Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Public hearing

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Public Hearing Room
14th floor
280 Slater Street
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Salle des audiences publiques
14e étage
280, rue Slater
Ottawa (Ontario)

Commission Members present

Ms Rumina Velshi
Dr. Sandor Demeter
Mr. Timothy Berube
Ms Kathy Penney
Dr. Marcel Lacroix

Commissaires présents

Mme Rumina Velshi
Dr Sandor Demeter
M. Timothy Berube
Mme Kathy Penney
M. Marcel Lacroix

Assistant Secretary:

Ms. Kelly McGee

Secrétaire-adjointe:

Me Kelly McGee

Senior General Counsel:

Ms. Lisa Thiele

Avocate-générale principale :

Me Lisa Thiele

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--- Upon commencing on Thursday, May 16, 2019
at 9:00 a.m. / L'audience débute le jeudi
16 mai 2019 à 9 h 00

Opening Remarks

THE PRESIDENT: Good morning and welcome to the continuation of the public hearings 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 we are holding this hearing in the Algonquin Traditional Territory.

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

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

On my right is Dr. Sandor Demeter; to my left are Dr. Marcel Lacroix, Ms Kathy Penney and Mr. Timothy Berube.

Ms Lisa Thiele, Senior General Counsel to the Commission, and Ms Kelly McGee, Assistant Secretary of

the Commission, are also joining us on the podium today.

I will now turn the floor to Ms McGee for a few opening remarks.

Kelly...?

Mme **McGEE :** Bonjour, Mesdames et Messieurs. Bienvenue à cette audience publique de la Commission canadienne de sûreté nucléaire.

Mon nom est Kelly McGee. Je suis la secrétaire adjointe de la Commission et j'aimerais aborder certains aspects touchant le déroulement des audiences.

During today's business, we have simultaneous interpretation.

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

Please 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. Les transcriptions se font dans l'une ou l'autre des langues officielles, compte tenu de la langue utilisée par le participant à l'audience publique.

Les transcriptions seront disponibles sur le site Web de la Commission dès la semaine prochaine.

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

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

As a courtesy to others in the room, please silence your cell phones and other electronic devices.

The agenda for this hearing was approved yesterday. The public hearing today is regarding the application by Best Theratronics for the renewal of their Class IB Nuclear Substance Processing Facility Operating Licence.

This is a one-part public hearing. The Notice of Public Hearing and Participant Funding was published on November 13th, 2018.

Participant funding was available to intervenors to prepare for and participate in this public hearing, but the Commission received no request for participant funding.

The public was invited to participate either by oral presentation or written submission. April

15th was the deadline for filing by intervenors. No interventions were filed.

The submissions from CNSC staff and Best Theratronics were filed respectively on March 19th and March 20th. They were made available on the CNSC website on March 21st, 2019.

May 8th was the deadline for filing of supplementary information and I note that supplementary submissions and presentations have been filed by Best Theratronics and CNSC staff.

We will begin with presentations by Best Theratronics and then CNSC staff, followed by rounds of questions.

Ms Velshi, President and Chief Executive Officer, will be presiding this hearing.

President Velshi...?

THE PRESIDENT: Thank you.

I would like to start the hearing by calling on the presentation from Best Theratronics, as outlined in Commission Member Documents 19-H2.1, 19-H2.1A, 19-H2.1B and 19-H2.1C.

I will turn to Mr. Suthanthiran for this presentation.

Good morning. The floor is yours.

MR. SUTHANTHIRAN: I go first?

THE PRESIDENT: Yes, please.

CMD 19-H2.1/19-H2.1A/19-H2.1B/19-H2.1C

Oral presentation by Best Theratronics Limited

MR. SUTHANTHIRAN: Good morning. Thank you very much for giving the opportunity.

This is the first time I have been here, so I am delighted to see a houseful of guests. My name is Krishnan Suthanthiran. I came in 1969 to Ottawa, September 7, on a cloudy, drizzly day, and a friend of mine, his brother-in-law was doing a post-doctorate fellowship at Carleton, he came and picked me up. He gave me a big lecture about the seatbelt. The next thing is when I went to the movie theatre I was looking for a seatbelt. So it was a humble beginning.

I came in 1976 to Theratronics as a young engineer trying to find out how to pour lead for a shipping container-shipping high-strength Cobalt-60 source to Liberia. I never thought that one day I will come and buy that -- buy the company.

Canada is probably the richest per capita and I was appreciative of the opportunity I had to come and

get a research assistantship to pursue my Master's degree in Mechanical Engineering. In return, I established several endowments for scholarships and donated a substantial sum of money to Carleton to purchase technology for the Mechanical Engineering Department.

We all have a purpose, we all have a dream and I call that a purposeful dream. In 1968 my father died of cancer of the colon. I watched him die for three years while I was doing my undergraduate engineering degree. When I was an undergraduate engineer my dream was to work in cancer research and treatment. I thought there must be some way to do things better.

In 1972 when I left Canada and then I became a permanent resident in the U.S., I was fortunate to get a job with an oncologist who is world-renowned and who was a pioneer in many of the new technologies.

For me this is a journey of 50 years trying to do something about cancer. In 2015, April 29th, I launched a Global War on Cancer. Recognizing my effort, Harvard University Medical School invited me as a keynote speaker every year when they established the Harvard Medical School Global Health Cancer Catalyst Summit.

Globally, the number one killer is cardiac. Number two is cancer. Number three is

negligence, misadministration, infections patients get in the hospital. So it is very much preventable. So I am globally establishing a healthcare delivery system, a hub-and-spoke model, express and mobile clinics linked to medical centres and super specialty medical centres to relieve the death and suffering from cancer, cardiac, diabetes and all diseases by 50 percent by the end of the next decade.

I lost my mother and in memory of my mother I established 3E, called Education, Empowerment and Equality, to promote women globally. So Theratronics is a jewel of Canada.

In the 1950s, then AECL, Atomic Energy of Canada Limited, scientists and engineers invented a Cobalt therapy machine called Theratron. Today there are more than 2000 units in use. Believe it or not, it is still the best technology in the entire world. People can talk about lots of things and as a private company and globally we are using the technology at practically every centre we are going to set up.

We just received an order from India alone 40 units, 10 units from Bangladesh. Every country uses the technology invented and manufactured in Canada, except Canada. Not a single hospital is using this technology.

Less than 3 percent of the medical products made in Canada are being used for Canadian hospitals.

So while I recognize my presentation may be long, and I just want to be short, I want to let you know we have a purpose and we have a dream and it is called a purposeful dream and we believe this Canadian-invented technology is the best and we intend to promote that globally. I travel on the average to at least 40 countries a year. So again, thank you very much for the opportunity and I will introduce Mojgan.

Mojgan is the most powerful woman in our company. She is the Director of Quality Assurance, Regulatory Affairs and Radiation Safety Officer. I don't think anybody else can have a more important position than that, so we call her the most powerful woman in the company. So when she wants something, I say, "Yes, ma'am". I don't argue with Quality and Regulatory.

Vasile Sabaiduc is a Cyclotron Engineer. Ten years ago we engaged in cyclotron manufacturing. We installed 70 MeV cyclotron in Italy. When we won the international tender for the 70 MeV cyclotron in Italy, we competed against a Belgian company and a European company who had been in that for 50 years. We won the tender, having never built a cyclotron before, because our

reputation globally is impeccable and there was a confidence that we will deliver what we said we are going to deliver. Today that cyclotron is the only 70 MeV working according to specification in the entire world and we continue to manufacture a range of cyclotrons.

The purpose here today is to explain to you what we do because I don't think that we are testing our cyclotron higher than 1 MeV. It may be 70 MeV, it may be 35 MeV, it may be 15 MeV, but they are all tested at the factory at 1 MeV, a small amount of current. So therefore, we want to let you know that our purpose here is that we feel that given the increase in licensing costs, as a small private company, it's a challenge for us and we would like to reduce that licence category so that we don't have to bear the burden of a very high cost of licensing.

I have chosen to be a totally owned private company mainly because every public company, every private equity-owned company, forecast is money, money, money. I don't know why everybody is chasing money because we don't take money with us. So our goal is to continue to be a privately owned small company. We want to do that, so we wanted to have most (indiscernible) and start that with the work we are here for. Thank you.

MS SOLEIMANI: Good morning. Mojgan

Soleimani, for the record.

Thank you very much for having me and giving me the opportunity to present Best Theratronics' past performance and an overview of our operation.

As Mr. Suthanthiran mentioned, we have three main product lines. We have a radiation therapy system using Cobalt-60 for cancer treatment, we have irradiators for blood and research using X-ray and Cesium-137 sources, and we have particle accelerators for medical isotope production.

We also have legacy depleted uranium in our facility. DU was used in our therapy heads as part of the shielding, but in later designs they were changed to tungsten. All the sealed sources stored at BTL are either in self-shielded blood irradiators -- we call them Gammacells -- or in Type B(U) transport packages, as shown in these pictures.

A commonly used C-146 capsule for teletherapy sources is shown in the last picture. C-146 capsules are usually 2 cm in diameter and 3.5 cm in length. All BTL sealed sources are a special form and they are double encapsulated.

These photos show different type B(U) transport packages BTL employs for transportation and also

storage of radioactive material. These containers weigh anywhere from 5,000 to 21,000 pounds and can carry up to 2.2 PBq of Cobalt and 3.7 PBq of Cesium.

BTL does not process or use nuclear substances. Cobalt-60 and Cesium-137 sources are fabricated by third-party suppliers and arrive to BTL already loaded in Type B(U) transport containers or self-shielded blood irradiators. The only exceptions are the following:

- BTL owns one research and development Class II prescribed equipment, shown on the picture, loaded with a special form double encapsulated Cobalt source with an activity 0.189 PBq.

- BTL also loads teletherapy heads with one cobalt source with activity of 0.4 to 0.45 PBq while source stays in the off and shielded position. This practice is to survey the loaded head for shielding integrity and compliance verification with the standards.

During the licensing period operations were within licensed limits.

BTL offers a return policy for sources and accepts the returns upon customer or end-user request. As per the IAEA definition of "waste", returned sources should not be categorized as waste by default. Returned sources

are reutilized and recycled before disposal as waste is considered.

During the licensing period BTL received on average 3 PBq of returned Cobalt sources and 0.5 PBq of Cesium. Of those, over 95 percent of returned Cobalt sources and over 80 percent of returned Cesium sources were successfully recycled.

During the licensing period, all Safety and Control Areas were rated as "satisfactory" by the CNSC, except for emergency management and fire protection in 2015. The performance rating for emergency management and fire protection was revised from "below expectations" in October 2015 to a "satisfactory" rating in November 2015. This change is a reflection of BTL having fulfilled all terms and conditions of an order issued by the CNSC with respect to a dust collector to comply with the *National Fire Code of Canada*.

During the licensing period environmental management procedures were revised, training programs updated and physical improvement to the security infrastructure was conducted.

Improvements to safety-related programs such as emergency preparedness and lead control were also implemented during the licensing period.

BTL is an ISO 9001 and ISO 13485 certified company and has implemented an extensive quality program. Several key improvements have been implemented within the licensing period. That includes:

- a risk-based assessment applied to the Corrective and Preventative Action (CAPA) system;

- development and implementation of an "opportunity for improvement";

- re-evaluation of all auditor qualifications; and also,

- transitioning to a paperless system to improve document control and recordkeeping.

During the licensing period a gap analysis to Management System Requirements for Nuclear Facilities was also completed. Improvements to the management system are currently underway in order to be compliant with this requirement.

BTL operates a workforce of approximately 150 personnel at its 413 March Road facility.

During the licensing period, BTL has implemented a systematic approach to training and has improved the training programs.

BTL will continue conducting reviews of the number of qualified personnel and of the training

program in accordance with CNSC Human Performance Management Personnel Training.

The use of an electronic training management system is planned to be implemented at BTL within the next licensing period. Providing in-house training on regulatory and licensing is also one of the priorities.

BTL has an extensive program to ensure operating performance is maintained. Corrective and Preventative Action system and internal audits are part of this program. BTL operations continued with little change within the licensing period and no licensed operating limits were exceeded.

A gap analysis to the reporting requirements was also conducted and relevant procedures were updated and revised as required.

BTL has implemented a strong and robust safety analysis framework surrounding its activities.

The key implementation of this safety analysis framework is the use of safety analysis reports. Safety analysis reports are undertaken as part of the initial design process or when there are changes to safety critical components.

These safety critical components include:

- Radiation Device and Class II Prescribed Equipment;

- radioactive material transport containers; and

- the facility.

Safety analysis reports are covered under BTL's design change procedure. During the licensing period safety analysis reports have been reviewed and concluded to be adequate; safety concerns were regularly discussed in both Health and Safety and Radiation Safety and Security Committee meetings; and also, an updated fire hazard analysis of the facility was completed within the licensing period.

The BTL facility at 413 March Road was initially designed by Atomic Energy of Canada Limited in approximately 1964 to 1965.

BTL has maintained a robust facility management framework. All work to the facility has been undertaken by qualified personnel.

Modifications and improvements that were initiated within the licensing period included roof replacement of the facility and upgrades to several of the facility's air conditioning units.

As per preventative maintenance program,

workplace inspections are performed by both Health and Safety Committee members on a monthly basis and issues and concerns are addressed immediately.

Overall, no major changes to the facility took place during the licensing period.

There are two aspects related to fitness for service.

The first is that of the facility and more specifically the areas where licensed activities are undertaken. The facility, as mentioned, is assessed on an ongoing basis by the Health and Safety Committee. Areas where licensed activities occur are also reviewed by the Radiation Safety and Security Committee.

The second aspect of the fitness for service is that of the equipment. BTL has implemented procedures to ensure all radiation monitoring equipment is calibrated and is in good working order. The equipment is checked on a monthly basis and calibrated by a third party annually or as needed.

BTL's radiation protection program is based on the ALARA -- as low as reasonably achievable -- principle, consistent with adequate training, proper planning for work and monitoring of employee radiation exposures.

Within the licensing period the ALARA procedure was updated and administration and action levels were lowered to better monitor doses and to detect and prevent unnecessary exposures.

The two tables in this slide represent the whole body doses and also the extremities for all nuclear energy workers at BTL. Please note that the doses reported are for all nuclear energy workers working under both servicing and Class 1B licences within Canada and also abroad.

During the licensing period two nuclear energy workers exceeded internal monthly action levels. Both nuclear energy workers are technical services staff at BTL and their doses are also reported on their Class II servicing licence.

The annual doses for these individuals were still well below the regulatory limit. Incident happened while conducting licensed activity on site. No adverse health effects were observed as a result of this incident, and work duties were adjusted in order to minimize radiation work for these two service technicians.

BTL maintains a robust health and safety program. This program is monitored by BTL's Health and Safety Committee. The committee meets monthly to review

all health and safety issues. As part of gap analysis with the new safety culture, BTL plans to assess employee safety culture through surveys. Additionally, safety and awareness trainings are to be conducted annually.

BTL is committed to safety and security of not only its personnel and public but also to the environment. With respect to radioactive environmental protection, BTL deals primarily with sealed sources. As such, there have been no release of radioactive material into the environment.

BTL environmental protection program is reviewed annually, and during the licensing period, BTL has decreased the amount of solid effluent and has properly disposed of hazardous waste by a qualified waste disposal company. An initiative was also started to reduce the amount of unused chemicals within the facility.

BTL has implemented and continuously maintains an emergency preparedness program. The emergency preparedness program covers all aspects of potential emergency situations. Fire drills were conducted annually during the licensing period. A gap analysis to CNSC Nuclear Emergency Preparedness and Response was also performed in 2018. Various updates to procedures and emergency drill planning were implemented.

A full-scale evacuation exercise involving Ottawa fire, police, and paramedics was also conducted during the licensing period. Facility familiarization tours are being offered to emergency responders on an ongoing basis.

BTL is a manufacturing organization. As a result of its operation, BTL produces different types of waste. BTL's priority is to prevent and minimize the generation of waste. To this end, BTL has established a waste management program to promote the safe handling and disposal of waste generated from its operation.

For the radioactive material located on site, BTL has an end-of-life management program which includes reutilization, recycling, and disposal as the last option. During the licensing period, BTL diligently and at a great expense has removed all legacy cobalt and most of cesium sources from its facility and transferred them to other licensees for reuse or disposal.

During the licensing period, a number of improvements have been employed to the security program, including facility and monitoring system upgrades. Concerns regarding the security of radioactive material have become an important topic in recent years. As such, BTL Radiation Safety Committee invited the involvement of

security personnel with committee meeting discussions.

BTL has been recently accepted to participate in the Transport Canada air cargo security program. Within the licensing period, air cargo security procedures have been created, training conducted, and audits and a tabletop exercise have been both completed, and full implementation of this program is the last step to be completed in 2019.

As mentioned earlier, DU was historically used in legacy cobalt-60 teletherapy units as shielding material. However, the DU shielding was replaced in later designs by tungsten. Decommissioned teletherapy units that contain DU are returned to BTL for end-of-life management. BTL provides interim storage to the legacy DU until shipped to a supplier for reuse or disposal.

I want to here mention there was an error in our CMD, section 3.13. So 3.13.2, under Past Performances, under Safeguards section. "Within the licensing period, BTL was" -- we say "was not chosen," but indeed, "was chosen by the IAEA for a Physical Inventory Verification" activity.

So within the licensing period, BTL was chosen by the IAEA for a physical inventory verification. The IAEA conducted the physical inventory verification on

October 13th and 14th of 2015. BTL received a satisfactory rating from the IAEA for this physical inventory-taking.

A gap analysis was also conducted to the safeguard and nuclear material accountancy. Consequently, updates to all safeguard-related procedures were made to improve the program.

BTL ships category 1 and 2 radioactive material worldwide, and as such has implemented a transport and packaging program that meets the requirement of CNSC packaging and transport of nuclear substances regulations and also the IAEA.

The category 1 and 2 sealed sources are shipped in certified type B(U) packages. During the licensing period, an emergency response assistance plan with Transport Canada was updated. A tabletop exercise with Transport Canada, contracted supporting companies, and BTL staff was conducted. This plan is valid until September 2023 and will be reviewed again prior to bulk shipment of DU for disposal.

During the licensing period, minor incidents with transport packages, including receipt of mislabelled containers, were reported to the CNSC as per licensing requirements. Again, I would like to mention that in Appendix 5, A5, Reportable Events, we are missing

three reportable events in the summary of the events, which we have printed a copy to be attached to our CMD.

BTL is a major importer and exporter of category 1 and 2 sealed sources, primarily cesium-137 and cobalt-60. BTL has implemented a robust import/export program. Due to the high activity of the sources, BTL obtains licences from the CNSC for their exports. When required, BTL also obtains appropriate permits from Department of Foreign Affairs for exports that may be controlled under Canada's export control list or various sanctions.

In July 2017, the estimated decommissioning cost of $1.8 million was approved by the CNSC. Throughout the licensing period, BTL has successfully recycled and disposed of over 500 cobalt-60 and cesium sources with a total activity of over 10 petabecquerels. The financial guarantee will be maintained on a continuing basis. As the decommissioning plan is revised due to ongoing decommissioning activities or changes to the operational program, the financial guarantee will be also revised.

BTL has implemented a public information and disclosure program to keep the public informed about the nature of our operations. The primary goal for the

public information program is to communicate BTL's operational activities to the surrounding community and provide an avenue for open community discussions surrounding BTL's proposed activities as they relate to health, safety, security, and the environment.

A community information session was held during the licensing period. An invitation to host the Algonquins of Ontario was also extended to them offering a tour of the facility and to answer any questions or concerns they may have regarding BTL's operation.

I now turn the floor to Mr. Sabaiduc for our cyclotron operation.

MR. SABAIDUC: Good morning. My name is Vasile Sabaiduc. I'm engineer in particle accelerators and director of the cyclotron operation at Best Theratronics, Ottawa.

Best Theratronics Limited manufactures a broad range of cyclotrons with energy starting from 15 to 70 megaelectron volts. The cyclotrons are designed for the main purpose of producing various radioisotopes utilized for diagnostic and therapeutic procedures in nuclear medical field as well as being used for nuclear studies in research laboratories around the world. Best Theratronics cyclotrons cover both application fields.

Presently, we have four energy models characterized by their maximum energy and beam current capability. These are B15P, delivering a maximum fix energy of 15 megaelectron volts; B25P, delivering variable energy from 15 to 20 and 25 megaelectron volts; B35P, which delivering variable energy from 15 to 35 megaelectron volts; and the last model in the line, B70P, delivering variable energy from 35 to 70 megaelectron volts.

All our cyclotrons are single particle accelerators delivering high-intensity proton beam to targets. The proton beam current capabilities ranges from 400 microamperes up to 1,000 microamperes. It is important that we mention in factory the cyclotrons are not capable for using any nuclear energy as we will further demonstrate.

All Best Theratronics cyclotrons are factory tested at energies below 1 megaelectron volt, where nuclear energy cannot be produced. So again, I do have a small error here, "cannot," in my speech.

Factory testing is performed through injection of the negative hydrogen ion beams and acceleration in the centre region of the cyclotron to energies below 1 MeV -- 1 megaelectron volt.

Safety measures preventing beam

acceleration above 1 MeV have been implemented in our design based on protocols from the Canadian cyclotron laboratory TRIUMF in Vancouver. These measures are internationally recognized and applied by all cyclotron manufacturers. The theoretical principles are scientifically documented and the engineering measures are implemented. They'll be further explained in our presentation.

Their practical implementation is ensured by a complex of three safety measures where each individual device is determined to be sufficient to prevent the beam from being accelerated above the energy 1 megaelectron volt from where nuclear radiation can be produced.

So these are:

(1) Beam intercept probe placed at the energy between 0.6 to 0.8 megaelectron volts and blocked on "high" intercept position.

(2) Beam suppression block, which is a solid block of aluminum positioned between magnet poles, completely obstructing the entire acceleration space up to 70 megaelectron volts energy.

And the last one,

(3) Disable the hardware activation, so the PLC signal controlling the beam intercept probe device

and the compressed air activating the probe.

B70P cyclotron factory mechanical assembly is equipped with both mechanical safety devices as presented at points 1 and 2 in previous slide. The safety devices are documented in factory drawings named Beam Suppression Block Installation, where specific notes indicates for those devices not to be removed during the factory testing. Their presence inhibits the beam of being accelerated in the machine. The drawing here quoted it is part of Best Theratronics quality assurance system and registered as a factory assembly documentation.

The drawing at left is showing the details of the mechanical installation of both devices, and at right it's highlighted in red, the first turns of the beam trajectory, the beam intercepting probe, and the beam suppression block.

The following slides will show in more detail the interception feature.

The slides on the screen is representing the cyclotron magnet in an open state, where the lower section -- we call it lower pole plate of the magnet -- consisting of hills and valleys, that's a typical cyclotron magnet structure -- it is shown.

The negative hydrogen beam is accelerated

in the circular trajectory in the medium plan of the cyclotron, a plan symmetric between the magnet poles.

The centre red line, the circular path, represents the theoretical beam trajectory from the axial beam injection point -- we call it beam start point -- into the machine, and up to the energy of 0.6, 0.8 megaelectron volts.

At right on the slides, we have the beam intercept probe. That is the first device intercepting the beam and providing beam current reading to characterize the beam transport up to or below 1 megaelectron volt. The probe is specifically designed sufficiently wide to intercept two consecutive beam trajectories for the entire space between the magnet use, also called in our terminology the magnet gap.

At left, we are showing the beam suppression block, a full body aluminum block sufficiently long and tall to completely obstruct the entire acceleration space between the magnet poles, a compact steel structure. The block is clearly engraved an instruction not to be removed during the factory assembly and testing.

The centre region of the cyclotron magnet is shown on an enlarged view on the slide to clearly

visualize the beam intercept mode first at 600 kiloelectron volts, secondly at 800 kiloelectron volts, as well as the safety added feature of the beam suppression block intercept mode starting from 800 kiloelectron volts and above.

The beam intercept probe, it's locked with the aid of a screw which shown in that slide, in place in the intercept position, view at left, and the air actuator moving the probe is disabled, compressed air supply and PLC controlled air switch disconnected during the entire factory testing.

Based on above considerations, we presented sufficient detail information and documented that the B70P cyclotron model factory assembly during the testing, it's not:

> "capable of producing nuclear energy or have a beam energy above 50MeV for beams of particle with a mass equal to or less than 4 atomic mass units"

-- as defined in the CNSC relevant documentation, the Class IB Nuclear Facility.

We are also bringing to the committee attention that above definition refers to capability, not design. While our B70P cyclotron is designed for, it is

not capable of producing nuclear energy as defined in the regulatory Act.

MS SOLEIMANI: I will continue the last two slides. Mojgan Soleimani, for the record.

While BTL appreciates the CNSC staff's support through the renewal process as well as their input and courteous communication throughout, BTL and CNSC staff have come to a respectful disagreement regarding BTL's request to replace its current Class IB licence with Class II facility and NSRD licences.

The difference of opinion turns on somewhat technical interpretations of the capability, interpretation of applicable regulations, as well as the broader policy objectives of the legislation.

There are essentially three questions shown on this slide of interpretation before the Commission.

I think the first question about capability was very well answered by Mr. Sabaiduc.

For the issue of waste, paragraph 19(a) of *General Nuclear Safety and Control Regulation* defines a nuclear facility as

> "a facility for the management, storage or disposal of waste ...

> [where] the resident inventory of ... waste is [more than 1 petabecquerel]."

However, the entire focus of the paragraph 19(a) is on waste, which is defined by the International Atomic Energy as material for which no further use is foreseen.

BTL's past performance shows that while it stores returned double-encapsulated sealed sources for a period of time, which may exceed 1 petabecquerel annually, such inventory is for resale, future use, recycling, and disposal, and as such, not all sources returned meet the definition of waste.

For the issue of processing and use, paragraph 1(d) of the *Class I Nuclear Facility Regulation* defines a Class IB nuclear facility

> "a plant ... for the processing or use, in a quantity greater than [1 petabecquerel] per calendar year, of nuclear substances ...."

BTL does not use or process nuclear substances in excess of 1 petabecquerel per calendar year. BTL has one research and development Class II prescribed equipment loaded with a double-encapsulated cobalt source

with an activity of 0.18 petabecquerel.

BTL also performs teletherapy head surveys, where one cobalt source with activity between 0.4 to 0.45 petabecquerel is loaded in a teletherapy head in a shielded and off position for a verification of shielding integrity.

Besides these two exceptions, BTL is essentially a distributor of radioactive material and does not use or process in excess of 1 petabecquerel.

The CNSC staff has also suggested that financial benefits, decreased duplication, and efficiency in responsiveness would occur to both BTL and the CNSC under a consolidated Class IB licence.

BTL respectfully disagrees with these arguments. Extremely intense oversight on a low-risk operation supports neither efficiency nor the achievement of financial benefits. The enormous difference in cost will only serve to erode BTL's ability to compete internationally against entities with similar risk profiles that are less intensely regulated by their jurisdiction in which they operate.

Over the licensing period, BTL has maintained programs and implemented improvements to ensure adequate provisions are in place for the protection of the

environment, employees, and the public. Over the licensing period, there were no significant changes in operations at BTL and there are no plans for significant changes in the future.

And as per the argument presented before the Commission Members, BTL believes that the regulatory oversight by Class II Facility and NSRD directorates, as it was prior to Class IB licence, is appropriate for BTL's current and future operation.

Thank you.

THE PRESIDENT: Thank you very much for your presentation.

I would now like to move to the presentation from CNSC staff as outlined in CMDs 19-H2, 19-H2.A, and 19-H2.B.

Ms Haidy Tadros for -- over to you.

CMD 19-H2/19-H2.A/19-H2.B

Oral presentation by CNSC staff

MS TADROS: Thank you, President Velshi, and good morning, Members of the Commission.

For the record, my name is Haidy Tadros. I am the director general of the Directorate of Nuclear

Cycle and Facilities Regulation.

With me today are my colleagues Dr. Caroline Ducros, director of the Nuclear Processing Facilities Division, as well as Mr. Ismail Erdebil and Mr. Waleed Khan, project officers within the same division.

We will be sharing in the presentation this morning.

Also present are CNSC experts and subject matter technical specialists who have participated in the review of the renewal application submitted by BTL and can answer any questions the Commission may have.

BTL is currently licensed by the CNSC for the development and testing of cobalt-60 teletherapy devices, the manufacturing of self-shielded irradiators, the storage of nuclear substances, and the operations of cyclotrons.

Before we begin our presentation, and for the record, I would like to go over a couple of errata that were found in CNSC staff's written submission.

The first, on page 12, section 3.1.3.3, Proposed Improvements section, it should say that there are currently no proposed improvements related to this safety and control area. The areas of improvements that are currently there, in staff's submission, have already been

implemented by the licensee.

The second errata is found on page 73, Appendix E. The title should say "Lost Time Incidences" rather than "Injuries."

The following slide provides an outline of CNSC staff's presentation.

We will briefly outline BTL's request for licensing and summarize CNSC staff's assessment of the application for a Class IB licence based on their operations.

Staff will also provide an overview of BTL's compliance history over the current licence period and other matters of regulatory interest before we finally summarize our recommendations for this renewal.

I will now pass the presentation on to my colleague Dr. Ducros to explain BTL's submission and their current operations.

DR. DUCROS: Good morning, President Velshi and Members of the Commission. For the record, I am Dr. Caroline Ducros. I'm the director of the Nuclear Processing Facilities Division.

I will now summarize the background behind the matter before the Commission today.

On September 7th, 2018, BTL submitted an

application for the renewal of its Class IB licence that authorizes operating particle accelerators (cyclotrons) for testing purposes, manufacturing prescribed equipment and radiation devices, research and development using teletherapy machines, and storage of sealed sources of nuclear substances.

I would like also to point out that a regulatory hold point is on the proposed licence before the Commission, which requires BTL to get prior approval from the Commission, or a person authorized by the Commission, before operating any particle accelerator, cyclotron, above 1 megaelectron-volt (MeV).

This hold point was added to ensure that the appropriate safety and control measures are in place prior to operating the particle accelerators. The hold point is on BTL's current licence issued by the Commission and during the current licence period BTL did not test any cyclotrons above 1 MeV.

In January 2019 CNSC Staff and BTL staff met to discuss BTL's intention to revert back to separate licences. In that meeting CNSC Staff communicated to BTL that the *Nuclear Safety and Control Act* and Regulations made under that act are based on capabilities of particle accelerator and not on how it is operated.

In addition, CNSC Staff explained that a resident inventory of waste, which is the case of BTL, includes sealed sources for which no further use is foreseen must remain below an activity level of 10 to the 15 becquerels or otherwise requires a Class 1B licence.

On February 15th, 2019 BTL submitted three additional licence applications for the manufacturing of radiation devices, the storage of nuclear substances, and the development and testing of Class 2 prescribed equipment.

BTL maintained that particle accelerators that operated below 1 MeV do not require a licence.

This slide presents the licensing history of BTL. Between 2008 and 2014 BTL operated under separate licences, these were development and testing Class 2 equipment, storage and device manufacturing. This was not an effective nor an efficient way to regulate this facility, where programs were identical for all three licences and duplications of effort ensued.

Consolidating these licences was the way forward at that time. Therefore, in 2014, when BTL expressed an interest in including the operation of particle accelerators, cyclotrons above 50 MeV as one of the licensed activities, CNSC Staff recommended that all

other licences be consolidated into one Class 1B licence.

BTL's current licence was issued by the Commission on July 1st, 2014. Reverting to separate licences will omit the particle accelerators.

As mentioned previously, a particle accelerator capable of producing a beam energy greater than 50 MeV is a Class 1 facility and therefore requires a Commission-issued licence regardless of the beam energy under which it is operated.

On September 7th, 2018 BTL applied for the renewal of the Class 1B licence. During the renewal process CNSC asked the licensee if it would like to test the particle accelerators, cyclotrons, above 1 MeV. BTL stated that while it does not have immediate plans to test above 1 MeV, it would like to have the flexibility in its licence to do so. This was the basis for the site-specific licence condition on the proposed licence.

The following slides present the definitions of a Class 1B nuclear facility and why CNSC Staff recommend a Class 1B licence for BTL.

The definition of a Class 1B facility defined in the Class 1 Nuclear Facilities Regulations includes a particle accelerator that is capable of producing a beam energy greater than 50 MeV. Class 2

particle accelerators are prescribed equipment with the capability of producing energy below 50 MeV.

BTL's current operations includes receiving used sealed sources from customers. The inventory of waste contained in nuclear substances varies throughout the year. In accordance with the Class 1 Nuclear Facilities Regulations, a facility for the management, storage or disposal of waste contained nuclear substances greater than 10 to the 15 becquerels is defined as a nuclear facility and requires to be licensed as such.

As mentioned previously, BTL has an inventory of sealed sources that are to be recycled, reused or transferred to a licensed long-term waste management facility. In other words, material for which there is no further use foreseen.

It can been seen on this slide that activities at the BTL facility fall under several CNSC licence types. As previously noted, BTL has an inventory of sealed sources. Its activities also include the manufacturing and operation of particle accelerators above 50 MeV, the manufacturing and testing of radiation devices, the development and testing of teletherapy machines and the receipt, use and distribution of sealed sources, some of which are used in research and development in BTL's

teletherapy machines.

These activities are currently consolidated into the Class 1B licence for efficiency and effectiveness of regulatory oversight.

The CNSC has considered the Class 1B licence application in close collaboration with specialists responsible for the oversight of Class 2 and nuclear substance activities.

For the following reasons, CNSC Staff are of the opinion that BTL requires a Class 1B licence. BTL's waste inventory at site is greater than 10 to the 15 becquerels.

BTL manufactures and operates a particle accelerator, cyclotron, with a capability greater than 50 MeV. BTL maintains a large and changing inventory, including high-risk sealed sources.

The additional licence applications that BTL submitted in February 2019 leading up to this Class 1B licence renewal do not include the Class 1B manufacturing and testing of particle accelerators, cyclotrons, with capabilities greater than 50 MeV and do not take into consideration the waste inventory greater than 10 to the 15 becquerels.

CNSC Staff also recommend that the sealed

source inventory for sources that are not deemed to be waste would be best regulated under a consolidated Class 1B licence for reasons of regulatory oversight efficiency.

I will now provide a brief background of BTL and then go over current operations at the BTL facility.

This slide presents an overview map of the location of BTL. BTL is located at 413 March Road in Kanata, and this location is within an industrial zone adjacent to the Nordion facility. The building highlighted in red represents the BTL facility. Nordion Canada Inc. is highlighted in blue.

The surrounding area is a mixture of residential, commercial and industrial zoning. In the 1960s the BTL building was part of Atomic Energy of Canada Ltd. until 1988 when it was sold to Nordion International. In 2008 it was sold to BTL, which is a privately-owned company.

Currently, BTL manufactures Cobalt-60 teletherapy machines, self-shielded irradiators and particle accelerators, cyclotrons, ranging in capacity from 15 to 70 MeV. BTL also stores sealed sources for two purposes: firstly, it uses sealed sources as either check sources for equipment calibration or as sources for

research projects; secondly, it stores used Cobalt-60 and Caesium-137 sources that are returned from customers. These sources are then reused, recycled or sent to licensed long-term waste management facilities.

BTL also handles depleted uranium from older teletherapy units which use depleted uranium for shielding. BTL has specific procedures in place for handling this material, and depleted uranium is no longer used as shielding in modern equipment.

This slide presents a high-level overview of the operations that are carried on at BTL. Currently, the storage of some of BTL's sealed sources and all hot cell-related work is contracted to Nordion. Irradiators that are manufactured at BTL are sent to Nordion where the Caesium-137 sealed sources are loaded into the equipment. The loaded equipment is then transferred back to BTL for final testing prior to shipment to customers.

In addition, BTL has a source that it keeps at its site that it uses for surveying teletherapy heads. Nordion manufactures the source for the end user, which is shipped at the same time as the empty teletherapy head.

I would like to point out that all work done at Nordion Inc. is under a separate CNSC-issued

licence.

Additionally, BTL manufactures particle accelerators, cyclotrons, which are tested at beam energies below 1 MeV prior to shipping.

I will now pass the presentation over to Mr. Ismail Erdebil, Senior Project Officer responsible for the renewal of the BTL licence.

MR. ERDEBIL: Good morning, Madam President, Members of the Commission. For the record, my name is Ismail Erdebil, Senior Project Officer in the Nuclear Processing facilities Division. I will present CNSC Staff's review of the licence application submitted by BTL.

CNSC Staff rates performance as either fully satisfactory, satisfactory, below expectations, or unacceptable.

CNSC Staff have reviewed the BTL Class 1B licence renewal application, conducted compliance verification activities through all site inspections and desktop reviews and have rated all safety and control areas as satisfactory. These ratings also take into consideration the licensee's past performance, the number of event occurrences and timely implementation of corrective action plans.

While CNSC Staff review all 14 safety control areas, this presentation focuses on three safety and control areas, specifically radiation protection, environmental protection, and conventional health and safety.

When considered together, these safety and control areas provide a meaningful overview of the safety performance of the licensee. Details on all safety and control areas can be found in the written submissions by CNSC Staff.

CNSC Staff assessed BTL's application against the regulatory requirements set out in 2.9.1 Environmental Protection, Environmental Principles, Assessments and Protection Measures.

Radioactive materials at BTL facilities is limited to sealed sources and depleted uranium, which is used as shielding for the sealed sources in teletherapy machines. Therefore, there are no radiological releases that would require controls or effluent monitoring.

As a result of BTL's operations, there are hazardous releases which are due to lead pouring and lead machining.

BTL obtained an environmental compliance approval in 2015 from the Ontario Ministry of the

Environment for atmospheric emissions. In addition, there are controls to reduce emissions such as filters, ventilation, and baghouse that removes particulates from the air before they are released into the environment.

In conclusion, CNSC Staff have determined that environmental monitoring is not warranted and the environment has been and continues to be protected as a result of operations at BTL.

During the current licence period all doses received by workers were well below the regulatory limits. The maximum effective dose to a nuclear energy worker was 0.98 millisieverts (mSv) in 2016 while the regulatory limit is 50 mSv per year. The maximum extremity dose to an individual was 3.70 mSv in 2017 while the regulatory limit is 500 mSv per year.

BTL has controlled areas where workers identified as non-nuclear energy workers are restricted from entering, as there's a potential for exceeding the annual public dose limit of 1 mSv.

Additionally, BTL revised its radiological action levels in 2016 to 4 mSv per year for nuclear energy workers.

Throughout the licence period there were no events related to this SCA except for one incident in

2018 where action levels were exceeded. In October 2018 two Class II servicing personnel performing work inside the BTL facility under a Class 1B licence exceeded radiation dose action levels during a source loading procedure for the purpose of testing the prototype teletherapy head at the facility. There were no adverse effects to the workers, and workers were assigned desk work thereafter to keep doses received below the regulatory limits.

Details of this event occurrence can be found in CNSC Staff's written submissions. The workers occasionally do work at the BTL facility under a separate CNSC licence.

The following table provides doses received by workers during the current licence period.

BTL submitted a conventional health and safety program which focuses on preventing workplace accidents and worker injuries. This program consists of the elimination and reduction of hazards, having a health and safety committee in place, conducting regulatory safety inspections, and the provision of personal protective equipment and first aid.

The health and safety committee oversees the conventional safety at BTL. It performs regular inspections in areas with potential hazards such as

chemical, fire or tripping, and address all employee complaints related to health and safety. Employees are encouraged to express concerns related to their health and safety, and CNSC Staff confirm during an on-site inspection that the issues raised by workers were resolved in a timely manner.

The following table provides the incident reports filed by workers every year; how many incidents were treated on-site versus off-site.

Finally, the last column shows whether the event led to a lost-time incident.

It is important to point out that employees at BTL are required to report all accidents, regardless of how minor. For example, this includes minor cuts and trips, and therefore the high number of reports can be justified.

Details of each lost-time incident can be found in Appendix E of CNSC Staff's written submission.

I will now pass the presentation to Mr. Waleed Khan, Project Officer in the Nuclear Processing Facilities Division.

MR. KHAN: Good morning, Madam Velshi and Members of the Commission. For the record, my name is Waleed Khan, Project Officer in the Nuclear Processing

Facilities Division.

During the current licensing period CNSC Staff conducted 12 on-site inspections and several technical assessments pertaining to all safety and control areas.

In 2015 BTL was issued an order, as they failed to comply with a condition of the Commission-issued licence. This licence condition required BTL to provide an acceptable financial guarantee. This order is now closed and will be discussed in more detail in the following sides.

During an inspection conducted in October 2015 a CNSC inspector found BTL to be in noncompliance with the *National Fire Code of Canada*. This noncompliance was related to a specific model of a dust collector that did not comply with regulatory requirements. A CNSC inspector issued an order to immediately seize operations of that dust collector and to comply with the *National Fire Code* prior to operating the dust collector again.

BTL is currently in compliance with all regulatory requirements and there are no outstanding enforcement actions.

In 2018 CNSC Staff developed a baseline inspection plan for BTL for increased efficiency and

effective regulatory oversight. As a result, there are currently five general inspections covering multiple safety and control areas and five focused-inspection planned for the next 10 years.

Depending on what the licensee has planned for the next year, an additional inspection may be added to the baseline inspection plan. In the event that there are open enforcement items from a previous inspection or that there is an event occurrence, a reactive inspection may be added to the inspection plan.

I will now go over other matters of regulatory interest.

As previously mentioned, BTL was ordered to dispose of or transfer all inventory in August 2015, as they failed to provide an acceptable financial guarantee to the Commission. Following a reduction in inventory, BTL resubmitted a list of inventory, an updated cost estimate, which was accepted by the Commission in July 2017.

Following the acceptance, BTL submitted two letters of credit for a total amount of $1.8 million. The preliminary decommissioning plans are reviewed every five years or when required by the Commission. The next review is to take place in 2022.

CNSC Staff are satisfied that the current

financial guarantee covers the cost of complete decommissioning of the BTL facility.

There are currently two proposed licence conditions that require the delegation of authority from the Commission to act as a person authorized by the Commission. The first one is a generic licence condition for which delegation of authority is common for Class 1B licences. Licence condition 3.2 states that the licensee shall implement a program for reporting to the Commission or a person authorized by the Commission.

Licence condition 15.1, which is a site-specific licence condition, states that the licensee shall not operate a cyclotron at beam energy greater than 1 MeV without prior authorization from the Commission or a person authorized by the Commission.

This licence condition was added to ensure that operation of cyclotrons is done in accordance with CNSC-approved plans.

CNSC Staff are proposing the delegation of authority to the Director of the Nuclear Processing Facilities Division, Director General of the Directorate of the Nuclear Cycle and Facilities Regulation, and the Executive Vice-President and Chief Regulatory Operations Officer of the Regulatory Operations Branch.

I will now pass the presentation back to Haidy Tadros.

MS TADROS: Thank you. Haidy Tadros, for the record. CNSC Staff recommend that the Commission renew the current Class 1B licence for a period of 10 years and authorize the delegation of authority to act as a person authorized by the Commission.

Should the Commission decide favourably on Staff's recommendation, the licence would consolidate all activities at BTL into one licence and will ensure consistent and effective regulatory oversight.

Thank you for your attention. We are available to take any questions you may have.

THE PRESIDENT: Thank you very much. We'll do one round of questions before taking a break.

So why don't I start with you, Dr. Lacroix?

MEMBER LACROIX: Well thank you, BTL, for the presentation and also, Staff, for the excellent presentation.

The burning question over here is BTL has submitted an application for the renewal of a Class 1 facility and simultaneously they submitted a request to revert back to three Class 2 licences.

I'm baffled by the simultaneity here. What is the strategy behind submitting an application for Class 1 and a request to revert back to Class 2 facilities?

The message that I get from BTL is that it seems to me that BTL is chasing two rabbits at the same time, and BTL is looking for the least burdensome regulation. This is the message that I get right now.

So I would like BTL to elaborate on this and then I would like Staff to reply.

Thank you.

MS SOLEIMANI: Thank you for the question. Mojgan Soleimani, for the record.

It was not simultaneously, Dr. Lacroix. We applied in 2018, September 2018, for a renewal of the Class 1B. While we were gathering information for the renewal, it came to light that our operation is not at all what we intended to be back in 2014 when we applied for a Class IB. In 2014 the intention was to test a cyclotron above 1 MeV which was requested by INFN, the research centre that we sold the 70 MeV cyclotron to.

Very shortly after that they realized that this is not possible and the contract was revised as such that we only test the cyclotron up to 1 MeV in the facility. Throughout the five years we never tested

cyclotron and our operation remained the same. So since 2008 up to now our operation has changed very little.

We used to operate under Class II NSRD licences prior to 2014. So while we were gathering information for the renewal of the licence it became more and more clear that a Class IB licence is not something that we would require. We submitted -- because we had a deadline we submitted the renewal application. We would not want to go for a period without a licence at all. We understood that we could not operate without a licence.

We submitted the renewal application, but further discussions happened within the company. We talked to our cyclotron team and other operational teams and everyone agreed that we could go back to our Class II NSRD licences.

In December 2018 we reached out to the CNSC and disclosed our intentions. Subsequent calls and conversations happened. CNSC's advice was to "Renew your licence and we will deal with any other requests you have afterwards because there is no time to issue the Class II, we don't have time to review both."

We agreed to wait until the renewal of the Class IB, but then internally we discussed and we thought that we are taking the Commission's time twice. Like right

after we renewed the licence for 10 years I would have been in front of you again for a Class II and you would have asked the same question from me, "A month ago you applied for a Class I and now you are asking to go back to Class II."

So we decided to disclose our intentions to the Commission, to the CNSC, with a formal application for Class II NSRD licences. That is what we did in February of 2015 -- February 15, 2019, I'm sorry, but we never took -- withdrew our Class IB renewal application, again for the reason of not -- we didn't want to go without a licence, to operate without a licence at any time. Because we were not sure if our Class II licences, the application for Class II NSRD would be approved before the renewal or before the expiration of the Class IB, we kept both applications, the renewal and the new licence applications, in at the same time.

I hope I answered your question.

MEMBER LACROIX: And what is the point of view of staff?

DR. DUCROS: Dr. Caroline Ducros, for the record.

Yes, that conveys some of the conversations that we had. I would like to clarify that

the staff recommendation was that we did not -- it wasn't just a matter of time, it was a matter of not having the supporting information to be assured that the level of waste was below 10 to the 15. As it currently stands, it is not. And it was also to do with the fact that in the previous licence we didn't have the issue of the cyclotron. So the Class II application and the two NSRD applications omit the cyclotron, which, if it is not licensed, is not regulated or overseen.

And prior to the 2014 Class I licence, BTL operated its waste under 10 to the 15 Bq on an annual basis. With the Class IB licence there are no limits to that level of waste and so reverting back we would need enough information to be able to support that that was even possible. And so the advice was we will go through, if you agree, and not revoke your application with the Class IB hearing and later on when you have the evidence to support those other applications we can move forward that way.

I also want to clarify that the Class II and the nuclear substance licences require a Designated Officer decision, so they would not come back before the Commission for those decisions.

THE PRESIDENT: Ms Penney...?

MEMBER PENNEY: Thanks. Thanks for that.

Nobody wants excessive regulation for sure. What we want is comprehensive and appropriate regulation. So the question is for the applicant.

You said that the Class IB licence would be an over-the-top regulatory burden. Can you tell us why you think that? What additional requirements are there associated with the licence you now hold?

MS SOLEIMANI: Mojgan Soleimani, for the record.

Thank you, Ms Penney, for the question.

We have -- as confirmed by the CNSC, we have received a satisfactory rating on all 14 Safety and Control Areas. So it is not that we are going to change our course of operations or perform any differently under any class of licence. So we continue with our operation as is, but one of the reasons that we think that Class I is above what we are doing is the financial cost simply, which is about 5 to 10 times more than Class II NSRD licences. And also, regulatory oversight, it is significantly more in terms of -- I just went through my presentation and I mentioned how many gap analyses were performed, which some of them are a requirement of a Class IB nuclear facility, like extensive environmental monitoring, which doesn't apply to us at all, as mentioned. All we have is sealed

sources and we don't release any radioactive material. Compared to other class IB licensees who deal with open material, they have unshielded radioactive material on site, they have operation in hot cells, we have none of that. All of our sources are shielded in heavy type B(U) containers and we don't use or process.

And I want to clarify about the waste as well. As per the IAEA, if there is another intention or other use for a source, we may not use it ourselves. If a source is returned from the field, it may not be good for our application, for a medical application, but we have been able to successfully transfer those sources to other licensees for other purposes, industrial or research purposes. So although the resident of returned sources at BTL may be in excess of 10 to the 15 Bq, or 1 PBq, not all of them should be classified as waste. Thank you.

MEMBER PENNEY: So just to make sure I understood what you said, you said that it will cost 5 to 10 times more and there is more monitoring, although you said there is no environmental monitoring, other than your provincial permit for air emissions. So more inspections, more requirement from the CNSC in terms of compliance activities; is that which you are saying? Like where does -- or is it the financial guarantee that is more? I

am just trying to get an understanding of what the burden is.

MS SOLEIMANI: I would say both extensive oversight and also the financial cost.

THE PRESIDENT: Staff, did you want to comment on that, please?

MS TADROS: Yes. Haidy Tadros, for the record.

So I would like to maybe bring us back to the definitions and the activities in the Act, because really that is where it starts for us. It starts with not how much is it going to cost to issue a licence, it is going to start with what are your licensed activities, what is your current operation, what do you need to do, and here is the appropriate licence under which you do it. So with that conversation there are three main considerations for this licence.

The first, as we have heard, is the cyclotron, the particle accelerator. It is a piece of equipment that is capable of nuclear energy above 50 MeV. That according to the definition of the Act and the Regulations is a Class IB facility.

The second is inventory. There is waste inventory and as per BTL's current annual compliance report

of the year 2018 they have defined that they have waste over 10 to the 15 Bq. That is a Class IB facility.

The other activities such as the possession and use of the nuclear substances in terms of their operations and how they function with bringing in sources, removing sources, it is a Class IB facility just in the sheer magnitude and complexity of the sources that they deal with.

So those are the three main defining principles and considerations why CNSC staff recommend a Class IB licence.

My colleagues have also defined how efficient it is to have this activity under one licence. So currently all of the programs that BTL has are BTL's programs and to look at it more efficiently by one regulator. So it doesn't come back to the cost. The cost is obviously an element of the regulatory process. It comes back to the definition and the activities of the Act and the Regulations for which the licence is being requested.

Perhaps my colleagues can provide a bit more detail on the level of information that I believe, Commissioner Penney, you were looking for with regards to the financial guarantees and the definitions

internationally.

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

I would like to clarify a couple of things.

I think, Dr. Lacroix, you asked a question with respect to licences and class of licence. I will start with the fact that the information we have before us is a Class IB licence and the only authority in this organization is you, the Commission, with respect to exempt or issue the licence as is. So I would like to leave you with that thought.

So yes, the applicant submitted two applications. One for the other application was not supporting the information for us to provide you with the recommendations. So I want to make it very clear, no one in this organization, even at my level, can exempt any applicant from a requirement, other than the Commission itself.

With respect to, Madam Penney, your question with respect to the financial guarantee, it is irrelevant to what class of a licence it is, it is based on the inventory and capability of the licensee. As you are fully aware, the licensee, previously their performance was

not very stellar with respect to capacity of financial guarantee against the inventory that they have in their possession and that's one of the key factors.

I think we are having a debate on a definition of the waste, but I would like to give some knowledge management here, being the old-timer who worked on the Code of Conduct of Radioactive Sources and the definition of the disused sources at the time.

Internationally we had to find a way to call sources disused sources, that means a source that is no longer capable to be used for its design intent. So in other words, if you are taking Cobalt to a therapy source, that source will reach its decay, a period of time where it cannot be used for patient treatment, not because it is not very radioactive, it is still categorized as a high risk source, but due to patient movement and the length of the treatment, so that is not used for its design purpose.

Internationally we had to call it a disused source in order to allow the return of sources from other member states of the IAEA so that they reduce the likelihood of loss of control of radioactive sources. Hence, you would see the terminology "disused sources". There are member states, for example the U.S., who cannot take back a source that is categorized as a waste, so we

have to call them a disused source. So the intent of a disused source fits within the category of waste because it is management of the source under regulatory control. So you can take the same source that would not be used for patient treatment, but you can use it for irradiation of blood or other types of activities. And I want to make it very, very clear.

In conclusion, the financial guarantee is irrelevant to the class of licence, it is based on the inventory of the possession of the licensee, and so as the licence is put in place based on the capacity of the operation, we cannot manage on a daily basis what the licensee is going to do. So this is the capacity. So they manage their operations on a daily basis and in a facility like BTL they improved quite significantly as a licensee, but the only barriers we have on many of their activities are administrative barriers and then that is one of the key elements that we put emphasis on management system procedural element at the Class IB level.

THE PRESIDENT: Mr. Jammal, I have some follow-up questions for some of the things that you have said, just for clarification.

So BTL has said that the definition of waste, and they quote the IAEA definition, that waste is

only if there is no further use and then it is going to get disposed, and because of their reuse and recycling their submission is that their inventory is less than 10 to the 15 Bq. Are you disputing that statement?

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

I will pass you on to my colleague to give you the precision. My understanding and my information that I have is that we could have done inspections at BTL by our staff, and the inventory that they have in their possession for the disused sources and the waste of nuclear substance is 7×10^{15} Bq. And I will refer it to Dr. Ducros for confirmation.

So from our perspective, is the inventory and the residual inventory that exists onsite at that facility greater than 1×10^{15} Bq.

THE PRESIDENT: So again, we are getting into the definition of waste. Can you show us details on what the inventory is, what BTL says is really waste, because you are planning on reusing or recycling some of it, and staff may have a different interpretation of that?

And while you are pulling that, the second one was around capability and the cyclotron. You mentioned that it's only administrative barriers, but what we heard

from BTL is they have significant design barriers to prevent the cyclotron from being tested at greater than 1 MeV. And I don't know if you definitively stated that, but you have no intention ever, at least not in the proposed licence period, to test greater than 1 MeV.

So the question to you, Mr. Jammal, is these are more than administrative barriers or are they not sufficient?

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

There are always administrative barriers that do exist. The cyclotron is one of -- what is presented by BTL is one way of controlling the beam and its energy. If you take it at the global level, from a regulatory perspective, an exposure, a radiography exposure source has a shutter and capability of keeping the source in a shielded position. We have had many events that were inappropriate handling of the shutter or the closure. I'm not saying it's the same thing happening here, but if you look at the cyclotron -- I'm going to get into the details with respect to the beam control. It is very easy, you can take that barrier and the beam will -- and the particle will get accelerated to a level by which it is going to hit the target and then potentially exceed the 1 MeV.

When I say administrative barrier, if the facility was before the Commission to test up to 70 MeV, we require them to have dedicated shielding around that accelerator in order to operate at that level. When I say administrative barrier, if a service personnel takes one screw out, then you have exceeded the 1 MeV and you are in the operation mode of that cyclotron.

So when I say administrative barrier, we need to have the proper regulatory oversight of that facility. It doesn't matter if it is Class II or not. There are requirements in place for adequate shielding because we take the safety case with respect to you lose control of the barriers that currently exist. So you need to have in place emergency buttons, you need to have in place a beam control, you have to have in place many layers and defence in depth with respect to the testing and the operation of that facility.

And that is what I mean about administrative barrier. You have two things: a barrier by which the -- on the cyclotron element is being installed and can be removed easily, even though it says "Do not remove", there is a sign on it; the same thing applies on the waveguide and the generation of the particle.

And again, there are other elements with

respect to the licensing itself. You have the arcing current, a dark current and many other potential capabilities that could expose a worker for inappropriate administrative barrier or inappropriate following the procedure that currently exists. And that is what I mean by administrative barrier.

THE PRESIDENT: So you have given us a lot to think about, I think it is a good time for us to take a break and then when we come back we will get BTL to respond and then staff to respond. So why don't we come back at 10:45. Thanks very much.

--- Upon recessing at 10:32 a.m. /

Suspension à 10 h 32

--- Upon resuming at 10:45 a.m. /

Reprise à 10 h 45

THE PRESIDENT: Thank you.

So we will continue from where we left off and what we will do is the first item, which is the cyclotron and its capability of being operated at greater than 1 MeV by BTL. You have heard from Mr. Jammal the regulator's concern, the CNSC staff's concerns about that. So we will get BTL to comment on that and then we will see what other questions -- and staff, if you have anything else to add on that particular issue -- we will come to the

waste one later -- then we will see if the Commission Members have any additional questions on that.

So over to you, Best.

MR. SABAIDUC: For the record, I am Vasile Sabaiduc.

Thank you very much for the questions from the Commission, also the comments from the CNSC staff. Being a science engineer in particle accelerators for 35 years and working on accelerators for way more than that, from high school, I have very in depth knowledge of the entire science and engineering which applies, and particularly with a quarter of a century in cyclotron for radioisotope production and research in Canada.

Firstly, a couple of comments which I would like to address.

There are no dark currents or just magic arc currents which would apply to these particle accelerators. And again, so the accelerator itself is not an open source. We cannot compare it with any other radioactive source based on radioisotopes either in use or produced.

There are presently in the world four to six manufacturers of medical cyclotrons for various energies. None of them is testing and injecting the beam

above 1 MeV in their machine. There is no international regulation on the cyclotron as a product. The entire industry of the particle accelerator, regardless that it is for radioisotope research, circular linear accelerator, it is not regulated. These are accelerators which are built with unique components and sometimes in multiples for the medical world. In particular a 70 MeV cyclotron, there are only three in the world, from which it happens that the Best Theratronics 70 MeV is the most performant, which has been demonstrated to the entire community and research laboratories.

The question of capability of our design, we all know and I emphasize again that Best Theratronics is a company which operates under a strict quality control system and regulatory, so ISO 9001 and the medical device manufacturing system 13485, and this is complying absolutely with all the requirements, which is the documented way for all the activities that are performed in the company, including for the cyclotrons.

So that means later that if we do have factory documentation which is active, it is in the proceeding and it has to be implemented in place, nobody will just do different. So if we do have a device which we declare that it will be there and we just ensure multiple

safety measures to be sure that that is not happening, to accelerate the beam above 1 MeV. That is a fact. It is there to say that it is not a questionable or debatable option. Again, none of the manufacturers are accelerating beams above that energy.

An additional reason that we are extremely careful not to do that is if anything would happen and the beam will be accelerated, it would soon become radioactive, and to ship a larger cyclotron like that, it is absolutely impossible because you cannot package it. One of the reasons that the Italian laboratory reverted, and they are just contractual requirement, because they knew that we cannot ship the cyclotron to them if we accelerate above 1 MeV. So the parts of the components, they could become radioactive and the machine has to be disassembled because it is 170 tonne electromagnet. It is impossible just to ship -- to disassemble and to ship a cyclotron of such magnitude. That means there will be no manufacturer of 70 MeV cyclotron, above 50 MeV in the world, which we can ship their equipment. These are extremely large machines.

So again, the physics and the quality assurance program and the practical testing which is done by any manufacturer in the world, not only Best Theratronics, it is to ensure that none of these components

they are becoming radioactive. Therefore, the equipment can be safely shipped without the additional strained difficulties of shipping radioactive materials.

THE PRESIDENT: Thank you.

Mr. Berube...?

MEMBER BERUBE: Okay. So I am listening to both sides of the discussion here and I am just trying to get some clarification. I think really what I'm hearing is there is some debate as to what capability really means. On the CNSC side I believe capability means design capability, full design potential capability. From the BTL side I think you are talking about the restricted operational tested capability based on blocking. Which definition is applicable is really the debate here at this point. Is this correct? People, do you agree on that? CNSC staff?

MS TADROS: Haidy Tadros, for the record.

So fundamentally I would agree that it comes down to that, but I would also want to stress that for the purposes of the Act, to limit risk we need to look at it from a holistic perspective, not get into defining who does what, when and where. So for the purposes of the Act, to ensure that risk is limited and the provision of being able to, the capability of nuclear energy being

produced from this piece of equipment is there, and that is how staff is looking at it per the definition and per the activities that are being proposed to be used with it.

MEMBER BERUBE: A comment, BTL, on that?

MR. SABAIDUC: The comment would be that no industry involved with a cyclotron does act under any regulation in regard to the producing of radioactive material. So BTL, Best Theratronics Limited, is just manufacturing the cyclotrons and testing them with the sufficiently safety measure underneath this energy 1 MeV.

And just coming back to the slide that we presented, this safety measure had been established by the Vancouver Cyclotron Laboratory, which is one of the most reputed scientific engineer expert bodies in the cyclotron design in the world. So we are guided by measures which have been defined like an industry standard.

MEMBER BERUBE: So just one other conversation that I need to have in that conjunction in terms of -- you are a design engineer, you are the right gentleman to ask this question. So when you are designing a 70 MeV cyclotron, how do you certify and test it for 70 MeV without actually spinning it up?

MR. SABAIDUC: The science and engineering of cyclotrons is dated close to 100 years ago. The first

was built and designed in 1928. Today these machines, which are complex devices, we started designing them, engineering after the model that has been simulated. So there is an extremely high level of certainty that once the trajectory of those -- final trajectory of the particle inside that cyclotron has been simulated with existing software records which are designed in laboratories, there is a practice of over 40-50 years which is documented that if the calculations are proper the machine it is performing. In other words, a beam which is accelerated for only three or four turns to low energy, below an MeV, the beam is coming out of the machine.

There are other scientific engineering criteria to estimate there have been losses. There is an entire set of parameters which are used to characterize this machine which are just listing in terms of pages, but the science and the software has been -- is available today for the manufacturers has been proven multiple times. And our machine 70 MeV, it's one of the medium-sized cyclotrons. Other research laboratories, they have way, way larger accelerators, which are calculated -- we build them with a high degree of confidence. It is demonstrated they outperform within their performance, within the specification. That is the reason that we are confident

that testing it at low energy, the beam it is there at present.

I would like to -- there are too many just parameters to mention. And again, there are way more parameters than can be implemented.

THE PRESIDENT: No, I think Mr. Berube got what he needed from you.

MEMBER BERUBE: Thank you.

THE PRESIDENT: Thank you.

Dr. Demeter...?

MEMBER DEMETER: Thank you.

Keeping on the cyclotron theme I want to talk about the hold point. So the hold point is if the licence applicant chooses to operate the cyclotron above 1 MeV that there is a hold point, but I want to get a sense from that hold point that if they are a Class IB facility with a cyclotron that can exceed 50 MeV, is the facility designed such that it can deal with the radiation safety issues relative to shielding? Because if they are Class IB it doesn't matter whether -- if they go above 1 MeV and the facility isn't capable, it doesn't matter because you can't go above 1 MeV if the facility can't deal with the shielding.

The second thing is, if they are a Class

IB facility and there is a hold point, what are you missing that requires you to have that hold point? It would seem that if they are a Class IB facility that has cyclotrons that are capable of more than 50 MeV they should have provided you all the information that required them -- that would allow them to operate safely above that. So what is missing? Why is this hold point in place I guess I'm asking?

DR. DUCROS: Dr. Caroline Ducros, for the record.

Yes, so the hold point is there in the event that BTL would want to test above 1 MeV, like you said, and what is missing -- so the hold point is so that they would have to come back to us with more evidence of the safety measures that would need to be put in place to go above the 1 MeV. So they aren't there now. They would have to provide evidence of that. They include a shielded -- more shielding to the facility, as you mentioned, interlocks and safety system to prevent access during operation. So those measures are not in place in the facility currently. And we are not disputing that under 1 MeV that there is any safety issue, but to go above 1 MeV they would have to come back to us and demonstrate that capability, that protection.

MEMBER DEMETER: Okay. So those are pretty structural things, facility design issues as well as radiation safety program issues?

DR. DUCROS: Yes. And to get into the details of that, I would pass it back to the experts on the accelerators to discuss more clearly what those are.

MEMBER DEMETER: From the applicant's point of view, does that concur with your understanding of your facility and its capabilities?

MS SOLEIMANI: Mojgan Soleimani, for the record.

Yes. We do not have the infrastructure to support testing above 1 MeV. We did a safety analysis report when we submitted the application for the Class IB, the safety analysis report, to turn the area that cyclotrons are tested, turn them into a bunker practically, but we never went ahead with changing the facility because, as I mentioned, the contract was such that we only test up to 1 MeV at the facility and the rest of the testing will be done once the cyclotron is installed at the end user facility and the testing will be done there in their bunker.

MEMBER DEMETER: Okay. Thank you. That clarifies that.

THE PRESIDENT: You mentioned there are many other such huge cyclotrons around. Maybe the question is for CNSC staff. So how are they regulated elsewhere as we compare to what is in front of us today? Can we draw any parallels?

DR. DUCROS: Dr. Caroline Ducros, for the record.

To put some context around the international piece that we have been discussing, the Integrated Regulatory Review Services (the IRRS) and the International Atomic Energy Agency (the IAEA) did an audit of the CNSC in 2009 and one of the suggestions was to ensure that there is a comprehensive and consistent safety regulation and oversight of low energy electron accelerators. And CNSC's response to that was that it intends to extend its regulatory oversight to include all electron accelerators with accelerating potential equal to or greater than 1 MeV.

So in terms of the interpretation of potential, that is equatable to capability, and when we are talking about accelerators that are not low energy accelerators but high capability accelerators, CNSC staff reviews this in the sense that internationally this is the direction that we have been guided to follow.

THE PRESIDENT: But is that the direction that -- I mean maybe there is an identical manufacturing facility elsewhere that produces 70 MeV cyclotrons but only tests them to 1 MeV. Are they regulated differently?

MR. JAMMAL: It's Ramzi Jammal, for the record. To complement Dr. Ducros' comment. Ms Velshi, you are asking what is happening on the international scene. If you look at the safety standards for the IAEA, there is a very well-established requirement with respect to activities and facilities and part of the activities encompass the accelerators. So the cyclotron is a particle accelerator, of course it has its own special characteristics.

So internationally if we take -- I can list many countries. Let's take the U.S. The U.S. NRC regulates some of the particle accelerators but they have a state agreement in place that oversees that production. If you take a look from a safety perspective, no one really relies on administrative barriers. So you have the facilities where depending if it is a self-shielded cyclotron -- not self-shielded but you have in place emergency stop buttons at the facility itself above and beyond what is on the accelerator itself. So there are the shielding control measures in place as a facility design so

that if there is any failure in the operation of the accelerator, so you have the physical barriers in place in defence in depth. So this is where the international benchmarking kicks in.

Are we at par with respect to the Class II requirement or Class IB requirement or from a safety requirement? The answer is yes, we are at par.

What Dr. Ducros has mentioned was when Canada was undergoing in 2009 an IRRS mission there was a gap on the level of the regulatory oversight by the CNSC, rather than the actual accelerator itself. So the proponent mentioned potential activation of the cyclotron. The activation will occur at a significant level if the testing is above 1 MeV because the proton is going to interact with the shielding, so then you will have an activation of the product.

We are not disputing the contractual agreement of the proponent, we are looking from a safety perspective and the capability of the machine while it is controlled via software or when there is a loss of control via the software, so, in other words, what other barriers are in place to ensure the safety of the workers and mainly the public.

THE PRESIDENT: So let me ask it slightly

differently. Do other countries define capability differently than the CNSC? Do they expect additional controls?

MR. JAMMAL: The answer is yes.

When you look at the safety standards of the IAEA, it's you oversee the regulatory control based on a capability of the maximum of the design. It is the capability with respect to the maximum of the design. No regulator is going to be watching on a daily basis, are they going to go above or below 1 MeV. That is the responsibility of the licensee, to make sure that they are working within their own safety conditions.

THE PRESIDENT: Thank you.

Did you have anything to add?

MR. SABAIDUC: For the record, Vasile Sabaiduc.

So we respectfully understand the comments and new information has been brought. I would like to bring to the attention of the committee that nothing applies to cyclotrons. So the regulation that has been mentioned from IAEA, it was for electron accelerators. 1 MeV for electron accelerator can only produce x-rays, no nuclear reactions. And the regulation again, as I recall it, mentioned it applies to facilities which are operating

this machine, not their manufacturers.

THE PRESIDENT: Thank you.

Dr. Lacroix...?

MEMBER LACROIX: From what I perceive here is that CNSC looks at the safety regulation of cyclotrons based on design, while BTL looks at -- the point of view of BTL is from the operation itself. So am I correct when I say that?

MR. SABAIDUC: So we did state that the cyclotron, while it is designed, in fact, it is not capable. So the regulation to -- the letter of -- the wording is mentioning applying to the capability of a cyclotron and we insist it not be confused with the capability to the design.

MEMBER LACROIX: And I do have a question, it might be a naive question, but we regulate a cyclotron according to the energy of the beam. What about the power of the beam itself from a radiation protection point of view? Does the current enter into the equation?

MR. SABAIDUC: The beam being less than 1 MeV, the power associated with the beam accelerator to low energy is insignificant. It is within 100 watts.

MEMBER LACROIX: Staff...?

MR. BROEDERS: Mark Broeders, for the

record. I am the Director of Accelerators in Class II Facilities Division.

So indeed, Dr. Lacroix, there is consideration of both beam energy and beam current. The beam energy is a convenient demarcation point to separate different groupings of accelerators into lower risk and higher risk facilities, i.e. Class II and Class I, but indeed once that determination is made, then the safety case that is proposed by the applicant would speak to the current and not have a direct impact, a proportional impact on the amount of radiation you would expect to see in the facility and then the commensurate physical design expectation would be scaled according to that expected current. So absolutely, the current and the beam energy together are important considerations when evaluating the appropriateness of the proposed design of the facility.

THE PRESIDENT: Ms Penney...?

MEMBER PENNEY: So if we go with -- or if the decision is separate licences, it means that the cyclotron, do I understand from staff that the cyclotron is not regulated?

DR. DUCROS: Dr. Caroline Ducros, for the record.

Yes, because in accordance with the Act,

the definition of the Act for a Class IB facility includes particle accelerators that are not Class II prescribed equipment. So if there is a particle accelerator that has a capability above 50 MeV it is a Class IB facility. So the decision at hand isn't whether this is a Class I or a Class II facility, it's whether it is a Class I facility or not, and if it's not then there is no regulation or oversight of the particle accelerator, which in the staff's opinion is not a risk that is worth taking.

MEMBER PENNEY: And so that aside, if we went with the three separate applications for some reason, is there a way to combine them for regulatory efficiency?

DR. DUCROS: Dr. Caroline Ducros, for the record.

Yes. So currently their Class I -- BTL's Class IB licence has all the activities that they have applied for in the Class II application and the two nuclear substance applications, minus the particle accelerator, the cyclotron. So they are combined now. Everything that happens at BTL is combined now, other than a servicing licence.

MEMBER PENNEY: But my question is, if we decide that they are Class II activities, can the applications be combined into one licence to reduce

regulatory burden?

DR. DUCROS: I am going to pass it back to the experts in accelerators and Class II facilities.

MR. MOSES: Colin Moses. I am the Director General of Nuclear Substances Regulation, for the record.

First of all, just to reiterate that it is not just the cyclotron operations that led to our conclusion that those activities are Class IB licences and so irrespective of the Commission decision on the capability there is also the resident inventory and waste inventory in the facility that would be factored into that decision.

Notwithstanding, we do offer the option of consolidated licences, so in many cases cyclotrons operate and produce and handle isotopes. If those operations were considered separately, then that would require a Class II licence for operation of the cyclotron and a nuclear substances and radiation device licence for the processing of the nuclear substances. However, for purposes of efficiency we offer consolidated licences to licensees who prefer to manage their operations under a single program.

THE PRESIDENT: Thank you.

Are we ready to move to our next issue on

waste then?

So staff, do you have a slide to show us what is the inventory and what is waste and not waste, please?

DR. DUCROS: Dr. Caroline Ducros, for the record.

Yes. I would point you to CMD 19-H2.A, the staff supplemental CMD, on page 5, Table 1. It's the management of waste at BTL during the licence period and this information in the table has been extracted from the 2018 annual compliance report, where BTL has identified waste as including sources that have no use beyond their original intent and are destined to be recycled or sent to long-term waste management. So in terms of the total number, there is 3.58×10^{15} Bq of waste that is either sent for reuse, transferred or shipped to another supplier, or else disposed.

THE PRESIDENT: So before I open it to the floor, just for clarification, BTL, your position is that it is only the disposal piece that you think is waste, not the reuse and the transfer piece?

MS SOLEIMANI: That is correct.

THE PRESIDENT: Okay. Mr. Berube, we will start with you.

MEMBER BERUBE: So we have the same problem we have with the cyclotrons and that is in the definition of what waste constitutes. So the issue really is to understand that underneath the regulatory environment, right, to get that straight. So just to be very, very clear, how does the CNSC define waste?

DR. GLENN: Karine Glenn, for the record. I am the Director of Waste and Decommissioning at the CNSC.

The definition of waste that we use is that it's a substance for which there is no intended use or no further intended use. With respect to disused sources, as Mr. Jammal has pointed out, the definition is slightly varied in order to allow certain member states to accept the return disused sources. So it is for which it is no longer intended for its original purpose and that is the definition the IAEA uses and it goes further to say that there could potentially be alternate uses or recycling of that material.

When we manage radioactive waste, so going back to the CSA standard as well as the IAEA guidance, we talk about waste hierarchy. And when we talk about waste hierarchy, it's a number of principles and steps that we follow when it comes to waste management for radioactive waste management.

And the first principle of that is avoiding waste. So you're trying to avoid producing waste.

The second one is you minimize the amount of waste produced.

After that, the next step is looking a reusing, recycling, and then your ultimate, final path that you could -- that we look at is disposal. So it's still all considered to be waste. The exit path is different. It might be recycled, it might be reused, or it might be disposed of.

Canada reports the disused sources as part of its waste inventory to the Joint Convention, and it has its own section in the Joint Convention. And it is included in the national inventory. And the latest one that was produced in 2017 includes the Best Theratronics disused sources as part of the waste inventory.

MEMBER BERUBE: Just to clarify, I'm trying to get this straight in my mind, because here it's very, very critical that we all understand the definition.

So basically, a source is produced. It's put in service. It's taken out of service because it's no longer useful in that particular application. And at that point, the IEAE says that this is now defined as waste. And what we do with it after that point is really depends

on what it might be useful for at that point. Is that correct?

DR. GLENN: That's correct. If we follow the waste hierarchy principles, that's exactly how it proceeds.

There is no way of knowing *a priori* what return disused sources will be recycled, which ones will be reused, and which ones will be eventually be disposed of. So until such a time as that decision is made, it is considered to be waste.

THE PRESIDENT: Thank you.

Dr. Demeter? So Dr. Lacroix? Any waste questions?

MEMBER LACROIX: Well yes, on Table 1, provided by CNSC staff, the total waste is 3.5 10^{15} becquerel. Does it include all sources, that is high-risk to low-risk sources?

DR. DUCROS: Caroline Ducros, for the record.

Yes, it does.

And I did want to follow on from my colleague, Madame Glenn's response. Since we don't know what *a priori* the waste will be used for once it's sent, it's worth noting that CNSC staff did an inspection at the

site on April 16th, and at that time, the inventory of that type of waste was 1.6 times 10^{15}.

THE PRESIDENT: Ms Penney?

MEMBER PENNEY: Just a question about when they were -- when Best Theratronics were actually licensed as a Class II facility, did their waste exceed this inventory? And did we -- or has it increased over the last licensing period, which is five years?

DR. DUCROS: Dr. Caroline Ducros, for the record.

Just to clarify, they have -- that would be under our nuclear substance licence that they had before the 2014. The Class II is just for the teletherapy machine, the prescribed equipment.

But to answer your question, yes, it remained below 10^{15}. When the class -- some of that waste was resided at Nordion Inc. at the time. And after the 2014 Class IB licence was put in place, the limits were -- there was no limit anymore, so there was less scrutiny over -- less need for scrutiny to keep it under 10^{15} becquerels throughput.

THE PRESIDENT: And question for Best again, in Table 1. In 2016 and 2017, even with your definition, you are over 10^{15} becquerel. **MS SOLEIMANI:**

Mojgan Soleimani, for the record.

Ms Velshi, that table shows overall sources received throughout the year, not an inventory at any given point in time. This is the total activity that received within the year.

THE PRESIDENT: So comparing this to 10^{15} inventory cap is not appropriate, is what you're saying.

MS SOLEIMANI: It is not.

THE PRESIDENT: So where do we get a snapshot of what's the maximum you have at any given time? Do you have that --

MS SOLEIMANI: I think April 16th inspection date is a good example of what we had on site on the date of the inspection, which was 1.6 petabecquerel of cesium and cobalt sources.

I would like to also mention and go back in time. In 2014 we had a resident inventory of disused sources at Nordion. All of that has now been disposed of at CNL. So they were legacy sources. We paid a fortune to get rid of all of that, and they are not in our licence anymore.

As for the current operations, in any given year, we receive around 3 petabecquerel, 3 times 10^{15} becquerel of disused sources.

On the day that the inspection happened, April 16, we had 1.6 petabecquerel, but around 1 petabecquerel of that, we have applied for an export permit. They are leaving our facility within the next two weeks. They are going to US for recycling.

So if that inspection had happened a month after, our resident inventory would have been 0.8. So I don't think that's a good indication inventory at any given time if we are within those limits of 10^{15}.

Our argument is what are the risks to those disused sources that are stored in our facility compared to new sources that are a lot more active and we have an inventory of them? What is the risk to those returned sources that is higher or puts us in a category of higher risk compared to the new sources that we have in inventory?

I think the purpose of the Act when they talk about waste is for waste facilities where they manage and handle the waste, meaning they have open material. At no time at BTL for new sources or returned sources we handle the sources in a way that a waste facility would handle, meaning in hot cells and open material.

Sources that are returned to our facility are in type B(U) containers. New sources that receive at

our facility are also in type B(U) containers. What is the difference between the two? And why is the waste so highly regulated and not the new material?

THE PRESIDENT: Thank you.

Staff comment on that?

MS TADROS: Haidy Tadros, for the record.

So maybe what we can do is start with the question of inventory as its total. Because I think we're zeroing in on waste, and it's important to zero in on the waste at one point, but I think it's also equally important to look at the current operations that are being proposed in their totality.

And as was stated, there is quite a heavy regulatory oversight on the new sources. They're category 1, 2, and 3 sources. They are highly regulated. I can refer to my colleagues who have the experience of what it takes to ensure from a security perspective, from an oversight perspective, and RP perspective what is involved. So that aspect of the conversation I think needs to be clear. It's not that these new sources aren't regulated.

So we come back to inventory. And even through this last conversation, what we've clearly seen is the nature of the operations at BTL is such that at any given time there could be new sources brought in, there

could be existing disused sources, there could be disused sources that are coming back.

And the operations as it currently exists gives a portrayal of an environment where, according to the definitions of what we have to work with of what is a nuclear facility and how do we delineate between the different classes of these facilities, that BTL is defined as a Class IB facility, given its operations.

So with that, perhaps I can refer to Dr. Ducros to give information on the inspection itself, because again I'd like to come back to something, President Velshi, you said about a snapshot in time, what does that mean. So Dr. Ducros can provide that information.

DR. DUCROS: Hi, Doctor Ducros, for the record.

Yeah, a couple of points. I understand the point being if the inspection had happened at another time there may be more waste. What is before staff when they assess an application is what is there now and what has happened over the last licensing period and what has happened over the last year according to the annual compliance report. So we cannot make recommendations to the Commission based on a hypothetical program moving forward.

At the inspection on April 16th, we looked to see what is the snapshot on the day of what is there. And our inspection findings was that at the time there was 1.6 times 10^{15} becquerels of inventory for which we could not foresee what the future use was, so back to CNSC's interpretation of waste based on the IAEA and CSA standard.

Having said that, in terms of regulating appropriately and giving the appropriate amount of oversight, it wouldn't be sufficient to be exactly at 1 times 10^{15} becquerels either. There would need to be enough of a buffer, because it's not efficient regulation to go on a daily basis and verify. This is the point that Mr. Jamal made earlier. It is up to the licensee to demonstrate that they can comfortably stay below the limits where the regulations would push this to a Class IB facility.

So in our view from the past year and for the past licensing period, we cannot make the claim that they are below that 1 times 10^{15} becquerels, and in which case they are a Class IB facility in terms of resident inventory of waste.

THE PRESIDENT: Thank you.

Any other waste questions? If not, Dr. Demeter, last round of questions.

MEMBER DEMETER: Thank you very much.

I'd like to refer to the applicant's CMD Table 6, which is the Class II Servicing NEWs - Effective dose (2018 monitoring ...) I'm using theirs because their 2018 data is updated since the CNSC.

So if I look at the maximum individual effective dose from 2014 to 2018, which is -- sorry, the page is 24, Table 6.

MS SOLEIMANI: I'm sorry, is that BTL's submission or CNSC's submission?

MEMBER DEMETER: It's BTL 19-H2.

MEMBER PENNEY: That's CNSC.

MEMBER DEMETER: That's CNSC?

MEMBER PENNEY: [indiscernible - speaking off microphone]

MEMBER DEMETER: Okay, I just read -- oh, sorry.

So I'll save the question to the licence applicant. Now I got to find the table again.

Okay, so sorry, it's CNSC's document, but it's the same table in yours, but their October -- their 2018 data's updated a bit.

So anyways, the --

UNIDENTIFIED SPEAKER: [indiscernible - speaking off microphone]

MEMBER DEMETER: Table 5.

UNIDENTIFIED SPEAKER: I thought it was Table 6?

MEMBER DEMETER: Table 5, and Table 6, but either of them, page 24.

This is the maximum effective dose between 2014 and 2018. And noting the regulatory limit is 50 millisieverts per year with an average of 100 over five years, so it's 20 a year over that five-year period.

What I'm noticing is this trend of going from 0.46 to 8.92. And although all of that is below the regulatory limit, it's a 20-fold increase over that five-year period in the maximum individual effective dose. And there was no comment in either CMD about the trend.

So I need to know why we've gone from 0.46 to 8.92. What's changed in your operations to increase the maximum effective dose?

MS SOLEIMANI: Mojgan Soleimani, for the record.

The operation stayed the same during the licensing period.

The jump in 2016, '17, and '18 partially is because of the lack of having in-house trained source loaders and we were using our Class II nuclear energy

workers that are -- their doses are usually reported on the Class II -- helping out with the operation inside the facility. So therefore, their doses was also reported on the Class I doses reported.

So and also in 2018 the jump is because of that incident that happened during a source loading, and two individuals got more than usual exposure, although well within the regulatory limit. But their doses were higher for that specific year. So the 8.92, around 8 millisieverts of that is related to that one incident.

MEMBER DEMETER: So as I understand it, some of your workers, their doses are ascribed to this, and some are ascribed to that. And you moved some staff over so that it changed where the dose was ascribed?

MS SOLEIMANI: We don't move them -- Mojgan Soleimani, for the record.

We don't move a staff. Some staff are under Class II.

MEMBER DEMETER: Yeah.

MS SOLEIMANI: That's our servicing licence that they service equipment. And some of our staff, the other staff are under Class I because they are manufacturing personnel.

MEMBER DEMETER: Okay.

MS SOLEIMANI: But it is specific for those three years that you see a higher increase in activities because the services staff, who normally have higher doses compared to the manufacturing staff, were also helping out for on site, inside the BTL facility operations, and then therefore their doses were also transferred on this licence too -- or reported under this licence as well as the Class II licence.

MEMBER DEMETER: And from CNSC's point of view, did this trend -- does that make sense from an operational view that this trend is reasonable based on their operations and the transfer of staff?

MR. ESTAN: Diego Estan, Radiation Protection Division, for the record.

I think it's important to note that specifically the 8.92 millisieverts in 2018 was due to that incident, that action level exceedance. And it's not really appropriate for training purposes to include something that's this kind of event.

So if you're to remove that event, the highest dose would've been around 1 millisievert, which kind of makes the trend disappear. So you'd have 0.4, 0.8, 2.2, 5.3, and then 1 if you remove the event. And so we're not concerned.

MEMBER DEMETER: I would suggest if you only have four years of data, you still have a trend. So if you didn't have 2018, how would you have interpreted that trend? I understand your point that 2018 would drop out. But you've got a trend for four years before that. How do you as a regulator explain how you interpreted that?

MS PURVIS: Caroline Purvis. I'm the director of the Radiation Protection Division.

I think I'll just complement Mr. Estan's answer in saying that there does appear to be a trend. I think that it's not surprising, given the explanation from the licensee.

Further complicating sort of the analysis of the data is the combining of the Class II servicing results with the nuclear energy workers that are not conducting that activity.

One should also note that during the 2015 to mid-2017 period, the duties were restricted and the licensed activities were restricted due to an order. So when you see the 2017 -- '16, '17, and '18 data increasing, that's a function of them resuming normal operations.

MEMBER DEMETER: Okay, thank you, that does help.

THE PRESIDENT: Dr. Lacroix?

MEMBER LACROIX: From what I gather, BTL is no longer using depleted uranium as a shielding material. Is that correct?

MS SOLEIMANI: Mojgan Soleimani, for the record.

That is correct.

MEMBER LACROIX: Okay. Also I read in the CMD 19-H2 on page 42, a document from CNSC, that BTL is in the process of completing an analysis concerning the implementation of CSA standards on the management of low and intermediate waste. So what are these wastes?

MS SOLEIMANI: Mojgan Soleimani, for the record.

When we took over the company back in 2008, a lot of legacy sources were transferred as part of the liability that was transferred to BTL. So our focus has been all along disposal, safe disposal or transfer to other licensee of these legacy sources.

So I can report that all those legacy sources, which is over 500 sources, cobalt and cesium, have been successfully removed from our licence.

MEMBER LACROIX: And these sources are considered as low and intermediate radioactive sources; right?

MS SOLEIMANI: That is correct.

THE PRESIDENT: Ms Penney?

MEMBER PENNEY: Back to radiation protection.

So in your presentation, and maybe you've already given me this answer, I'm looking at slide 17, Radiation Protection, and it tells me total workers monitored, average dose, maximum dose -- or in yours it's average effective dose, maximum individual number of NEWs. And then in CNSC staff it's total workers, average dose, maximum -- and so they're different numbers, different numbers of NEWs, different numbers of average dose.

And so my question to both you and staff is why are these numbers in radiation protection so different?

MS SOLEIMANI: Mojgan Soleimani, for the record.

I'm sorry it's a bit confusing, because as mentioned, we have two licenses. And we have nuclear energy workers that work under Class II licence, and we have nuclear energy workers that work under Class I licence.

We also have nuclear energy workers who are our staff that travel around the world and perform

servicing to our radioactive devices or our teletherapy units.

For the purpose of monitoring the dose to the individual, which is the most important factor for us, we are not separating the doses that are for the work that is performed in Canada and abroad. So we have -- they have one badge that they use throughout the year for all the work that they do, regardless of being in Canada or abroad.

And also when those service personnel are involved in operating an activity that is covered under Class I, which is everything we do inside the facility, then their doses are transferred to our Class IB licence as well. So there is duplication of reporting of doses.

So if we include the Class II servicing licence or if we don't, and I think the discrepancy is because of that.

MEMBER PENNEY: Your number of NEWs is less than the number of NEWs that's in the CNSC slide, which is slide 17. And so I am confused. And the doses are also different.

You know, CNSC, do we get the proponent to report combined totals when -- you know, or do they report separately for their two licences? I wasn't aware they had two licences.

DR. DUCROS: Caroline Ducros, for the record.

So on our second slide, slide 18, to clarify for the 2018 numbers, those are the numbers that went to April 30th, which is based on when we had the licence application data. So our numbers in our table are based on the information that we received as part of the Class IB renewal application.

I would have to get BTL to confirm, but the numbers in their table I think are for the full year. Is that correct?

MS SOLEIMANI: That is correct. Our numbers are for the full 2018, including the last quarter, the last two quarters, which I don't think CNSC had at the time when we applied for our licensing application.

MR. MOSES: And sorry, Colin Moses, director general, Nuclear Substance Regulation, for the record.

Just to clarify too with respect to your question around the licences that BTL holds. So this hearing and the discussions today are about the activities that they undertake at the Best Theratronics Limited facility in Kanata. They also undertake servicing of Class II equipment across Canada. And so the Class II licence

that was referred to is to cover those activities that are in large part done at third parties or other locations outside of that Best Theratronics facility in Kanata.

THE PRESIDENT: So a follow-up question on when Best employees are outside Canada, what are the requirements at to the inclusion of those doses and what if something happened there? Like, what's our jurisdiction there?

MS TADROS: Haidy Tadros, for the record. Our colleagues in radiation protection deal with such circumstances, so I would ask Ms Caroline Purvis to give some details there.

MS PURVIS: Caroline Purvis, Director of the Radiation Protection Division, for the record.

With respect to this licensee, because they have personnel that do travel across the country, but also, as I understand it, internationally, they're Canadian workers, they have a responsibility to monitor their exposures. This is not the only licensee, there's others that we licence as well.

For all intent and purposes, they are maintaining their exposures below the dose limits that are prescribed in Canada, and we would be verifying that.

To compliment that, the National Dose

Registry, which is the repository of exposure records for Canadian workers, has the capability of including doses that are received outside of Canada in an individual's record so that their lifetime doses can be complete and include all exposures received.

THE PRESIDENT: Thank you. Mr. Berube.

MEMBER BERUBE: This is a question for BTL with regard to cyclotrons. Because this is a licensing hearing, obviously for the next 10 years or whatever it turns out to be, do you have intention at this point or plans to test your cyclotrons at over 1 MeV in the next period of time?

MR. SABAIDUC: Vasile Sabaiduc, for the record. No.

THE PRESIDENT: Dr. Demeter.

MEMBER DEMETER: I think I have just one clarification question and then a more substantive one.

Under the licence conditions, and I'm looking at CNSC Staff's CMD on page 81, licence condition 15.2 is not applicable to the current -- this says:

> "The licence does not authorize the licensee to export for a valid period a nuclear substance or radioactive sealed source whose corresponding

activity is equal to or grater than the value set out in column 2."

(As Read)

Is this a new licence condition that came out of some other regulatory process that's going to be new to all licensees? Is that why it's here now and it wasn't there before? Just a clarification for that.

MS TADROS: Haidy Tadros, for the record. No, this is not a new licence condition. We can provide our specialists who have been working on the past licence with regards to BTL, Ms Ann Erdman, to perhaps give you some detail on the history of that specific licence condition, but it's one that existed before.

MS ERDMAN: Ann Erdman, for the record. I worked on this licence at the renewal time in 2014, so I'm well aware of why the condition was not on the licence at that time, and I also worked on drafting this licence for this application.

At the time the licence was put together back in 2014 it wasn't that BTL did not apply and obtain separate licences for the export of the high-risk sources, because BTL has that program in place and does apply to the CNSC for those sources. At that time, it wasn't added to the licence because it wasn't felt at that point it was

necessary to put on the licence.

However, over these last five years we've just realized, and also based on other licences that have been issued by the Commission, that this should be added to the licence as BTL does export other things that do not require the separate export licences.

That being said, we added this on the licence for clarity purposes to ensure that BTL understands completely, and the public, that they have to obtain a separate licence for the high-risk sources, but this licence is for the other nuclear substances in their possession.

So it's just very clear for everybody that would read the licence. I hope this answers the question.

MEMBER DEMETER: It does, thank you.

THE PRESIDENT: Dr. Lacroix.

MEMBER LACROIX: This is a question for BTL concerning the security.

I have read in your submission that you are developing a vehicle search program for all vehicles that are entering your buildings.

Is there such a protocol for vehicles that are leaving your buildings?

MS SOLEIMANI: Mojgan Soleimani, for the

record. We do not -- there are no vehicles in the building. So employees, if that's the question, employees park in the parking lot. The building is access-controlled, only it's with your employee badge you can enter the building, and you are not allowed to bring your car in the building.

MEMBER LACROIX: Yeah, I should have said the premises.

MS SOLEIMANI: So, yeah, the premises, no, we have an open parking lot that staff park their cars. But, as mentioned, the access to the building, to the facility, is controlled.

THE PRESIDENT: Ms Penney.

MEMBER PENNEY: Thanks. This is a question for CNSC Staff.

So regardless of what class of licence we decide, is this a competent operator? Your review of the safety and control areas, you're giving them a rating of satisfactory across the board.

My question is, have you got any concerns given their reluctance to take a Class 1B licence?

DR. DUCROS: Dr. Caroline Ducros, for the record. Yes, Staff's assessment of the application and of past performance is that they are competent to carryout the

activities that are proposed in the licence.

The type of licence, I would reiterate, is based on the *Nuclear Safety Control Act* and Regulations. A different type of licence is not necessarily considered a lower licence, it's considered the appropriate licence for the activities that are proposed. I think that that's getting a little bit blurred in the discussion, so I just wanted to make that very clear.

Thank you.

THE PRESIDENT: Okay. Anyone with anymore questions?

MEMBER DEMETER: I'm now on the applicant's CMD, page 14 out of 42, looking at challenges under their operating performance. One of the challenges they comment on is, "Staff turnover within a short period of time poses a challenge in maintaining operating performance at an efficient level."

I want to get a sense from Staff whether the staff turnover, which is a metric for possible operational issues when you're dealing with safety and making sure people are all on board, whether staff turnover has been an issue relative to performance in this facility?

MS TADROS: Haidy Tadros, for the record. While we don't necessarily zero in on staff turnover as an

indicator of performance or challenges, holistically when we look at an operating performance of a licensee we look at their capability, their capacity, their training program, their management system, the ensemble of all the programs coming together to reassure and provide confidence that: 1) they are executing and implementing their programs as they've defined them for the Commission and for Staff; and, 2) that, in doing so, they can foresee any potential of risk of disturbance to that operation, and potentially one of the areas could be resourcing, staff turnover and as such.

So when we conduct our compliance inspections, when we look at desktop reviews changing programs we not necessarily keep an eye on how many staff have come and gone from a facility, but more so what is the training of those individuals like, have they maintained their qualifications, do they continue to perform according to what the licensee's management system indicates?

I will perhaps pass this on to our colleagues in human performance program so that they can give you an ensemble of how that area of the work in terms of resources and training are looked at, if you prefer?

MEMBER DEMETER: Well, just whether or not you've flagged -- whether CNSC has flagged -- they've

listed it as a challenge, whether or not CNSC, you know, if they've looked at it and said it's maybe a challenge but it isn't a risk. That's really all I want to know, is if it's been noted and assessed and determined that it doesn't have an adverse impact on their operations. Not the methodology, but just --

DR. DUCROS: Thank you for the clarity, yes. Yes, when we do inspections we look at those types of records, we ask those kinds of questions, there's also interviews. If it's identified as a risk, in fact that gives us a little bit more comfort that measures are going to be put in place to ensure that everyone's trained. So that's part of our assessment.

In that respect, we still concluded for this factor that it's satisfactory and we're comfortable moving forward that staff personnel is trained to do what they need to do.

MEMBER DEMETER: Okay, thank you.

THE PRESIDENT: Anyone with anymore questions?

I wanted to get from Best just a confirmation, and I think you've covered this. In 2014 when you asked for a Class 1B licence as opposed to a Class 2, what was the driver for that? Was that the cyclotron,

the 70 MeV cyclotron?

MS. SOLEIMANI: Mojgan Soleimani, for the record. Yes, that was the driver.

THE PRESIDENT: Because it was new at that time?

MS. SOLEIMANI: That is correct.

THE PRESIDENT: Okay, thank you. So before we conclude the hearing I'll turn the floor over to you, Best, for any final words you may have.

MR. SCHWISBERG: For the record, my name is Sam Schwisberg and I've been asked to make the closing remarks for reasons unknown. However, having been accorded that duty, I shall do so.

I think the really difficult issues you have before you are the definitions, the appropriate interpretations of the words, "capability" and "waste." I would suggest that your role should be informed, to a certain extent at least, by the general policy objectives as laid out in the legislation.

I'm sure you're well familiar with them, but as you well know Sections 3 and 9 of the Statute direct that risk is to be assessed in reasonable terms and consistent with international regulation.

So as a consequence of that, I would

suggest that the words "capability" and "waste" have to be interpreted within the lens of those policy objectives.

Speaking of that, when we look at the risk profiles of the activities of BTL we note, dealing first with waste, that the organization is not a waste handler, it never handles unshielded material and, as a consequence of that, it does not present the risk profile of a waste manager, and that the word "waste" should be construed accordingly.

Again, in terms of capability, the cyclotron, the particle accelerator, in fact has a capability, but only a design capability as it sits on the floor of the operation. So the word "capability" should be construed in accordance with the objectives of the legislation and, therefore, the narrower interpretation of that should be accorded. Because it doesn't present the risk of a particle accelerator of a cyclotron that can produce the types of energies that we're speaking of as being necessarily or requiring regulation.

So if one looks at the broad policy objectives of the legislation, we would suggest that the interpretations of those two words put forward by Best are reasonable, safe, and consistent with the policy objectives of the legislation.

I would also clarify one or two points which came up. There was some suggestion that it was the quantum of the financial guarantee that was the source of our concerns about the costing. It's actually the licensing fees. The difference between the licensing fees are substantial, five to 10 times, I think my colleague said. So we thought we'd like to draw that to your attention as well.

Once again, to a certain extent, we feel that the level of regulation being presented here is for non-existent risk. We're more than happy and eager to comply with the regulatory burden, if you will, because we are committed to safety. But when it goes to the point of regulating risk that doesn't really exist, we think that's going beyond the parameters of the legislation, as suggested by Sections and 3 and 9 of the Statute.

Thank you so much.

THE PRESIDENT: Thank you, and thank you for your participation and, Staff, thank you for your presentations and participation as well.

Kelly, over to you for any closing remarks.

MS McGEE: This brings to a close the public hearing with respect to this matter.

It is propose that the Commission confer with regards to the information that has been considered and then determine if further information is needed or if the Commission is ready to proceed with a decision. So we will advise accordingly.

If you borrowed interpretation devices, just a reminder to return them at the reception and claim your identification card.

Thank you for your participation.

--- Whereupon the hearing concluded at 11:51 a.m. /
L'audience s'est terminée à 11 h 51