonquins of Ontario, the Algonquins of Pikwakanagan First Nation, Anna Tilman, Kebaowek First Nation, and Women in Nuclear.

A total of 21 interventions were received. There is an Indigenous grouping of themes that include engagement and communication with Indigenous groups; participation of Indigenous groups of monitoring activities; and consideration of Indigenous knowledge.

With respect to the activities being proposed, there was themes of the proposed molybdenum-99 process, waste handling, specific nuclear substances for processing activities not listed, and the potential

increase in the production of radioisotopes.

The license term and the health and safety of the workforce, including nuclear energy workers and contractors were also raised.

I will now present information on CNSC staff's proposed licence and *Licence Conditions Handbook*, and staff's area of focus should a licence be granted.

BWXT Medical is requesting a 10-year licence term. The proposed licence includes standard licence conditions and a draft *Licence Conditions Handbook* or LCH, for short. The draft LCH uses the CNSC standard template which includes a preamble and compliance verification criteria such as CNSC regulatory documents and CSA group standards.

Guidance is also provided, where applicable, enhancing the effectiveness of the safety and control measures for each safety and control area.

CNSC staff supports the requested 10-year licence terms for the following reasons:

Number one, since BWXT Medical's acquisition in 2018, the nuclear medicine production facility has continued to be operated in a safe manner under Nordion's Class 1B licence. For example, as we have seen in earlier sliders, doses to workers remain well below regulatory limits.

Secondly, many of the current BWXT Medical personnel and management working in a nuclear medicine production facility are former experienced Nordion employees. The safe operation of the facility is maintained as personnel continue to follow the same processes and procedures that were in place before the acquisition by BWXT Medical.

Finally, the requested 10-year term is consistent with CNSC licences issued to other nuclear facilities across Canada.

Should a licence be granted, compliance activities will include aspects such as inspections, document and report reviews, and an assessment of any changes to licensee's programs against the licencing basis and safety case.

CNSC staff will report annually to the Commission and the public and Indigenous groups through the regulatory oversight report. The regulatory oversight report summarizes CNSC staff's assessment of the safety performance of the uranium and nuclear processing facilities.

The Nordion BWXT Medical relationship has been touched on in a few spots in our presentation and BWXT Medical has likewise described this in their CMD and presentation, but to summarize here, there will be two main

aspects attributed to the co-location in the same building. One, is Nordion acting as a subcontractor to BWXT Medical for different services at site? Some examples are provided here, such as security-related aspects.

The second aspect pertains to the implementation of its programs and activities that might overlap with that of Nordion as a Class 1B licensee. To address this, joint mechanisms will be established to manage these. For example, a joint environment health and safety committee will be established to review different aspects such as environmental performance data, incidents related to occupational health, safety and environment and the sharing of operating experience.

Regardless of the activities, whether they are subcontracted to Nordion or if there is a joint program element, BWXT will have ultimate responsibility and accountability for all of its activities if issued a license.

I will now outline CNSC staff's conclusions and recommendations for BWXT Medical's licence application.

CNSC staff conclude based on the technical assessment of BWXT Medical's application and supporting information that BWXT Medical is qualified to carry on the activities requested in its licence application. The

requested activities are within the facilities current licensing basis, and BWXT Medical's operations will remain protective of the public health and environment.

CNSC staff also conclude that BWXT Medical's proposed financial guarantee is acceptable. BWXT Medical's proposed financial guarantee of approximately $10.54 million is a credible cost estimate and the financial guarantee instruments, a letter of credit for $2.6 million, and a surety bond for approximately $7.94 million are acceptable.

CNSC staff recommend that the Commission issue a nuclear substance processing facility licence to BWXT Medical for a 10-year period with the proposed license conditions and authorize the delegation of authority set out in the CMD, and accept the proposed financial guarantee and direct BWXT Medical to provide the original instruments within 90 days of the issuance of a decision on this matter.

Thank you. Merci.

We're able to respond to any questions that you may have.

THE PRESIDENT: Thank you, CNSC Staff, for the presentation.

We will now move to the interventions.

Marc, I'll turn it over to you for a few

introductory remarks please.

MR. LEBLANC: Merci, Madame le Présidente.

Yes, we will now move to the oral presentations from the intervenors. Before we start, I would like to remind intervenors appearing before the Commission today that we have allocated 10 minutes for each oral presentation, and we would appreciate your assistance in helping us maintain that schedule as much as possible.

Your more detailed written submission has already been read by the Members, and will be duly considered. There will be time for questions for the Commission after each presentation and there is no time limit ascribed for the question period.

I will ask that once your presentation is over and the associated question period, that you leave the Zoom session. You will be able to continue following the hearing via the live webcast on the CNSC website.

Madame la Présidente.

THE PRESIDENT: Thank you. The first submission is from the Algonquins of Pikwàkanagàn First Nation as outlined in CMDs 21-H5.9 and 21-H5.9A.

Ms. Two-Axe Kohoko is making the presentation. I'll turn the floor over to you.

CMD 21-H5.9/21-H5.9A

Oral presentation by

Algonquins of Pikwàkanagàn First Nation

MS. TWO-AXE KOHOKO: Meegwetch, thank you.

Hi everybody, my name is Amanda Two-Axe Kohoko, I'm currently the Consultation Coordinator in Economic Development for the Algonquins of Pikwàkanagàn First Nation. So thank you again for allowing me to deliver this presentation.

So I'm going to be having a discussion about background on the First Nation and who we are, and then a small slide on the BWXT facility, impacts on the First Nation's rights and interests, followed by recommendations, and then the conclusion.

So a little bit about the First Nation. The Algonquins of Pikwàkanagàn First Nation is located on the shores of Golden Lake and the Bonnechere River in Renfrew County.

Our First Nation is a progressive community established in 1873, following by a petition to purchase our own land. This resulted in the Golden Lake Indian Reserve No. 39.

Today our community is driven by strategic plans administrated and delivered by Pikwàkanagàn

administrative team and an elected Chief and Council serving over 450 people on reserve and a broad membership of approximately 2,700 people off reserve.

And the Band Office provides programs and services that manage the same level of core services as a municipality and township. A key service is provided through the Economic Development Department to develop and promote Pikwàkanagàn First Nation as thriving, living and working sustainable Algonquin community.

So our members are active harvesters across the territory. Projects within the First Nation territory require full direct engagement with our nation and accommodation of the First Nation rights. The First Nation territory has seen multiple nuclear sector projects over time, and this is regarding the importation, production use and disposal of radioactive materials, has had adverse impacts on the environment of the First Nation unceded territory and the First Nation's Aboriginal rights.

The First Nation members are concerned about the project-specific cumulative effects from nuclear projects. And the consent to build/operate these facilities within the First Nation territory was never sought. So our First Nation's seeking greater participation and collaboration on the facility, physical works and activities, monitoring and oversight with both

the licensee and CNSC going forward.

So a little bit about the facility itself. All activities currently occur within an existing nuclear substance processing facility, and has been in operation for several decades.

If issued a licence, BWXT will be come the licensee responsible for the safe operations of the medical isotope facility. The facility currently produces medical isotopes. And also to acknowledge that the facility is located 115 kilometres east from the First Nation community.

So in regards to impacts on the First Nation's rights and interests, we determined that there is low likelihood of significant adverse impacts on the First Nation's rights and interests.

AOPFN screening determined that the production of medical isotopes will have a significant positive impact on human health. The proposed activities are predicted to have measurable impacts on human health and the environment. The proponent will use an existing proven, robust and effective management system for safety.

The CNSC has established an adequate oversight program from a technical perspective. And AOPFN remains concerned that that application or regulatory oversight process did not make adequate steps to gather,

include or consider Indigenous knowledge and the First Nation's expectations regarding Indigenous consultation, engagement and monitoring programs.

So the path to reconciliation is not just about avoiding significant adverse impacts on the environment. Agents like the Crown and CNSC and BWXT should be recognizing that project planning, decision making and the opportunity to develop requires building meaningful relationships with Indigenous Nations.

One of the biggest concerns with the nuclear sector for Indigenous people is that decisions are made without meaningful engagement or consultation of Indigenous people, leaving us disempowered and on the outside looking in. So this contributes to the fear of stigma associated with the nuclear sector, which we'll deal with on a day-to-day basis.

MR. LEBLANC: If I may, Ms. Two-Axe Kohoko, it's Marc Leblanc, Commission Secretary, our interpreters are having difficulty following you. So if you need a bit more time, if you can, just reduce the speed of your allocution so that the interpreters can follow and they can fully translate all the important information you're conveying. Thank you.

MS. TWO-AXE KOHOKO: Okay. So I'm talking too fast. Sorry.

So no meaningful reference of Indigenous knowledge integration is provided in any of the documentation of BWXT's application. Indigenous knowledge is not sought or integrated into the considerations. No licence conditions proposed by CNSC Staff related to Indigenous knowledge. Indigenous knowledge must be included in all stages of the project's lifecycle.

CNSC's Indigenous knowledge policy framework needs improvement. So our application has those recommendations for improvement.

So the first recommendation is in regards to Indigenous knowledge should be of equal importance to western science and CNSC processes and decision making.

Currently, in our experience, that is not the case. The First Nation recommends that a series of additional updates be made to the CNSC Indigenous knowledge and policy framework as laid out in detail in our written submission.

We are happy to answer any questions by the Commission on any of those specific recommendations. In fact, one of the reasons we can't go into further detail in our presentation today is related to our recommendation that additional time be given for Indigenous groups to present at the Commission hearing.

AOPFN recommends that CNSC Staff and BWXT

and the Commission itself considers and further engage with the First Nation and other impacted Indigenous Nations on what licence conditions could entrench the need to consider Indigenous knowledge alongside western-specific knowledge in the data collection, analysis and decision making related to project monitoring and management moving forward.

AOPFN appreciates provisions of participant funding provided by CNSC. CNSC Staff's submission to the Commission does not recommend any licence conditions related to Indigenous knowledge, Indigenous consultation, engagement or Indigenous role in monitoring.

AOPFN hopes to be involved in the project beyond document review and email correspondence with both BWXT and CNSC. The best way to ensure is through licence conditions.

So in regards to Recommendation No. 3, AOPFN seeks a licence condition identifying the need for the proponent to engage effective Indigenous groups in defining end land use goals and criteria for the facility and in project closure planning.

Recommendation No. 4. AOPFN seeks greater understanding of involvement in decisions related to how waste from the facility should be handled if it is going to be stored on the First Nation's traditional territory.

This requires a licence condition or other venue for this critical issue to be subject to compliance and enforcement.

Recommendation No. 5. AOPFN recommends adherence by both CNSC and BWXT to the requirements of the United Nations Declaration on the Rights of Indigenous Peoples, including Free, Prior and Informed Consent by Indigenous people regarding projects that involve the management, storage and disposal of radioactive and other hazardous waste materials.

Recommendation No. 6. AOPFN recommends a condition to the licence requiring BWXT to report on an annual basis to the CNSC on how it has engaged and supported areas of Indigenous groups in project planning, monitoring and management, with the annual report subject to Indigenous groups' verification prior to being filed with CNSC.

Recommendation No. 7. CNSC to develop deeper engagement requirements for proponents within Indigenous groups in its forthcoming review of reference document here, Indigenous Engagement, including through a meaningful, extensive and funded consultation process with Indigenous groups impacted by the nuclear sector

And in regards to Recommendation No. 8, the First Nation recommends that CNSC works with Indigenous groups to develop indicators and metrics for reviewing

effective Indigenous engagement.

So our recommendations in regards to Indigenous involvement in monitoring programs. So monitoring exclusive Indigenous groups is critical, an entire layer of knowledge is missing. Minimal opportunities for greater Indigenous participation in CNSC monitoring activities has been identified to date. BWXT has identified no role for Indigenous people in monitoring programs. AOPFN would like to see that projects include independent Indigenous Monitoring Programs.

Recommendation No. 9. So the First Nation requests that the Commission direct CNSC Staff to engage impacted Indigenous groups in a meaningful way in monitoring and management of the project, and report on the results to the Commission with reports verified by Indigenous groups involved.

The First Nation also recommends that CNSC work with AOPFN and other Indigenous groups to develop funded meaningful roles for Indigenous monitors in CNSC's compliance and verification monitoring, including but not limited to the BWXT facility.

So in conclusion, the First Nation appreciates the opportunity to provide comments and recommendations in the interest of building a regulatory process for nuclear projects in our traditional territory

that embraces Canada's commitment to reconciliation and commitments to implement UNDRIP.

AOPFN hopes our 10 recommendations will be implemented in order to address shortcomings in current considerations of Indigenous knowledge, Indigenous consultation and engagement, and Indigenous involvement in monitoring.

Meegwetch, thank you.

THE PRESIDENT: Meegwetch, Ms. Two-Axe Kohoko.

I'll turn to the floor for questions from Commission Members, and we'll start with Ms. Maharaj.

MEMBER MAHARAJ: Thank you, Madam Velshi. And thank you, Ms. Two-Axe Kohoko, for your presentation and your slides, they're very informative.

I just wanted to ask you a couple of questions for context first. You indicated that the First Nation's community is located on the shores of Golden Lake, and that this particular facility is about 115 kilometres east of the community, have I got that right?

MS. TWO-AXE KOHOKO: Yes.

MEMBER MAHARAJ: Okay. And your traditional territory, your Nation's traditional territory encompasses that area where the facility is located and the river system, is that right?

MS. TWO-AXE KOHOKO: Yeah.

MEMBER MAHARAJ: Okay, perfect. So what I heard you say is that the Nation is interested in ensuring that its traditional rights are not negatively impacted by the facility.

Can you describe a little bit more for me about the traditional harvesting that your First Nation does, and whether it includes activities like fishing in the river that is close to the facility?

MS. TWO-AXE KOHOKO: Right. Thank you for your question. So in regards to harvesting, harvesting comes from Aboriginal rights, so that includes fishing, hunting, picking up medicinal plants, trapping.

So because this project is located in our traditional territory and our traditional territory covers 9 million acres, so it's all of Ottawa, almost up to Temiskaming. So we can say that -- because our membership is over 2,700, and that means 2,700 have the ability to practice their Aboriginal rights. So I'm not saying that they're not fishing in those rivers located to the facility.

So that would be my answer, is that -- like, I personally don't know if we are, but I'm probably -- yes, they are. I know -- like, you know, I can only speak to my family and like, you know, where we

traditionally harvest and hunt. You know, right now we're all in the Algonquin Park because, you know, this is where, you know, they told us where we can hunt right now.

So it really depends on how every other First Nation band member of the Pikwàkanagàn does harvest.

MEMBER MAHARAJ: Okay, thank you. When you speak about the interface between the environmental impact and the traditional territories, is there a particular example that you can give us about how the environment affects your traditional rights and if there's any impact from the facility on the environment that you're particularly worried about?

MS. TWO-AXE KOHOKO: Well, first, I just wanted to clarify what do you mean by interface?

MEMBER MAHARAJ: So, for example, if the facility is discharging some kind of contaminant into the water system and that affects the fish, then the fishing is part of your traditional activity, and I could see how that might be an interface or a link between the environmental impact and your traditional rights.

Is there an example that you can give us to help understand how you are concerned?

MS. TWO-AXE KOHOKO: Right. Well, I know with our review in regards to this project, we thought that this project would not cause any significant adverse

effects just because we don't see that there's going to be a spill or anything like that going into the river. So I'm just trying to think of an example on the spot.

But our intervention's really about, you know, setting up the relationships between CNSC, the proponent and the First Nation that has not yet existed. Because we don't really think that there's any significant adverse effects from this project to the First Nation.

MEMBER MAHARAJ: Okay, perfect. And then just along that same track, and then I'll turn it over to my colleague. With respect to your comments about monitoring and being involved in the independent environmental monitoring program, are environmental impacts the driver or the reason that your community is looking for that involvement, or is it more relationship-based and participation-based? What's the goal you're seeking to achieve?

MS. TWO-AXE KOHOKO: Yeah, absolutely. So monitoring is something that through engagement with our members, the community and staff and chief and council, monitoring has been coming up, you know, many times that the band members have been bringing up because of their connection to the environment, to the land, and the significance and culturally importance to wildlife, the animals, aquatic species.

And, you know, we actively participate in harvesting and hunting, you know, for four to six months of the year every year, so there's a real deep connection. And the only way that we, the members, have been saying that we need to develop a monitoring program. The one that we're trying to develop right now is called -- it's a Guardian Monitoring Program, which we've also explained in our application submission.

Because we need to be able to monitor these projects ourselves and report back to our community and chief and council. Because having other proponents monitor and report to us, it just doesn't give verification or validate to the community members that, you know, that this project is actually being monitored safely.

Because it's someone else telling us that it's being monitored, and it's not us going there and to see for ourselves and for us to, you know, actually monitor the project and report to the community.

So that's basically, you know, why it's in our intervention is, you know, it's coming from the community members, this is what they want to see. And it's something that we want to apply to all the nuclear facilities in our traditional territory, is a monitoring component that will be led by the Algonquins of Pikwàkanagàn First Nation.

MEMBER MAHARAJ: Okay. So is the Guardian Program then the same as the Indigenous Monitoring Program that you referred to in your oral submission?

MS. TWO-AXE KOHOKO: No. Well, yes and no. The Indigenous Monitoring Program is -- well, right now it's developed by -- like through a First Nation-led program with one project, and it hasn't been expanded to multiple projects. So in my intervention I'm bringing up that program, that that is the plan. Hopefully, that we can expand this project.

So right now it's just like a pilot project that the First Nation is currently developing right now, so in hopes that we would expand it further and maybe on this project as well.

MEMBER MAHARAJ: Okay. And then my last question is what is your First Nation's biggest challenge in actually developing and conducting an independent monitoring program regardless of what the Commission may or may not do? What is the hurdle or the thing you have to overcome in order to have that program yourselves?

MS. TWO-AXE KOHOKO: So I guess the main thing is funding, capacity, resources. The only way this program can be sustainable is if I have proponents participating and contribute to the monitoring program that the First Nation is leading. And right now, I don't -- we

don't know if there's any government support or government and industry funding. So I think that is our biggest challenge.

MEMBER MAHARAJ: Great. Thank you so much. I appreciate your answers to my questions.

MS. TWO-AXE KOHOKO: Miigwech.

THE PRESIDENT: Maybe I'll just ask a follow up question, Ms. Two-Axe Kohoko, to what Ms. Maharaj was asking around your recommendations nine and 10, to make sure that I understand what it is that you're asking.

One is that you want to be engaged -- more engaged with the CNSC's independent environmental monitoring program. You are also suggesting that there should be an independent Indigenous monitoring program, independent of what the CNSC is doing.

So help me understand what do you see as additional value of having the Indigenous independent environmental monitoring program, given that there is the CNSC one that you already want to be involved in, in making sure that it's providing objective information from that.

MS. TWO-AXE KOHOKO: Yeah. So I think -- well, in regards to the CNSC's Indigenous monitoring, we find that, like, we do get invited, and I know sometimes when we do get invited it's be email. And the thing is if it's, like, a busy time of year it's very difficult for us

to respond and adequate -- provide an actual person from the community to participate. So I don't think we've been able to participate to date because that happened. Because usually, you know, you have -- you have like, a few weeks to say that you want to participate.

So that's been the challenges, you know, because in my -- working in my First Nation, we're all wearing multiple hats. Like, because currently I know I'm the Consultation Coordinator, but I'm also acting as a Manager of Economic Development, and I'm acting as a Board Member. So we're -- we just -- we wear so many hats and sometimes the correspondence emails all come at once and I can't respond to everybody.

But the -- in regards to the guardian program, this is a program that the First Nation is leading. So that means, we're taking direction on when it's the best time and when it's most suitable, and how the program is going to be developed in working and engaging with our community members is the best option for us.

THE PRESIDENT: Thanks very much for that.

Dr. Demeter?

MEMBER DEMETER: Thank you very much for your presentation, Ms. Two-Axe Kohoko.

I have a question for CNSC Staff. The intervenor brought up the issue of no specific licence

condition for Indigenous knowledge incorporation or consultation. But perhaps you could speak to that, if it's not in a specific licence condition, are those issues of consultation and inclusion of Indigenous knowledge and involvement with the First Nations groups covered off elsewhere that -- to ensure that there is some process that ensures that those areas are covered off?

MS. MURTHY: Kavita Murthy, for the record.

Before I pass it on to Adam Levine of the Aboriginal Consultation and Participant Funding Program, I want to bring in the concept of the licencing basis and all the documents submitted by the licensee, which includes a program for Indigenous consultation and engagement that is a part of their -- the documents that they have submitted. So there is -- there is definitely an incorporation of that into the *Licence Conditions Handbook* that provides for requirements related to this subject.

Adam Levine, please go ahead and provide more information. Thank you.

MR. LEVINE: Thank you very much. My name is Adam Levine, I'm the Team Lead for Indigenous Relations and Participant Funding.

So yes, absolutely, there is multiple layers of how we ensure that Indigenous engagement and

consultation is occurring with regards to different licence applications and processes, as well as the consideration of Indigenous knowledge.

So first for Indigenous engagement, as Ms. Murthy just explained, under the licensee's public information and disclosure program, Indigenous groups are listed as one of the key target audiences that they need to be communicating with. And we look at it through their annual compliance reports to ensure that they're talking and engaging with the appropriate Indigenous groups, and that we as CNSC Staff are hearing what the concerns are and topics of conversation.

And we also report on that through the regulatory oversight reports, and also look at that more specifically for any licence application that's coming before the Commission, like this licence amendment. Then on top of that, the CNSC, we take it very seriously, our role in obligations around consultation and engagement with Indigenous Peoples.

So for every single licence application coming before the Commission, we do a thorough assessment of the potential impacts of that application on potential and established Indigenous or Treaty rights, and then engage all the potentially interested or affected Indigenous groups to make sure they're aware of the licence

application and can access participant funding, answer their questions and concerns and make sure that they're involved and have their voices heard in the process.

And we're also continuing to talk to the licensee and applicant as well, to make sure that they're also engaging groups and raising concerns to us, and often we meet all together between all parties to have those discussions.

And then on the Indigenous knowledge side -- this is something that's new and emerging for us and many organizations across the federal government. We believe we're making great strides in that area, as Ms. Two-Axe Kohoko explained, that we did -- are developing an Indigenous knowledge framework that's based off the federal framework for working with Indigenous knowledge. And Amanda's team did review our draft framework and provided some excellent feedback which we incorporated, and we talked to Amanda about that and we're going to be announcing more on that soon.

But we do look at how we can incorporate Indigenous knowledge for every licence application, it just -- the knowledge and information is owned by the communities themselves, and they have to authorize us and help us to understand when it applies and how best to incorporate that.

MEMBER DEMETER: Thank you.

And I was quite intrigued with the Indigenous environmental monitoring framework, and I noted in other applications there was a considerable amount of independent work by some of the Indigenous and Aboriginal groups on such environmental monitoring, such as a country food collection, providing specimens, helping to identify species at risk. Is that a -- an option for -- given the size of the land that's involved here and the different geological or geographical structures?

Is there an opportunity to expand involvement beyond the, you know, consultation about the independent monitoring -- environment monitoring program to something more autonomous and self-directed that could be collaborative with the groups that are involved? Is there a model for Indigenous environmental monitoring that's supported by either the licensee, or CNSC, that's sort of a value add to the IAMP?

MS. MURTHY: Kavita Murthy, for the record. I would like to call Ms. Kiza Sauvé of the Health Sciences and Environmental Compliance Division to provide the response to that.

But Dr. Demeter, as we have in the -- in other sampling campaigns, the value added of having Indigenous participation, in terms of giving us information

on the valued components, is definitely something we have noted. So Kiza?

MS. SAUVÉ: So Kiza Sauvé, for the record, the Director of Health Science and Environmental Compliance Division.

As we've talked previously in other hearings, in Northern Saskatchewan where the communities are -- well, it's almost all Indigenous communities in the North -- we have the Eastern Athabasca Regional Monitoring Program, which is a program funded by -- it's tripartite funding, so the province, CNSC, and the industry funds this program, and it uses community monitors from Indigenous communities.

So it's a great example of a program in an area where there's, you know, industry and Indigenous communities and that's it to come in the area. So that's maybe a good example of where Indigenous monitoring is already occurring.

Through the independent environmental monitoring program, every year we're adding more and more Indigenous involvement to our monitoring. We're often having Indigenous members, as Amanda mentioned, joining the team, and we're working with AOPFN as we go forward to try and, you know, notification earlier on, start discussions earlier on. And we know that they haven't been able to

join us yet, but that doesn't mean that they won't in the future.

We've got lots of sampling coming up in the Chalk River area, as an example. For this facility, the last time it was sampled was in 2018. We expect to be back there in the next few years, not for sure when. But we'll definitely continue those engagements and discussions.

MS. MURTHY: Thank you, Kiza. Adam Levine, please go ahead.

MR. LEVINE: Thank you. Adam Levine, for the record.

So in addition to what Ms. Sauvé just explained about the IEMP, we're collaborating a lot with AOPFN on gathering traditional knowledge and land use information that we've funded through our PFP. The first of a kind Algonquin traditional knowledge and land use study. These were specific to some ongoing major projects in their area, the NSDF and NPD projects.

But as part of it, they did interview community members and Elders that ranged the broader territory, and this is a great opportunity to use this as baseline information to help inform future IEMP sampling campaigns and our collaboration. And it's something that we want to sit down and talk to AOPFN more about, of how we

enhance the IEMP working together and what their vision is moving forward for monitoring throughout their territory. It's something we're very, very interested in looking at from a broader perspective.

We recognize there's a lot of nuclear facilities we regulate in their territory. So we're fully committed to the relationship and obviously right now our big focus with them is on these EA projects, NSDF and NPD. But we do want to broaden that out in the coming months to talk more about the long-term relationship and how we can collaborate on these different areas, because we see a lot of value in that and so we'll be talking to Amanda and her team shortly about that.

Thank you.

MEMBER DEMETER: Okay. Thank you.

I wanted to reassure the intervenor, Ms. Two-Axe Kohoko that I will be drilling down really deep about waste streams with other interventions. That was the other issue you brought up and there's a lot of questions that I will have as well. So that issue you brought up will be covered in depth as we go through -- through the day, and it's also a number of questions I have. So I want to reassure you that that issue will be -- will be discussed.

I don't have any further questions. Thank

you very much.

THE PRESIDENT: Thank you. Maybe I'll turn to BWXT Medical and get their perspective on this intervention and the recommendations in there. So even though the premise is that this project is -- has a low likelihood of a significant adverse impact, the intervenor has raised concerns that there has not been adequate leave for consultation and engagement.

So maybe I'll start with BWXT Medical and then -- then go to CNSC Staff for their reaction for the overall suite of recommendations. So BWXT Medical?

MS. KAVANAGH: Jackie Kavanagh, for the record. I'd like to direct that question to Ms. Cutler.

MS. CUTLER: Natalie Cutler, for the record. I am very grateful for Amanda Two-Axe Kohoko's presentation and we have -- we have reached out at several points to engage with Algonquins of Pikwakanagan and unfortunately, because of the Covid-19 pandemic that's taken place predominantly by email and follow up calls, and Ms. Two-Axe Kohoko has shared with us how busy her teams is, and so we look forward to engaging in person, when it's safe to do so.

Our priority is to understand the objectives of the community as it relates to community concerns, environmental monitoring, and other key areas

that she has shared with us in the meeting that we had in late May. And we're committed to understanding those concerns, addressing them where we can, and having a long-term meaningful dialogue with Algonquins of Pikwakanagan.

Thank you.

THE PRESIDENT: Thank you. CNSC Staff?

MS. MURTHY: Kavita Murthy, for the record.

So I want to start off by saying that we have also noted the -- in these recommendations, a desire expressed to be more involved with the CNSC in having discussions and establishing regular communications and including environmental monitoring, independent environmental monitoring, as well as being able to have a little bit more insight into the activities that the licensee is conducting. So these have been noted.

The Commission is aware that we are looking at incorporating Indigenous participants and inspections, as soon as the pandemic is over we hope to get more action on that. Those are some things that we are already -- that are already in place.

In addition to that, as Adam Levine has pointed out, there is a lot of work afoot at the CNSC to establishing terms of reference and essentially

establishing the engage -- rules of engagement with Indigenous communities.

So Adam, if you would like to add on that, if there is anything that I have missed, please go ahead.

MR. LEVINE: Yes, thank you very much. Adam Levine, for the record.

So just to add on that the recommendations are really helpful for us CNSC Staff and I think for BWXT as well, to understand AOPFN's vision.

They are -- our activities and the activities we regulate are, you know, throughout their territory and we have a lot to work on. We view them as -- a lot of the recommendations, as being broader, as part of the broader engagement relationship and not necessarily directly tied to this BWXT licence amendment application. But they are really helpful for us to understand where Amanda and her team, and her Nation, want to see the relationship and our work together, going forward.

And so we're going to go back and talk with them about what that looks like, and talk about, do we want to more formalize that through a terms of reference and create a workplan that tries to prioritize these things? Because the challenge we're finding, just like Amanda outlined, is around capacity and time. There is so much going on, priority is set right now on the

environmental assessments and major projects in their territory, for good reason. But we can't forget about these other activities and the broader relationship.

So we need to carve out time to do both those things. So we're going to work with Amanda directly to figure out how we do that, because we're already meeting weekly with her and her team on the major projects. So if we can find time to add in these other conversations, I think it would be really important because we would like to make progress just as much as they do.

Thank you.

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

So Ms. Two-Axe Kohoko, you've heard from both the proponent, as well as the CNSC, their commitment -- strong commitment and willingness to engage more fully with you and your Nation. And not look at just this -- certainly from the CNSC's perspective -- not only look at this one licensee, but the overall picture of nuclear facilities in your territories and make sure that it's being looked at in a more aggregate manner.

So let me ask you if you have any final comments you'd like to make. But I do want to thank you very much for your very valuable intervention.

MS. TWO-AXE KOHOKO: Yes. Thank you. So

I just want to say thank you for, you know, the time today. I really appreciate being able to deliver this oral presentation to really give a perspective of the First Nations views, in regards to this facility and our relationship in regards to consultation and engagement and meaningful relationships built with those required with CNSC and BWXT. I guess we'll be building that relationship sooner.

All right, thank you.

THE PRESIDENT: Thank you very much. So with that, we'll -- let's take a health break for 15 minutes or so and resume at 11:35 a.m. Eastern Standard Time. Thank you.

--- Upon recessing at 11:20 a.m. /
Suspension à 11 h 20
--- Upon resuming at 11:35 a.m. /
Reprise à 11 h 35

THE PRESIDENT: Welcome back.

Our next presentation is from the Canadian Nuclear Isotope Council as outlined in CMD 21-H5.4

I understand that Mr. Thiele will present this submission.

Mr. Thiele, over to you.

MR. THIELE: Good morning, and thank you very much for the opportunity to present here today.

On behalf of the Canadian Nuclear Isotope Council, we are pleased to offer our support for BWXT Medical's application for a Class 1B licence.

The Canadian Nuclear Isotope Council is an independent organization consisting of representatives from various levels within the Canadian Health Centre, the nuclear industry, research bodies specifically to advocate for our country's role in the production of the world's supply of isotopes.

The CNIC serves as a voice in safeguarding the continued availability of isotopes, ensuring that our public policies are risk-informed, science-based and support the highest levels of public health and safety.

A secure supply of a diverse portfolio of isotopes is essential to maintaining and improving our standard of living. Isotopes are used every day to verify the safety of our roadways, discover and develop natural resources, testing natural products and support research and mental health and aging. They are also our main source of clean energy and are critical in the healthcare sector where they are used to not only diagnose, but -- and treat cancer -- or, sorry, treat disease, but also to sterilize medical supplies.

The landscape of medical isotope production in Canada is diverse due in large part to its world -- its longstanding and world class research into reactor and accelerator technology. Canada is a leader in reactor construction and applications in the production of medical isotopes that have been used globally for the past several decades.

Medical isotope production represents key ways in which CNIC members like BWXT Medical deliver changeable impact to Canadians generating clear, economic and societal benefits.

The clearest and widest-reaching benefits come from an enabling of lifesaving medical treatments by providing medical isotopes for patient use through collaborations with its partners. CNIC members enable the diagnosis, treatment of disease in fields as diverse as cardiology, oncology and neurology. This work ranges from supplying standard imaging isotopes to hospitals and clinics, to providing novel isotopes to support cutting-edge research into Parkinson’s disease, Alzheimer’s and terminal cancers.

BWXT Medical is a founding member of the Canadian Nuclear Isotope Council and continues to demonstrate its broader impact by providing its customers who conduct lifesaving medical procedures for patients

around the world and benefit of decades of experience in the development, manufacturing and delivery of medical isotopes and radiopharmaceuticals.

BWXT's impact on the medical isotopes sector, as an experienced manufacturer and supplier of medical isotopes and radiopharmaceuticals for research, diagnostic and therapeutic uses cannot be understated. Quite simply, BWXT's medical products are relied upon by clinicians and patients all over the world.

BWXT Medical's Kanata operations produce and supply Indium-111, a diagnostic radiopharmaceutical use in the assessment of inflammation and infection. This helps in the assessment and inflammation and infection for example in a diabetic foot; TheraSphere, a sterile active implantable Class III medical device used in the treatment of cancer. BWXT is currently under contract with -- by Boston Scientific to supply this product; and, in the very near future will produce Technetium-99.

In 2018 BWXT announced its innovative technology to produce Molybdenum-99, the parent isotope of Thechnetium-99 which is used in over 40 million diagnostic imaging procedures every year worldwide to diagnose cancer, coronary artery disease, and other adverse medical conditions.

Pending approval from FDA and Health

Canada BWXT Medical experts expect to provide a stable, reliable, long-term supply of Technetium-99 supporting the growing demand for diagnostics across the continent for many years to come. This is transformational leadership from the Canadian Isotope Sector.

At the same time, BWXT Medical continues to contribute to its local community and the Canadian economy. Since the 2018 acquisition by BWXT Technologies, BWXT Medical has significantly expanded its workforce from across nearly 120 individuals to 200-plus skilled professionals. Coupled with this growth is an uncompromising industry-leading safety from BWXT operating in one of the most highly regulated industries in the world whose number one priority has always been the safety of its employees, members of the public and the environment.

Canadians have identified that guarding and supporting our nuclear knowledge infrastructure is important for both our healthcare and safety. Canadians want to remain at the forefront of research and development, commercializing and the supply of medical isotopes.

In a 2019 CNIC study that we conducted, we revealed that nearly two-thirds of Canadians expressed concern about our country ceding its leadership position in isotope supply with nearly one-third of respondents being

seriously concerned.

The support goes further than that. Sixty-three percent of Canadians support the provincial and federal governments adopting a pan-Canadian strategy to secure a global supply of isotopes from Canada. Taken together, these two indicators clearly demonstrate that isotope leadership is important to Canadians and are largely in favour of government playing a critical role in helping to shape this. Canadian policymakers should be acutely aware of the previous challenges Canadians and global citizens face during alarming isotope supply shortage. These potential vulnerabilities can be overcome through creating redundancy in supply and supporting Canada's isotope industry such as through this medical licence application by BWXT.

The future of medical isotopes in Canada looks bright, thanks to companies like BWXT. As we move into a new decade, medical isotope-based technologies are being developed and exported from Canada. The medical isotope-based therapies and treatment regimes are entering clinical trials and final verification and validation processes that are required by Heath Canada before they come available to physicians.

Canadian researchers continue to develop innovative targeting molecules, radiolabeling strategies

and medical isotope production methodologies to ensure that the pipeline to clinical trials remains full.

If Canada is to maintain its standing as a leading force in global science and enjoy the associated economic and societal benefits, the nation must invest in the isotope infrastructure and support its companies. The work of BWXT is a prime example of the excellence being demonstrated in this sector and a very necessary component to our global and Canadian isotope ecosystem.

Investments to support Canada's isotope research and production have a long-lasting output -- impact, sorry, on the outlook and promise of a cure for cancer. Canada's isotope innovations continue to serve as a model for delivering tangible impact using science to find solutions to real-world challenges.

Canada has a long and successful history of developing new radiopharmaceuticals and medical isotope-based devices. If Canada is to continue to innovate, this work must be supported.

Bringing a new medical isotope device from the design phase to a Phase I Clinical Trial takes several years or even decades and requires interdisciplinary collaboration across many fields. Canada has a roster of experts in translational medical isotope research in universities from coast to coast, research organizations

like BWXT -- sorry, research organizations like BC Cancer and needing companies like BWXT as well as the Canadian Nuclear Laboratories. Their work provides direct benefit to Canadians by bringing branches of multinational clinical trials to Canada, providing Canadians with timely access to new radio pharmaceuticals.

For these reasons, the CNIC is happy to support BWXT Medical's application for its Class I licence extension. BWXT Medical is an integral part of the Ontario nuclear ecosystem, supporting jobs and prosperity while never sacrificing safety standards.

Thank you for the opportunity to present today, and that concludes my presentation.

THE PRESIDENT: Thank you for the presentation, Mr. Thiele.

Opening it up for questions.

Dr. Demeter?

MEMBER DEMETER: Thank you, Mr. Thiele.

I read your intervention and I wasn't aware of your organization prior to reading the intervention, and I went on your webpage which has a number of things, but doesn't really have a vision, mission or chart. But then I saw your partner list which is expansive between academic, healthcare, industry and suppliers.

As an organization, are you more of an

information-sharing clearinghouse, and when you come up with a statement like you did today with -- with your intervention, how do you achieve consensus amongst your partners that that represents that vast swath of interests?

MR. THIELE: Yeah, absolutely. Thank you very much for the question.

So, to address kind of the -- the first part of your question, we -- the CNIC is -- has really two -- one mandate its objectives which is kind of two-part: It is to advocate and educate. So, through our broad membership we seek consensus by obviously trying to speak on behalf of what is a broad Canadian isotope ecosystem, but it's a group that has largely lacked a cohesive voice for a number of years. Much of the work of this sector really is largely unrecognized or unknown to Canadian until they are kind of educated and learn more about what's going on.

Now, there are diverse interests within our membership. As you mentioned, we are research institutions, we are power reactor like the British Power and OPGs of the world. We have medical isotope specialist like BWXT and CPDC and many others, but our main message is that this is a sector that it holds great potential for the Canadian economy. It's a sector that we have an opportunity to lead in, given our historical nature with --

with a longstanding research that happened at NRU prior to its closure, and the continued investment from these companies that we represent to this day. So, of course, any coalition-based member organization like ours it is impossible to have 100 percent agreement on every single policy front that we put forward, but the general statements that we put forward together as a -- as a coalition represent the broad interests of the group, and that's really to -- to demonstrate the importance of this sector to Canada as well as patients around the world.

MEMBER DEMETER: Thank you.

THE PRESIDENT: Ms. Maharaj?

MEMBER MAHARAJ: Thank you very much for your presentation, Mr. Thiele. I believe my colleague has covered my question, so I don't have anything further for you today.

MR. THIELE: Awesome. Thank you.

THE PRESIDENT: Thank you again, Mr. Thiele, for your submission.

And we'll move to our next presentation then, which is from the Organization of the Canadian Nuclear Industries as outlined in CMD 21-H5.6.

Dr. Oberth, I believe you're making the presentation, so over to you.

DR. OBERTH: All right. Are we okay, now?

Am I on the screen and you can see me and hear me; that's good.

Thank you for the opportunity to come before the Commission today, which I have done in the past, so I don't intend to spend any time talking about OCNI. I'll assume you know who I am. And, I will also apologize for not bringing the level of technical expertise that my colleague Andrew Thiele brought a few moments ago.

You know, OCNI, like CNIC, is an association of companies, but our expertise certainly is not focused on isotopes, like the CNIC.

But I do want to say that I'm here to represent OCNI and speak on behalf and support BWXT Medical's application for a Class 1B licence to undertake nuclear medicine-related operations in Kanata.

BWXT Medical is a division of BWXT Canada which has been a longstanding 35-year member of OCNI. And in my capacity of CEO of OCNI I've personally observed BWXT Canada's high standards of quality and its commitment to worker and public safety and community engagement.

So, you know, I'm therefore very confident that BWXT Medical, should they receive the operating licence from the CNSC, would continue to produce the same medical isotopes as previously produced by the predecessor company, Nordion, and would produce them reliably, safely,

and while meeting and exceeding all nuclear and health-related requirements.

As you've heard from previous submissions, BWXT Medical delivers medical isotopes to hospitals, radiopharmaceutical companies worldwide, that conduct life-saving medical procedures for patients.

The quality of the medical isotope products that BWXT delivers is based upon the previous experience of its predecessor company in delivering those same medical isotopes and radiopharmaceuticals.

Now, since the acquisition in 2018 of Nordion, BWXT Medical has actually expanded its workforce from approximately 120 staff to now over 200 skilled professionals that develop new and innovative and very important life-saving medical isotopes for the medical industry.

BWXT Medical is now developing an innovative way to produce Mo-99, which is really the workhorse of medical diagnostic procedure with over 40 million procedures annually every year to diagnose, cancer, coronary disease, and other life-threatening conditions.

Pending further approvals from the FDA and Health Canada, BWXT Medical will also begin to provide a reliable long-term supply of Tc-99m, which is increasingly in demand as an important diagnostic tool.

So therefore, we feel it's important from both a Canadian and a worldwide public health perspective that BWXT Medical be granted this licence to continue to operate and produce medical isotopes at the facility in Kanata.

In addition, I want to add that BWXT has an excellent track record in working with local communities and communicating and addressing concerns raised by those communities. This is largely done through an excellent public information website where community members can find up-to-date and detailed information about BWXT Medical isotopes. And they can also sign-up to BWXT Medical's email list to receive current updates.

So, for these reasons, and many other cited by my predecessor on this panel, Andrew, OCNI strongly supports the application of BWXT Medical.

Just three remaining points I guess I want to make in conclusion. Medical isotopes are saving lives worldwide everyday, a critical part of our worldwide health system. Canada has been a leader in the field of medical isotopes and must continue to be a leader in meeting this increasing demand for the highest quality medical isotopes.

BWXT Medical has demonstrated over many years of working in the nuclear sector, and now the medical isotope sector, that it can produce those isotopes to the

highest qualities of safety and rigour required by the industry and by the licence that they are now seeking.

Thank you for your time.

THE PRESIDENT: Thank you, Dr. Oberth, for your intervention.

Ms. Maharaj, any questions?

MEMBER MAHARAJ: Thank you, Dr. Oberth. I just have one question for you. Could you speak to the comment in your submission where you say that you've personally observed BWXT Canada's high standards for quality and its commitment to worker and public safety?

Have you been employed by Nordion? Can you just describe the relationship and how you've been able to provide that detail of information to the Commission today?

DR. OBERTH: Well, I'm not claiming that I have done the rigour of a CNSC inspection.

MEMBER MAHARAJ: Of course.

DR. OBERTH: But as President of OCNI, I quite frequently have visited our member facilities, and in particular when we have delegations from offshore.

So I have hosted delegations from a number of countries at both BWXT's facility in Cambridge and at its facility in Peterborough, and during those visits BWXT staff and executives have talked about their quality programs, have given us tours and have shown us in

walkarounds at the plant how they manage worker safety, how they manage quality and how they ensure that everything that leaves that plant is of the highest standard.

So that's the extent of my observations from a good number of visits to their facilities. But it's not a CNSC inspection.

MEMBER MAHARAJ: No, of course not, and I didn't mean to imply that it ought to have been.

You know, I'm not overly familiar with you, sir, if you could just give me a little bit of your background? I'm intrigued by your recent statement that you've visits with other organizations when they're visiting. Just in a nutshell, I'm sure your résumé's very long.

DR. OBERTH: Thank you for asking, because I happen to be celebrating my 10th anniversary here with OCNI, and my career in nuclear goes back a good number of years, I even had the pleasure of working with Ms. Rumina Velshi a number of years ago and I learned much with her. So I can take some gratitude from her leadership and inspiration to where my career has gone.

But in my role at OCNI one of the things we do is we take our member companies into international markets and we also host delegations from off-shore markets in Romania, Argentina, the UK, the US, China and Korea are

some of the countries we've visited and hosted delegations.

So part of my role is to be I guess an ambassador for the Canadian nuclear industry worldwide and to invite organizations from other countries and their nuclear industries to come to Canada and learn about the strong capability of our supply chain of which I am very proud.

MEMBER MAHARAJ: Awesome. Thank you very much, I appreciate that.

DR. OBERTH: It almost seems as if I planted that questions.

--- Laughter / Rires

DR. OBERTH: Well, thank you.

MEMBER MAHARAJ: You're welcome.

THE PRESIDENT: Dr. Demeter.

MEMBER DEMETER: Thank you for your presentation. I don't have any further questions.

THE PRESIDENT: I have a question for BWXT Medical following Dr. Oberth's intervention, and from your presentation as well. And it's around your staffing and projections looking forward.

You've grown significantly in just the last two and a half years or so from 120 to 200. Where do you see yourselves say five or 10 years from now, and particularly once Mo-99 line of business is developed if

you get the approvals?

MS. KAVANAGH: Jackie Kavanagh, for the record. I'll direct that question to Martyn Coombs.

MR. COOMBS: Thank you. I'm Martyn Coombs, for the record. President Velshi, it's a great question, and my board asks me this sort of question all the time.

I would say that we see ourselves growing and we're very ambitious. We would like to have more employees on site, but not tremendously more employees on site, because we've invested a lot in automation to be able to do things in not such a manual fashion.

So we're about 200 people today, as you pointed out. I imagine in five or 10 years' time it may be 300 people or maybe a little more, to give you some idea.

In terms of products, I think there'll be similar sort of products that we do at the moment in addition to the current products but, again, not many many more. But the products we will do will be very focused and very good products and more on the therapeutic side, like TheraSphere™, but used for manufacture directly to the patient.

So I hope that answers your question. I'm not sure I can answer a lot more granularity, or maybe a little bit more. Does that answer the question?

PRESIDENT VELSHI: Yes, it does. Thank you very much.

Dr. Oberth, thank you for your intervention, always a pleasure seeing you.

DR. OBERTH: Good, thank you.

PRESIDENT VELSHI: Our next presentation is from Nordion, as outlined in CMD 21-H5.12, and I believe we have Mr. Brooks for this presentation.

Over to you, sir.

CMD 21-H5.12

Oral presentation by Nordion

MR. BROOKS: Can you hear me?

THE PRESIDENT: Yes, we can.

MR. BROOKS: Oh, excellent, thank you.

Thank you, President Velshi, and Commission Members. I'm Kevin Brooks, I'm the President of Nordion, and Nordion's honoured to be here today intervening in support of BWXT Medical's application for a Class 1B operating licence.

With me today is Richard Wassenaar who is Nordion's Director of Regulatory & Environmental Health and Safety.

We have submitted a written intervention

and today I would like to highlight a few of the points, key points, for the Commission, and then would be pleased to answer any questions that you or the Commission would have, President Velshi.

This year, Nordion is excited to celebrate its 75th anniversary as a company, and this speaks to the value, dedication and sustainability of our business, part of which has recently been divested to BWXT Medical, which is why we're here today.

We have been operating in our Kanata, Ontario facility on 447 March Road for over 50 years, and during this time the business has seen many changes. One such change important to this meeting is in 2018 Nordion divested what is commonly referred to as the medical isotopes business to BWXT Medical.

As BWXT Medical noted in their presentation, the sale included isotopes such as Indium-111 and Yttrium-90. Two isotopes that are key in the diagnosis of infection and the treatment of cancer.

Nordion retained a portion of the business related to the isotope Cobalt-60, which Nordion processes into sealed sources that are a critical component to the health care supply chain, specifically for the sterilization of single-use medical devices, cancer therapy and food safety.

The facility at 447 March Road is designed such that the Cobalt sealed-source production occurs in a separate portion of the facility from the medical isotopes production purchased by BWXT Medical.

Moving forward, Nordion will continue to operate Cobalt-60 production facility under the current Class 1B licence. BWXT Medical has leased that portion of the facility related to the other medical isotopes and will operate under their own Class 1B licence should it be grated, which we encourage the Commission to approve.

Nordion's business is focused on Cobalt-60 sealed sources, our currently plan is not to duplicate those activities proposed under BWXT Medical's licence application.

Nordion has committed to the CNSC to revise and update our key licensing documents to reflect Nordion business should BWXT be granted their licence.

With respect to BWXT Medical, Nordion fully supports their application. Many of the documents submitted in support of their application are Nordion procedures and policies that have been defined in the safe operation of the facility to date ensuring the safety of the people and the environment.

Since the sale of the medical isotopes business in August of 2018, Nordion has continued to

operate the entire facility under the current Class 1B licence with BWXT Medical acting as a contractor under Nordion's oversight and in the framework reviewed by the CNSC.

BWXT Medical has continued to use the Nordion processes and procedures. This oversight framework was the focus of a CNSC inspection in 2020. We are very pleased to report that no notices of noncompliance were identified during this inspection.

The Nordion policies and procedures that form the base of BWXT Medical's licence application before you today have been audited and reviewed by the CNSC Staff over decades and provides a strong framework for BWXT Medical to build upon as they look to expand their business.

Nordion and BWXT Medical recognize that we will be two licensees sharing a single address, and with Nordion as the landlord.

We have worked closely with BWXT Medical to develop joint programs so that the 447 March Road site, as a whole, ensures the protection of people and the environment. These joint programs will cover security, environmental monitoring, and emergency response.

In addition, Nordion and BWXT Medical have developed a joint EHS committee to review mattes of site

environmental and safety significance.

BWXT Medical will be taking a critical role in supplying much-needed medical isotopes to treat and diagnose disease such as heart disease, infection, and cancer.

This includes the work to create a more stable supply of Technetium-99m which is an important medical isotope not only for Canadians, but also the world. BWXT Medical will be doing so on a solid foundation of the Nordion management system for safety framework, and as a successful -- and ensuring the safety of people, the community and the environment.

We fully support the work BWXT Medical is undertaking and encourage the Commission to approve their licence request.

President Velshi, I thank you for this opportunity to address the Commission, and we'll take any questions at this point in time.

THE PRESIDENT: Thank you very much, Mr. Brooks.

Let's start with Ms. Maharaj for questions then.

MEMBER MAHARAJ: Thank you very much, Mr. Brooks, for that presentation.

I'd like to focus a couple of questions

with respect to the joint programs that Nordion and BWXT are proposing to operate on a go-forward basis if the Commission grants the licence.

You've indicated that your Cobalt-60 facility is in a separate part of the building than the facilities for the NMF -- NMP, the other part.

MR. BROOKS: NMPF.

MEMBER MAHARAJ: Right. But some of the programs that you're purporting or proposing to operate jointly are things like fire safety --

MR. BROOKS: Right.

MEMBER MAHARAJ: -- and facility safety. How will those programs serve both parts of the building if the operations are separate?

MR. BROOKS: Okay. Thank you very much for that question.

I will invite Dr. Wassenaar to respond to that question.

DR. WASSENAAR: Thank you. Richard Wassenaar, for the record, Director of Regulatory & EHS at Nordion.

Very good question. We've worked with, and I'll BWXT speak to this as well afterwards, but we've been working very closely with them as landlord and licensee, as two licensee, within this facility, how that

might work.

And really what it comes down to is we are one facility that is connected, so they aren't separate buildings. And so we recognize that these are shared services, you know, there's one sprinkler system, you know, there's sort of one emergency response plan, right? If there a fire in the building, we're going to respond as a whole.

And so we are working through and we've developed those programs, which really are the programs that had been in place to date, and I think that's key as well, is this is not new, right? We've done this already.

Over the years, you know, Kevin has mentioned the business has changed under Nordion even. We've added isotopes, we've removed isotopes, we've changed what we've done within that nuclear medicine facility, and we've updated the emergency response and the fire protection plans accordingly. And this really is just an extension of that

So what it requires is some more communication between the two companies to make sure we remain aligned, and that's why we've proposed the Environmental Health and Safety Joint Committee where we can review those items and make sure that, going forward, we continue with the shared programs as one site.

MEMBER MAHARAJ: Okay, thank you. And then with respect to the joint committee, how is representation on the committee determined?

MR. WASSENAAR: Very good question. Richard Wassenaar, for the record.

So we've actually already identified that early on when we set-up the divestiture of that part of the company. So within the lease agreement we've already identified how many members from each side, those will be appointed from the corresponding company.

So Nordion will identify I think it's four, and BWXT will also identify four within the significant areas, that will include health and safety, radiation protection, facilities and engineering. Those members will come together to meet on a regular basis as a joint committee reviewing the same items that we basically have been reviewing already through the current committee.

So, again, we're really using what we've put into place already, and that has worked very well to set the framework for what's happening in the future.

So, honestly, it's really the same people that are meeting, except we'll be meeting as two different licensees, but the same people are involved.

MEMBER MAHARAJ: And eight is an even number. Do you have terms of reference or some method for

resolving a tie?

MR. WASSENAAR: Very good question. Yes, I would have to look at -- don't quote me on four, I have to check the documents again to see whether it was four or five. And there are absolutely items in there that talk about if there is ties, how we would resolve it.

To be honest, at this point the committee works in a consensus manner, similar to what the Commission does as well. And so there's a lot of discussions before we get to the consensus. To date, we haven't really seen that kind of loggerhead where we've had to sort of have that tying vote come in, and I suspect moving forward I don't foresee that either. Again, both companies are very strong in health and safety, and that's really what the committee is looking at.

So if we had to get to that point, there are mechanisms in place.

MEMBER MAHARAJ: Okay. And then with respect to the ultimate responsibility. As the landlord, do you then retain that ultimate responsibility for the physical security of the premises, the guardhouse, the fencing, whatever those particular physical aspects are?

MR. WASSENAAR: Richard Wassenaar, for the record again. Good question, and I think Mr. McAllister noted that in his presentation as well.

So as it relates to the BWXT licence, Nordion will be providing those service, but BWXT will be responsible for their part of it. So in so much that Nordion's providing the overall security and whatever that might entail, you know, door locks and card readers and that sort of thing, on the BWXT licensed activities portion BWXT is responsible.

So if they have issues, they need to come back to us and say, we need more card readers, to remain compliant with our licence or we need more security guards or whatever the item may be. As noted in the CNSC Staff's report, they are responsible for their licence and we are merely a contractor in that respect, but we will work closely with them.

MEMBER MAHARAJ: Okay. Perhaps then I can ask a similar question of BWXT, because I see a gap. And there's always a risk of a gap when two parties are working together collaboratively, but there can always be a break.

And so I'm curious perhaps to hear from BWXT if they're going to be responsible for security, how will they establish control if consensus isn't achieved? Because you're the contractor, so they're responsible.

MS. KAVANAGH: Jackie Kavanagh, for the record.

As Mr. Wassenaar indicated, both companies

will be ultimately responsible for the -- for their own licences and ensuring that licence conditions are met. Yes, Nordion will be providing some services to us, as Richard indicated, similar to a subcontractor.

BWXT is ultimately responsible, and we will be -- so should the CNSC, let's say put different requirements on BWXT than on Nordion, then we would have a discussion with Nordion with regard to our new requirements and how we would need Nordion to adjust the services being provided to us to ensure that we meet our licence requirements.

And one of the main objectives of the Joint Environmental Health and Safety Committee is to ensure that each company is able to maintain compliance with their own licences, and that goes beyond the committee itself. As Richard mentioned, it is part of the terms of the acquisition and the terms of the landlord arrangement. So we each have a vested interest to ensure that this arrangement is working for each company.

Part of the responsibility of the Joint Environmental Health and Safety Committee is going to be to ensure that neither company is making a negative impact to licencing basis for the other company, and also that neither company is making a negative impact on health and safety of our workers, or the public, or the environment.

That scope of -- of engagement for the subcommittee was laid out in documentation that we provided to the CNSC as part of our licence application; the terms of engagement, the composition of the committee, and the items that the committee would be reviewing, the information we would be sharing, and where the ultimate decision making resides.

And as Richard indicated, you know, to date and since the acquisition, key BWXT Medical employees have been continuing to participate in the Nordion Environmental Health and Safety Committee, and we've done that -- many of us have done it for many years prior as long term Nordion employees, prior to the acquisition. So we're quite familiar with that process and we believe that we have, you know, the systems in place to ensure that each company will be able to maintain compliance to their own licence.

Thank you.

MEMBER MAHARAJ: Thank you very much, Ms. Kavanagh.

Those are my questions, Madam Velshi.

THE PRESIDENT: Thank you.

Just one clarification before I turn to Dr. Demeter. The Commission, much as we would like consensus, based on how we operate we are all independent Commission Members and make our own decisions

independently. So sometimes we do have minority decisions as well.

Dr. Demeter, over to you.

MEMBER DEMETER: Thank you for the presentation, and I think this is a good time to -- now that Nordion has given a presentation and BWXTs.

So Nordion is the current licence holder and I'll stick to the -- sort of an emergency planning theme that's been raised, and there was -- on BWXT's written intervention H5-1, there was a section talking about partnering with Nordion and local fire and police, and to ensure safe appropriate response to emergencies. But the last sentence of the kind of concerned me. It says:

"Where possible, emergency response drills will be attended by the local fire department, hazardous materials representatives and paramedics who will all participate as exercise players, allowing for all players to improve interoperability of response."

And that's on page 45.

Now, I can see where applicable would be reasonable depending on the nature of the drill, but "where possible", it makes it sound like if they are available they can attend. But these are really important drills. So I'm not comfortable with "where possible" is relative to

fired drill.

So perhaps Nordion can give me a sense of right now, with -- as the current licensee, is this the way it's at, that when you hold a drill, if possible the local fire department or fire paramedic will attend, or is it you plan it so that they can attend? I'm just a bit uncomfortable with the "where possible". And then I'll ask BWXT to talk about their interpretation of that, and maybe CNSC can chime in as to what their expectation is.

MR. BROOKS: Richard, I think you can best answer that.

MR. WASSENAAR: Richard Wassenaar, for the record.

Again, I'd like to focus on the BWXT application and not on the Nordion licence aspect. So I'll keep it short and then pass it off, probably to Jackie to speak to BWXT.

The current environment -- or sorry. The current emergency response program, we do absolutely engage those key stakeholders such as paramedics, or firefighters, or police as may be required, as applicable. Insomuch as they can -- or insomuch as they wish to participate, and I think that's the key, is we provide opportunities, and we work very -- as much as we can to make sure they have those opportunities.

They may not choose to participate. They may decide they're too busy and not just for the one day that we scheduled. So you know, we don't schedule, you know, we're going to do an emergency response Tuesday, if you're available please show up. You know, we will work beforehand with those emergency response groups to try to find a time that works for everyone. But ultimately, we can't force them.

So they may decide that this is just not a high priority for them, they -- whatever, they came last year, they're happy with everything, they've got other things they need to be doing. So that's where that terminology, I think, maybe is coming from.

But I'll pass it off to Jackie to speak to the actual application.

MS. KAVANAGH: Jackie Kavanagh, for the record.

So as Richard indicated, we do plan to invite the first responders when we're having an exercise. So the invitations do go out. But what we have heard from the first responder organizations is if at the time of the exercise that we have planned, if they have other operational priorities, for example, if they are called to a more immediate incident that has occurred then they will not participate.

So sometimes we may plan, and the indication is that they will participate, but there could be that last minute call that comes in and then the first responder is not able to participate.

I would like to indicate that, as part of our preparation for this hearing, and as part of our licence application, we -- BWXT extended an invitation to the Ottawa Fire Services to come and meet with us and the Ottawa Fire Services accepted that invitation and we provided a tour of our facility. I believe it was back in February, and subsequently, after the tour we had a meeting with them to review and ensure that they understood that we are, you know, a separate company going for a separate licence.

The Ottawa Fire Services, unfortunately, was not in the position to participate in the hearing. They did provide to us a letter of support in which they indicated that we had a high level of engagement with them, with regard to our licence application and the hearing. And they did indicate that, you know, the -- the Ottawa Fire Services is happy with that level of engagement. And we think that having those routine site visits with our first responders, especially if they're unavailable to attend an exercise that we're doing, can help supplement their engagement, you know, should we have an emergency

onsite.

Thank you.

MEMBER DEMETER: And I guess for CNSC Staff, this is an application -- a first time application by this licensee. It's currently held by Nordion. What has been your experience in the value -- in the drills that have been conducted to date and participation by outside first responders? Has it been satisfactory? That's the CNSC Staff, on review of the applicant?

MS. MURTHY: Kavita Murthy, for the record. I believe subject matter experts from the Emergency Management Program Division are ready to respond. So over to you, Elaine.

MS. KANASEWICH: Good morning, this is Elaine Kanasewich, I'm currently the Acting Director for the Emergency Management and Programs Division.

Indeed, we have a very good history of compliance with Nordion. That is done though the conduct of inspections and observation of drills. And similar to what was stated previously by Ms. Kavanagh of Nordion, one of the licence requirements -- the licence condition requirements of BWXT, as well as Nordion, would be to follow the requirements of the standard, a 393 -- N393 standard, which requires that each of the licensees conduct fire response drills.

And in order to support these drills, service agreements have been entered into effect by both Nordion, as well as now BWXT Medical, with the Ottawa Fire Services. So Ottawa Fire Services should be participating in these drills that are conducted separately by both Nordion under their licence conditions, as well as BWXT Medical under their licence conditions.

Now, an example of where they possibly might not be able to attend is, for example, during Covid. So where certain activities had to be curtailed because of limited availability and restrictions. We were able to conduct these drills and oversight in different capacities, such as through tabletop exercises, and training opportunities. And then those will resume again with the participation of the Ottawa Fire Services when the epidemiology permits.

So with regards to your question on compliance history, I'm actually going to turn to my specialist, David Wallace, who can give you a little bit more information about the past performance of Nordion, and then therefore, what we project for the performance of BWXT Medical.

Thank you.

MR. WALLACE: Hello. David Wallace, for the record. I'm an Emergency Preparedness Specialist with

the CNSC.

Yeah, so you know, historically we've had very good engagement through all members of the first responder community. In this case, we'd be focussed on Ottawa Fire, and yeah, they're very -- they're very engaged. They are willing to participate.

We've had many very good discussions with Ottawa Fire, actually leading into this licence hearing. BWXT, you know, they proactively went out and they arranged for their own service agreement, even though there's already an agreement in place with the -- with Nordion, and they're co-located at the same facility.

So Ottawa Fire Services, they committed through this service agreement that they will participate in any training activities, you know, any walkthroughs, any tabletop exercises, and in addition they will -- they are happy to participate in the annual drills, the annual fire response drills, which are a requirement by BWXT under CSA N393.

So all facilities are required to have a fire response capability. BWXT relies on an offsite capability in this case, and as part of that there is an annual drill requirement which requires that fire response capability to be present, and in this case, it would be reliant on Ottawa Fire Services.

So yeah, like Elaine said, there are situations where they may not be available on that given day, but you know, those discussions need to take place and, you know, we need to try to accommodate them accordingly.

They are -- they have other priorities, obviously, with their day to day work fighting fires in the community, but we've had a very good willingness of them to engage and participate in drills at all licensee facilities.

MEMBER DEMETER: Okay. Well, thank you for that background. That's helped me understand it better.

MS. MURTHY: Dr. Demeter?

MEMBER DEMETER: Yes?

MS. MURTHY: I'm sorry to interrupt you. I just wanted to correct something on the record. Ms. Kavanagh is in fact a BWXT Medical Employee and not a member of the Nordion team.

MEMBER DEMETER: Okay. Thank you all for that background. It helped me understand the issue a bit more.

THE PRESIDENT: I had a question for Nordion, but I think Staff will probably want to add to that.

I want to get a handle of exactly what's going to change in your licence, your *Licence Condition Handbook*, your financial guarantees, etcetera, if BWXT Medical gets its licence. From Staff submission it was, there would be no change to your licence, but there would be a change to your *Licence Condition Handbook*.

So tell me what is the change to the *Licence Condition Handbook*?

MS. MURTHY: Kavita Murthy, for the record.

I'll ask Mr. Andrew McAllister to provide the details of the changes to the *Licence Conditions Handbook*.

Thank you.

MR. McALLISTER: Thank you, Ms. Murthy.

At a high level, President Velshi, the *Licence Condition Handbook* will be updated to remove those aspects related to the operation of the nuclear medicine production facility. So that's going to be the focus of that, and we'll have that in place moving forward, should a licence be granted to BWXT Medical on their application.

In addition, Nordion will be updating their financial guarantee to reflect the change in the scope of their operations moving forward.

THE PRESIDENT: So Mr. McAllister, as I

looked at the *Licence Condition Handbook* that's been proposed for BWXT Medical, on the section on licenced activities in 2.4, it's fairly general. There is nothing mentioning NWMF, nothing saying no cobolt-60 handling kind of thing.

So just wondered, where is that specificity on what exactly is permitted and what isn't? If I were to compare the two licences, the proposed one for BWXT Medical and the current one for Nordion, would there be any difference in the licence or is that a pretty standard licence?

MR. McALLISTER: Andrew McAllister, for the record.

I'll see if either Jason Duhaime, who is the Project Officer for both facilities, or perhaps another colleague can provide that sort of precision that you're looking for, President Velshi.

THE PRESIDENT: Well, if you can then look the *Licence Condition Handbook* that's been proposed for BWXT Medical 2.4, so this is page 3 of 57, and look at licenced activities, I'd really like to see how that compares with what's currently with Nordion. Because it just seems very general. I mean, I really don't know what's being approved.

MS. MURTHY: Kavita Murthy, for the

record.

So the current -- the licences for the two sites in addition -- in terms of what's -- what the content is, they look very similar, you are right. In terms of the standardization exercise that we have gone through, we have landed on a licence that, apart from describing the facility where it is located -- it in this case the street address also happens to be the same. Where you will find the difference is in the reference to documents which are in the *Licence Conditions Handbook*.

The application that BWXT made to get -- as a part of their submission, that application is a reference document in the *Licence Conditions Handbook.* Everything that they are proposing to do is described in that. That's where the limits and the activity limitations come from. So the *Licence Conditions Handbook* will contain references to BWXT's submissions, their programs, their activities they are proposing to do. So those will be different for BWXT from Nordion.

THE PRESIDENT: So, Ms. Murthy, that's helpful. Can you -- it would really help me if you were actually to connect -- help me connect the dots. So where in the *Licence Condition Handbook* would I see a reference to the application and then the section in the application on exactly what are the activities that are being requested

for approval?

MS. MURTHY: Kavita Murthy, for the record.

I will -- I'm getting a notice here that it is in Section G1 of the *Licence Condition Handbook*. I would like to have either Andrew McAlliser or Jason Duhaime walk us through it.

THE PRESIDENT: Okay.

MS. MURTHY: Also, you will note that in the CMD itself, in Appendix B of the CMD, we have listed all of the applicable documents that were assessed for the licence -- in our review of the licence. So I -- Andrew, if you're ready to go on, or if you want to hand it off to Jason, please go ahead.

MR. McALLISTER: Thank you, Ms. Murthy.

I'm just calling up the document right now. And so I would just draw the Commission's attention to, as indicated, page -- Section G1 in the *LCH* starts at page 5 ---

THE PRESIDENT: Okay.

MR. McALLISTER: --- of 57. And as it indicates, it gives a sort of, generic definition of the licencing basis. And as we've heard, the -- it's been the regulatory requirements, the different safety control measures, the programs, the different aspects contained

within an application, and that helps establish the boundary by which they will be operating under.

In addition, it lays out the different compliance and verification criteria with respect to other applicable legislation outside of the *Nuclear Safety and Control Act*. The -- but it's really structured so that at a high level, we can look at what's being proposed to ensure that it remains within the licencing basis.

And certainly the -- the structure of that is premised upon, when something is being proposed, looking at this licence condition -- at this licence condition with respect to the licencing basis, is safety going to be -- remain neutral, remain positive, or perhaps in a negative direction? And so, we're looking at that and this licence condition helps facilitate those aspects.

THE PRESIDENT: Okay. So I'm still not quite sure.

Maybe help me understand what would change in the *Licence Condition Handbook* for Nordion? Would it specifically carve out the NWMF?

MR. McALLISTER: As -- Andrew McAllister, for the record.

As indicated, the intention would be to remove those aspects related to the operation of the NMPF. Yeah.

THE PRESIDENT: Okay. And then the financial guarantees would come later for -- for Nordion. And I'm just trying to appreciate really, what is changing? The work is remaining pretty much the same, it's just someone else who's now the licence holder. And the programs are going to be the same. So if I were to look at the -- the action levels, say, under the Radiation Protection Program for instance, for BWXT Medical, would those be the same as what Nordion has today?

MS. KAVANAGH: Jackie Kavanagh, for the record.

I'll defer this question to Richard DeCaire.

MR. DeCAIRE: Richard DeCaire, for the record.

I think the draft of the *Licence Condition Handbook* -- I'll just go to the section myself, so excuse me while I look away. So the action levels for radiation dose are remaining the same.

THE PRESIDENT: So let me ask you, given that the high doses really come from the cobalt handling side of the business, does that make sense?

MR. DeCAIRE: Well, as you know, there's two -- sorry, Richard DeCaire, for the record.

There are two things about that. One is

we're in a period of transition where we're going to be doing new processes, and we also have to revisit our action levels periodically.

THE PRESIDENT: Okay.

MR. DeCAIRE: That's a requirement of the licence. So those two things combined will require us to look at them. Certainly, currently with the two processes we're doing right now, we could envision doing that, but we will be very rapidly getting into the development phases of a new process, and then we'll -- for molybdenum-99, and that will inform whether that needs revising or not, and that should -- we should start to have those insights within the next 12 months.

THE PRESIDENT: So, would it be -- I don't know it's too simplistic to say, BWXT Medical has pretty much adopted Nordion's programs kind of lock, stock and barrel and the only thing changed is the name and the branding?

MR. DeCAIRE: I would say that one of the things that's been discussed but not really hit upon is at the working level there are some important provisions in place. For instance, we talk about emergency response.

So, emergency response, one of the key job titles is the radiation surveyor. So, they -- they train to escort the fire department into the building and it is

the intention of both sides of the company to maintain the same training requirements.

Whether a Nordion radiation surveyor is hired, or a BWXT radiation surveyor is hired, we will jointly respond to emergencies on both sides and from an operational day-to-day basis this group is somewhat shared in their services. If there's work to be done for a Nordion task or a BWXT task, it's preferentially done by an employee of that company. But if an employee of that company is not available then the other employee for the other company will do it.

And that's really the way we maintain some of these things that I think the Commission has some concerns around.

How are we doing to do that? Well, boots on the ground. That's our intention to maintain the capabilities we've always had and the understanding of each other's processes and the joint health and safety committee -- sorry, joint EHA committee is our mechanism to make sure that the people who are critical in responding to emergencies are -- are always kept advised and trained on the various aspects of the two different companies' operations.

Thank you.

THE PRESIDENT: Thank you.

Mr. Jammal?

MR. JAMMAL: Thank you, Madam Velshi, and Members of the Commission. Sorry, I don't have the video on because I have a bandwidth issue so I'm going to go just oral, if you'll allow me, Madam Velshi.

If you take a look at Section 9 of the LCH, in it there's under Environmental Protection, there is a Table, and I would like to walk the Commission through two things: The DRLs is a facility release. BWXT is a segment of that facility, and so is Nordion, so the impact is a facility release with respect to the DRLs and the other requirements that we impose on them.

As the Commission is deliberating or contemplating accepting the licence application for BWXT, Nordion is still responsible for all of that activity until the Commission issues the licence for BWXT. We want to make sure that there is regulatory control at all times for that facility.

Your question with respect to what are the binding elements associated with the licensed activity that BWXT will be authorized to do, the licensing basis clearly states that they will not be handling Cobolt-60, they will only be doing the nuclear medicine processing facility associated with the activities and mainly open sources, Indium and so on and so forth. So, that is the binding element within the licensing basis of that operation, and

the LCH will be amended based on the hearing and the record of the decision of the Commission, and that we will put those compliance verifications in place after you have rendered your decision with respect to recommendations from the staff.

I hope I answered your question, Madam Velshi.

THE PRESIDENT: Very well. Thank you, Mr. Jammal.

Dr. Demeter?

MEMBER DEMETER: Thank you. I'll lower my hand. There.

So, I had the same question as the President about the specificity of the activities that we were considering, and I noted in the staff CMD on area A2, a detailed summary of CNSC's assessment of the application, it gives in that comment, it says the activity to be licensed and purpose, and the name, maximum quantity and form of any nuclear substance to be encompassed. And they're all related to Attachment 1.

I looked far and hard for Attachment 1 and I don't see it. You know, maybe you can correct me, but that's the kind of detail I want. That Attachment 1 would tell me specifically what we're licensing, what isotope, what maximum activities can you possess at any one time,

and what activities are we licensing. So, is Attachment 1 available? Is it somewhere hidden in here that I missed? What is Attachment 1? And that's on page 70 of your H5 CMD.

MS MURTHY: Kavita Murthy, for the record.

If you'll just give me a minute, I'm looking to see who is -- who is going to be able to respond to that.

Dr. Demeter, it doesn't look like we can give you a quick response to that, so if you will allow me, we will come back perhaps after the break and give you the response?

MEMBER DEMETER: Yeah, okay. That's the kind of information I'd be looking for. Thank you.

THE PRESIDENT: Ms. Maharaj?

MEMBER MAHARAJ: There we go, I'm off mute.

I just wanted to follow up with a couple of perhaps easier questions with respect to the process around your emergency response plan.

What is the frequency of review -- and perhaps staff could answer this -- what is the frequency of review required of an emergency response plan, particularly where we're looking at a situation where the Nordion facility licence is due to expire, unless extended, in

2025, which in this regulatory world is coming up relatively quickly?

MS. MURTHY: Kavita Murthy, for the record.

I'll ask our -- the director of the emergency management program division to respond to this question, please.

MS. KANASEWICH: Thank you very much. Elaine Kanasewich, for the record.

The requirement is to follow what's in the licence condition, so I wouldn't say there is a set requirement. It's just that each of the licensees, in this case Nordion and BWXT Medical will have to conduct drills. They'll have to ensure that their staff are trained and ready to respond, and then we'll also be conducting various other oversight actions such as inspections, desktop reviews of procedures -- have any procedures changed that will likely require a review by us, possibly an inspection. But there is no set requirement per se for -- for any of the drills and the exercises in the inspections. It's really just part of our standard inspection and oversight program.

Thank you.

MEMBER MAHARAJ: So perhaps before you go, Ms. Kana -- I'm sorry, Kana -- Kanasewich, I'm having

difficulty with your name. I apologize if I've -- if I've made an error.

Just as a follow up on that question then, if CNSC doesn't have a specific time for review for something like an emergency response plan, would -- I'm trying to understand what would be a triggering event? Like what order of magnitude would a triggering event be that would cause CNSC to come in and say, 'We need to do a review.'

MS. KANASEWICH: Thank you. Elaine Kanasewich, for the record.

Again, a change to a program, a change -- for example COVID is a good example where there were certain expectations, like minimum shift complement or in the case that we discussed earlier where we would normally require the participation of fire services in an exercise, they had to do some changes. So, in instances like this we might require some sort of alternate verification like the desktop review, or a tabletop exercise, so it's really some sort of a major change to what we basically assessed and expect that -- as part of a licensing process. So, in this case we're -- we're doing the licensing hearing.

There's a licensing basis, and we -- we look at the scenarios that BWXT Medical has -- has envisioned and then therefore the emergency plans and

procedures that they put in place to deal with these hazards. And it's all hazards, it's not just fire or radiation; it's all hazards like you know a hurricane, snow conditions, all that stuff. So, if a hazard were to change, as well, like if they found a new fault line, for example, under the facility and there's a new earthquake hazard, that would require a revision. That's a significant enough change that we would require some sort of a revision to the -- and maybe additional oversight or changed oversight to the program.

So, examples, major changes to both the program itself as well as the hazards that influence the program.

I hope that helps you.

MEMBER MAHARAJ: Thank you. Yeah, absolutely, thank you, that -- that does help. And in your answer, you've raised my final question for you which is, we've spoken and focussed a lot on I think what are the more likely hazards, fire, that sort of thing -- fire, flood, snow. But does the emergency -- doesn't the emergency response plan need to address and create drills for more significant kind of threats like a sabotage of -- a sabotage or a physical assault to the building?

MS. MURTHY: Kavita Murthy, for the record.

Ms. Maharaj, yes, so there is. That would fall within the security program that they would need to have for the site, so depending on the risk level of the activity that is being conducted at the site, there is a level of requirement with respect to security and the scenarios that would have to be part of any security exercise. So, this would not be Ms. Kanasewich's group, but another group within the CNSC that would be doing that.

I want to go -- really touch quickly on baseline compliance programs for these types of facilities. So, within the risk-informed decision-making or regulatory decision-making, when we establish a baseline compliance program for a site of this nature, we evaluate every risk that the facility has, and based on the risk of the facility we set a schedule for inspections.

So, the compliance program looks at, in this case we were talking about emergency management, so we would look at emergency management and where we would evaluate on the spectrum of risk, where that would fall for this type of facility, and we would determine how many times over a period of 10 years that facility would have to be inspected.

So, that would be a baseline number that we would arrive at to say that if everything remained stable and everything was normal, let's say we would visit

this facility every two years -- I'm not sure that that's the right number, but for the purposes of illustration, let's say it's every two years. But let's say that in the intervening time something happens at the site and we have reason -- because we do have other compliance activities, so an inspector might notice a fire hazard, for instance, that has not been addressed, and so then we have always got the power to have an additional inspection added on.

So, in addition to program changes, there's also the observations that we get from our routine inspections, and there are inspections where we would actually take a team of people who are specialized in emergency preparedness because there was an indicator that told us that there was something that needed to be looked at, at the site.

MEMBER MAHARAJ: Thank you very much.

THE PRESIDENT: MS. Murthy, a very quick question for you. Do we have any other cases where we have two licensees that share one facility?

MS. MURTHY: Kavita Murthy, for the record.

So, we have been looking at that, obviously, to see where we have had this. So, on this scale, like and in the Class 1, where the only example I can -- I can think of, and there might be others, so I'm

sure my colleagues who are listening might -- might provide more, is the Douglas Point site which is on the Bruce Power site, so they are not -- they are not in the same building but they are on the same -- on the same Class 1 site. And you may be aware already, but they do share some services. So, arrangements for security and emergency preparedness they share.

In the nuclear substance world, it has also happened that we have had the Ottawa Hospital, which has had inside the Ottawa Hospital Nuclear Medicine Department, there was a section that was licensed to GE, which was doing some of the medical isotope work; so there have been pockets -- it is not common, it is still -- it still does happen.

THE PRESIDENT: Thank you.

Mr. Jamal?

MR. JAMMAL: Thank you, Madam Velshi. Again, apologies for the bandwidth.

Just to remind the Commission and provide the Commission -- Madam Velshi, and Members of the Commission -- we do have the Western Management Facilities. So, our Bruce site is a single site that is overseen by two. Like, you've got the Bruce Power component -- sorry, Bruce Power and the OPG component.

Now, my point here is the experience we

have with single sites with multiple licensees, as Ms. Kavita Murthy mentioned it's not like the building the way it is at Nordion. But we do have experience from -- from where licensees will transfer products. Like me speak of Orano with respect to the refineries in Saskatchewan for Orano Mining, but it's not identical to what you have before you here, but there are similarities with respect to shared responsibilities and at the same time we hold the licensee -- if BWXT gets the licence, regardless who is implementing the programs -- their employees or their contractors -- if Nordion is a contractor hired by BWXT to execute safety, security, fire response, the holder which is BWXT licence holder, is responsible to meet all of our requirements and that will be the final decision of responsibility for BWXT.

So, if Nordion is a contractor, they are responsible to meet our requirements.

If a BWXT employee is implementing the program, they have the ultimate responsibility.

And if there is a need for us on non-compliance, we'll apply our enforcement from restricting the licence activity. And if there is a need, we'll shut down the operations.

THE PRESIDENT: Okay. Thank you very much.

Thank you, Mr. Brooks and the Nordion team for your intervention.

We'll take a break now for lunch and resume at 1:15 p.m., Eastern Standard Time. Thank you.

--- Upon recessing at 12:53 p.m. /
Suspension à 12 h 53
--- Upon resuming at 1:50 p.m. /
Reprise à 13 h 50

THE PRESIDENT: Good afternoon and welcome back, everyone.

We will move to our next presentation, which is from the Kebaowek First Nation, as outlined in CMD 21-H5.20 and CMD 21-H5.20A.

I understand that Ms. Verna McGregor will be offering us a prayer and opening remarks before the presentation.

Ms. McGregor, the floor is yours.

CMD 21-H5.20/21-H5.20A

Oral presentation by Kebaowek First Nation

ALGONQUIN KNOWLEDGE KEEPER McGREGOR: Meegwetch. Hello, everybody.

(Anishinabe spoken)

I am from Kitigan Zibi, and I would like to invite you to our traditional lands here. Ottawa-Gatineau forms our traditional lands, in addition to the Ottawa River watershed. As the Algonquin Nation too, as well, the land is unceded, meaning that we have never signed treaty to the lands here on contact, and this is affirmed also with the Royal Proclamation of 1763.

On that note, I would like to welcome you here to our gathering. Just a reminder too, because we always had concerns about the issue of nuclear and nuclear waste, which was not here prior to contact. But one of the teachings again goes back with the dreamcatcher, where commercially today says, oh, it filters dreams. But, no, the symbolism of that, it reminds us that everything is interconnected. One of the basic teachings is the spider teaching. The spider wove the web of life, and the web of life connects everything. One of the biggest teachings of that is, what we do to the earth, we do to ourselves.

Our people were always aware of that on contact, and one of the biggest, biggest observations sitting with the elders, one of their stories, which was oral, was also that, with the waters, with the newcomers coming here, how there was a lack of respect for the water, that they threw all the waste in the water and then we turn

around and drink it.

Again too, as well, it affects all life, because of that interconnectedness, and especially the women because women are the life-givers, and when you're giving birth, you break your water. And that's why they call women keepers of the water, and men are keepers of the fire. So it's that connection also, because our biggest life-giver is Mother Earth. And when we poison her waters, it's like poisoning ourselves too, because 60 to 70 percent of our bodies is water.

So, on that note I say meegwetch.

(Anishinabe spoken)

I have a little tobacco here. I'm just saying: Thank you, Creator, for all that you've given us too, as well. Please guide our relatives here well today in coming together, and remind them too as well -- also too, as well, that we're gifted the earth and that we have a responsibility to look after the earth. Thank you for all the waters that the Grandmother Moon guides the waters to, and women are keepers of the water. Thank you for the air that we breathe, that we have a good life here. Thank you for the fire. The men are keepers of the fire, and the fire is the eternal fire. The fire of the earth, which nuclear is part of this now, causing the fire of the earth and everything in it.

So guide us well. We don't ask things in vain, and hope that you guide us well for the next Seven Generations. Meegwetch.

THE PRESIDENT: Meegwetch. Ms. McGregor, who is making the presentation for the Kebaowek First Nation?

ALGONQUIN KNOWLEDGE KEEPER McGREGOR: I believe it would be Rosann Van Schie.

THE PRESIDENT: Okay. Miss Van Schie, over to you then. Thank you.

MS. VAN SCHIE: Thank you, Madam Chair, and thank you Knowledge Keeper Verna McGregor for your prayers in your own language. It's a testament to the resilience of the Algonquin people on this territory. I want to thank the other Commissioners for giving us this opportunity today for Kebaowek First Nation to present our comments on the application for Class 1-B licence for BWXT Medical.

I'm joined today by my colleague, McKaylii Jawbone. She is an environmental technician at Keboewek First Nation, and she is going to start the presentation off for us and I will continue afterwards.

MS. JAWBONE: Good afternoon, everyone. My name is McKaylii Jawbone, as Rosann just said. I'm here today just to give a quick introduction to Kebaowek First

Nation and who we are.

Kebaowek First Nation is one of 11 distinct First Nations that make up the Algonquin Nation. Nine are located in Québec and two are in Ontario. KFN's traditional territory lies on either side of the Ottawa River basin where our 1,000 members live, work, and exercise our Aboriginal rights, including Aboriginal title in both Ontario and Québec.

As an Algonquin First Nation government who represents the Algonquin rights and titleholders to the area of the BWXT Medical project and also to areas that may be affected by this project, our duty is to protect our lands, our waters, our environment for our present and future generations.

The BWXT licensing project is located within and has the potential to significantly affect the shared traditional territories of the Algonquin Anishinaabek Nation.

And I'll pass it over to Roseann.

MS. VAN SCHIE: Thank you, McKaylii. So our first topic is the duty to consult. We would like to raise with the Commission, Kebaowek First Nation and the Algonquin-Anishinaabe Tribal Council are currently petitioning the Minister of Natural Resources, Seamus O'Regan, to try to resolve the ongoing consultation crisis

between the CNSC and the Algonquin Nation on various nuclear project proposals on Algonquin lands.

I know Chief Haymond can't make it here today, but he would like to emphasize that Kebaowek First Nations does not endorse itself or acknowledge any claims to any Aboriginal or treaty rights made by the Algonquins of Ontario or any members of the Algonquins of Ontario. Kebaowek First Nation does not recognize the AoO as an entity entitled to consultation and accommodation.

Before making the BWXT Medical licence decision, we're asking that the Commission demonstrates how it's contributed to meeting the obligations for the duty to consult, as per Section 35 of the Constitution, and the extent to which it has also met the requirements of the U.N. Declaration on the Rights of Indigenous Peoples, including Article 32 regarding free, prior, and informed consent, which would be prior to the approval of any project affecting, I'll say in this case, Algonquin lands and territories and other resources, particularly in connection with the development, utilization, or exploitation of mineral, water, or other resources.

In the Tribunal context, it's really important that UNDRIP is adapted, and we don't feel we should be negotiating for this new role. So hopefully this is something that we can consider in this licence

application.

Next slide, please.

If the CNSC is to discharge its duty to consult, the CNSC must demonstrate in Indigenous communities, including Kebaowek, we're engaged in making a licensing decision (stream lost / diffusion perdue) What was heard and how it factored into the licence decision. Indeed, we have a problem here. BWXT's Indigenous Engagement Plan was among the documents that we had requested, and we were denied access. So to date, there really hasn't been meaningful consultation with Kebaowek necessary to allow the licence to be granted.

Once again, this lends itself to UNDRIP being a minimum framework for the relationship between Aboriginal peoples and the Canadian state, and nuclear development decisions across Canada.

So we're asking the Commission to recognize International Human Rights Law where UNDRIP is an instrument that's been developed over 30 years, and start looking at how we reconcile the Canadian Nuclear Safety Act so it can align with the principles and values of UNDRIP.

International law is enforceable in Canadian law and UNDRIP is an instrument or a yardstick to changing perceptions and unacceptable norms around consultation and accommodation where free, prior, and

informed consent must be considered, and not just in the context of how infringement on Section 35 rights might occur.

I would also like to bring the Commission's attention to something in line with what Knowledge Keeper Verna McGregor presented, and that's Indigenous peoples have the right under UNDRIP Article 25 to maintain and strengthen their distinctive spiritual relationship with their traditionally owned and otherwise occupied and used lands, territories, waters and other resources. It's imperative that they have the ability (stream lost / diffusion perdue) to hold this right (stream lost / diffusion perdue).

Reforming licensing assessment and the role of the Algonquin-Anishinaabe Nation in such assessment requires Canadian Nuclear Safety Commission's understanding that neutrality, respect, and consultation are integral to Algonquin social and political organization on a number of levels. So we're hoping that we can start discussing what is the new norm in our consultation here with the CNSC going forward.

Next slide, please.

Something else that the Canadian Nuclear Safety Commission can take a closer look at in terms of integrating Indigenous knowledge. Indigenous knowledge is

rooted in the traditional life of the Algonquin people. It has an important contribution to make to decision-making. Indigenous knowledge refers to the broad base of knowledge held by individuals and collectively by communities. It may be based on spiritual teachings, personal observation and experience, or passed on from one generation to another through oral and/or written traditions. Indigenous knowledge provides necessary perspective, knowledge, and values for the -- I'll say tribunal process, but as well the impact assessment process, and there's some confusion about -- these are a variety of processes right now in environmental assessment within government, but we can talk about that in more detail later.

But traditional knowledge may, for example, contribute to the description of the existing physical, biological, and human environments, natural cycles, resource distribution and abundance, long- and short-term trends and the use of lands and land and water resources. It may also contribute to project siting and design, identification of issues, the evaluation of potential effects and their significance, the effectiveness of proposed mitigation, cumulative impacts, and a consideration of independent Indigenous follow-up and monitoring programs. We haven't identified this case within the application.

The next slide goes over the nuclear history on Algonquin-Anishinaabe lands.

It's important for Kebaowek to note, and the Algonquin Nation, that before the Government of Canada completed construction of Chalk River Laboratories (stream lost / diffusion perdue) in 1944, no assessment licence approval was undertaken with the Algonquin-Anishinaabe Nation to determine how the nuclear complex might affect upstream and downstream areas of the Kitchissippi/Ottawa River. No thought was given to how the nuclear complex might affect the members of the Algonquin-Anishinaabe Nation, their dependence on the then plentiful watershed resources of the Kitchissippi, or their multigenerational socio-cultural connection to the places and customs associated with the Ottawa River.

Kebaowek First Nation and the Algonquin-Anishinaabe Nation were never consulted on the nuclear development and relicensing of the Chalk River nuclear operations, and this is Kebaowek's first consultation on the Nordion complex.

So the history has been one of poor consultation and it has become normative. We are really seeking to address past injustices and repair past harms and systemic discrimination. We are looking for proper resourcing around issues, the development and

implementation of accountability, respect, understanding, good relations just as a foundation of meaningful engagement, which is the law under the Supreme Court, Section 35.

We would also like to just add in again that there is a growing body of international law since the 1990s protecting human rights. So we're hoping for a coordinated approach.

We would also like to see the Minister of Environment working alongside with NRCan and CNSC and of course engaging in Nation to Nation, where there's some space for some real conversations and setting out a plan together.

The next slide, please.

In this particular consultation, access was denied to a number of copies of documents referenced in the CNSC Staff/Commission Members Document, and references to numerous documents were all deemed internal and not provided. So this certainly doesn't lead itself to the ability for the communities to have free, prior, and informed consent on this particular project. There's definitely a big gap in the knowledge to make comments on this particular application. So this includes the Environmental Protection Program, the Environmental Management (stream lost / diffusion perdue) Indigenous

Engagement Program.

So Kebaowek First Nation is asking the Commission to provide a response in writing explaining how the Federal Crown sought to address concerns which have already been raised by Kebaowek. We have outstanding concerns and, as a minimum, request the CNSC to make all these documents referenced by the Staff publicly available.

When this type of event occurs, when we are in a consultation agreement with the CNSC, it's hard to know what industry and the CNSC are doing here. So we really need space for real conversations and of course disclosure of all the documents. Moving forward, like setting up an action plan so we have a proper consultation framework for each of these projects.

The next slide is about licence-specific deficiencies. I'm not sure how my time is here, Chair.

THE PRESIDENT: Take your time.

MS. VAN SCHIE: Okay, thank you. All right.

There's a summary of comments that we have to do with the licence deficiencies. One is environment reporting and health. There's been no outreach with Kebaowek First Nation to discuss our role in the environmental monitoring and oversight. We request the following licence-specific changes to be made and new

conditions added:

The first is participation by Kebaowek First Nation and other interested First Nations should be provided through an independent environmental committee where participating First Nations will have full and equal participatory rights to technical monitoring and oversight matters. The terms of reference for such a committee, with capacity planning, shall be established within 12 months of any licence being granted.

And the second point here is BWXT Medical shall prepare and provide quarterly reports to Kebaowek with costs related to Kebaowek's understanding and responding to such reporting being covered by BWXT Medical.

The next slide is to do with the Independent Environmental Monitoring Program.

So Indigenous involvement within the development of the IEMP should not be a *post hoc* licensing requirement. The CNSC should have provided opportunities for Kebaowek to provide input on an IEMP and provide meaningful results to our community. (stream lost / diffusion perdue) CSNC's approach to engagement, commitment, or involvement comes after rather than precedes the licensing hearing.

In terms of radioactive waste, this is a very complicated subject for the communities. It's of

great interest for them to further engage on. The Canadian Nuclear Safety Commission should set out in writing how it considered and complied with UNDRIP in making the recommendation that this licence be granted for a period of 10 years and expressly require that theFPIC principle be upheld.

UNDRIP Article 29(2):

> "States shall take effective measures to ensure that no storage or disposal of hazardous materials shall take place in the lands or territories of indigenous peoples without their free, prior and informed consent."

We would like to voice support for another intervenor's intervention, Anna Tilman, as she goes into more details on nuclear waste. Definitely the communities have concerns about nuclear waste at a regional and international level. We do support the Anishinaabek Iroquois caucus' declaration on nuclear waste to the CNSC, and also the City of Ottawa's recent request to Minister Wilkinson for comprehensive assessment on regional nuclear waste that includes any direction of nuclear waste to Chalk River by BWXT.

I will say we are kind of in the dark right now on what is happening with radioactive waste on

the territory, but we are hoping this FPIC principle can be upheld and we can build that into a further action plan on consultation.

The next slide, please.

In terms of the order requested, given the information we've just raised, we are requesting that the Commission deny BWXT Medical's request for a 10-year licence until the duty to consult is met.

I will just get McKaylii to conclude with the next two slides.

MS. JAWBONE: For over 7,000 years, the forest and waterways have provided Algonquin and Anishinaabek people our livelihood, food, energy and materials, landscapes, spiritual grounds, economic trade, and our peace of mind.

The past 300 years, Algonquins have witnessed the results of an exploitive management regime. Much of our traditional territory and livelihoods have been significantly degraded, and many ecosystems have permanent or severe damage, all the while Algonquin people have suffered disproportionate cultural destruction, displacement, and poverty.

KFN is working with other Algonquin community partners to develop new models and legal institutions of decision-making, federally and

provincially, that respect meaningful interaction between proponents, authorities, and affected Algonquin communities in the environmental reviews and project licensing process.

Next slide.

If there are any questions, you could contact us. Here is my info. And, yeah, meegwetch.

THE PRESIDENT: Meegwetch. And a special thank you to Knowledge Keeper McGregor for the prayers, and to both Ms. Jawbone and Van Schie for your presentation.

You may not know, because it was only yesterday that I sent a letter to Chief Haymond, again reconfirming the CNSC's commitment for continuing a dialogue, a commitment for consultation and engagement, and I look forward to discussion this afternoon, and how we keep that channel open.

So let's start with Dr. Dementer with any questions.

MEMBER DEMETER: Thank you very much for sharing the stories, the prayer, and the intervention.

I do have a question for BWXT and for CNSC Staff in relation to the sharing of information.

I understand that there are some things that are technically proprietary relative to patents or business, that some documents are protected for security reasons. But it seems that some of the documents requested

by the intervenor don't really necessarily fall into those camps. And I wonder, once something is referenced in a CNSC Staff CMD, unless it meets a measure of, "We can't release this for specific reasons," how do we decide, you know, whether that can be released or not? Because it sounds reasonable that some of these requested documents don't meet those criteria, and we've referenced them so they become a matter of public -- they're in the public table. So help me understand why some of these documents cannot be released. And what is the test for releasing them once they've been referenced by our staff?

So I'm not sure who wants to start first, CNSC Staff or BWXT.

MS. CUTLER: Natalie Cutler, for the record, BWXT.

BWXT, when we receive requests for documentation, we do take those requests seriously. And we did receive requests for several documents from Ms. Jawbone. And at that time, within the next business day, we provided all requested documents in the way of summaries, in lieu of redacting the program document that may have had sensitive or internal information.

I would like the opportunity to clarify that the Indigenous Engagement Program is part and parcel of our public information and disclosure program, which

includes Indigenous engagement, and that summary was provided. So that that is a clarification I'd like to make, that that is included in the summary we provided.

In addition, the summary we provided on environmental protection and management was inclusive of both the Nordion Environmental Protection program and the Environmental Management System Manual that was provided.

So we do endeavour to provide as much information as we can and we're eager to speak with the Kebaowek First Nation to ensure their questions are answered and that we can discuss the summaries and any contents that they feel may still be required for their understanding.

Thank you.

MEMBER DEMETER: Before we move on to CNSC, I would like to clarify a couple of things.

The documents were referenced by staff in their CMD are the full documents, not the summaries, I suspect? You submitted the full documents to CNSC?

MS. CUTLER: Natalie Cutler, for the record.

BWXT submitted full documents as part of our application. However, the documents that we provide for the public, when requested, we provide them in summary format for public consumption.

MEMBER DEMETER: Can you provide me an example of what would be considered needing to be redacted in a public disclosure and engagement document? What type of information that you would consider to need to be redacted? What's a -- go ahead.

MS. CUTLER: Yes. Natalie Cutler, for the record.

A lot of times it's internal information, such as processes that we may have, contact information that would be included in terms of the target, the target audience, you know, names and contact information.

When we've engaged with the public, we've been asked to provide information that is helpful and to the point, and so we've endeavoured to do that with our summaries. But understanding what you're saying, I believe our summaries are inclusive of the type of information that would be considered helpful to the public as our program documents are concerned.

MEMBER DEMETER: Okay. And staff?

MS. MURTHY: Kavita Murthy for the record.

With respect to releasing CNSC documents, we apply the test of whether this is protected information or not and release them. It is a little bit more complicated when it comes to releasing information we have received as a part of a licence application.

While yes, we get the full documents to conduct our reviews, when a document pertains to programs that belong to licensees, we do not release them. We encourage intervenors to get those documents directly from the applicants.

That said, to our Participant Funding Program and the Indigenous Relations Group, through ongoing discussions we try to facilitate release of documents. So in this case, I believe CNSC staff were not aware that there were difficulties. However, in order to give a bit more precision, I will ask Adam Levine to respond.

MR. LEVINE: Thank you very much. Adam Levine for the record.

So in this particular case, once CNSC staff were made aware of Kebaowek First Nation's specific document request, we worked to identify which documents they were asking for, which ones met the different criteria Ms. Murthy laid out, and provided the ones that were CNSC documentation and then referred them to BWXT directly for anything that is BWXT's own proprietary information or their own documentation which is third party. So BWXT worked directly with Kebaowek to provide what information they could, and we encouraged BWXT to follow up directly with Kebaowek to discuss their facility, their licence application further, and we did the same as well. I'm

happy to provide more information on our engagement with Kebaowek as needed.

THE PRESIDENT: Before Dr. Demeter continues, this is not the first time we've heard issues like this from intervenors. The proponent says, "I provided a summary, which I think is more than adequate to meet their needs," the Intervenor doesn't think so, and the reason particularly around the engagement plan or program that, Ms. Cutler, you have given, in the absence of trust. Well, I don't know what else is in the program. Is it just personal information? Did you consider just redacting it and sending that?

I just find that when we come to this point in the process to find out, "Well, I didn't get the information that I need," and you can see why the engagement program is pretty essential for them, because this is an indication of how they're going to be involved in this.

MS. CUTLER: Natalie Cutler, for the record.

I do understand that thinking, and engagement is extremely important to all of us at BWXT, which is why we did request to meet, and we did hope to be able to discuss and determine a point of contact.

At this point -- and I know that they're

very busy -- our email requests for a point of contact have not been answered yet, and we do want to discuss our programs in detail, and the program documents are a starting point for that, and we will certainly look at how we can be more helpful in providing more fulsome documents versus summaries. However, we do try to provide summaries that are easy to digest in lieu of redacting documents because we feel that they're more user-friendly.

But we do understand your thinking and we're committed to making sure that questions are answered and we remain available for that engagement, you know, for the duration of our licence up to receiving it and make ourselves available.

THE PRESIDENT: Thank you. Dr. Demeter?

MEMBER DEMETER: I'll stop there for now.

THE PRESIDENT: Ms. Maharaj?

MS. VAN SCHIE: Excuse me, Madame Chair.

THE PRESIDENT: Yes. Go ahead, Ms. Van Schie.

MS. VAN SCHIE: Just in addition to the comments by Commissioner Demeter and Madame Cutler.

On page 12 of our submission there's a detailed list of all the documents that we referenced that we have needed to be meaningfully consulted. And the information that was provided in the summary documents by

BWXT was just repetitive of the actual licensing document and it can't be considered equal or in-depth or in any further detail that we were requiring.

And when we did ask the CNSC for the documents first, we did get a message where they had communicated (stream lost / diffusion perdue) and they were told that they were proprietary. So this issue definitely remains unresolved and we would like to see those detailed documents and a proper review and consultation framework engagement agreement. Thank you.

THE PRESIDENT: Thank you for that.

Ms. Maharaj?

MEMBER MAHARAJ: Thank you, Madam Velshi.

Thank you as well for the presentation and Knowledge Keeper McGregor for your prayers.

I would like to ask a few questions around a slightly different issue. I think we will probably come back to this issue of consultation and depth of consultation again. But I would like to understand from the First Nation's point of view, what traditional rights are you seeing as being affected by this particular development? And I won't plant ideas in your head. I'm just going to ask a wide-open question. What traditional rights do you see as being impacted and how?

MS. VAN SCHIE: Thank you for that

question, Commissioner. I am actually not a member of the First Nation but I do work as an advisor, and perhaps McKaylii can add her comments after.

But I will say the *Delgamuukw* decision under the Supreme Court that there is an economic component, so definitely social and economic considerations. And when you look at the history of the displacement of the Algonquin peoples on their own territories, particularly in Ottawa, you know, since the early 1800s, that's never been reconciled. So we're actually starting to look at what the calls to action in the TRC are at that point, you know, the Truth and Reconciliation Commission, and how you can better accommodate those calls to action, including being more inclusive in the assessment of elders, women, you know, applying a lens of gender-based analysis, as well as Knowledge Keeper Verna mentioned, women as water keepers. It's a big role for the Algonquin-Anishinaabe women, and certainly with the residential school system, women were denied access to teachings and teaching their own children. So this is a big reconciliation piece going forward.

Thank you for that question. It's a broad answer.

MEMBER MAHARAJ: Perhaps then I could ask Ms. Jawbone if she has anything more to add, specifically

with respect to the activities of the KFN in the area. Are there particular impacts to specific activities or not?

MS. JAWBONE: I would say yes, based on practising our traditional rights. And the environment is one of the main concerns, the natural resources, the waterways, the lands -- anything that would have an impact on the environment affects us greatly, and that's always a major concern.

MEMBER MAHARAJ: Please, Knowledge Keeper McGregor, if you have something to add, that would be great.

ALGONQUIN KNOWLEDGE KEEPER McGREGOR: For us, I am from Kitigan Zibi Anishinabeg and relate to as well -- my ancestral land is also Ottawa. But also now when we were really colonized in the creation of the reserve to today, it evolved too that where in the 1980s too as well, there was a finding of uranium in the water on reserve. As a result of that, we were all put on bottled water until they finally tested all the wells. So not all the wells tested for uranium, but a number of them did. I think it was like 40 percent.

So what happened today too, as well, is we see the fallout of that too, as well. When we have -- we have the -- even the Maniwaki area with the rates of cancer, but also the health fallout of -- we attribute it

back to the years of drinking water that's been tainted with uranium.

That was our big concern too, as well, a number of years ago, even with the Frontenac mines too, where you have the open pit uranium because, again, what are the studies and the impacts of the people? And for us it wasn't -- yes, we see it from a community level, but I said what happens when, for example, Ottawa is downriver from, for example, any nuclear activity and it's the general population that's impacted by this, translating into long-term health care costs too in an aging population.

So that's where for us, yes, it does impact our Aboriginal rights, maybe our Aboriginal right to also clean water.

MEMBER MAHARAJ: I see. Thank you very much, Knowledge Keeper McGregor.

With respect then to water quality, what we have seen in the application documents from BWXT is that there is very, very low impact to the water. Does that help make your concern less?

ALGONQUIN KNOWLEDGE KEEPER McGREGOR: Not really. And also too because how does that come -- also too, as well, like the airborne, all the interconnectedness of the safety? And again, that's where consultation would

come in. And I think that's why Rosann and Kebaowek First Nation and also the Algonquin Nation have been asking for also too, as well, the documentation and the concern over the vetting of the documents too. So if it's that safe, why is there also the vetting of documents? So it's that openness and transparency when -- and also in the consultation process. I don't know if that makes sense.

MEMBER MAHARAJ: Yes, yes. That makes a lot of sense.

One of the other points that you raised in your submission was that you would like to have more involvement in monitoring. Have you been invited to participate in the Independent Environmental Monitoring Program by the CNSC?

ALGONQUIN KNOWLEDGE KEEPER McGREGOR: I would pass that over to Rosann and McKaylii.

MS. VAN SCHIE: Thank you. No, we have not been requested to participate in that at the BWXT Nordion facility.

MEMBER MAHARAJ: So perhaps then I can ask Staff that question.

We have heard that there have been outreaches to other First Nations to participate in the IEMP, and my question is: To what extent, if at all, has KFN been invited, and if not, why not?

MS. MURTHY: Thank you. Kavita Murthy, for the record. I'll pass this question to Kiza Sauvé for a response, please.

MS. SAUVÉ: Thank you, Ms. Murthy.

Kiza Sauvé for the record. I'm the Director of Health Science and Environmental Compliance Division. I hope my audio is better this time. I heard I was a bit quiet last time.

In terms of BWXT Medical, no, we have not reached out because we haven't done an IEMP campaign since 2018 in that area. We are likely going there in the next year or two. However, we are going to be in Pembroke this year. And on February 26th, we did send some communication to the KFN, and we recognize how busy they are. We have not heard back for that particular campaign. We do have campaigns in the near future on the Chalk River area as well. And so, as the relationship is building, we hope to have their involvement more in either the planning, being out in the field, however they want to be involved.

I'm not sure if Mr. Adam Levine wants to add anything more in terms of that relationship side.

MR. LEVINE: Thank you. Adam Levine for the record.

And just to add in that, for the 2018 sampling campaign, we can reach out to the

Algonquin-Anishinabeg Nation Tribal Council, which Kebaowek First Nation is a part of and partners with. At that time, that was the method of communication with the Algonquin communities that AANTC represents.

And it was more recently, since 2019, that Rosanne and Kebaowek First Nation came forward to want to engage more directly with us, which is great, and we're happy to do so when they want to and are ready. But we did reach out, and we always want to get Indigenous communities, in whatever area we're working in, to engage with us on IEMP and other matters. So we really hope that Kebaowek First Nation takes us up on our offer that we sent out in February to engage with us more on the (stream lost / diffusion perdue) sampling campaign and future ones, as it's something that's of interest to them. Thank you.

MEMBER MAHARAJ: Thank you very much. If I could just ask BWXT to comment on whether they have reached out to the KFN to participate in any environmental monitoring or sampling programs that you may have conducted on your own.

MS. CUTLER: Natalie Cutler for the record.

We are in the early days of outreach with KFN, and I'll admit that we haven't yet had a conversation.

We had, as Adam had reached out to the Algonquin-Anishinaabe Tribal Council to engage and determine where there was interest with its member communities, and we were very pleased to have been contacted by Kebaowek First Nation ahead of the hearing.

And so on April 30th, which was just a couple days before I believe the interventions were due, we were asked for the documentation, which we provided in the next business day, and we at that point requested confirmation of point of contact to engage going forward because we would like to initiate those meetings. We look forward to speaking with them as it relates to environmental monitoring, public engagement, community support, and everything in between.

So I hope that answers the question. But we have not yet had a discussion on environmental monitoring. Thank you.

MEMBER MAHARAJ: Thank you very much. That answers my question.

Madam Chair, that's that topic for the moment.

THE PRESIDENT: Thank you very much. Maybe I'll just follow up with a couple of points on that.

In your presentation, Ms. Van Schie, you used the words "consultation crisis with the CNSC." So

clearly great displeasure over the state of things, is how I read that.

What I'm hearing from CNSC staff, what I'm also hearing from the applicant in front of us today, that the two parties are trying to connect -- or the three parties are trying to connect, but it seems like it's in early stages. The commitment seems to be there -- not quite sure. It hasn't been tested yet.

But I really want to get to the bit about the duty to consult. I absolutely agree on the reconciliation part. And I know that you feel you haven't got the appropriate documentation, or information, or there hasn't been the requisite transparency for you to feel comfortable.

Staff's assessment has been that for this particular application in front of us, where really nothing is changing other than who is going to be running the business, the work stays the same, the way it's operated stays the same, that it's not -- like the current operation, it's not likely to cause any adverse impact to the environment or to the safety.

So, again, from a Section 35 perspective, the duty to consult, you know, given the range of that, I think what we're hearing is there's absolutely a commitment to build a relationship, and I strongly encourage greater

transparency. I absolutely hear you on the documents you've asked for and why you wouldn't get them when they're so fundamental to you getting reassurance that things are being well-managed.

But tell me, what more would you like? What would you like? They said they're reaching out, want to sit down and walk you through, involve you with the monitoring. What would success look like for you?

MS. VAN SCHIE: Thank you for that question, Madame Chair. I'll start, and perhaps McKaylii and Verna McGregor can add in.

As I mentioned, I'm an outsider to the communities. I'm just an advisor. But I can say that the starting point in consultation and this discussion is, like, when you're a new person in the community or you're visiting communities, people try to connect who you are and what you're doing there. Like, that seems to me vital in this discussion. I mean, I've worked with the communities almost 20 years now, and that is the main thing: The introduction. (stream lost / diffusion perdue) Who are you, where do you come from? What are your intentions?

I know BWXT is a new entity, it's a new business entity. It is operating on Algonquin unceded lands. The community knows absolutely -- not much, other than what was in the application document, about this

company. We need a better sense of what their plans are going forward and who they are.

And so as well in consultation within the community it was always family to family, band to band, nation to nation. So I think it's moving forward to this relationship with the CNSC and the government that is nation-to-nation based. What does reconciliation look like? How is it defined? And not a unilateral definition coming from the government.

We just commented on nuclear waste policy, and one of the principles of the engagement was reconciliation. So how do we have the conversation? Like, what is the stage for the conversation? And, of course, that should be based on early engagement. And we haven't had early engagement with BWXT, and the communities really do not know much about BWXT or have they offered, you know, to come in and make presentations about who they are in advance.

And I think this is really important, especially given what we are reading in Ms. Tilman's report, and what we're hearing from other nuclear experts in terms of waste import and export. So of course they're talking about exporting product, but we're understanding the government feels there's a responsibility or treaty to bring that waste back, and so most businesses are

interested in increasing production, increasing, you know, their supply networks, and we have to really ask the serious question: How much waste is coming back? How do we have that conversation in this early engagement? How are things fully disclosed? It just hasn't happened. And that's why we're asking that the licensing decision not be made at this point. Thank you.

THE PRESIDENT: Thank you. Do Ms. Jawbone or Ms. McGregor want to add anything to that? It's a very helpful response.

Ms. Kavanagh, you have your hand up?

MS. KAVANAGH: Yes. Thank you, Madam President.

I just wanted to speak to the provision of the requested documents and the summaries that we provided. So by way of example, information on our safety analysis was requested, so we provided an overview that touched on and described the activities that are conducted at the facility, as well as how we view safety and our defence and depth mechanisms, and we talked about our administrative controls and engineered controls.

What we did not provide was the in-depth calculations and hazard risk assessment. We did provide the conclusions of that safety analysis. The other document summaries would be similar in nature. So we

excluded details about how the work is actually conducted and by whom within the facility.

Now, we certainly look forward to engagement with the First Nation to identify where we can provide more information to them. And just by way of example, for previous hearings and discussions, we have provided excerpts from some of our documents in lieu of providing an entire document or redacting it. So I think there is a way forward. What we look forward to is that initial engagement and continued engagement so we can better understand how we can potentially add to the summary documents that we provided and ensure that the First Nation has and feels that they're receiving meaningful information from us. Thank you.

THE PRESIDENT: Ms. Kavanagh, I'm going to really drive this further because this is so close to what we are trying to do, which is, to build trust requires transparency.

You talked about the safety analysis one. That one I can understand that. But look at numbers 5, 9, 17 and 40. One is your environmental health and safety policy. That's one you should be proud of. Share that with the world. Reporting and notification requirements. Surely that is one you want to be totally transparent on. We've talked about the disclosure program.

So instead of saying, "Here's the summary and what we need to add," I would suggest you look at these documents and say, "What do I really need to redact?" Otherwise, it is in the public domain. Because that's the way we can have the kind of conversations that are necessary and build trust and relationships.

So I want you to change the lens through which you see these documents, is my suggestion to you.

MS. KAVANAGH: Yes. Thank you, Madam President. We hear your message and we will adjust our view of the documentation and ensure that we initiate those discussions with the First Nation.

THE PRESIDENT: Thank you. Ms. McGregor?

ALGONQUIN KNOWLEDGE KEEPER McGREGOR: I'm just going to echo on what Rosann mentioned, because I've done other work in the past and historically too, as well, where the concern about nuclear waste, and that's where the transparency is needed too, as well, because we've all seen First Nations communities where 67 percent are in rural/remote locations, are the potential sites for nuclear waste storage.

And again too, as well, they see it as an economic development opportunity for our marginalized communities.

I remember going to an event a number of

years ago and I said, "Well, you know, we're always seen as disposable, really," but at the same time because, yes, we're out of sight, out of mind, even with nuclear waste storage. I said but the other problem is also too, as well, another thing is, though, if, for example, Toronto -- at that time it was the Bruce Nuclear Plant. I said Toronto benefits from nuclear power. I said one of our teachings is taking responsibility, so if you benefit from nuclear power, then Toronto needs to take responsibility for nuclear waste storage on their land. So if it's so safe, it should be also safe to bury it in a high-density populated area if it's that safe.

But the other part is -- well, there are other factors to that too, as well.

So that's the concern, and that's where the transparency is needed because of also the history of just moving forward, and I think that's what reconciliation is all about, is doing things in a different way, and with truth and honesty too and then making an informed decision.

The other part -- I'll just give another story, what happened, though, in terms of the consultation process. About four years ago, Ottawa Hydro came to our community and they were redoing the Chaudière Dam and they were just coming for consultation in terms of the process and it was just an exercise. But what happened is, we

raised the issue where the elders were raising this issue for a number of years, 25 years. They said, "What about the eels?" When they built that dam in 1906, there was no consultation and it wiped out the fish population, the American eel. So what are you doing to bring that back? They had their conversation, then they left.

About two years later, they brought us back in for another meeting. And one of the meetings is what they had -- what they did was they did install a fish elevator and they had the engineer there who also -- which was a woman -- and she explained they augmented the fish elevator for the baby eels. And I said, "That's reconciliation through consultation."

So sometimes we fear consultation and conflict. But sometimes, if handled properly, it may lead to other avenues. But, again, you've got to go there. And I think that's what we're doing today.

THE PRESIDENT: Thank you for sharing that.

Dr. Demeter, any further questions?

MEMBER DEMETER: I'm good. Thank you.

THE PRESIDENT: Ms. Maharaj?

MEMBER MAHARAJ: I've asked my questions. Thank you, Madam Velshi.

THE PRESIDENT: Thank you to the folks

from Kebaowek First Nation. Thank you very much for your intervention. Please take my greetings to Chief Haymond and tell him I look forward to meeting with him in the very near future. Thank you.

ALGONQUIN KNOWLEDGE KEEPER McGREGOR: Meegwetch.

THE PRESIDENT: Meegwetch.

Our next presentation is from Ms. Anna Tilman, one you have heard about a lot already, as outlined in CMD 21-H5.5 and CMD 21-H5.5A.

Ms. Tilman, the floor is yours.

CMD 21-H5.5/21-H5.5A

Oral presentation by Anna Tilman

MS. TILMAN: I am trying to do this properly. So can you see me? I see you, but I don't see me. So what works?

THE PRESIDENT: We see a shadow of you and we see a slide.

MS. TILMAN: Okay, great. I would like to start out with some opening comments, and thank you very much for recognizing some of the work I've done with the previous group.

I'm not opposed to nuclear medicine

per se, and I'll talk a bit about that later. What I'm concerned about is the secure and safe supply, particularly of technetium. We have witnessed a shortage in the past.

I am also concerned about the proposed patent process as submitted by BWXT and whether that would at all be a barrier to supply in Canada or elsewhere.

I'm also concerned about the methodology. It's not so much that proposed by BWXT, but as well the methodology where, as we receive technetium now, whether it's produced by reactors using highly enriched uranium. We don't know.

I'm receiving messages that my internet connection is unstable, by the way, just to let you know.

So let's go to the next slide, please.

What the current licence includes has already been discussed. So I don't really need to read the slide. We know what it doesn't include is the cobalt-60 production. But both these portions are housed under one facility, and actually I think it becomes confusing.

Next slide, please.

The acquisition terms of BWXT. That was completed in 2018. And it's a 20-year lease with Nordion with renewals, five years, as it says, and activities currently authorized are independent of the gamma technology business. That's the cobalt production.

As a result, the licence amendment or Commission approval wasn't required. At the time -- and these numbers are subject to variation -- approximately 118 employees, half of the personnel were hired by BWXT Medical, and now we have approximately 200 employees.

Next slide, please.

As to what its proposed operations, in excess of 1.0×10^{15} Bq per year isotopes would be manufactured. Isotopes greater than a year half-life would not be manufactured. And the total radioactive material would be below what's called historical production levels. That's from BWXT's paper.

However, there's no reference given as to the specific particular nuclear substances that are being proposed to be manufactured or the activity or the half-lives. That is an omission.

Next slide, please.

Going to the history of molybdenum-99. It was first produced, as I'm sure you know, by the fission of highly enriched uranium targets at Chalk River, which ceased in 2016.

Now ,we know BWXT has developed a new technology to produce molybdenum-99 using a target of molybdenum-98, the other isotope, irradiated in a reactor. And BWXT Medical is anticipating a launch of this

methodology in late 2022. And it will require the approval of both Health Canada and the U.S. FDA.

There are so many factors involved in there. Time is slipping by. A lot of focus is on COVID-related and other related areas. Delays can occur and should be expected in this new technology.

Next slide, please.

CNSC has reviewed, as we know and talked about, BWXT's proposals and has recommended that a licence, a Class 1-B licence, be issued for a 10-year period and it accepts the financial guarantee.

Next slide, please.

However, a 10-year licence alone creates a problem. It is a lengthy time. Does it allow for the oversight needed to ensure that there's safe and continuous production of molybdenum-99 or any of the other isotopes, which we don't know yet, to be produced. How does CNSC plan to intersect in this period? Will it have set interim reviews of operations and what is the frequency?

Emergency plans. What plans are there in case of an interruption causing delays in production of molybdenum-99? This is the critical thing if you want to get technetium out. This is what caused a problem ages go.

Next slide, please.

The other question is, currently BWXT is

manufacturing two medical isotopes. That's from reading from their report, yttrium and indium, but I'm not sure whether they're going to continue production of these in the 10-year licence request. I have not found out any information on that.

Next slide, please.

Now, the other part is, what isotopes will they be manufacturing other than what they might be manufacturing from the previous slide?

So as it was stated in their document, they tend to manufacture nuclear substances in excess of 10^{15} Bq per year. We don't know what substances they are. We know that there's isotopes, they say, with greater than half-year life span would not be manufactured. However, there will be impurities with longer half-lives. From a scientific perspective, this is totally unscientific. It makes no sense. We don't know what BWXT Medical is intending to produce and so on.

It is an obligation of the CNSC to require BWXT to identify these substances, what function they would serve in medical treatments, and the specific impurities. Only then should CNSC purview be to permit this production of specific isotopes or not.

Next slide, please.

A shortage. We know about that shortage

that occurred over 10 years ago and the experience. There was a world-wide shortage of technetium-99. So it is critical that whatever methodology is used, and hopefully a much safer one, be carried out without interruption. Can BWXT and the CNSC guarantee sufficient and adequate supply of essential isotopes, both domestic and for international use?

The next point is of concern for me, is the patent approach limited or restrictive? I do not know. I cannot tell. But it concerns me that we have that kind of approach.

Next slide, please.

Nuclear energy workers. Now, here I find a disconnect. There's either inequity in protection between those working in the active areas and those who visit the active areas. There's also concerns about contractor nuclear energy workers. Why are they being subject to radiation limits set for non-nuclear energy workers?

I would imagine there will be new hires come on. Would they become contractor NEWs and then not subject to the same level of protection as the permanent workers? This is a critical issue as well.

Next slide, please.

I would highly recommend regarding

workers' health that emergency response plans by both Nordion and BWXT be reviewed and upgraded routinely.

The issue of radioactive waste that got a lot of mention at the last presentation, transferring these wastes off-site and just putting them in landfills or using clearance levels to displace the waste and minimize the amount is not getting rid of the waste. It's just taking it from one place, putting it elsewhere. That's not very good.

Now, BWXT Medical says it's committed to provide employees with a safe and healthy environment and address efforts to prevent pollution and minimize waste. We need to see more of what that means, both for the workers and for preventing pollution and minimizing waste. And that does not mean clearing the waste and putting it into ordinary landfills.

Next slide, please.

How and with what frequency will CNSC and Health Canada monitor operations to ensure the safety of the employees and the surrounding communities, and how will the company itself adapt to a changing market in the manufacturing of specific and novel medical isotopes?

Next slide, please.

Going to the Federal Government. What role, what plans are they going to put in place if there is

a lack of supply affecting the production of molybdenum and, of course, technetium-99 and other medical isotopes? And how who will the Government of Canada deal with issues such as transferability, trading and selling of assets of a private company, namely BWXT Medical, and the implications that such activities would have domestically and internationally?

Next slide, please.

Now starting with my conclusion and comments.

I believe the CNSC must reject BWXT's 10-year licence, and restrict it, if they're going to continue with the licence, to a limited time. There's too much that is not known at present.

BWXT is in the process of preparing a decommissioning plan; this must be subject to public review.

Workers, be they nuclear energy workers, non-nuclear energy workers, must be provided with full and equitable protection from exposure to radiation and other hazardous substances.

Other means. This is another area of producing many isotopes that can be used other than nuclear reactors.

Cyclotrons. That needs to be further

researched.

Also, I want to say the safety and supply of essential medication is paramount, and that takes precedence over company profits.

So I urge CNSC to review, in all seriousness, the 10-year length of the subject, respond to what is not given in the documents of BWXT as to what it intends to produce, and what impurities they imagine would be in that production. There is lots that is not given in the documents that needs clarification.

And with that, thank you very much.

THE PRESIDENT: Thank you, Ms. Tilman, for your submission.

We will start with Dr. Demeter with questions, please.

MEMBER DEMETER: Thank you, Ms. Tilman, and I'm going to pick up on the waste topic now.

We've heard that activities will carry on as usual. There won't be much change. But there is a change that you will be -- BWXT will be in the business of receiving molybdenum-99 and manufacturing molybdenum-99/technetium-99 generators, which is new, and I'm not sure if there's been a commercial production of generators in Canada to this scale before because, prior to this, I think most of the molybdenum-99 was shipped south

and then put in generators and then shipped back north.

So I'm going to first, as an overarch, the safety case is based on the radioactive element being produced, whether it's an alpha, beta, gamma emitter, and the chemical qualities; whether it's volatile or not. Those are all really important elements to understand the safety case. And that's why I was asking before, what isotopes are going to be produced, by what quantities, and that helps drive the decisions based on waste streams.

So I'm going to stick with the moly-99. I suspect, although it's sort of hidden in there -- not hidden, it's a bit discussed, but not directly -- that there's going to be a neutron activation of a solid molybdenum-98 target in a CANDU reactor setting and you're going to take that moly-99 and process it and put it into generators.

Now the waste streams from that will depend on the purity of your molybdenum-98. So talk to me about the purity of the molybdenum-99 you're going to get, and then how you're going to deal with anticipated impurities. And what waste stream does that generate?

I'll say that to BWXT.

MS. KAVANAGH: Jackie Kavanagh, for the record. I will direct that question to Mr. Decaire.

MR. DECAIRE: Richard Decaire, for the

record. I'm just making a note here; I want to make sure I got the question correct. So it's what impurities were being generated, and what was the other part? There were two parts.

MEMBER DEMETER: Well, you're going to receive probably neutron activated moly-99, and if the source target is not 100 percent moly-98 you're might get a number of impurities of other activated products that will create a waste stream.

MR. DECAIRE: Yeah.

MEMBER DEMETER: What other impurities are you anticipating, and what's their waste stream, and how are you going to manage it?

MR. DECAIRE: Great. Yeah. So the material we're irradiating is actually natural molybdenum. So molybdenum, I think, has six stable isotopes which include molybdenum-92, 94, 95, 96, 97, 98, and 100. So it's more than that. It's seven. A lot of stable isotopes there.

And it exists in very pure form because it's used in the metallurgical industry. I like riding bikes. If anybody had a steel bicycle, chrome-moly bicycle, the molybdenum there is very high purity. So we can take that commercially available molybdenum, 99-point-whatever percent, and what we've done to start, is

there's a raw material purity spec that comes with any kind of material like that.

So it will say it might have up to this amount of iron in it, or this amount of whatever element. So what we can do, through calculation, is estimate a worst case with those impurity levels because we may get variation from batch to batch, what the radionuclidic impurities would be, which aren't creating the molybdenum-98 into 99 which is the thing we want.

So of course we've done that, and we've also done test irradiations. And through our test irradiations we can see that the raw material is better than the raw material spec. It doesn't have as many impurities in it, but we still want to hold onto that idea that it could be up to that level. So far everything we've seen is fairly consistent from the supply that we have. And the specs that we go to, it's like a published specification of a certain type of molybdenum that the metallurgical industry has to sell, and that's what we put in the reactors.

So we've done a few test irradiations. And of course for our -- what are we going to do with the waste? How much waste do we accumulate? What dose rates come off of it? How much decay is required? That's something that I do as the manager of radiation safety, to

understand how we accommodate that within our facility until we can decay it to a point where it goes to a CNSC-licensed waste facility. So that's been done. It needs to be further vetted, though, for when we get into development runs and validation runs over the next 12 months.

THE PRESIDENT: Thank you. Dr. Demeter, maybe this is a good time to see if staff have an update to the question you had asked and that they were going to follow up on around levels of activity that are permitted under the --

MEMBER DEMETER: Sure.

THE PRESIDENT: Ms. Murthy?

MS. MURTHY: Thank you. Kavita Murthy, for the record.

Dr. Demeter, you asked about Attachment 1 which is referenced in staff CMD 21-H5, on page 70. In fact, the attachment refers to the attachment that was appended to the letter we received from BWXT. So the BWXT letter had an attachment, which was their application. So Attachment 1 is the application that BWXT submitted. The application, which is the licence application, is referenced in the licence condition handbook under "Licence Condition G.1," on page 129 of staff submission. The licence application is also posted on BWXT Medical's public

website under their "What we do" pages.

The document has a table, and in that table it has information on the isotopes that will be processed at the facility greater than 1×10^{15} Bq per calendar year of molybdenum-99 in solid form, gaseous, and any other liquid form. And then for various other radio isotopes, atomic numbers 1 to 89, less than -- half-lives of less than one year.

This is identical to the activities that were approved for the nuclear medicine processing facility under the Nordion licence.

BWXT is proposing to continue with the processing of yttrium and indium, as well as the proposed moly-99 process that staff have assessed and determined as being within the licensing basis.

Any proposed new medical isotopes would be assessed against the licensing basis and we would report them to you as part of our regulatory oversight report.

So I hope that answers your question.

MEMBER DEMETER: It does. Yeah, it does. Thank you.

MS. MURTHY: Thank you. I had another point, but if you have a question on this, I'll wait.

MEMBER DEMETER: I had another question on the generator manufacturing.

One of the things with generators is they require shielding, and I don't know if you're going to start up a whole new production facility for the lead shielding for your generators or if you're going to buy it totally encapsulated. But if you're going to be managing or handling lead, are there any specific risks associated with that, and how are you going to manage sort of the occupational health and safety aspects of lead in a manufacturing process, which would be new to you right now. To BWXT, please.

MS. KAVANAGH: Jackie Kavanagh, for the record. I'll direct that question to Richard Decaire.

MR. DECAIRE: Richard Decaire, for the record.

We do use lead right now in the shipment of TheraSphere Y-90 and also for indium-111. However, the molybdenum-99 generators will be shielded by a combination of steel cladded -- stainless steel cladded depleted uranium at the base and tungsten on top. So the new product won't involve handling lead, and the depleted uranium is, as I said, enclosed in stainless steel. And CNSC requires a minimum 6-month verification that those depleted uranium shields are intact.

Thank you.

MEMBER DEMETER: Thank you. I was going

to ask about the depleted uranium, and I wasn't sure if it was still being used but I guess it is. It has other nuances. But I'll stop there. Thank you.

THE PRESIDENT: Thank you. Ms. Maharaj?

MEMBER MAHARAJ: Thank you, Madam Chair. This is a question for the staff just to continue with the line of information that Ms. Murthy has just provided us with.

I just wanted to ask a little bit more detail about the concept of other isotopes that could be produced during the applied-for licence term.

You've indicated that, if BWXT submits that they want to produce a different isotope, that it would be compared against the licence basis and you would let us know at the Commission.

Could you help me understand that process just in a little bit more detail, and what controls you have in place in your process to ensure that the potential isotopes also meet with all of the other safety considerations that are present.

MS. MURTHY: Yes, I can. Thank you for that question. Kavita Murthy, for the record.

So the concept of licensing basis is essentially -- it essentially looks at a safe operating envelope. If you can imagine what can be done under the

conditions that the facility is in, that will still be -- will still be within the bounds of releases to the environment, protection of workers, protection of the public.

So in a lot of cases, these assume worst case scenarios. So they assume, like, you're using the maximum amount that you can, and then so what is the result? And so the analysis that is going into that is called the safety analysis report. And essentially that's where they will have -- they will provide to us specifications about what is allowed in that facility.

So the licensing basis basically defines both the programs that they have in place, the safety and control measures they have in place, the systems they have in place in order to function within the bounds of their safe operating envelope in order to provide for flexibility, to a certain extent, to do other isotopes.

What we require them to do, is when they introduce something that is different from what you have seen today, is to provide us with prior notification of what they're proposing to do, the methods they're going to use, and the onus is on the licensee or the applicant to demonstrate to us that the introduction of a new process that may not have been discussed today is still within the licensing basis for the site, in that in introducing that

process does not introduce something that was not considered by the Commission when it granted the licence.

So that evaluation and that assessment is done by the applicant, or the licensee, and provided to CNSC Staff. And what CNSC Staff do when they receive such a submission, is we have our environmental protection, radiation protection, and our subject matter experts who evaluate it and assess it, and come to a conclusion on whether or not the licensing basis is respected in that particular process. And if the conclusion is that, yes, it is, then we will give approval. At the Staff level, the approval is given for that process to go ahead.

In September there is a hearing on McClean Lake where such a thing was proposed by an existing licensee, and staff came to the conclusion that it was not within the licensing basis. And when that happens, then the licensee has to come in front of the Commission, and the Commission is the one that hears the licensee's proposal and approves or not the fact that they can go ahead.

So that hopefully addresses the question you asked.

So essentially what we're doing is we're drawing a box around what's allowed, and we are saying that does not mean that tomorrow, if BWXT got a licence, that

they can go and produce anything that falls within that. It means that introduction of new processes also has a rigour of review and approval from CNSC staff.

MEMBER MAHARAJ: Thank you. That's extremely helpful, Ms. Murthy. But what it raises for me in my mind is the part of the process that seems to be missing, to me, is how does the public and -- including First Nations -- we've heard a lot about consultation gaps by First Nations or desire to have more input early in the process -- how does your process for assessing potential other isotopes account for the public to know that something is new?

MS. MURTHY: Kavita Murthy, for the record.

So continuing on. In our annual compliance reports -- I'm sorry, not annual compliance -- regulatory oversight reports that we report to the Commission every year, we do include a list of changes to the facility that were done in that year. So there isn't a live update of the information, but there is information that is updated.

So, for instance, if -- let's say a new process is introduced and that goes through approval at staff level within the licensing basis, there is a change to the licence condition handbook to include new processes

that are now submitted by the licensee and accepted by CNSC staff. So we do provide an update to the public in a public forum and to the Commission on the changes that have been made to the licence.

In several instances we will go back to the Commission and we will report to them on what new processes have been introduced. We don't do every one of them, but, significant ones, we will.

MEMBER MAHARAJ: With respect, though, Ms. Murthy, I can hear the clamour in the back of my head that updated notice is not consultation about a new process and a new product being produced. And I'm not expecting you to say your process is something other than it is right now. I understand you've told us what the process is. I just will put that on your radar screen for now, because I do think there's a substantial difference between notification and informing the public of something versus consulting, and I think we might hear about that.

THE PRESIDENT: Thank you.

Ms. Murthy, just for greater clarity. If this was under the Nordion licence that the moly-99 or technetium-99m process was being contemplated, that would have triggered what you're calling, where Nordion would have sent something to staff and staff would have reviewed to confirm that was within the licensing basis?

MS. MURTHY: That is correct.

THE PRESIDENT: Thank you. And then, as far as this box that you have talked about, when, you know -- when I think -- when you just gave your response on Attachment 1, et cetera, was that they're planning on manufacturing greater than 1×10^{15} Bq per year, that's not a box, right, that's saying it's going to be greater than something. So how do you actually put a limit to that or does one expect to put a limit to that, or it's, you know, consistent with historical levels, but we don't really know what the historical levels were because they've clearly changed over time.

MS. MURTHY: So the greater than 10^{15} is what brings BWXT's team to the Class 1-B grouping of facilities.

So the second part of your question is what is "greater than"? You know, it could be -- how much greater than. So, yes, we -- then that's where the facility's safety analysis and the bounds related to DRLs, releases, waste streams, doses, all of those come in.

So, again, historical values, I am probably not equipped to speak about the historical values right now, but I can definitely find someone, or perhaps BWXT can speak to it. But they have given us, and we know the production numbers that they have had because they

report them to us through the annual compliance report. So we do have that information on hand.

THE PRESIDENT: Thank you. Mr. Jammal?

MR. JAMMAL: Thank you, Madam President. Can you hear me?

THE PRESIDENT: Yes, we can.

MR. JAMMAL: I'd like to provide clarity for Commissioner Maharaj with respect to her question on consultation.

As you are providing the approval, or thinking of providing approval for this application, the consultation process before you is part of the bounding element with respect to the licenced activity that's being proposed. If there are any changes in the operations, then, as Madam Murthy mentioned, it will be outside the licensing basis, hence it will trigger us to come before you, the Commission, for an amendment, and it will trigger everything else.

But the consultation process is not a one-off communication. The licensee has the responsibility for disclosure and public information, and they are meeting our requirement by informing their stakeholders with respect to activities on their site, that it be a submission to the CNSC with respect to a safety case -- not an amendment of safety case, but a proposal with respect to

the molybdenum production.

So they have a public disclosure program in place that we request of them to communicate with their stakeholders.

But I want to go back to the fact, if the Commission approves this licence and the bounding envelope of this licence, the consultation, and all engagement is taken into account in providing the envelope and the licensing basis, and the bounding element, and at the same time the licensee has obligation to disclose, according to their program that was approved by the CNSC, to disclose that information to the public and the ROR, as mentioned by Kavita, it does include written interventions according to the proceedings that will be established by the Commission.

So there are pillars in place where the public can engage with respect to changes within the bounding of the licensing basis or outside the bounding, which will become a full proceedings under the Commission.

I hope I answered your question.

MEMBER MAHARAJ: Yes. Thank you so much.

THE PRESIDENT: Thank you, Mr. Jammal.

Dr. Demeter, further questions right now?

MEMBER DEMETER: I have just a quick fact question and then a question for Ms. Tilman.

On the staff CMD, supporting detail C-1,

there's a list of air emissions monitoring for 2015 to 2019, and it gives by isotope and it gives a DRL. Then there's a second DRL that must have come into place between 2017 and 2018. And, for most of the DRLs for the isotopes, they've remained stable or gone down through time. But for cobalt, the DRL, prior to 2015 was 70.1 GBq per year. But between 2017 and 2018, it went up to 250 GBq per year. So it's the only one where the DRL changed upward or didn't stay the same.

So maybe you can explain to me why that is. Why the DRL changed to a higher limit for cobalt?

MS. MURTHY: I'll ask Kiza Sauvé to respond to the question. Thank you.

MS. SAUVÉ: Thank you. Kiza Sauve; I'm the Director of Health Science and Environmental Compliance Division.

So the revised DRLs are based on a revised version of their DRL document, and a more recent version of the CSA standard N288.1.

When calculating DRLs, the accepted methodology is to be as realistic as possible while maintaining adequate conservatism to account for uncertainties in the model or model parameters. Generally, the more realistic the model and the less conservative it is and the higher the DRLs will be because the critical

receptor would require a higher level of exposure to receive a 1 mSv per year does.

So the large increase in the DRL for cobalt-60 is attributed to a more conservative safety factor that was applied to the previous version's DRL calculation and has since been adjusted. So a reminder, the DRL considers the critical pathway analysis and the most probable location of the highest radiation exposure, and that is looking at the radiation exposure of 1 mSv per year.

So the main -- really, what we're looking at is, you know, the CSA Standard N288.1 gets the changes and evolves over time, and when they did the revised version, that's what happened to the cobalt DRL.

MEMBER DEMETER: Okay. So it was under revision. Okay. Thank you. I just noted it was an exception to the table.

Ms. Tilman, you know, I think something needs to be on the record here. You asked a question: Contractor NEWs are subject to radiation limits set for non-NEWs even though they may be permitted to handle radioactive material.

I wonder if you're aware someone who's not considered a nuclear energy worker has an annual dose limit of 50 mSv in any one year or 100 over five, and a non-NEW,

it would be considered like a member of the public, which would have a radiation dose limit of 1 mSv per year.

So, in fact, the contractor non-NEWs have a much more conservative strict limit based on this intervention, on the licensee, than the permanent worker. So I was a bit confused to why you thought the contractors were being disadvantaged. In fact, their radiation dose limits are much more conservative and much more protective than the regular workers.

MS. TILMAN: Well, there is general confusion in going through that whole section of BWXT's report, and I'll admit to that confusion. It seemed that there were people that could move to the more active areas and not where they required equipment that a NEW would be wearing in terms of detection.

So I think part of what you presumed to be my confusion, is my confusion I'm getting from the actual work that was done on this. It was confusing.

My sense was that people that are hired as a contractor -- and this has happened in other nuclear facilities as well -- usually have a higher rate of dose levels than ones that are permanently employed. This is typical of all these reactors that I've been involved in. So I was wondering: What is going on here at this place? There's a confusing mixed bag of exposure limits, and I'm

thinking, if there's going to be more hires taken on, will they be classified in a way that is more protective or less protective?

I mean, the facility is complicated by the fact that they can move, let's say -- I don't know if they move from the cobalt facility, which tends to have higher rates of exposure into the other facilities, but I tell you, reading that stuff was extremely confusing to me as well. And that was the best I could make out. There's some kind of discrepancy going on. So my question is: You're going to be hiring people to work there. Will they be classified as NEWs, depending what level of contact they're going to come in with, the more radiated facility, or non-NEWs. And I'm not sure how that's going to work.

So sorry, Dr. Demeter, if I am not answering you directly, but there is confusion.

MEMBER DEMETER: I understand that, and I see a hand up that might help explain it. But I know that people who are hired into a nuclear facility are assessed based on their potential exposure and a trigger to whether or not they become a NEW or not is based on predetermined risk. Maybe BWXT has a response. I see Mr. Decaire has a hand up.

MR. DECAIRE: Thank you. Richard Decaire, for the record.

Yeah, I think the source of the confusion is my fault because I decided to do something different than the other licensees in Canada, maybe around 20 years ago, on the Nordion site.

We were looking at contractors -- and we were not using a lot of contractors, certainly in no way to handle radioactive materials. So I desired to have more control over our operations.

So with our own employees, you know, we have procedures, we have training, et cetera. But a contractor coming in for the day, or someone coming in, say, to -- we have people who maintain our lifting devices -- you know, forklifts, pallet trucks, that sort of thing. To me, that shouldn't be someone who's a nuclear energy worker who's subject to higher dose limits. I think we should have control over that person. So they get training so they're allowed to have access to the active area, but they're not allowed to handle radioactive materials and they understand where the radioactive materials are, and they aren't allowed to be present around them for any length of time, and they have to check in with our radiation safety technicians to make sure that there's no changes to our operations.

So it was interesting, because reading through your intervention, I was confused too about what it

was. But I know the source of the confusion is, 20 years ago, I went a different direction than the rest of the -- than most Canadian licensees who have contractors in.

They have them signed in as NEWs, so those employers have to give them proper training, and then they're subject to the higher dose limits. That's not what I wanted to do here. I wanted to have more control over operations.

So, in fact, they are kept to lower limits. And I think that was the right thing to do for us, for our operations. It's no comment on other licensees, but that made sense for us. Thank you.

MEMBER DEMETER: Thank you very much.

THE PRESIDENT: Thanks for that clarification. What it does do, though, is it -- the average dose of NEWs comes down as a result of that because you've now got a bigger population. You're shaking your head, Mr. Decaire.

MR. DECAIRE: Yeah, Richard Decaire, for the record.

So when we report in the annual compliance report, contractors are separated out.

THE PRESIDENT: Good.

MR. DECAIRE: And we also go into further detail about active area NEWs and non-active area NEWs. We

go into further granularity about that as well. So I think all the information is in our annual report. But I can see why, since we do have other practices than other licensees, can causes some confusion. Thanks.

THE PRESIDENT: Your drivers were all right. Better to have a more informed workforce and give them what the NEWs get on that.

So Ms. Tilman, I know you had questions around the licence term. I'm sure we're going to get to that later with other intervenors. So I do want to thank you for your intervention and the issues that you have raised that has allowed this discussion to happen. So thank you very much for that.

MS. TILMAN: Thank you.

THE PRESIDENT: Okay. We will move to our next presentation then. Oh, sorry. Ms. Kavanagh, you had your hand up?

MS. KAVANAGH: Yes. Jackie Kavanagh, for the record.

I would just like to correct a statement that was made earlier when there was discussion around emergency response.

So the CNSC staff had indicated that BWXT Medical has in place a service agreement with the Ottawa Fire Services. At this point in time, we're still pursuing

an agreement with the Ottawa Fire Services.

THE PRESIDENT: Thank you for that.

Our next presentation is from the Canadian Nuclear Association, as outlined in CMD 21-H5.18, and I will turn the floor over to Mr. Gorman.

CMD 21-H5.18

Oral presentation by Canadian Nuclear Association

MR. GORMAN: Good afternoon, President Velshi, Madam Chair; and good afternoon, Commissioners. My name is John Gorman, I am the President and CEO for the Canadian Nuclear Association. My remarks today are just verbal. I do not have a slide presentation.

I do have a colleague with me this afternoon from the CNA team, Riley Found, who has more technical background in the nuclear medical isotope industry and has toured the BWXT Medical's Kanata facility many times.

So the Canadian Nuclear Association has -- just a quick word about us -- over 120 members representing 76,000 Canadians employed directly or indirectly, generating clean electricity, researching, producing nuclear medicine, exploring and mining uranium and promoting Canada's leadership, world-wide leadership, in

science and technology, innovation.

I appreciate the opportunity to say a few words in support of BWXT Medical's application for a Class 1-B nuclear substance processing facility operating licence. You have already received a written intervention from the CNA. However, I want to highlight a few key aspects in today's hearing, especially BWXT's commitment to safety, to the environment, and to the importance of medical isotopes, both domestically and internationally.

The CNA believes it's important to note that the Kanata facility, which started operations in 1946, has been safely operating under its current 1-B licence since 2015. BWXT Medical has been safely operating the Kanata facility since 2018 when it purchased the business. This licence application is for the existing processes, the existing facility, and operated with existing staff, as has already been noted earlier during these representations.

We would also like to highlight that BWXT has a long history of safe operations and its number one priority is the health and safety of its employees, members of the public and the environment. BWXT's commitment to this has been clearly demonstrated through its strong performance in all of the 14 safety and control areas detailed in their application.

Whether it be for sterilization,

treatment, or diagnosis, nuclear isotopes save lives. World-wide there are more than 40 million medical procedures performed each year using isotopes, with about 36 million for diagnostic nuclear medicine and 4 million for radiation therapy.

In developed countries about one person in 50 has a nuclear diagnostic procedure each year. In Canada, this means about 760,000 diagnostic procedures and 76,000 radiation therapy procedures each year. In fact, this past year alone, Canada provided enough Cobalt-60 to sterilize over 20 billion pairs of gloves or swabs critical in the fight against CoVID. Medical isotopes are an important part of Canada's innovation agenda.

According to a study in 2019 for the CNA, medical isotopes support about 8,500 jobs in the nuclear industry across Canada. At one point Canada produced about 40 percent of the world's supply of molybdenum-99, the precursor of technetium-99m, the most widely used isotope in nuclear medicine.

Since the NRU reactor was taken offline in 2018 -- that's of course the National Research Universal reactor was taken offline in 2018, Canada has had to rely on importing technetium-99m from various other reactors and Canada is no longer the world leader in producing medical isotopes.

However, operating under the current 1-B licence for the Kanata facility, BWXT Medical produces two radiopharmaceuticals and is nearing the ability to produce a stable, reliable and long-term domestic supply of technetium-99m. This will pave the way for Canada to regain its status as a world leader in the medical isotope industry.

One of the challenges the nuclear industry faces is the lack of understanding of radiation exposure among the general public, and as the Commission knows well, radiation occurs naturally, and the public is continuously exposed to small amounts of radiation. CNA notes that on average each year, the Canadian public is exposed to 1.8 millisieverts of natural background radiation. In contrast, in 2019, the dose to a member of the public from the Kanata facility was approximately 0.00087 millisieverts or 0.05 percent.

I would also like to note that BWXT recognizes the importance of Indigenous engagement and is committed to working with Indigenous communities. BWXT has been a member of the Canadian Council for Aboriginal Business since 2017 and is participating in the CCAB's Progressive Aboriginal Relations program, the PAR, at the committed level. BWXT has identified its communities of interest for the Kanata site and its Indigenous relations

committee uses the PAR program framework to guide meaningful engagement for these communities.

In our view, BWXT has clearly demonstrated excellent practices in its ability to carry out activities safely and reliably in support of their licence. The application and supporting documentation reaffirm this commitment to protect employees, the Canadian public, and the environment. This ongoing operation of the facility will enable Canada to keep building its leadership in the medical isotope industry.

Therefore, the Canadian Nuclear Association is pleased to support this application for a 10-year Class 1-B licence for the operation of BWXT's Medical's Kanata facility.

I would like to close by thanking the Commission for the opportunity to provide our views on the licence application, and I am, of course, available with my colleague, Riley Found, to address questions, should you have them. Thank you.

THE PRESIDENT: Thank you very much for your submission, Mr. Gorman.

Ms. Maharaj, over to you.

MEMBER MAHARAJ: Thank you so much for your submission, Mr. Gorman. I don't have any questions for you this afternoon.

THE PRESIDENT: Dr. Demeter?

MEMBER DEMETER: I want to say also thank you for your presentation. I don't have any specific questions for you, thank you.

THE PRESIDENT: Okay, Mr. Gorman, you had it easy today. Thank you again.

MR. GORMAN: Thank you. Bye-bye.

THE PRESIDENT: Okay. We're going to take a break now and let's get back at four o'clock Eastern Standard Time.

--- Upon recessing at 3:46 p.m. /
Suspension à 15 h 46
--- Upon resuming at 4:00 p.m. /
Reprise à 16 h 00

THE PRESIDENT: The next presentation is from Women in Nuclear, as outlined in CMD 21-H5.14. Ms. McBride is here with us to make this presentation.

Ms. McBride, over to you.

CMD 21-H5.14

Oral presentation by Women in Nuclear

MS. McBRIDE: Thank you, President Velshi,

Commission Members.

I am the President of Women in Nuclear Canada, and with me today is Mr. Phil Larabie, an external consultant who partnered with Women in Canada to support our intervention activities, as presented to you in writing as well as in person today.

Across Canada, we have more than 3,000 members and growing, with the majority of our membership located right here in Ontario. Our members come from a variety of work experiences and education. We represent women and men working at all levels of the business in many different areas. While we have many men within our membership population, more than 95 percent of our members are women.

Since 2004, WIN Canada has worked towards three challenging goals: The first, to develop a dialogue with the public through the contribution of nuclear and radiation technologies, people in society.

The second is to support the professional development of our members and across all chapters.

And finally, WIN Canada works to promote career interest in nuclear engineering, STEM, the trades, and other nuclear-related professions, especially among women and young people.

I will invite Mr. Larabie to provide

comments on his activities and our review before the Commission.

MR. LARABIE: Thank you, Lisa.

As Lisa mentioned, the focus of this segment is the survey conducted by WIN in April of this year, aimed at gathering member input on BWXT's application and any areas concern or support thereof.

The survey was distributed to the WIN membership, which is more than 3,300 members. In total, 279 individuals responded in whole or in part to the survey, which provided valuable insight into the areas of comfort, concern, and a desire to learn more about both medical isotopes in general and BWXT processes in particular.

Thematically, the top concerns identified from the survey respondents' perspective in the nuclear field are (1) radiation dose management during child-bearing years, including both the woman and the man during the conception phase and the woman during the pregnancy; (2) ergonomics. It was noted that, generally speaking, ergonomic concerns are somewhat different for women than men, for example, when it comes to lifting heavy loads, and this should be a consideration; (3) safety of their family and/or children.

Whether the risks stem from radioactive

releases of the environment, non-radioactive chemical releases or other factors, several respondents stated that to be a concern.

The BWXT licence application describes a multi-faceted approach to ensuring the safety of their employees and the general public. Mapping the survey concerns into the framework of the BWXT licence application demonstrates that BWXT has management processes and controls in place to ensure the concerns are adequately addressed.

The report submitted to the CNSC by WIN Canada lists the specific BWXT management system elements that are brought to bear on each of these three areas of concern identified, and interested parties are encouraged to refer to that for details.

Overall, the conclusion is that BWXT has controls in place to properly manage the risks associated with each of the concerns. Most importantly, these controls are already in place and have been demonstrated to be effective, as evidenced by prior CNSC audits and site visits to BWXT, as well as the predecessor medical isotope business conducted by Nordion in the Kanata facility for over 40 years.

It is also worth noting 100 percent of the respondents believe that medical isotopes are important,

with 84 percent expressing a concern about a shortage of medical isotopes. Almost half the respondents, 48 percent, have had a close personal experience with medical isotopes, defined as either the respondent themself or a member of their family having undergone a nuclear medicine procedure. Clearly an assured supply of medical isotopes being produced safely is seen as a critical element of health care for Canadian individuals and the broader community.

MS. McBRIDE: In conclusion, 92 percent of respondents support BWXT's Class 1-B licence application because they believe the BWXT's Medical isotope processing facility is beneficial to Canadians.

From a woman's viewpoint, 80 percent of respondents support BWXT's Class 1-B licence application because they believe BWXT's medical isotope processing facility is beneficial to women. It can therefore be seen that there's tremendous support for this medical isotope initiative in the WIN community. For these reasons and the reasons cited by Mr. Larabie, WIN Canada supports the application of the Commission today. Thank you.

THE PRESIDENT: Thank you, Ms. McBride and Mr. Larabie, for the presentation.

We will turn to Dr. Demeter for questions, please.

MEMBER DEMETER: Thank you for the

presentation, and I really enjoyed going through all the survey data. There was a lot of charts and graphs, and informative.

I had a question -- I appreciate the summary and the metric of overall support.

I wanted to get a sense -- you said you had over 3,000 members. Do you have a sense of what proportion of women working in nuclear-related industries are members of WIN? I wanted to get a sense of the bigger picture, and of your membership, how much does that cover women working in nuclear industries?

MS. McBRIDE: Thank you. Approximately 20 percent of our membership is represented across the employee population. There's about 22 percent female representation working in the nuclear industry in Canada. If we look at 76,000 employees, when you take our membership, we represent roughly 20 percent of women in the nuclear industry.

MEMBER DEMETER: Thank you. I didn't have any other questions.

THE PRESIDENT: Thank you. Ms. Maharaj?

MEMBER MAHARAJ: Just one question with respect to the number of responses you had on the survey. It looks like it's just under 10 percent. Was there a reluctance for people to participate, or do you have any

other sense of why the responses were limited to 10 percent?

MS. McBRIDE: I couldn't -- thank you for the question. I couldn't say for sure except, I -- if I could perhaps wager a guess, this is the first survey that we have done to support a licence application. We would like to do this more in the future. So we will be increasing our communication efforts with our members about the importance of their engagement through this type of process so that we can represent their interests in front of you today.

MEMBER MAHARAJ: Thank you.

THE PRESIDENT: And maybe a follow-up to that. Of the 279 respondents, how many of them were BWXT employees? Could you tell?

MS. McBRIDE: I -- I'll invite Mr. Larabie to add a comment after this, but I believe in the survey, of the individuals who responded to the survey, there were 13 people that responded that are employees of the BWXT Medical facility.

THE PRESIDENT: And then maybe a question to BWXT Medical. Of your 200 employees, how many of them are women?

MS. KAVANAGH: Jackie Kavanagh for the record. I will direct the question to Natalie Cutler.

MS. CUTLER: Natalie Cutler for the record.

I'm trying to recall our data right now, and I might have to get back to you, President Velshi, with that -- if I can clarify? You're asking what percentage of our employees, or number of employees at BWXT Medical, are women; correct?

THE PRESIDENT: That's correct.

MS. CUTLER: I will get back to you very shortly with that information. Thank you.

THE PRESIDENT: I think we may actually have a response. Go ahead.

MR. COOMBS: So Martyn Coombs, for the record. As the president, I should know this sort of stuff, but I think it's about 40 or 50 on the site here at Kanata, and we also have a Vancouver site which also has maybe 15 women, to give you some idea. So I'm thinking, why didn't more respond?

Thinking back to the earlier question. I think 10 percent response rate to a survey is actually quite high, in my experience. Often people are reluctant to take the time to do this. Anyway, that gives you some idea of the proportions.

THE PRESIDENT: Thank you for that. Actually, our experience has been generally -- I mean, Lisa

did say this was the first survey. This is a great opportunity for women to actually express their expectations, concerns, and provide feedback so the response rate tends to be higher. And if you're at about 40 percent or so out of 80, if 13 responded, and I don't know how many of them are WIN members. But interesting anyways.

And given what you've seen -- again, to BWXT Medical -- given what you've seen in these results, particularly around ergonomics, any surprise in there? Do you have any special initiatives to address? Any special concerns of women in your workforce?

MS. KAVANAGH: Jackie Kavanagh, for the record.

So as we're introducing changes in the facility or new processes, as part of our review we do hazard risk assessment, and so ergonomics is one of those aspects that we look at. So we would be looking at any differences that might be introduced by an employee's ability to lift a heavy weight, if need be. We look at ability to see into ourselves, whether there's any elevation devices that are needed, steps or the like, and we would take that into consideration as part of that, and that is part of our normal process here.

THE PRESIDENT: Thank you. And I know

you're kind of probably new to the Commission proceedings, but I know for your next appearance in front of the Commission, these are standard questions from me. This is a subject very, very near to my heart. And the advice I would give you is using a GBA+ lens in all your processes, because you will find that different segments of the population have different needs, and the need to have that more inclusivity in your controls.

So thank you to WIN Canada for the presentation. We look forward to seeing surveys like this which provide greater insight on what the concerns and thoughts are. So thank you.

MS. McBRIDE: Thank you.

THE PRESIDENT: We'll move to our next presentation, which is from Boston Scientific, as outlined in CMD 21-H5.19, and I'll turn the floor to Mr. Mullett, please.

CMD 21-H5.19

Oral presentation by Boston Scientific

MR. MULLETT: Hello. Thank you very much, President Velshi, and all the Commission Members for the opportunity to speak in support of BWXT Medical's licence, Class 1-B licence submission.

My name is Dr. Wayne Mullett. I'm the Global Director for Boston Scientific, overseeing TheraSphere supply and development.

Boston Scientific is a very large global medical device company providing health care solutions in various different areas, such as urology, gynaecology, electrophysiology, neuromodulation, neurovascular modulation, cardiac surgery, interventional cardiology, and more relevant to the discussions here today, interventional oncology, which is the business unit that I work in.

My primary responsibilities as Global Director at BSC is oversight of the supply chain, all the way from raw materials right out to final delivery of that therapeutic device at the hospital for patient treatment.

So TheraSphere is a radiotherapeutic product which is composed of small glass radioactive microspheres. To give you some perspective, they're about half the width of a human hair, and anywhere from about 1 to 8 million of these radioactive microspheres are directly implanted inside a patient's tumor.

So it's a way, through exploiting the vascularity of some of these tumors, is a way to do very selective internal radiotherapy.

The product presently is used in 40 different countries, including Canada. The primary market

is in the U.S., but it is also used in Canada as well. To date, we've treated with the TheraSphere product over 35,000 patients for liver cancer, and based on the unmet medical need that we see for liver cancer, we're on target this year to treat over 10,000 patients in Canada, the U.S., and 38 different countries around the globe.

As you may or may not be aware, liver cancer, the prognosis for that disease is not great. The five-year median survival rate for someone who is diagnosed with liver cancer is only 15 percent. So there really is, you know, a strong unmet medical need and a need to have a product like TheraSphere to be able to treat this critical disease.

In terms of the relationship that I have with BWXT, they are the contract manufacturer for the TheraSphere product. So I get to have the opportunity to work with BWXT on a near daily basis.

So as a Global Director overseeing the TheraSphere supply chain at Boston Scientific, we're responsible for working with the hospitals, taking in the orders specific for the patient treatments, and then we provide that information on a daily basis to BWXT so that they can make the necessary doses and have them shipped out in time to be received at the hospital to treat patients all around the globe, as I mentioned.

In those types of interactions that I have with BWXT, I can confidently say and have a very strong confidence in their ability in the work that they do. All the decisions that are made at BWXT are first and foremost focused on their compliance towards all nuclear and health regulations. They also place a large emphasis on their safety of the staff and their surroundings.

Boston Scientific is very confident in the ability of BWXT to continue further reliable manufacturing of the TheraSphere product and, in fact, we're also looking at extending the use of the TheraSphere product to other indications.

As an example, we've been working with BWXT to develop clinical trial material to kick off a very pivotal first-in-man study for the treatment of glioblastoma. I'm very excited to say that this fall we'll be treating for the first time ever patients with brain tumors with the use of the TheraSphere product. And that material will be made from the BWXT facility.

Just to wrap up. In terms of the use of the product and the ability of BWXT, I think based on their very strong commitment and safety culture, strong track record through reliable manufacturing, I hope the CNSC will approve the Class 1-B licence for BWXT.

Thank you, and I'm open for any questions.

THE PRESIDENT: Thank you, Mr. Mullett, for your submission.

Ms. Maharaj?

MEMBER MAHARAJ: Thank you very much, Dr. Mullet. Your presentation was fantastic and I don't have any specific questions for you.

THE PRESIDENT: Okay. Dr. Demeter?

MEMBER DEMETER: Thank you for your presentation.

I wanted to get a perspective, because we heard earlier about medical isotope supplies and how many millions of people are treated every year and the role of molybdenum and technetium.

With regard to TheraSphere in Canada, how many players are in the game of providing Yttrium-based B-therapy for liver cancer? Is TheraSphere the only player in the Canadian market?

MR. MULLETT: Wayne Mullett for the record.

So that's a good question. In terms of Yttrium 90 microspheres, which are used for the treatment of liver cancer, in the Canadian market there is another competitor called -- from Sirtex, it's a product called SIR-Spheres, which has an indication for a treatment of liver cancer. That product is a lower specific activity

product, so it's unable to deliver the same levels of radiation therapy to a patient treatment.

I would also like to point out that in the U.S., TheraSphere is the only indicated product, the only Y-90 microsphere indicated product for liver cancers.

MEMBER DEMETER: Thank you. That puts some perspective on the product and how many players there are or are not. Thank you.

THE PRESIDENT: Thank you very much, Mr. Mullett, for your intervention today. We appreciate that.

MR. MULLETT: You're welcome.

THE PRESIDENT: So we'll move to our next presentation, which I believe is our final oral presentation today, and it's from Bruce Power as outlined in CMD 21-H5.22, and I'll turn the floor over to Mr. Scongack for the presentation.

CMD 21-H5.22

Oral presentation by Bruce Power

MR. SCONGACK: Great. Thank you very much, Madam President. I really appreciate the opportunity to present today.

As noted for the record, my name is James

Scongack, and I'm the Executive Vice President of Corporate Affairs and Operational Services at Bruce Power and I also serve as chair of the Canadian Nuclear Isotope Council, and I believe you heard from my colleague Andrew Thiele in a separate intervention earlier today.

Before I share with you some comments and perspectives on what I think is a very important licence application, I do want to acknowledge the fact that I am joining you today from the traditional territories of the Saugeen Ojibway Nation, the historic Saugeen Métis, and the Métis Nation of Ontario.

Before I talk about the BWXT application and proposal in particular, I just want to remind everybody of Bruce Power's role in the area of medical isotopes.

For many decades on the Bruce site we have produced most specific activity Cobalt-60, and that was referred to earlier as being used for sterilization. Obviously the other part of this facility, which is operated by Nordion, is where that Cobalt-60 is processed. But we also produce a high specific activity Cobalt-60 which is used to treat brain tumors and breast cancer.

We have, as a company, really focused on the medical isotope area over the last number of years and in 2022 do look forward to getting into the production of short-term, short-lived medical isotopes.

I would also note that Bruce Power has partnered with the Saugeen Ojibway Nation, through an initiative called "teaming up to fight the sickness." In Ojibway it stands for Gamzook'aamin aakoziwin, and that was a name that was selected by elders in the Saugeen Ojibway Nation. So that's a bit of background on our role in isotopes, and we're very excited about what it means.

One of the things, I think, maybe because I'm going last, which I think is important to anchor on, there's been a lot of good discussion today, a lot of good questions, always healthy challenges, which is what we expect in the nuclear industry. But I really want to make sure we end today by reminding ourselves why we're here.

So today is Wednesday, June 9th of 2021. And today we will have -- of our fellow Canadians, we will have 617 Canadians diagnosed with cancer today here in Canada. We'll have 228 of our fellow Canadians die of cancer. And I think that's really important for us to all remember here when we're having this conversation.

The world needs medical isotopes to diagnose cancer, to fight cancer, to sterilize our medical equipment for our frontline health care workers, and as we've seen recently in the fight against CoVID-19. I think we can't lose sight of this. Because we're not only having a conversation today about a licence application that

obviously has to meet the highest safety standards both in terms of the public, in terms of the community and employees, but it's a facility that is really important to Canada's growing role, I believe, and something I am very excited about, in the production of medical isotopes.

You have a company here in BWXT that has decided to make a major investment to return Canada to our leadership position in the area of isotopes, and while this is an existing facility, it's an existing facility that's going to be renewed, reconstituted, and put us back on the map.

The depth that exists within BWXT, both in terms of the elements of the facility that they've inherited from previous owner Nordion, but also the expertise in BWXT, as somebody who does an extensive amount of work in our nuclear industry, I think it's a really important partner in terms of demonstrating that track record.

Obviously commitment to safety is absolutely important, and what I would say as we continue to look to the track record that this facility has demonstrated over many years, one of the things we always focus on in nuclear is a commitment to continuous improvement, and you can see that very clearly in BWXT's licence application and their comments, their commitment to

continuous improvement. And that's not only continuous improvement when it comes to safety and isotope production, but it's also continuous improvement in terms of how they want to engage their employees, how they want a more diverse workforce, how they can engage the community, and obviously some commentary today with respect to Indigenous communities, which are absolutely critical.

In Canada, on an annual basis, there will be 1.5 million diagnostic imaging procedures carried out. 36 million globally. And what I really want to remind people of as I wrap up, and I would be delighted to take any questions, is the world is counting on Canada to step into this space. You know, we ceded our leadership position a number of years ago, and I think what we've seen, and I speak from the work we've done with the Canadian Nuclear Isotope Council and Cyclotron's institutions, nuclear reactors, the medical community, and Canada is really here on the verge of reclaiming our global leadership position, which I think is exciting.

But most importantly, to those 617 Canadians today who are going to be diagnosed with cancer, they're counting on companies like BWXT to get it right, to be there, to provide the isotopes that are needed to treat those fellow Canadians, but also treat people around the world. And I think we ought to not lose sight about that,

because I believe one of the elements we haven't talked enough about in this licence application is its broader societal benefit and really what it means for Canada and what it means for patients.

So I really appreciate, Madam President, the opportunity to present today. I know I'm the last up, so I don't know how many questions there will be, but it was really important for me personally to present because I've been a huge supporter of BWXT and the work they're doing, and more importantly, some of the people they've brought from around the world to drive this operation. So I would be happy to take any questions Commissioners may have. Thank you.

THE PRESIDENT: Thank you very much, Mr. Scongack, for that. I don't think you will be surprised that there wasn't much discussion about the larger benefits to society because that's not the mandate of this Commission. Our role is to just confirm that BWXT Medical is qualified and will make sure that they make adequate provisions for the safety of their workers, the public, and the environment as opposed to the larger context that you shared with us -- which is very valuable, but again, not surprising that we didn't have much discussion on that.

So with that, let me open it up to

Commission Members for questions. Dr. Demeter?

MEMBER DEMETER: Thank you. Mr. Scongack, just on a personal note, you can understand, based on my day job, I truly appreciate the role of medical isotopes and the benefit they supply to society.

Saying that, I wanted to get a sense -- we talked about -- what we're going to do at BWXT and there's some predication relative to Health Canada and the FDA with regards to the market and use in humans, and there's also the front end about the production in a CANDU reactor in the Canadian setting.

I wanted to get a sense from staff, just generally so I understand the front end of this business, is what regulatory processes does the producer of the moly-99 have to go through before it gets to BWXT? What's the front end of this? Do they apply for a licence variation or exception or a process variation? What is the sort of rigour for the production, the start of this process, before it gets to BWXT?

MS. MURTHY: Kavita Murthy, for the record. I will pass this question to Mr. Ramzi Jammal for a response. Please go ahead, Ramzi.

MR. JAMMAL: Thank you, Ms. Murthy.

I will keep my response very, very high, and if I freeze on you, I'll turn off the video.

There is an application coming before the Commission with respect to the licence amendment proposed for Bruce Power in order to produce the moly from a commercial reactor.

I'm sorry, I'll take it back. There is an application for isotope production from Bruce Power to different radionuclide, but there is another application that the CMD will be going out publicly with respect to OPG producing of moly from a CANDU operating. So I will leave it at the high level.

With respect to the Commission proceedings, we will be going -- a determination has been made that the application is beyond the safety case of the existing operation, or as Ms. Murthy mentioned it before, to be within the safe operating envelope. That's where we'll be coming before you as a Commission for your approval for the licence amendment for Bruce Power in the short term, and short term is coming up sooner than the OPG.

So I will leave it for you and your deliberation with respect to licence amendment. But the process, our regular due process kicks in, as we mentioned before, with respect to the safety case and the applications that come before you. So I'm not giving you a detailed answer, but I just want to confirm publicly that

the deliberation and decision in the proceedings will take place in the public domain.

MEMBER DEMETER: That does answer my question. There's a process in place, and I know where it's going to go. Thank you very much.

THE PRESIDENT: Mr. Jammal, maybe a follow-up to that, because I think a slide that BWXT Medical shared with us showed two potential sources for moly-99. One was Darlington and another one was MURR. Maybe I'll ask BWXT Medical to tell us. Tell me what MURR is and then maybe --

MR. JAMMAL: Is it for me? It's the MURR reactor. It's the research reactor or a reactor in the U.S. that produces molybdenum.

THE PRESIDENT: Thank you.

Ms. Maharaj?

MEMBER MAHARAJ: I just have one question for you, Mr. Scongack. Sorry if I said that wrong.

In your intervention, you indicated that there's a memorandum of understanding between Bruce Power, BWXT, and isoGen to ensure a reliable redundant supply of medical isotopes in Canada. Is that a precursor, that MOU a precursor to producing more of the molybdenum-99, or is it a totally separate kind of isotope?

MR. SCONGACK: It's a really good

question. So, for the record, James Scongack.

So we entered into a MOU with BWXT on this.

If I sort of take a step back from medical isotopes for a second and I think about what are power reactors typically? It's to generate electricity, right? And how do we ensure that we have reliable electricity? Well, we have redundancy.

At Bruce site, we have eight reactors, even if there's one on refurbishment, even if there's one on outage. Darlington, the same case, as is Pickering.

One of the areas we worked with at BWXT on was to enter into an MOU to say, down the road, many years down the road, depending on where the supply of molybdenum-99 comes from, we will keep a close watch on this to see if they would like to use our facility, or OPG, for redundant supply, additional backup supply of molybdenum-99.

I can tell you that while we keep in contact, and that's a long-term option for us, Bruce Power has no plans at this time to be producing molybdenum-99. It's very clear that Darlington has that capability. But it is a long-term option.

Because one of the things we do know is, and in particular when you look around the world, as we

have developing countries and growing middle classes in many, many countries, which we want to see, those countries are going to have higher demands for modern health care, and that is going to be in areas like diagnostics and therapeutics. So we believe that over time there's only going to be a growing demand for this, and we want to keep that door open and really learn as much as we could through the process.

MEMBER MAHARAJ: Thank you very much.

That's my question, Madam Velshi.

THE PRESIDENT: Okay. Thank you. Again, thank you again, Mr. Scongack, for your intervention today. Thank you.

MR. SCONGACK: Thanks for having me.

THE PRESIDENT: So this concludes the oral presentations by intervenors. Note that with respect to written interventions, the Commission is now taking a different approach. Instead of the Secretary referring to each written intervention and asking Commission members if there are any questions, the members will instead ensure that their questions arising from written interventions are addressed as part of the general round of questions. The written interventions are listed in the agenda for those of you who want to look at the complete list.

So we will start with a general round of

questions and I'll start with Ms. Maharaj.

MEMBER MAHARAJ: Thank you, Madam Velshi. My question is for BWXT. Probably Mr. Coombs is the one to answer. I would like to speak about the financial guarantee and the corporate structure.

I understand that BWXT Medical is the applicant in this case and that the financial guarantee is comprised of two pieces: a letter of credit and a surety bond.

Could you explain, just sort of given my particular background, could you explain your corporate structure in terms of where your parent lies and what your ownership structure is, and how can the Commission be assured that that letter of credit is going to have staying power?

MR. COOMBS: Martyn Coombs, for the record, and thank you for the question.

So BWXT Medical is a wholly owned subsidiary of BWXT and through the Nuclear Power Group within Canada. So we're a business unit in our own right, but we belong 100 percent to BWXT, which is a publicly quoted company in the U.S. So we're 100 percent owned. And that company, the current market capitalization of that company, I think, is around $6 billion. So it's a very large company focused on the nuclear energy. And we're the

only business unit focused on nuclear medicine.

In terms of, are we good for that letter of credit -- which I think is the question?

MEMBER MAHARAJ: (laughing) A little classless, but, I'm sorry, it's been a long day.

MR. COOMBS: I think we are. Obviously our word is our bond and we're backed with our parent company, which has been kind enough to back our bold ideas.

Some of the things I didn't say earlier, but obviously James intimated them. You know, we've invested a lot of money into this. A lot of money. It's a big investment for our parent company. Hundreds of millions of dollars, frankly. So they've been very bold, but they've done it because they think there's a reason and there's a return. And it's our job now to make sure that it works and we can fulfill patients' needs, and we have a growing business, and that we make money and that we're a generating company going forward.

So our plan is to be successful. We think we have got a great product in a world where there's a shortage of that product because it's based on research reactors. So we think we will be successful. But in any case, we're backed by our parent company that owns us 100 percent. So I hope that answers your question.

MEMBER MAHARAJ: Parental guarantee is

always a nice thing to have, so my children tell me.

Just one follow-up question then for staff on the same issue. With respect to the cost of decommissioning this particular facility, when I look at $10 million, that brings to my mind the assumption that the decommissioning plan is to abandon in place the facility at end of life. Is that the case, or does that $10 million include return to level, gravelled industrial site?

MS. MURTHY: Kavita Murthy for the record. We have specialists from the Waste and Decommissioning Division online to answer that question. I'll pass the mic to Patrick Burton.

MR. BURTON: Good afternoon, everyone. My name is Patrick Burton. I'm the Acting Director of the Waste and Decommissioning Division here at the CNSC for the record.

So as part of this licence application, BWXT was required to provide a preliminary decommissioning plan to us and they did so and we evaluated that. So that is the foundation of the dollar value that is then assigned to the financial guarantee. So we make sure that dollar value is predicated on a credible scope of work to decommission that facility.

Also included in the preliminary decommissioning plan is the idea of an end state. The

licensee, or in this case the applicant, states their intended end state. And in this case the intended end state is unrestricted use. So that means clean.

It is somewhat unusual. We touched earlier in the day on the idea that they are tenants in this building, so obviously the decommissioning plan will have interactions with whatever Nordion does with the building from that point. But just to be clear, that the end state that is proposed by the BWXT, and accepted by CNSC staff, is unrestricted use.

MEMBER MAHARAJ: And do you apply a discount rate to that value to account for the time value of money?

MR. BURTON: We do, yes. And there's contingency in there as well to account for uncertainties that we don't know to account for yet.

Mr. Coombs mentioned that their word is their bond. That's a wonderful sentiment. We require them to have enforceable instruments, legally enforceable instruments. These instruments are reviewed by our subject matter experts in decommissioning. They're also reviewed by our lawyers and our finance experts, and so these instruments are legally enforceable and the money is payable to the Commission on request if certain conditions are met.

MEMBER MAHARAJ: Thank you.

THE PRESIDENT: Dr. Demeter?

MEMBER DEMETER: I had one question arising out of one of the written presentations. It was talking about whether or not there would be any uranium on-site, and we heard that the shielding for the generators is going to be depleted uranium.

I wanted to ask CNSC staff, are there any regulatory additional requirements to transport and receipt of molybdenum generators that are shielded with depleted uranium versus shielded with lead?

MS. MURTHY: Kavita Murthy, for the record. I don't -- I don't believe so. I am going to -- yes. So I have the person who can respond to that question now. I'll have Mr. Francois Dagenais speak to this. Thank you.

MR. DAGENAIS: Yeah, good afternoon. So this is Francois Dagenais. I'm a transport officer with the CNSC for the record.

In regards to the transport package, there is no difference. The transport of the package or the material will have to meet all regulatory requirements in regards to the Packaging and Transport of Nuclear Substance Regulations and Transport Canada's Transportation of Dangerous Goods Regulations.

And the packages -- so for the packages, transporting the moly to BWXT's facility -- sorry -- will have to be a certified package. So the quantities in that package will be sufficient that the package will need to be certified, which that means the design of the package will be certified by the CNSC prior to use. So I think hopefully that answers the question.

MS. MURTHY: Dr. Demeter, I want to make sure, first your question on regulatory requirements are specific to DU, because there are some safeguards aspects to it --

MEMBER DEMETER: Yeah, I'm thinking if I'm a hospital and I have got two suppliers that can give me a moly generator, and one uses lead and one uses depleted uranium, do I see a difference from a regulatory point of view at my end in receiving that and returning it, or is it within the same confines as the lead-lined generator?

MS. MURTHY: Thank you for the clarification. David Moroz from the International Safeguards Division is online. So David, please go ahead.

MR. MOROZ: David Moroz, Director of the International Safeguards Division.

So you're asking about the regulatory requirements, and there would be requirements on depleted uranium shielding to be declared for safeguards purposes

and reported to the International Atomic Energy Agency, and in principle, subject to verification. The way that depleted uranium shielding works right now for technetium generators, because they're all housed outside of Canada, they're filled, as you commented I think earlier in the discussion, they're built in the United States and then shipped to Canada, they're considered material in transit.

For ones that are hosted here in Canada, they would be declared at the facilities of the owner of the generators, but they would be either exempted from safeguards and they would not be routinely reported for transit within Canada. They would spend a short time at the hospital in transit and they would come back for refilling. So the verification would be at point of origin.

MEMBER DEMETER: Thank you. That's very clear. Thank you.

THE PRESIDENT: Thank you. I have a few short questions that I would like to get through.

The first one is to BWXT Medical. And on your outreach you talked about some recent events that you had -- I think it was March. I can't remember now.

Give me a sense of the kinds of concerns that you hear from the community about the operations.

MS. CUTLER: Natalie Cutler, for the

record.

Thank you for that question.

Yes, we did hold a webinar in March due to the CoVID-19 pandemic. We would have liked to have had an event in the community to meet people face-to-face, but I think we're all in that same boat.

We didn't have a lot of questions, but there was one question about some construction on the site. There are some construction trailers due to work that's taking place inside the existing facility to prepare our operations for the new product that's in development, the molybdenum-99 generators, and so we answered accordingly. But we did not receive any concerning questions in our webinar, which, you know, we wanted those. So we'll continue to have events like that because they make us stronger when we understand concerns. So these interventions that we've had today, we consider those inputs for us to help improve our public information program, and we'll continue to reach out to our neighbours, our stakeholders, Indigenous communities, to understand more of their questions and concerns so that we can improve and be more transparent.

THE PRESIDENT: Thank you. And my second one, also to BWXT Medical, is: In your CMD, when you discuss the 14 safety and control areas, I think a standard

statement for all of them is, you know, there are no challenges of note or no requests of CNSC. You know, there may be plans for continuous improvement. But from your perspective, what do you see as the biggest challenges to reach your vision? I'd just like to understand some of the key risk areas.

MS. KAVANAGH: Jackie Kavanagh, for the record.

So with regard to the licence and the management system for safety, we will be moving ahead to implement some of those processes that Nordion is currently overseeing. We will have to establish our environmental health and safety committee, and we will have to establish the joint Nordion-BWXT Medical EHS committee.

So I think maybe our biggest challenges going forward are to ensure that we have that effective working relationship with Nordion on the programs where we're working together. We have to ensure that BWXT and Nordion are able to be compliant to their own licences. So that's going to require a level of cooperation and communication going forward.

In the past three years, working under the Nordion licence, we've established many of those communication channels. In the future, they will be slightly different, as Mr. Wassenaar from Nordion

indicated. We'll be dealing with maybe different groups of people than we currently are. So those things were already under discussion with Nordion now so that we're in a position, should the licence be issued to us, that we can launch those immediately. Thank you.

THE PRESIDENT: Thank you.

Ms. Maharaj, back to you.

MEMBER MAHARAJ: I have a couple of questions for BWXT with respect to their environmental impacts. And these are rather specific, so I do have PDF pages, for the record, just to help the recording secretaries along a little bit.

But I was looking at whether or not you can give us some more insight with respect to the location of your sensors for air quality inside the building and in your stack releases.

MS. KAVANAGH: Jackie Kavanagh, for the record.

I'll ask Mr. Decaire to respond to the question.

MR. DECAIRE: Richard Decaire for the record. So I just want to make a note. So stack monitoring and breathing air monitoring?

MEMBER MAHARAJ: Yes. Around PDF page 32 of your submission, if that helps.

MR. DECAIRE: I don't know if I need it.

So we have three stacks that BWXT Medical monitors right now, and that will continue. It's at the release point of the stack where -- we have various systems that combine, so maybe, you know, there will be different hot cell banks connecting, fume hood banks, glove box banks, and they'll all connect to a particular stack. So once all those are finalized into one big airflow mass, then we sample across -- call it a rake, a sample at several points to get a representative sample as it goes out. So we do that monitoring. And that's where our release, air release values come from, and that will continue.

In terms of breathing air, we have two approaches to that. One is something we call a 24-hour air filter. So that's -- it's quite simple. It's a filter disc that is impregnated with activated charcoal and it picks up particulate as well as radio iodines. You know, we used to be a large supplier of radio iodines from this facility in the past under Nordion. As a result -- you know, those are messy materials. They get volatile quite easily.

So we had a very comprehensive program that we've continued to this day, and we have either these 24-hour air filters in areas where we have less concern.

In areas where we have more concern, then we have continuous air monitors that monitor the breathing air. And were they to detect anything, they would alarm locally as well as on our instrument monitoring panel which sends alarms to a system that the radiation surveyors monitor. So whether we need 24-hour air filters, just so we have the evidence that we're not getting airborne, or continuous air monitors, comes out of the hazard and risk analysis when we set up a new process.

So something like TheraSphere, it's glass beads, and Wayne Mullett from Boston Scientific described the size of them, and we haven't seen evidence of that product ever in the breathing air zones where our personnel work. We still collect the data, but things like radio iodines, it was very common to have, in the processing areas, you could find airborne. So several precautions were put in place for those types of processes, respiratory equipment was required, respirator fit testing and surveillance, medical surveillance, posting of the doors, you know, that -- there would be chains put across the doors because a sign doesn't cut it. So we have a lot of experience doing that.

But the products we have now, including the new molybdenum one, they don't have volatiles in them. So we'll be continuing to collect that data and looking to

confirm that there are no volatiles in it that should not be there. And that doesn't extend just to the processing, but also to the quality control testing.

So I think one of the questions earlier was, what are the challenges? So I always think of radiation safety. So we're designing all these processes and there are so many different aspects, and that's one of them. We have to ensure that that's done correctly.

But we start with, when we look at a new process, we talk to the chemists who understand all the various parts of the process. Is there the opportunity to get this material airborne? Like, what is the likelihood? And we model that. And that's where all our safety instrumentation comes from. It's really at the very beginning steps of a new process idea.

MEMBER MAHARAJ: Thank you. That's very informative. How frequently is your stack sampling?

MR. DECAIRE: So the stack sampling, there's two kinds of sampling. One is a filter that we collect on a weekly basis, but the other is, there's instrumentation along the way that is continuous. That's not our qualitative numbers but it's process controls.

Also, we have detectors on filters on our hot cells in bulk processing that are underground -- we call them "in a trench", so those filters are shielded for

the protection of the employees. We have the in-cell filters, which do most of the heavy lifting, and we credit our FSARS and our FSARS that they do nothing because we can't test them in place, but we know they do most of the heavy lifting in terms of removal of contaminants into the nuclear ventilation system, and then it goes into the trench filters. So our moly process will go into trench filters where there will be radiation detectors on them. And then before they get upstairs to our mechanical room, there's another set of filters. We sample the air in the duct.

So all our various processes -- we have a lot of information and we can intervene immediately. So although we collect the stack samples for quantitative assessments on a weekly basis, we already know what's going on pretty much before we get that information.

MEMBER MAHARAJ: So would those earlier processes alarm and cause your facility to stop air flow if they trigger?

MR. DECAIRE: You would never want to stop air flow. That protects the workers. But it would -- if it were to alarm, it would be an indication that the radiation surveyors who are there whenever there's processing going on, need to investigate, and they have the authority to stop any process. So whether you're a manager

or whatever, it doesn't matter. If the surveyor says the process is stopped, the process is stopped.

MEMBER MAHARAJ: Perfect. Thank you very much.

MR. DECAIRE: You're welcome.

THE PRESIDENT: Dr. Demeter?

MEMBER DEMETER: Thank you. I'm going to change track a bit here.

I'm looking at BWXT's leadership organizational structure, figure 7, page 12 of their CMD. And maybe, you know, you can correct me if I'm wrong or CNSC can correct me.

Normally I like to see a dotted line between the senior manager of radiation safety or the corporate radiation safety officer directly to the president rather than having to go through an intermediary, because there are times when you don't want to be bogged down in a hierarchical vertical organizational structure without the ability to have direct access that's predetermined and allowed based on their organizational structure, and I don't see that here.

So maybe BWXT can comment on whether or not that's a reasonable assumption for me to have, that there should be direct access to the senior radiation safety officer equivalent, or maybe CNSC can comment as to

what the sort of industry standard is for such operations and access to the top brass from the radiation safety senior officer. Start with BWXT.

MS. KAVANAGH: Jackie Kavanagh, for the record. I'll ask Mr. Coombs to reply to that.

MR. COOMBS: Martyn Coombs, for the record. And I think it's a valid question. There's an organization chart, but it's also the way we work as a company in our culture and our spirit.

As you've already heard, I think, Richard is not a shy person, and if there's a problem, he is not hesitant to raise my and other people's attention, or even a potential problem. So I think the way we work here is very much as a team and I would be involved if anything looked like there may be a potential problem emerging and would then discuss it with Richard, and Bill, and others. So I hope I make sense.

MEMBER DEMETER: And for CNSC: Is this structure more the industry standard than the exception? I'm just curious. Because if you have someone who is not -- who is a bit more shy and timid, you don't want to rely on personalities to work your way up the chain. You want the structure to emulate the function versus the other way around.

But from CNSC's point of view, what's the

usual dotted connection between the Senior Radiation Safety Officer position and the CEO?

MS. MURTHY: Kavita Murthy, for the record.

We haven't done a comparison organization by organization, but I can definitely confirm to you that we are not prescriptive on whether there is a dotted line or not.

There is a lot of observation we get -- a lot of intelligence we get from observing the interactions between key people in the organization and looking at the safety culture indicators for the organization. So we have seen situations where a dotted line has existed but has not worked, and we have seen a situation where dotted lines are not there and it has worked.

With respect to whether this is prescribed anywhere, I don't believe there is. Definitely there is greater emphasis on having open communications and having a safety culture that allows people to raise issues no matter what position they occupy in the organization.

MEMBER DEMETER: Thank you.

THE PRESIDENT: Mr. Decaire?

MR. DECAIRE: Yeah, I'm not going to be shy.

So I've been here 25 years, and I can't

recall a time when we had direct reporting to the President or CEO of the organization. Previous to the 25 years here, I was RSO at a teaching and research hospital in Montréal for five years. And I think it works very well the same way. The president was not involved directly in that either, but what's required is senior management has to be involved either at the, you know, standard radiation safety committee. We had one of the vice presidents of the hospital on that, and at the HS committee, which is our committee here -- I assume it will be named that once we have our licence and we're separated from Nordion -- and then we'll have the joint HS committee. Senior management has to be involved at that level, and I think that's pretty much a requirement from the CNSC, and I think that's the only way it works properly.

People have to understand their responsibility and what's required to run the facility safely. And I think when -- it doesn't have to be Martyn at that meeting. It has to be people who understand that we need the resources to do things correctly and understand the hazards and the liabilities we're taking on as individuals and as a company, and I think that comes through those committees and that understanding of what's acceptable and what's not. Then that gets communicated out to the top person. In my 30 years of experience now, I've

found that's very successful.

MEMBER DEMETER: That helps a lot. Thank you.

THE PRESIDENT: I have a question for Staff and it's around the term of licence where Staff is recommending a 10-year licence. We've heard from some intervenors that perhaps a shorter term is appropriate given that the applicant doesn't really have a track record and, you know, there are some growing pains that they will likely encounter as they move into this new way of doing business and working alongside Nordion.

Can you share with us your considerations, both on the pros and cons of a 10-year licence term?

MS. MURTHY: Kavita Murthy, for the record.

I will pass this question to Mr. Andrew McAllister to respond.

I do want to note that in making our recommendations, some of the things that you have just pointed out were things that we considered. The fact that this is a new licensee with no new entrant into the Canadian nuclear sector. So we did look at that. We looked at the interrelationship between Nordion and BWXT and how that would play out.

But looking at what they have proposed and

looking at the methods and the tools that we, as a regulator have, we came to the conclusion that a 10-year licence could be justified.

So I will hand it over to Andrew McAllister now, please. Thank you.

MR. McALLISTER: Thank you, Ms. Murthy.

So some of the factors that went in when we were looking at the licence term, we stepped back and asked ourselves: Are they qualified? Will they be able to adequately protect the environment, workers, health? We look at it in a couple of different ways. One was sort of more from an organizational perspective. In other words, the activities that are to be conducted are the same and within the current licensing basis. Secondly is that the programs and the associated processes and procedures that have ensured that the nuclear medical licensing facility operates safely are the same as proposed by BWXT Medical. And finally, the risk profile for the nuclear medicine production facility is well understood from a safety and environmental perspective. For example, risk to the environment and to the public is negligible.

And then we look at the personnel aspect, because that's equally as important, and we've heard just a discussion around that structure. And that is, we've heard earlier that a large portion of the BWXT Medical workforce,

including both management and employees, are former Nordion staff with experience in being a Class 1-B licensee. As well, BWXT has, as a contractor, been working in the nuclear medicine production facility safely since 2018, using the aforementioned programs, processes, and procedures.

So those are some factors that entered into our determination on the proposed licence term by the licensee -- by the applicant, sorry, was appropriate.

THE PRESIDENT: Thank you very much for that, Mr. McAllister.

Ms. Maharaj, final round.

MEMBER MAHARAJ: Final topic area.

This topic area is one that was raised by a couple of intervenors, both First Nations as well as Ms. Tilman wanted to understand better how the applicant is planning to handle the waste that's produced by the process, whether or not there are any risks associated with that waste, radioactive risk in general terms, and what kind of consultation they might be given in order to help develop those plans for waste management?

So it's a big, chunky question, but I think -- I think if you can give us a sense of the process of how waste is managed and where those risks might be, that's a great start.

MS. KAVANAGH: Jackie Kavanagh, for the record.

I'll direct your first question to Richard Decaire.

MR. DECAIRE: Which is everything but the consultation part.

MS. KAVANAGH: Correct.

MR. DECAIRE: So that will go to Natalie.

Yeah. So my part is the handling of the waste and the risk. I had some explanation of calculations that we've done, mostly I've done, for estimating how long we have to hold our waste to decay it, to transport it offsite, risks associated with it.

And I think one thing that I've been -- no one's brought up, is we have our existing processes and waste streams for TheraSphere Y-90 and Indium-111 Oxyquinoline, and we're going into this molybdenum-99. And I think a lot of the questions are around molybdenum-99 and those waste streams.

So from my perspective, the waste that we generated on this site in the past for molybdenum, getting fission molybdenum, stuff that left our building here, is not going to look greatly different in terms of the half-life of the impurities in it and the amounts the activities generated.

What is very different globally, though, is the production method. So the production method right now in most of the world that's been discussed is taking enriched uranium, whether it's highly enriched uranium or low enriched uranium, and you split it in two. And 6 percent of the time you get molybdenum-99. The rest of the time you get other stuff that you don't want, but you still have the enriched uranium.

In the old process that was done on this site, Chalk River, at the NRU reactor, would split the enriched uranium and they would do an initial processing, and they have a lot of waste, including now the contaminated enriched uranium. This irradiation of natural molybdenum that we're doing takes all that section in Chalk River away. So, globally speaking, if everyone switched to this production method, there would be a lot less radioactive waste because you wouldn't be involving the fissioning of enriched uranium.

So in terms of risk, in terms of volatile components, radioxenons that get released, et cetera, that's what happens when you fission uranium-235 to make molybdenum. And we're not part of that anymore. So all these fission gasses, radio iodines that get produced in that as well, are nonexistent in our process.

But as I said, what we're going to be

sending out the door to me looks similar in terms to what we described before from our process when it had most of those things stripped out at Chalk River, the radio iodines, radioxenons, there was some amount in them when it arrived here, and the alpha emitters, stuff like that, would stay in Chalk River. We're not seeing any of that. So, globally speaking, the risks are greatly reduced with this molybdenum-99 process.

I hope that answers that part of the question.

MEMBER MAHARAJ: It does. Thank you.

MS. KAVANAGH: Jackie Kavanagh for the record. I'll direct the second part with regard to consultation to Natalie Cutler.

MS. CUTLER: Natalie Cutler, for the record.

As is usually the case when we're engaging with Indigenous communities and there's a desire to understand a technical component, we will bring to our meeting, whether that's virtual or in person, a subject matter expert on this particular subject that is of interest to be covered. So we would certainly bring Mr. Decaire with us to any discussion regarding waste management. Ms. Kavanagh has always been present at our meetings as well. And it's just an important element to

ensure that questions can be answered on the spot. And typically we do this through provision of a PowerPoint presentation with visuals. We find visuals help either in the way of going through our annual compliance report data, we find that that's helpful.

And typically what we find is just sharing that information, much like Richard just did, in layperson terms, is helpful in allaying concerns. And we look forward to doing that with the intervenors that we heard from today and other Indigenous communities that may be interested in hearing from us.

So really that's our approach, is to determine upfront the area of concern or interest, and to bring the appropriate BWXT subject matter expert with us to the meeting and to every meeting that they may want to discuss a particular topic. I hope that helps.

MEMBER MAHARAJ: That does. And so you've heard today that both of the First Nations involved want that; is that right?

MS. CUTLER: Natalie Cutler, for the record.

We have. And we will be reaching back out to ensure that those topics, and any other topics that they are interested in knowing more about, have representative experts from BWXT present at the meeting.

MEMBER MAHARAJ: Thank you very much. Those are my questions, Madam Velshi.

THE PRESIDENT: Thank you. Dr. Demeter?

MEMBER DEMETER: Thank you. I have one -- sort of one final question to BWXT.

So I want to get a sense of the tracking of inventory and control systems. So if a CNSC inspector showed up at noon tomorrow and asked you, "How much product do you have on hand that's product? How much do you have in a waste stream? How much are you expecting to receive today or ship out today?" is that the kind of information system you have that could say, yes, we have this much activity with these isotopes coming in, this is how much we have on hand that's ready for product, these are the waste streams. Is that the kind of information that you'd have available to an inspector?

MS. KAVANAGH: Jackie Kavanagh, for the record.

So, yes, we would. We actually have a documented procedure for how we would collect all that information should we be asked for it during an inspection. So we do have a business management system that kind of tracks shipments or orders to customers. We also have waste areas that have inventories. We have an inventory of smaller sources, like check sources, non-product sources.

So our procedure actually directs us to how we would collect all that information should we be asked for it. And we believe we could provide that in a fairly timely manner, should we be requested to.

MEMBER DEMETER: Is that information database updated on a realtime basis day-to-day internally so that you wouldn't have to go and reconstruct it?

MS. KAVANAGH: It's updated, but -- fairly frequently. But part of our process for being able to give, let's say, the accurate inventory of what's in the facility, is that for certain material such as shipments that have been packaged for a customer, they may show in our inventory system as being moved out, so we would have to visually go to a couple of those areas where the shipments are staged and just do an accurate count there because it is possible that, you know, a truck may have arrived to take away some of those packages. So in those areas we would actually go down there and we would do a visual count and inventory of those areas. But for the other materials, we either have it in our business management system, Oracle, or we have it in Excel tracking sheets.

MEMBER DEMETER: Thank you.

THE PRESIDENT: Mr. Decaire?

MR. DECAIRE: Richard Decaire for the

record. Jackie gave an excellent answer. I just thought I'd add, in our ordering system when we get product irradiated at a reactor, we have an expectation that it will have a certain activity. That has to be confirmed when it gets here. So the product arrives typically in a tidy package, it goes into one of our hot cells, and then we take a measurement on it.

So for TheraSphere, that's something routine that happens, and that will happen in the molybdenum process as well. There's an expectation that it will be, you know, this range of activity, and we measure it, it's this range, and now we know what we can dispense. So that's the sort of information that, when Wayne Mullett was there, you know, we'll share with him what specific activity we have that goes into the ordering system. And for TheraSphere they would tell us to dispense the following for patients, and in case we get extra orders, dispense the following units. And that would be held, and it would either be sold or it would be held until the expiry date of the product, typically it's two weeks for both those products, and then that would then be transferred into the waste system.

So there's an element of time there where we don't know exactly what we've got, we have an idea, but then it goes into the system and then it's confirmed.

THE PRESIDENT: Thank you. And thank you to BWXT Medical team and to CNSC staff for your patience with responding to our questions in such a thorough manner.

So before concluding the hearing, I'll turn the floor to BWXT Medical for final remarks. Mr. Coombs, over to you.

Closing Remarks

MR. COOMBS: Martyn Coombs for the record.

So on behalf of BWXT Medical, I would like to thank President Velshi and the Commission, the CNSC, and all the intervenors for your precious time today to submit. It's quite informative feedback, I think. It was very useful for us. I hope the responses we give are useful in assessing our application.

We are very proud of the work we do for patients and trying to do meaningful and valuable things that help people recover from illness. But as you pointed out, the mandate here is about safety, and we are very concentrated and serious and focused on that through all of our systems, and our culture, and our people. So I hope that came through strongly in our discussion, and thank you to the Commission for consideration of our licence application, and obviously we're very keen to move forward.

So thank you.

THE PRESIDENT: Thank you. And thank you to everyone for your participation in this hearing.

Marc, I'll turn it over to you for closing remarks, please.

MR. LEBLANC: Merci, madame la présidente.

This brings to a close the public hearing on BWXT's medical application. With respect to this matter, it is proposed that the Commission confers with regards to the information that it has considered and then determine if further information is needed or if the Commission is ready to proceed with a decision. We will advise all participants accordingly.

The public hearing on Ontario Power Generation's application on the Darlington Nuclear Project will begin tomorrow at 9 a.m. I also wish you a nice rest of the day and join the President in thanking all participants, but also all the staff that are in the background and the interpreters, for whom I think a few of them it was the first time dealing with nuclear matters, and I listened in and it was pretty spectacular, so congratulations, and thank you to everybody else who contributed to today's proceeding.

Merci.

--- Whereupon the hearing adjourned at 5:18 p.m., to resume on Thursday, June 10, 2021 at 9:00 a.m. / L'audience est ajournée à 17 h 18 pour reprendre le jeudi 10 juin 2021 à 9 h 00