Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Public meeting

Réunion publique

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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

Dr. Michael Binder
Dr. Moyra McDill
Mr. Dan Tolgyesi
Dr. Sandy McEwan
Ms Rumina Velshi
Dr. Ronald Barriault

Commissaires présents

M. Michael Binder
Mme Moyra McDill
M. Dan Tolgyesi
Dr Sandy McEwan
Mme Rumina Velshi
Dr Ronald Barriault

Secretary:

Mr. Marc Leblanc

Secrétaire:

M. Marc Leblanc

Senior General Counsel:

Mr. Jacques Lavoie

Avocat général principal :

Me Jacques Lavoie

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Ottawa, Ontario / Ottawa (Ontario)

--- Upon resuming on Thursday, January 6, 2014
at 0903 / L'audience reprend le jeudi
6 janvier 2014 à 0903

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

Again, we have simultaneous translation and we would ask that you keep the pace of speech relatively slow so that the translators can keep up.

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

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

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

Please silence your cell phones

and other electronic devices.

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

I'd like to note that the *Nuclear Safety and Control Act* authorizes the Commission to hold meetings for the conduct of its business and that the agenda was approved yesterday. Please refer to the agenda 14-M2.A for the complete list of items to be presented today.

Mr. President.

LE PRÉSIDENT : Merci, Marc.

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

Mon nom est Michael Binder. Je suis le président de la Commission canadienne de sûreté nucléaire. Je vous souhaite la bienvenue and welcome to all of you joining us via webcast.

I would like to start by introducing the Members of the Commission.

On my right -- oops.

On my left --

--- Laughter / Rires

THE PRESIDENT: They're changing

the order here always to confuse me.

On my left are Dr. Sandy McEwan, Ms Rumina Velshi and Dr. Ronald Barriault.

On my right are Dr. Moyra McDill and Mr. Dan Tolgyesi.

We have heard from Marc Leblanc, the Commission's Secretary, and we also have with us here today Mr. Jacques Lavoie, Senior General Counsel of the Commission.

The first item on the agenda is a presentation by CNSC staff of a report on the compliance activities following the discovery of dose records not submitted to the National Dose Registry, as outlined in CMD 14-M5.

This matter was first presented to the Commission in May 2013 and an update was provided in August 2013.

I notice that we have a representative from AECL here, but we will start with a presentation from CNSC and I understand that Dr. Thompson will make the presentation.

Please proceed.

CMD 14-M5

Oral presentation by CNSC staff

DR. THOMPSON : Merci. Bonjour, Monsieur le Président, Mesdames et Messieurs les Commissaires. Mon nom est Patty Thompson. I'm the Director General of the Directorate of Environmental and Radiation Protection and Assessment and I'm also the Designated Officer for Dosimetry Services.

I'm here today with Ms Melanie Rickard, the Acting Director of the Radiation and Health Sciences Division, and Mr. Tristan Barr, the Dosimetry Services Specialist to present an update to the Commission on a previous event reported to you, as you mentioned.

We're also accompanied by CNSC staff involved in licensing assessments and compliance oversight of the AECL Chalk River licences.

We are here to update you on the issue that was initially raised in an Event Initial Report through CMD 13-M31 on May 15, 2013.

Specifically, we committed to update the Commission on AECL's implementation of corrective actions associated with this event, Early Event Report.

CNSC staff inspected AECL's

dosimetry services on November 19, 2013 to verify the implementation of the corrective actions identified by AECL.

While there, another unplanned event was reported by AECL dosimetry service.

Today, we would like to update you on the results of the inspection and the status of the follow-up actions that stemmed from the inspection.

We also wish to inform you of the details of the second unplanned event, and finally share with you the next steps regarding those issues.

I will now pass the presentation to Ms Rickard.

MS RICKARD: Good morning.

To start, we'll begin with a brief overview of the regulatory requirements for the dosimetry service that had significance for the purpose of this update.

AECL has an in-house dosimetry service licence that supports their operating licence. AECL is a complex facility and the dosimetry service offers many methods or measurement techniques that are tailored to the

hazards of the facility.

Section 5 of the *Radiation Protection Regulations* requires that the licensee, in this case the AECL facility, ascertain dose to persons. The dosimetry service at AECL carries out this function.

Section 19 of the *Radiation Protection Regulations* requires that doses that are measured by licensed dosimetry services shall be filed with the National Dose Registry.

CNSC Regulatory Standard S-106 Revision 1 sets out many of the technical and quality assurance requirements for dosimetry services.

Finally, the dosimetry service licence conditions also set out requirements that include that the licensee must report unplanned events to the CNSC.

The term "unplanned event" is used to describe anything that can affect accuracy and reliability of the dose results generated by the dosimetry service.

In this update we will touch on the interaction between the Operational Radiation Protection Program as well as the Dosimetry

Service Program at AECL. As such, part of the organizational structure of AECL is shown on this slide.

Note that the Manager of the Dosimetry Service Licence and the Radiation Protection Program both report to the Director of the Radiation Protection and Environmental Protection Division. It is unusual that the person responsible for the Dosimetry Service Licence does not have direct authority over the dosimetry activities.

This organizational chart reflects recent changes at AECL but does not match the description of the organization and responsibilities for the Dosimetry Program that was reflected in the licence application. We will be following up with AECL on this matter.

Now, we move into the details of the update.

This slide shows a timeline of significant events.

In preparation for the Chalk River Lab's annual update in February of last year, CNSC staff requested dose information from the National Dose Registry in order to compare and validate the

information provided by AECL.

In doing so, CNSC staff identified some discrepancies. These discrepancies were brought to the attention of AECL staff via letter on March 11th, 2013.

A short time later, AECL reported to the CNSC an unplanned event that involved over 1,600 doses not having been entered into the National Dose Registry, thus being non-compliant with Section 19 of the *Radiation Protection Regulations*.

This event, which will be discussed in more detail, led CNSC staff to raise an EIR with the Commission. This EIR was presented to the Commission on May 15th, 2013, via CMD 13-M31.

During that meeting, staff committed to reporting back to the Commission once the corrective actions proposed were implemented by AECL and CNSC staff had conducted an inspection to verify the implementation.

On November 19th, CNSC staff carried out the inspection and discovered that the corrective actions had not been fully implemented.

At the end of the inspection, AECL

staff also reported another unplanned event that involved tritium measurements not being assessed for dose. CNSC staff informed the Secretariat of the Commission of this event.

The remainder of this presentation will discuss the status of both events and the proposed path forward.

The EIR presented to the Commission in May of 2013 involved 1,650 doses that, while assigned to workers, had not been transmitted to the NDR as required by section 19 of the *Radiation Protection Regulations*. These doses span the period of 2009 to 2012.

These doses had been calculated by AECL Radiation Protection staff because the primary means of measurement, the TLD, had either been lost or damaged, such that it could not be used. These doses were very small, in the order of 0.05 mSv per person.

The reason for the failure to submit the doses was that the required verification step had not been completed.

As a result of the event, AECL staff, in consultation with CNSC staff, proposed three corrective actions to be implemented by

September 30th, 2013.

Note that all 1,650 doses have since been submitted to the National Dose Registry.

On November 19th, 2013, CNSC staff went to AECL Chalk River to determine whether the corrective actions had been implemented.

The corrective actions and status are summarized as follows.

Corrective active number 1 was to create a deviation from procedure to allow all records to be quickly transferred to the NDR and to train staff on this procedure.

A "deviation from procedure" is a term used in the AECL Quality Assurance Program that allows for a short-term correction to be made to a procedure without immediately changing the procedure itself. Note, however, that a deviation from procedure is a written document.

While the deviation from procedure did exist and the records had indeed been transferred to the NDR, there was no evidence that staff had been trained. This was an administrative error that would not have affected the work performed since the staff were aware of

the deviation from procedure document.

Corrective action number 2 was to generate a chain of custody process for manually entered doses. While the process was observed by the inspectors, there was an absence of documentation to support it.

Finally, corrective action number 3 was to initiate electronic verification of manually entered doses. While the process was in place, there was no documented procedures to support the process.

Additionally, CNSC staff had reviewed the proposed corrective actions and AECL had also committed specifically to identify the follow-up actions that would be required if the verification revealed doses that had not been processed and to identify the assignment of responsibilities for the review of the verification of these reports.

These elements were not available at the time of the inspection and there was no evidence to indicate that the verifications were being reviewed or acted upon by management.

As a result of the inspection, four Action Notices were raised to address each of

the deficiencies previously noted.

Finally, a Directive was raised to require all of these Action Notices to be implemented by March 31st, 2014.

Note that, since this presentation was finalized, AECL has submitted a response to the inspection that has addressed all four Action Notices as well as the Directive.

CNSC staff are reviewing the documented procedures that were submitted in order to assess whether they adequately address the deficiencies.

CNSC staff will provide a written response to AECL following the completed review. Should any further actions be required, these will be communicated in the written response.

Now, we move to a second event that was mentioned previously today.

This event was reported to the CNSC inspectors at the end of the November 19th inspection. The event involved doses to 115 contractors who had bioassay samples analyzed for the presence of tritium but the results of the analysis were not converted into radiation doses to those workers.

The dose results were not calculated because the software program used for the calculation required an employee number. Contractors had not been assigned employee numbers.

The doses per worker were very small. The maximum dose was 0.23 mSv and the average was 0.08 mSv.

Also, CNSC staff would like to correct at this time an error in the CMD that indicates 121 samples were not converted into dose. As I mentioned, the 121 actually referred to a number of contractors, not samples. Further, AECL has since determined that there were 115 contractors affected, not 121. This was information we received after the CMD was issued.

As a result of the two events described here today and the duration of time that these events went undetected, for several years, CNSC staff are planning additional compliance enforcement activities.

CNSC staff will be conducting an inspection of the Dosimetry Service as well as aspects of the operational Radiation Protection Program to evaluate the interface between the two.

In addition, CNSC staff feel that the internal auditing process and the management oversight at AECL Dosimetry Service should be assessed and potentially improved.

While the process had identified these two events, these were problems that existed for some time before they were discovered and CNSC's questioning and inspection may have contributed to the discoveries.

CNSC staff have discussed both compliance and licensing actions that can be taken to mitigate the risk of similar events in the future.

Among them, a review of the licensing process and Dosimetry Services is under way, with a plan to use the Licence Condition Handbook process that has been successfully applied to the facility licence.

This Licence Condition Handbook will provide an opportunity for the licensee and CNSC staff to ensure that all licence program documentation is up to date and implemented as recorded in the Handbook.

Additionally, we will utilize CNSC site inspectors, where possible, to conduct

baseline compliance activities. This will increase the on-site presence and we believe will result in improved oversight and compliance.

I will now pass the presentation over to Dr. Thompson.

DR. THOMPSON: To gain confidence that other licensees are not at risk of experiencing similar events, CNSC staff will be sharing information with other licensees.

CNSC staff are also proposing changes to our Compliance Program.

Oversight of the Dosimetry Service is a relatively young program as requirements were first introduced formally in 2000 with the coming into force of the *Radiation Protection Regulations*, as well as the supporting Regulatory Standard S-106 Revision 1 that came into force in 2006 with a phase-in period.

While the Compliance Program and licensing changes will be considered as a consequence of these events, this update is intended to provide the follow-up information required to close the original Event Initial Report that was reported to the Commission in May 2013.

AECL has now implemented the corrective actions that were committed to when the EIR was presented.

CNSC staff are reviewing the procedures that have recently been submitted in response to the Action Notices and Directive.

AECL will submit the Effectiveness Report at the end of April and CNSC staff will follow up with AECL to ensure that any issues identified in the report will be addressed appropriately.

This will effectively close the Event Initial Report and CNSC staff will continue to monitor the progress on dose reporting to the National Dose Registry.

Compliance with any remedial actions that are required in response to the additional event involving tritium doses to contractors will be monitored through the Designated Officer and the Compliance Assurance Program.

This concludes our presentation on AECL's response to the unplanned event and staff's actions.

We are now available to respond to

your questions.

THE PRESIDENT: Thank you.

Before opening up the floor for questioning, we have AECL here. I'm wondering whether you have any comments.

MR. LESCO: Yes. Thank you, Mr. President and Members of the Commission.

Good morning. For the record, my name is Randy Lesco and I'm AECL's Vice-President of Operations and Chief Nuclear Officer.

With me today is George Dolinar. He is AECL's Director of Radiation Protection and Environmental Protection.

Together, we are prepared to provide a brief statement to the Commission and respond to Commission Members' questions regarding our dosimetry system discussed in CNSC staff's CMD.

Let me begin by stating AECL acknowledges non-conformance with our Dosimetry Licence for dose reporting to the National Dose Registry, NDR.

We operate a Dosimetry Service and we are committed to meeting our licence requirements.

In April 2013 and again in November 2013, AECL self-identified and reported to CNSC staff issues related to reporting doses.

As a result of our initial event in April, AECL committed to three corrective actions to be completed by September 30th, 2013.

CNSC staff performed an inspection in November to confirm the status of our corrective actions.

AECL completed two of the corrective actions. However, CNSC staff raised concerns with our closure criteria.

The third corrective action related to a formal procedure was not completed because of lack of oversight.

The CNSC November inspection and findings resulted in four Action Notices and one Directive. This involved issuing two procedures and documenting associated staff training.

AECL has completed all the Action Notices and the one Directive. Closure evidence has been formally submitted to CNSC staff.

During improvements of our corporate Dosimetry System, a separate tritium dose record issue was identified and reported to

CNSC staff in November.

AECL has completed a Detailed Event Report and identified three corrective actions. Two of the corrective actions have already been completed. Information on procedural changes have been formally submitted to CNSC Staff. The third corrective action related to further dosimetry system software upgrades will be completed next year.

Our dosimetry service operates under a quality assurance program meeting CNSC licence requirements and regulatory standard S-106. As such, our dosimetry service is subject to internal program reviews, audits and self-assessments. Each of these mechanisms provides opportunity for improvement. Through our internal corrective action program, a cause analysis will be conducted to look for other opportunities to improve.

I would like to state that there is no safety significance to these events, only small doses were involved. If the dose and bio acidity results were significant, other mechanisms within our program would have triggered further technical review, management action and reporting.

At no time were dose or bio acidity results missing.

A small number of records had not been transferred to the NDR. The issues have been corrected. Required dose reporting has been performed. With the new and updated procedures in place, required transfer doses to the NDR will continue.

As part of continuous improvement, we have reviewed our dosimetry process which identified further improvements, such as further upgrades to our dosimetry system software, improve management of contractor and visitor information and increased benchmarking with other nuclear laboratories and their dosimetry programs starting this month.

This concludes my remarks and we are prepared to answer any questions that the Commission would have.

Thank you.

THE PRESIDENT: Okay, thank you. So let's open up the floor for questions. I will start with Monsieur Tolgyesi.

MEMBRE TOLGYESI : Merci, Monsieur le Président. When you look at these numbers'

information theirs seems to be low, 1600, 50/520,000, just .3, 121/10,000 is .12. So yes, statistically they are low, but if you consider the risk of consequences and how they were managed, these omissions, they are important.

However, I am not preoccupied by really a number, I worry for something else. These examples demonstrate a simple lack of written procedures, lack of control, reporting, lack of follow-up and a non-respective commitment.

Does it demonstrate a kind of laissez-aller or sloppiness in the safety culture; I hope not, but I consider that it clearly demonstrates an important lack of management and the management practices at AECL and I think that this is something that the Commission cannot tolerate.

So I have a question, one question to Staff. On page 5, 1.3, Additional Event Report, you are saying that these 121 urine samples, doses were .23 and average was .08 and these limits for nuclear workers are 50 mSv.

If you talk about visitors and contractors, should it not be considered the limit as 1 mSv when you compare that, because we are

talking about visitors and contractors so, therefore, the importance of -- relative importance its' increasing.

MS RICKARD: Melanie Rickard, for the record. We were focusing here on the contractors, so this event is specific to the contractors and under AECL's RP program, the contractors are nuclear energy workers, so the dose limit is as indicated in the CMD.

For visitors, depending on -- certainly depending on what they are doing, I'm quite certain that some of the visitors would not be considered NEWs and perhaps AECL can clarify that matter.

MEMBER TOLGYESI: Could you clarify?

MR. DOLINAR: Good morning, Mr. President and Members of the Commission. My name is George Dolinar, for the record. So the subject at hand here is regarding nuclear energy workers and bioassay results. So visitors and non-nuclear energy workers would not be subject to bioassay, so we are focusing here on nuclear energy workers.

So the staff CMD positioned this correctly.

THE PRESIDENT: Thank you. Dr. Barriault...?

MEMBER BARRIAULT: Thank you, Mr. Chairman. I have very serious concerns to reflect Mr. Tolgyesi's comments regarding what has happened here.

Our system is based on a system of timely, honest reporting on behalf of the industry and the oversight of the CNSC, and what I'm seeing here really is a question of good luck rather than good management, and to the fact that we didn't have any seriously or injured workers.

We are here to protect the worker, the environment and the public and not nuclear proliferation and if we can't fulfil the mandate of our *Act* because of faulty reporting systems, then we have a serious problem.

I would like to know at this time really how the AECL scored on management for example last year; was it acceptable or unacceptable? I would like to know how they scored on radio protection; was it acceptable or unacceptable?

So I would like to ask CNSC to comment on this, if you don't mind.

MR. ELDER: Peter Elder, for the record. So this is overall on the site. I will start with the radiation protection one because actually it's -- in terms of they have consistently had a "Satisfactory" on radiation protection.

And when we looked at it from the worker control point of view in this event, the day-to-day controls that AECL uses are their internal system. So all the doses were in their internal system that they use for day-to-day manager, making sure knowing what his workers were exposed to, the workers knowing what -- getting their doses is all from that internal system.

The problem was then that was not completely transferred into the National Dose Registry. So there would be issue if these workers moved around.

In terms of management system, we have reported consistently concerns about AECL's management system. AECL has a very -- is making a change to a new CSA standard on management system and we are watching that transition very closely. It is still in progress, but AECL is making the expected progress on the implementation of the

management system, which is the same management system that nuclear power plants work.

So we are very looking at these events and we work closely with anything that comes from the dosimetry inspections and see if this is consistent to any wider issues we see within the site.

So this was not necessarily -- you know, in looking at what we were looking at, and we will look certainly, internal audit, one area is that the new standard definitely has clear rules around as to how you do internal audit and AECL is moving towards those.

MEMBER BARRIAULT: You know, I guess it begs the question, do we have similar problems existing in other organizations that we are not aware of? Because this is a question of -- you know, the issue is not being reported I guess. Is there a follow-up system with any of the other organizations to make sure that they don't have a similar problem?

I don't know if you can comment on that. I guess what I'm asking is for you folks to look at your crystal balls and say, hey, you know, what's going on here.

As I mentioned earlier, our whole system is based on honest reporting and timely reporting and if it's not done, then our hands are tied in terms of what we can do or what we cannot do unless we organize a completely different oversight system to supervise all of this.

I don't know if you can comment on that now. Would AECL at this point care to comment on this, on these issues?

Thank you.

MR. DOLINAR: George Dolinar, for the record. So with the last item you raised in terms of, you know, what is happening with other licensees with respect to dosimetry, what I can report is AECL, you know, through our COG partners has a mechanism for informing them of these events and that is in process. So, in fact, it will be this week that this will go to a COG, a CANDU Owners' Group screening meeting, so these events, these two events have been reported and so from that the industry is aware.

I can't speak to the question, it's probably more suited for the CNSC Staff about what their observations are with other licensees.

MEMBER BARRIAULT: CNSC, do you

care to comment on this comment?

DR. THOMPSON: Patsy Thompson, for the record. The requirements for the dosimetry service licence, in addition to the sections of the regulations that Ms Rickard outlined earlier, there is the CNSC regulatory standard S-106 Rev. 1, Revision 1, that does include both technical requirements for measuring doses, but also quality assurance requirements that are specific to the dosimetry service licence.

Some of those quality requirements include self-assessments, internal audits and reporting of unplanned events.

The manner in which CNSC Staff is made aware of the results of self-assessments and internal audits is through the annual compliance report that our dosimetry service licensees submit to the CNSC. We use that information as a means of looking horizontally at issues specific to the dosimetry service licence to see how to better focus our compliance activities on issues that seem to be more prevalent across the licensees.

In terms of reporting events from AECL, I will ask Mr. Barr or Ms Rickard to answer in more detail.

I would like, though, to go back to the comments that were made in terms of reporting to the National Dose Registry.

Reporting to the National Dose Registry is an important mechanism to make sure that the worker records in Canada are as complete as can be on a very long timeframe. The information has been available since the early to mid-60s depending on the licensees. This information is used nationally and internationally for health studies and the rigorousness and the quality of that data is important, but it is also important in terms of, as was mentioned earlier, making sure that workers such as contractors who move from one licensee to the other, this is one way for the CNSC to, by querying the National Dose Registry, to make sure that there are no unplanned exposures to workers.

So it's an important element of the mechanisms in place in Canada for worker controls essentially.

MEMBER BARRIAULT: Does the CNSC lack tools with which to do this monitoring and reporting to the National Dose Registry and the actual Dose Registry of the different plants? Do

you have a mechanism to go over this? And is there a lack of tools to do this on behalf of the CNSC?

DR. THOMPSON: Patsy Thompson, for the record. I will ask Mr. Barr to talk about the committee that is in place between Health Canada and the CNSC in terms of regular updates on any issues with the NDR and also some of the work that is done through Health Canada to do some verification as we had done last January to validate the doses being reported by AECL.

MR. BARR: Tristan Barr, for the record. So in terms of access to the NDR and our tools, we do have routine meetings with the National Dose Registry and work in conjunction with them to assess and ensure that licensees are submitting the doses that they are supposed to submit for nuclear energy workers who are receiving those doses that are measured by dosimetry services. So we have ongoing interaction there to identify any issues that come up on their side.

Additionally, we inspect and evaluate reports, we go to sites to inspect compliance with the reporting mechanisms as

discussed today, so we look at the licensee side to ensure that those are going in.

However, it should be noted that not all doses go to the NDR because there are many doses that aren't measured by licensed dosimetry services. So while it provides a mechanism for review and verification, it's not necessarily the end all of dose records because the licensees have responsibilities for tracking and ascertaining those doses and updating their own dose records from previous licensees where, say, contractors have worked or their employees have worked.

So I think that answers for both access and verification.

MEMBER BARRIAULT: Thank you. I will give a chance to somebody else.

THE PRESIDENT: I really want to zero in to be a little bit more precise. Can you not do annual reconciliation between the records that AECL keeps on the books and what is in the Health Canada on the books and if there are differences, you find another way of ascertaining whether the correct data has been submitted?

What's the matter with that process and why aren't you guys doing it

automatically?

--- Pause

MS RICKARD: Sorry about that.

Yes, the answer is we can do it for facilities that use exclusively licensed dosimetry services for nuclear energy workers. We know that the requirements link the dose from that licensed dosimetry service into the NDR.

As Mr. Barr mentioned, in some cases we certainly can't do it because some licensees, they don't use a licensed --

THE PRESIDENT: Don't -- listen, we had this conversation in the last meeting with the GE Hitachi about licensed and not licensed. Let's put this aside, this is a whole different topic that we need to discuss.

But in those areas where they all are licensee, NPPs and AECL, why aren't you doing it automatically, or are you doing it automatically?

MS RICKARD: We are sampling. We are sampling on a yearly basis and have been doing it for a while now to try to do a verification. We have not done it exclusively across the board. I shouldn't say "exclusively", we haven't done it

completely across the board.

The short answer is, yes, it can be done. Obviously it will take time and resources, but if it's deemed to be very important, we can find a way to make that happen.

THE PRESIDENT: Well, if you would have done it, then you wouldn't have to rely on AECL so finding kind of a deficiency, it would be automatically.

A subsidiary question, does AECL have access to the NDR data?

DR. THOMPSON: Patsy Thompson, for the record. If I could, before AECL takes the microphone. Just a reminder that it is through CNSC Staff's verification with the NDR of doses reported by AECL last year that we found discrepancies and those discrepancies essentially were reported back to AECL and led to some further verifications that revealed the unplanned event.

So in that case it was action of the CNSC through the NDR verification.

So obviously there is value in doing this and we will be moving forward on a risk-informed basis starting with the high risk licensees.

I would also like to mention that CNSC Staff has been trending worker dose information across the nuclear facilities that we license and this document is updated on a regular basis and is published on our website. It's Info-210. There used to be a number that has changed, but we have been doing this trending essentially by having access to the NDR data.

MR. DOLINAR: George Dolinar, for the record. I understand sort of the generic nature of your question so I can only speak for AECL, I can't speak for licensees in terms of querying the NDR.

AECL has no ability to query the NDR, so that's, you know, I guess the purview of the CNSC and Health Canada. We can request individual records through a process of submitting a request -- a formal request and then receiving that request -- information back on that specific item, but we don't have any ability to query the National Dose Registry.

THE PRESIDENT: You know, maybe it's a bit off topic, but it seems to me there is an automated database that you keep, there is an automated database that Health Canada keeps, what

am I missing here? Why aren't we making sure that the two records reconcile with each other? It is so obvious to me, am I missing something here?

I know there is maybe a timing issue, but on an annual basis why don't you do a self-monitoring and verification that the processes are correct? What am I missing?

DR. THOMPSON: Patsy Thompson, for the record. If I could, there is a response to that question and I will ask Tristan Barr to explain the initiative in place at Health Canada to make this possible.

MR. BARR: Tristan Barr, for the record. One of the action items that we have been working on with Health Canada and the NDR is to encourage them -- and they have initiated the project to develop this -- is to encourage a mechanism so that the NDR can reflect back to the licensees when data is submitted.

Currently the system, it being an old database, is not able to do that. So the licensees who submit data to the NDR get confirmation that the data was submitted, however, they don't get confirmation of the data that was received and how it was received.

So in terms of validating that the results that the dosimetry service have are the same as the ones that the NDR has, this is the missing link and we are currently working on developing that with the NDR.

THE PRESIDENT: Is there a time horizon to this? Do they need some help or a push?

MR. BARR: I have no doubt that they would appreciate funds to do this, they are short staffed and that has been a common -- a consistent concern for the NDR and they are working through their shared IT services now to develop those capabilities, but apparently it's making it difficult.

THE PRESIDENT: Is it the same kind of a challenge with the rest of the licensees, the NPPs for example?

MR. BARR: Yes. Sorry, Tristan Barr, for the record. Yes, all licensees have the same issue in that they can't get reflected back the data that went into the NDR.

THE PRESIDENT: So does it make sense to get the industry collectively to try to help to fix this problem?

DR. THOMPSON: Patsy Thompson, for the record. Just to reflect back on the changes that Health Canada has been implementing over the last five years, they are in the process of introducing a new system for the National Dose Registry and they have introduced much more rigorous quality control in terms of the data handling and management.

In terms of the issues you have just raised, I will ask that it be put on the agenda for the next quarterly meeting between the CNSC and Health Canada. So we will bring this to Health Canada's attention and see whether we can help facilitate or expedite the process.

THE PRESIDENT: Okay, thank you. Dr. Barriault, I interrupted you.

MEMBER BARRIAULT: No, that's fine, Mr. President. I will give a chance to somebody else to ask questions.

THE PRESIDENT: Okay.

MEMBER BARRIAULT: Thank you.

THE PRESIDENT: Dr. McEwan...?

MEMBER McEWAN: Thank you, Mr. President. I will echo the comments of Mr. Tolgyesi and Dr. Barriault at the beginning.

I would like to go a little bit further back in the chain, because we have been focusing on the manual entry of the data and transfer to NDR. If I read your data correctly, for the first event 825 individuals didn't give their badges back and, therefore, through the chain that we have discussed did not make their records -- their records did not make it to the NDR.

How many -- what percentage of your contractors failed to give their badges back and did make it to the NDR and what mechanisms do you have in place to ensure that dosimeters are given back before the contractor leaves the site?

Because that seems to me to be the fundamental issue here is that, you know, I'm guessing it's a lot more than 825 who didn't give the dosimeters back.

MR. DOLINAR: George Dolinar, for the record.

I don't have a precise number for you in terms of the number of contractors that may not have returned badges but we would have, you know, performed the dose assessment and reported doses. So I don't have that number with me.

However, I guess, you know, some clarification on this item is that, first of all, this took place over a period of years and at the previous May 13th Commission Meeting this issue was raised. There was discussion about penalties to contractors for missing or lost photo dosimeter badges.

So AECL has in our terms and conditions for most of our contracts a penalty now. It's $1,000 for lost or missing badges. We haven't exercised an actual penalty yet but we have notified several contractors that badges were not in the racks when they should have been. So we've used a threat of the fine that's in our terms and conditions. We've noticed an improvement.

In addition, dosimetry staff have been looking more closely at contractor badges and that's also probably improved the situation.

So there has been a couple of mechanisms. One is we are exercising a penalty clause and terms and conditions associated with contractors and the contractors are aware of that. And so that's provided some improvement.

And, secondly, dosimetry services

has been paying more close attention than we were in the past to dosimeters coming from contractors. That's also helped improve the situation.

MEMBER McEWAN: So for the individual contractor who comes onto site and gets a badge does he have to give up a driving licence or something that ensures that there is an aide memoire to pick it up -- to drop it off leaving the site?

MR. DOLINAR: There is no such requirement.

THE PRESIDENT: Educate me. What's the difference if they had the electronic monitor? Those things automatically relay the data or they have to be still manually -- in other words, what I'm trying to say if they had one of those electronic things, the data, you may not get -- they may not give it to you back but at least the data is captured.

Did I get it right?

MR. DOLINAR: So the issue that we're speaking about are TLDS, thermal luminescent dosimeters as opposed to things like PADs which would record dose and be able to download those automatically for example. So we use PADs,

personal alarm dosimeters which record dose rate and overall dose for jobs where we expect individuals to incur a dose of note.

For the contractors in question, the 825 contractors and the 1650 dose records associated with them, we know that the vast majority of these doses were small. Some of those, if not all, were due to missing badges. That was certainly a significant factor.

But, just to be clear, in that original 825 it was not all due to contractors. There were other, you know, badges missing and other issues.

THE PRESIDENT: So it's not feasible to give everybody that electronic device. Is that what you're saying?

MR. DOLINAR: Correct.

MEMBER McEWAN: So does staff have any comments? Because it seems to me that if you correct the front end you are less likely to run into errors at the back end.

MR. LESCO: Randy Lesco, for the record.

Perhaps I could help out here. As part of our improvement situation here we are

looking at how we are managing contractor relations. So you know we are looking now on ways that we can improve the front end as you point out.

THE PRESIDENT: Well, maybe you are a good test ground because what I'm worried about, if that's a phenomenon that is across the whole industry in the MPP there are thousands of contractors annually.

If they are going to go into a refurbishment process there is all kinds of external people. And you are doing Port Hope. I want to understand is loss of those devices common practice and if it is then we have got a real issue everywhere.

DR. THOMPSON: Patsy Thompson, for the record.

I think the potential -- the loss of the badges, you know, can happen just physically depending on what workers are doing. But in terms of a more comprehensive response to your question about managing of contractor doses for NPPs and, you know, the sheer number of contractors, perhaps I could ask Miss Caroline Purvis to speak to some of the focused inspections

that were done specifically on contractor dose control.

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

Yeah, certainly I can report that as part of our baseline compliance plan for the nuclear power plants which also, as you rightly mentioned, have many contractors coming on and off their site, this particular past year we have focused on worker dose control and also contractor control.

So certainly we are very interested to ensure that licensees are having mechanisms in place to manage contractor doses, to ensure that their dose histories are ascertained before they are put into a radiological environment, and of course, also, that that dose information is retained by the licensee for reporting purposes to the NDR.

Going back to your question about the dosimeters themselves, TLDs, of course, are issued to workers going into radiological areas so that they can ascertain the dose. Hard barriers for return of those TLDs, there is many processes

that are in place but it is possible for a contractor to leave with their TLD at a power plant as well. It really speaks more to the culture and to the organization reinforcing good positive radiological principles.

THE PRESIDENT: Okay.

MEMBER McEWAN: So would CNSC staff have any idea what percentage of badges don't get returned, because that to me seems a fundamental number that we should understand?

MS PURVIS: Caroline Purvis, for the record.

I certainly don't have those numbers on hand. What I can tell you is licensees do have mechanisms and processes in place to determine or estimate a dose should the TLD become lost, dropped or not returned.

In those areas where the worker is in a radiological environment where there is a risk they would be also wearing an electronic dosimeter. So that is a second record that can be used to estimate the dose should the dosimeter record be lost.

MEMBER McEWAN: So it's theoretically possibly for a contractor to work on

five different sites, not return his badge for all of those five sites, and we'd have no record of it?

MS PURVIS: I think that, no, it would not be theoretically possible that they would move from site to site without any dose information being ascertained.

As I mentioned, it could happen once that they could walk out with one. Obviously, it did at AECL. But there is a responsibility for licensees to ascertain that worker's dose. They know they have been in a radiological environment and they do have processes in place to estimate the dose through other means. And it's also, of course, the contractor's responsibility in their organization to manage their workers.

DR. THOMPSON: Perhaps, Dr. McEwan, if I could just add something?

In this case the doses for the workers were ascertained. The issue was not in terms of workers not being -- you know, doses for those workers not being identified. It was a matter of those doses not being transferred for the NDR. So there was appropriate controls in

place to protect those contractors.

MEMBER McEWAN: But the doses were calculated.

THE PRESIDENT: Estimated.

MEMBER McEWAN: Estimated.

DR. THOMPSON: Patsy Thompson, for the record.

Yes, through a variety of means including in some cases personal alarming dosimeters and other means.

THE PRESIDENT: Mr. Jammal, do you want to add?

MR. JAMMAL: Ramzi Jammal, for the record.

Dr. McEwan, you're asking a very -- a practitioner's question. There are two elements. You are ascertaining the dose with respect to the individual potential received dose and the issuance of the dosimeter by the licensee.

The licensee has full responsibility and they should be aware and they are aware from most of us who were in the field before. Every time you issue a dosimeter to an individual the licensee assigns a number that is provided, okay, to the dosimetry service, a reader

of that dosimeter. And at the end of the period of the monitoring the licensee receives an account of how many badges were sent to that dosimeter reader and how many were not sent.

It's an obligation on the licensee to determine two things: Were these badges lost or why were they not then provided to the dosimeter service provider which is licensed by the CNSC? So that's the obligation of the licensee.

So your question is very valid. Do we know how many have not been returned? We don't ask the licensee to provide this information but it's very easily obtained from them based on the printout of the dosimetry doses how many badges were returned and how many badges were not tried.

And we will keep account of such discrepancies to make sure that the licensee will make sure that they are accountable to the oversight of the individual who received that dosimeter.

So yes, that data can be obtained and the licensee has that responsibility to do that accounting and we'll make sure it will be

reported to us.

THE PRESIDENT: I think there's work to be done in this area.

I think that -- and look, it's not a safety issue, as you have said, because normally the doses are very, very low. So people feel comfortable while estimating if you lose the dosimeter, you know, so you can actually do an estimation, a proxy for it.

But I think based on -- I'm actually a fan of quality data so it can give some real quality health studies.

So it's really important to have this data integrity as much as you can. We'd like to get some comfort level that the integrity of the whole NDR system is up to snuff. But this is for something that I think staff should focus on with the industry.

I'd like to turn to Dr. McDill now.

MEMBER McDILL: Thank you.

One of the themes that has come up over the years, and I've used the word before, is this lack of convergence between staff and AECL about what has actually happened, what are the

expectations of staff with respect to a certain action item and AECL's response to the action item and how or what will be done to make sure it's confirmed.

Again, today, we've heard staff say that it was its checking of records that initiated a response on the part of AECL and AECL has again today said it self-reported the first incident. So I'm not sure. I don't know where that action -- where is the difference? Because I think it's that kind of difference of opinion that's causing a lot of this challenge over the years.

Today, AECL, if I understood correctly, said that you believed you had completed two of the action items. And staff says that you had not. So obviously there is once again this problem with what is it we are supposed to do and how is it we prove that it's done?

My first question is: AECL, when you say you believed that you had completed two, on what basis did you believe that they were complete? And then: Staff, why was that not enough or how did it fall apart?

With the two, the third one

obviously it's not -- it's not complete.

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

So when we had identified corrective actions and we stated that we had completed them, you know, obviously we didn't meet staff's expectations in terms of having those completed.

I think from AECL as a licensee, I think there is an obligation to making sure that we have a consensus with CNSC staff as to actually what is the actual crucial criteria, right?

And so going forward, my expectation is that when we get -- when we offer corrective actions, when we get action notices, when we get directives -- my expectation, as I say, we have an absolute understanding and a clear criteria going forward.

DR. THOMPSON: Patsy Thompson, for the record.

Before I ask Tristan Barr to specifically answer the question on the divergence between CNSC staff and AECL on the status of the corrective actions, I'd like to mention that when we look at how corrective actions are being

implemented, we look at it in terms of not just the -- you know, the technical requirements, but also the procedural and management system requirements.

Obviously, in these cases what we reviewed was the implementation of corrective actions against a standard like S106. We have one that does have requirements for documentation control, documentation training of workers. But I'll ask Tristan Barr to speak specifically to those two action notices, to corrective actions.

MR. BARR: Tristan Barr, for the record.

So Dr. Thompson answered the essential elements here, but the two corrective actions that we are talking about were, one, to create this deviation of procedure to expedite the submission of records to the NDR and, two, was to improve the chain of custody system. They were to devise a system and have a centralized location. They did draft or write that deviation from procedure appropriately and they did devise a system for chain of custody and had a centralized location.

However, upon inspection when we

looked at both the deviation from procedure and the chain of custody system, for the deviation of procedure they did not comply with the requirements of S106 Revision 1 that specifically required that employees be trained on that, on any work level procedure that will ensure the quality of the data in the corporate dosimetry system in this case. So that's a requirement that is standard for all processes within the dosimetry licence.

With regards to the second, the chain of custody, there is a requirement that all processes be documented. And so given that they had created a process but there was no documentation to accompany that process it was non-compliant again with the requirements of S106 Revision 1 which is the technical and quality assurance standard for all dosimetry processes.

So I hope that answers the question.

But, yes, they did complete -- they did initiate the things they needed to initiate. However, they didn't implement them as per the quality requirements for a dosimetry service.

MEMBER McDILL: Thank you.

So AECL, I am assuming that somebody sent up to the top the information that it was complete? I'm assuming that, Mr. Lesco, you don't go down to the lab and say, "Show me the documentation". Maybe you do.

So somewhere in the system at AECL this back check against the red doc is not occurring. Can you address where that's not occurring? Do you know where it's not occurring?

MR. DOLINAR: George Dolinar, for the record.

So I'd just like to just step back for a moment and just lead you through what was indicated in the corrective action and what AECL had performed. So this deviation from procedure or, probably more commonly referred to in the industry as an "instruction to staff", was regarding an existing procedure where several steps were modified. In fact, they were no longer required.

The three staff who normally perform this function were involved in the preparation of the deviation from procedure or ITS. It was discussed at branch meetings.

In total, five staff -- so we have some redundancy in case somebody is away -- in total five staff at any point in time might be required to use this instruction to staff or deviation from procedure. So they were communicated. This was communicated. The requirements for the procedure were communicated.

What we lacked when the CNSC came to inspect this, they asked for training records. Those signed training records were not available. So that was sort of corrective action, number one.

So that's sort of the nature of the discrepancy. I think this is largely consistent with what Tristan Barr had just communicated but that's the understanding.

So what I want to return to, though, is that there was some discussion about these corrective actions in correspondence between AECL and CNSC staff and this is what led to the issue with the third corrective action.

So the third corrective action; due to some correspondence AECL agreed to prepare a procedure. And that was the nature of the discrepancy and where it's not a discrepancy. So I agree that we did not prepare that procedure

which we had agreed to in subsequent correspondence with the CNSC staff.

You had raised another question earlier and this was with respect to divergence of opinion as to reporting of events or discovery. Just to be clear, there are sort of two classes of items here. One which is referred to in the CNSC staff presentation, an event from March of 2013. This was a discrepancy with the NDR dose records.

So we did not discover that. That was discovered by CNSC staff. We've never claimed to have discovered that. We can't query the NDR database. So this was discovered by CNSC staff.

I think CNSC staff have suggested that as a result of that, AECL has done further work looking for issues.

I guess the backdrop that I would present you with is, we have been undergoing a series of upgrades to our corporate dosimetry system involving a third party software contractor. As a result of defining some of the requirements and the contractor asking us questions about these changes several of our technicians have been querying and looking at the effects of the proposed changes and upgrades.

This is in fact what's led us to -- into the two events that we have reported.

MEMBER McDILL: In some respects the friction is healthy between the two, the regulator and the proponent, but it's sort of an ongoing theme.

How can this be fixed so that we don't have staff going in and doing an inspection and it's not complete? There must be -- there must be a step missing or consultation missing somewhere.

DR. THOMPSON: Patsy Thompson, for the record.

Obviously, the expectation of the regulator is that the licensee is in full compliance with the requirements. And in those cases the licence application for AECL was assessed against not just the radiation protection regulations but the standard. In correspondence between AECL and the CNSC we in fact reminded AECL that, you know, their corrective actions had to be in full compliance with S106.

So beyond documenting expectations and reminding licensees of expectations, conducting inspections and other compliance

activities is the mechanism that we have.

We have the ability to have meetings, for example, with licensees when there are generic issues that affect a number of licensees in terms of understanding the requirements. But in the case that we have today in relation to the events that have been documented, this is clearly not a complex technical issue and the standard has, in fact, been in place since 2006.

And all licensees have documentation that align with the standard, so the expectation is that that documentation is being fully implemented.

THE PRESIDENT: But are you taking -- you have another instrument that -- to clarify requirement.

Are you using the Licence Condition Handbook to further clarify the kind of requirement so there's no misunderstanding about what the expectations are?

DR. THOMPSON: Patsy Thompson, for the record.

As we mentioned during our presentation, there are currently no Licence

Condition Handbooks with the dosimetry licences. It is an initiative that will be moving forward for the next fiscal year where the licensing requirements will be documented in Licence Condition Handbook.

In this case, we're also looking at the convergence with the annual compliance reports because the dosimetry service licences are quite straightforward. The documentation -- it's essentially a way of managing the changes to documentation that are made over the licensing period, which is going to be -- is between five and 10 years, depending on the -- where we are with the licence renewals.

But it's certainly the Licence Condition Handbooks will be introduced.

THE PRESIDENT: Dr. McDill?

MEMBER McDILL: I think I'll pass it along.

THE PRESIDENT: Ms Velshi?

MEMBER VELSHI: Thank you, Mr. President.

In my two years on the Commission, I have never heard the Commission so unanimously express their concern over the inadequacy or

perceived inadequacy of the licensee's compliance with requirements and whether it's use of adjectives like "sloppiness" or whatever.

So my first question to staff is, was administering of the AMP considered at this stage? As you walked us through the requirements of the dosimetry licence, you know, there was non-compliance in every area, not only once, but over again.

So help me understand why this would not be triggered at this stage.

DR. THOMPSON: Patsy Thompson, for the record.

The ability to administer administrative monetary penalty is relatively recent to the CNSC, so last January, it wasn't a tool that was yet available.

We have considered for the events in the fall the lack of full implementation of corrective actions whether an administrative monetary penalty would be appropriate. We have not reached the stage where other compliance enforcement activities, we think, would have value.

One of the things that we have

identified is that we are keeping the possibility of an administrative monetary penalty for the next phase of the work that the AECL is going to submit to the CNSC in terms of the appropriateness of their investigation of cause and their review of their management oversight of the dosimetry service licence.

MEMBER VELSHI: I just want to leave that thought with you. I can understand of spring of last year, but I think fall of this year when you did your inspections and when the other event was reported, which was a greater systemic issue, whether the timing was right.

My second area is, again, more directed to staff on your oversight.

And as we look at the first three corrective actions after the first inspection after the first event, why would a review of the adequacy of the annual self-audit not have been part of a corrective action?

You know, this was an issue that had been there for at least four years. We've heard from AECL they have no way of interrogating the National Dose Register, but that doesn't mean they shouldn't have been able to identify this

problem themselves if they -- if their annual self-audit was robust enough, and that would have indicated to them that these doses were not getting reported to the NDR.

So again, a question on the adequacy of the corrective actions there. I'll give you a couple of examples.

On slide 8 where you talked about after your inspection, you came up with four action notices, there was still no mention on adequacy of management review at that time and a need for further action.

So here are non-compliances, corrective actions that haven't been completed on time. Sounds like AECL was surprised that CNSC felt that they hadn't -- that they still weren't in compliance which, again, shows why did that not get triggered until the second incident was reported.

So I guess my question to staff is, from your perspective, are they learning through you on your oversight and are you being proactive enough in ensuring that the licensee understands the seriousness of this and does the appropriate thing?

DR. THOMPSON: Patsy Thompson, for the record.

Before answering your specific questions on lessons learned and some of the requirements for management review and review of self-audits, in terms of the statements that have been made about the NDR and the ability of AECL to query the NDR, there's clearly the possibility for AECL or any other licensee to request from the NDR their annual collective doses, their maximum-minimum-average doses. And so that possibility is there.

And certainly there's no impediment for AECL or other licensees to get that information from AECL (sic), but they're only able to get their own information. But they can certainly get all of that information from the National Dose Registry.

In terms of lessons learned for CNSC staff and the -- I guess the -- an earlier response in terms of requesting that AECL conduct a review of their self-audit, self-assessment program, in 2007 there was a large CNSC Type 1 inspection or audit of the dosimetry service licence.

At that time, there had been a number of findings in terms of gaps in the management system, quality assurance at AECL for the dosimetry service licence.

AECL had submitted corrective actions to address the deficiencies identified during the inspection, and staff had found those corrective actions to be satisfactory.

Obviously, with what we've observed since last January, could we have -- should we have requested a management review sooner? Probably. And it's something that we have now asked AECL to do.

But we are doing a lessons learned, and it's something that we have considered not just for this, but for other licensees looking at annual compliance reports to look at our compliance strategy moving forward.

MEMBER VELSHI: Thank you.

AECL, this second event that you reported to CNSC in November, when did you become aware of it, and how?

MR. DOLINAR: George Dolinar, for the record.

We became aware of this the day

before in terms of the -- you know, the scope and the time period from which these bio assay results were not further processed in our system, the day before the CNSC inspection.

So we reported it to the CNSC verbally during their visit to Chalk River.

MEMBER VELSHI: And how did you become aware that these doses were not getting assigned?

MR. DOLINAR: So much like the earlier event regarding the 1,650 doses, because of various upgrades that are taking place to our software systems, we're looking more broadly at, you know, so here's a change that we need to be made, what gets impacted if this change is made. We're doing verification of those types of activities, so we have a technician who was effectively doing various queries to make sure the changes that we were considering implementing wouldn't cause issues, and that's when this 121 -- 115 is the correct number, but initially in the CMD it was indicated as 121 contractors, so...

MEMBER VELSHI: And I think it said that had the doses been higher, there were other checks and balances in the system that would

have picked this up.

Can you elaborate on what those other checks and balances are?

MR. DOLINAR: Certainly. George Dolinar, for the record.

So when a bio assay, in this case a tritium urine sample, is submitted, an aliquot of that sample is subject to scintillation counting.

At that point in the process, it turns out a number of Becquerels per litre, and so we have a number of bio assay recommendation levels associated with that Becquerel per litre value.

So what would happen is there are a number of sort of -- there are four different bio assay recommendation levels. There's a trigger level, a minor, a caution and a removal.

At the caution level and removal level, this is when that bio assay, the Becquerel per litre, number gets flagged and the RP program from dosimetry gets notified that we've got a worker that has this level of tritium in their urine, and so immediate steps are taken to determine why that is, remove the individual from

the workplace.

And so this is the manual mode that kicks in when we have an extraordinary result.

And you know, just for completeness, you know, we had not even reached the lowest level or a trigger level which, you know, indicates that something's a little bit unusual. So it's very far from the levels I've just mentioned to you, the removal level, you know.

So our bio assay results were very, very small compared to those BRLs.

MEMBER VELSHI: And would any of these contractors have submitted more than one sample, you know, over two periods or over a couple of days?

MR. DOLINAR: Correct. So for these -- for the specific contractors, a number of them had submitted more than one sample.

MEMBER VELSHI: Okay. So it's 115 contractors, but more than 115 samples.

So wouldn't the contract administrator or contract manager, whoever, I mean, who's -- if they're submitting bio assay

samples, they're doing radioactive work, as they're prepared to do work, is that not a requirement that you look at the results of your last bio assay sample to make sure that there have not been any unexpected uptakes?

And should that not have been another control to say, hey, how come my bio assay result isn't posted?

MR. DOLINAR: So I -- George Dolinar, for the record.

So I'll mention, you know, a couple of other factors here.

So on the calculation of the dose and reporting to NDR, you know, so there's an issue there that, you know, we've discussed at great detail.

On the other hand, when it comes to worker safety, which is where the radiological protection program sort of steps in, these mechanisms provide for adequate worker safety on the job.

Your question is with respect to, you know, oversight of those contractors per se. So again, for the safety of the contractors or any worker, the manager or the contract sponsor would

be informed, along with RP, had we achieved these BRLs, but we were well below those. And that's the reason that there was no action taken.

MEMBER VELSHI: And because I've got some history in this, I'm going to belabour this a bit because sometimes there -- it hasn't been triggered because maybe the sample was not analyzed. And not that that was the case here. It just didn't get reported and assigned.

You know, Mr. Elder was asked this question, I think, by Dr. Barriault on the adequacy of CNSC's radiation protection program or management system, and he said radiation protection program is fine because the doses had been assigned for dose control purposes.

But for these bio assay results, and I understand that they weren't high enough to trigger it, but there is no means for someone to know is my -- have I not been told about this because it was high or maybe because it just wasn't read out? And like those, you know, lost TLDs, for instance, and is there a gap in there?

As a contract administrator, should I not be checking what was the result of my bio -- of my contractor's bio assay sample before

I give them more work?

MR. DOLINAR: George Dolinar, for the record.

So we believe that there is room for improvement in this area. And as part of our opening remarks, we certainly mentioned that that was one of the areas that we're looking for improvement going forward.

MEMBER VELSHI: So on that note, I know the CNSC has assigned a number of actions and notice to you.

Have you done any other root cause analysis, particularly from a management system review, on what could you do better, differently next time around?

MR. DOLINAR: So I'm not -- George Dolinar, for the record.

Are you asking about past root cause analysis or --

MEMBER VELSHI: Specifically as a result of the second incident and the AECL's -- I'm sorry, CNSC's inspection of November where they found your actions were not completed to their satisfaction.

MR. DOLINAR: Thank you. George

Dolinar, for the record.

So we are planning to do a cause analysis. We -- you know, we believe that the issues that were identified have been corrected by the actions we've taken and the procedures that we put in place, so we believe that those are remedied.

The benefit of a further cause analysis would be to identify further areas for improvement.

MEMBER VELSHI: And my last comment to staff is, as we talked about this reconciliation of the licensee's dose information in NDR, perhaps you may want to consider a requirement for them to do an annual reconciliation or whether it's a full reconciliation or sampling.

And I don't know what the reg doc requires them to do.

DR. THOMPSON: Patsy Thompson, for the record.

We have taken note of that.

THE PRESIDENT: Thank you.

Anybody else?

MR. ELDER: Peter Elder, for the

record.

I just want to clarify the statement about RP program. That was based on the information we have to date. We are asking -- we have outstanding questions around the tritium and the contractors.

So we agree we want to make -- we're still questioning and querying could there have been a case -- we understand some of the controls are in place, but how wide is this one and how are they controlling contractors in general around these ones.

So it's not -- the assessment is this is what we had seen so far, recognizing there are open questions around the second event.

THE PRESIDENT: Okay. I have -- can we see the organization chart slide back on?

Okay. I'm trying to understand, who is actually -- whose name is on the licence for the dosimetry service? Who's the licensee?

MR. BARR: Tristan Barr, for the record.

The licensee is AECL, and the representative of the licence at the time of application was Andy Bugg, who's now been replaced

by Kevin Wegner.

So Kevin Wegner is what we call the applicant authority, and he's the radiation program authority.

THE PRESIDENT: So he's actually the manager of the dosimetry services?

MR. BARR: Well, that doesn't align with this -- with this organizational chart.

We did pull this organizational chart for the purpose of the CMD presentation, and we did confirm that in the licence application, the program manager is responsible for designating, for example, the manager of the dosimetry service and providing funding for the dosimetry service, et cetera, so has the ability to make the changes required in the event of problems with the licence. But that doesn't align with what we see here.

THE PRESIDENT: So don't we need to change at least that?

I mean, we are picky on licence -- licensee, the clarity about who the licensee.

And to Mr. Lesco, you know, as the regulator, we actually are preoccupied with health, safety, et cetera. So should you, I

assume, as the nuclear CNO.

Is that the right organization structure? And I don't want to put anybody on the spot here and I'm not being personal here.

Just in terms of structure, shouldn't these kind of issues should be higher in the organization chart in terms of direct, almost daily attention?

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

The people who are in charge in terms of, for example, radiation protection program will report directly to me, so there is that relationship with respect to their accountability is to me with respect to licence.

So recognizing that there's line management in place in terms of their day-to-day duties and that both the dosimetry program as well as the RP program actually reports through to George Dolinar.

So currently, I'm satisfied about how we're organized structurally in terms of our commitments to meeting our licence obligations.

THE PRESIDENT: But that's a real, you know, large span of control in terms of the

whole health and safety and environment, et cetera.

I just am worried about whether, you know, you intervene or your intervention is -- or the oversight is as frequent as it should be on some of those issues or some -- I'm asking the question properly -- or some of those issues raised to you in the frequency it's deserved.

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

So we have -- I conduct quarterly reviews with all matters of HSSE. I report them to both the Executive Committee as well as the Board of Directors, so I have a direct line of accountability in terms of providing sufficient oversight to making sure that we are compliant with our site licence conditions.

THE PRESIDENT: I think both organizations could take a look about what -- you know, we have a very strong view on NPP structures. I'm not sure that AECL does not require the same kind of scrutiny.

DR. THOMPSON: If you allow me, Mr. Binder, Patsy Thompson, for the record.

We did, during the presentation

and from Mr. Barr's comments, is that the structure that is currently in place as a result of changes at AECL does not reflect the description in the dosimestry service licence application, nor does the -- at least what we're able to see -- the responsibilities and the authorities of the person responsible for the licence do not appear to jive with what we've seen.

So it's something that we found out essentially last week as we were preparing for the Commission meeting, and we will be following up with AECL to make sure that the licence and the licence -- the person responsible for the licence has the appropriate authority.

THE PRESIDENT: Okay, thank you.

Any final question, observation? Anything, final comments?

Okay. Thank you. Thank you very much.

Okay. We'll take a 10-minute break. Thank you.

--- Upon recessing at 10:34 a.m. /

Suspension à 10 h 34

--- Upon resuming at 10:48 a.m. /

Reprise à 10 h 48

THE PRESIDENT: The next item on the agenda is a presentation by CNSC Staff on Counterfeit, Fraudulent and Suspect Items, as outlined in CMD 14-M3.

I understand that Ms Heppell-Masys will make the presentation.

Please proceed.

CMD 14-M3

Oral presentation by CNSC staff

MS HEPPELL-MASYS: Thank you.

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

My name is Kathleen Heppell-Masys. I am the Director General of Directorate of Safety Management in the Technical Support Branch of the CNSC.

With me today from our Directorate are Mr. Pierre Lahaie, Director of the Management Systems Division; Mr. Paul Wong, who is a Management System Specialist; Mr. Gerry Frappier, the Director General of the Directorate of Assessment and Analysis, and members of his team

are also with us to offer technical support in the areas of fitness for service and defence-in-depth.

As well, I understand that we have some members of the industry that are here with us today. Mr. Terry Davies from Point Lepreau and I believe Mr. Frank Saunders from Bruce Power are here with us today. They can answer further questions.

The purpose of today's presentation is to provide you with a briefing on the topic of Counterfeit, Fraudulent and Suspect Items, more commonly referred to as CFSI.

This subject surfaced in other countries in the last few years and we thought it would be useful to make a presentation on that subject.

Product counterfeiting is not a new phenomenon. It has been going on since the dawn of commercial trade. To give this some perspective, counterfeiting of coinage dates back to ancient times and the earliest record of art forgery dates back to 1524.

To date, numerous consumer products are subject to counterfeiting.

Bringing this back to today's

nuclear industry, recent international reporting of instances of CFSI has underscored not only the importance of detection and control provided by robust supply management processes but also the defence of systems, structures and components as they relate to defence-in-depth.

I will now turn to the outline of today's presentation.

Our presentation will start with a brief background about CFSI in general and will include some illustrations of the different types of CFSI.

We will then describe the factors that are contributing to the threat of counterfeit and fraudulent items into the supply chain.

Some examples of CFSI reported internationally will be provided and the actions taken by the international community to address this threat.

We will talk about the measures we have in place in the Canadian regulatory framework to address counterfeit and fraudulent items and the actions the industry has taken.

An explanation of the various layers of defence we currently have against CFSI

will be given.

We will end with a description of the initiatives we are taking to further address counterfeit and fraudulent items.

What are counterfeit, fraudulent and suspect items?

The definitions you see on the slides are those adopted by the Nuclear Energy Agency, NEA.

"Counterfeit items" are defined as items that are intentionally manufactured or altered to imitate a legitimate product without the legal right to do so. For example, items would not be made of the appropriate material, labels or tags might have been altered, or casting marks might have been ground off and stamped with other markings.

"Fraudulent items" are defined as those items that are intentionally misrepresented to be something they are not, whose material performance or characteristics are knowingly misrepresented. For example, items can have incorrect identification and falsified or inaccurate certification, including testing certification.

"Suspect items" are defined as items where there is a suspicion that the item may be counterfeit or fraudulent. There would be an indication by visual inspection or testing that they may not conform to the accepted standards, specifications or technical requirements.

When we talk about CFSI in this presentation, we will be discussing items where there was an intent to deceive. This does not include items that are non-conforming due to design or production defects, damage during shipping, handling or storage, and improper installation.

Let's look at a few generic illustrations of counterfeit items gathered from literature for the purpose of demonstrating the types of CFSI that can be encountered.

On this slide, we can see differences in paint colour and the markings on the body of the two valves. It would not be immediately evident which one is the counterfeit item.

In this case, the marking on the counterfeit valve was added by grinding and welding, whereas that of the proper valve was cast

into the body.

For the circuit board, the counterfeit board has on the right a button in the wrong location and is physically thinner than the genuine circuit board.

On this next slide, we're looking at the product labels of circuit breakers. The labels for the genuine and counterfeit breakers look very different and on the surface it is difficult to tell which would be counterfeit. The counterfeit breaker label is missing many of the features of the genuine item, such as the word "LISTED" and a sequence of alphanumeric characters.

Moving on to an illustration of a fraudulent item, it is a case of documentation containing false information about the material being supplied. The document certified non-nuclear-grade steel as nuclear-grade steel. These fraudulent documents were supplied by a foreign company on a U.S. company's letterhead.

So, those were a few examples.

Let us now look at the factors that are contributing to instances of counterfeit and fraudulent items worldwide. Let's discuss

those four factors.

First, there have been changes to the nuclear supply chain over time, such as:

- a more globalized economy;

- the relocation of manufacturing centres offshore;

- the arrival of Internet-based suppliers; and

- an overall increased length and complexity of the supply chain.

Second, there is increased difficulty in procuring replacement parts. The original manufacturer may no longer be making the part. There is a smaller and smaller pool of manufacturers undertaking the stringent demands for the rigorous testing and documentation needed for some nuclear-grade items.

A third factor contributing to the increase in potential CFSI cases is the increased demand of nuclear components. This increased demand is caused by a number of sources including, for example, aging and obsolescence of existing equipment and new build projects.

Some of the modern electronics used in digital instrumentation and control

technology tend to have a shorter lifecycle compared to the traditional analog components. This in turn increases the frequency that these components need to be replaced.

The final factor that we will discuss is the challenge in detecting counterfeit and fraudulent items.

Traditional procurement programs were designed to identify and manage non-conforming parts and services. The criteria used to confirm the quality of products during receipt inspection and testing generally assumed vendor integrity and the criteria were not focused on identifying an intent to deceive.

As a result, these programs were not originally designed to detect counterfeit and fraudulent items. Since, additional measures have been put in place to do this.

With modern off-the-shelf technology it has become easier to replicate traditional manufacturing processes, allowing for the ease of counterfeit production that resembles the genuine products.

CFSIs that are embedded in a black box would also present challenges for detection.

We will now take a look at some of the cases of CFSI reported worldwide.

There were a number of CFSI cases in the U.S. in the late 1980s and early 1990s. More recently, there have been reported cases of CFSI in the U.S. with electrical equipment and valves such as the equipment that we looked at in the earlier slides.

A CFSI case was reported in Japan where the test data was falsified.

In response to a survey by the Nuclear Energy Agency in 2011, the other countries listed on this slide reported that they have not detected cases of CFSI.

The recent CFSI cases in Korea have been widely reported in the media.

In September 2012, Korean regulators received an outside tip regarding CFSI. The regulators then conducted a special investigation of all 23 operating units in South Korea. Two reactors were shut down while another two were allowed to continue operation while the fraudulent parts were being replaced.

These fraudulent parts came from eight separate suppliers who falsified

certificates for over 13,000 components. Over 6,000 of these components were installed in the power plants. These were for non-safety related equipment.

Later on that year, further investigation uncovered new instances of falsified certificates at two other reactors. An additional 1,000 components were affected, which included reactor water cooling system components; pumps and cylinder heads for diesel engines; and raw materials for parts.

In April 2013, Korean authorities received another outside tip. Upon investigation, the authorities discovered that control cables that had failed a required test were supplied with falsified certificates to four reactors.

Tests on the cables had been conducted by a Canadian company who documented that the cables had failed. However, the test results were then modified by a Korean company to state that the cables met requirements.

The Korean regulator shut down two operating reactors and delayed the startup of two other reactors.

The cables have since been

replaced and the Korean regulator has now given the operators the approval to restart operations.

Around the world, the topic of CFSI has generated international interest. International organizations have discussed this topic and have issued various reports.

The IAEA, for example, has issued a TECDOC providing guidance on CFSI.

The Committee on Nuclear Regulatory Activities, CNRA, of the Nuclear Energy Agency has a Working Group focusing on operating experience.

In 2010, this Working Group identified CFSI as a focus topic. The group sent a survey to all member countries and produced a report in 2011 based on the results of the survey.

The CNRA then formed a Task Group in 2011 to further explore CFSI issues and to identify measures to enhance the integrity of the supply chain.

This Task Group issued a report in February 2013 documenting causal factors of CFSI, the importance of an engaged and informed supply chain, suggestions on actions and controls that licensees and suppliers should consider, and

recommendations for actions to be taken by regulatory bodies.

The CFSI Task Group recommended to regulators that they:

- enhance their regulations and guidance to explicitly address CFSI;

- that they define expectations and protocols for handling CFSI;

- they assess licensees' CFSI programs; and

- share any CFSI information across the industry.

The USNRC has taken a very active hands-on approach in dealing with CFSI.

As was previously mentioned, during the late 1980s and early 1990s, there were attempts to introduce CFSI into U.S. nuclear facilities. The USNRC and the nuclear power industry performed a major reassessment of the supply chain and USNRC personnel assisted investigators and law enforcement officials to identify and prosecute the sources of these materials.

In addition, the USNRC issued several general communications to the industry

providing specific information related to CFSI activity, which led to a reduction in these occurrences in the U.S. for the next decade.

In September 2010, the U.S. Office of the Inspector General performed an audit on the USNRC's Vendor Inspection Program.

This audit determined that the USNRC's overall approach to CFSI was primarily reactive and that the agency could strengthen its approach by implementing more proactive elements. It also recommended that a formal agency-wide strategy and plan to monitor and evaluate CFSI should be developed and implemented.

In response to the audit report, a Task Force was created to focus on the key issues:

- keeping CFSI out of the nuclear supply chain;

- communicating CFSI;

- actions that should be taken following the USNRC being notified of a case of a CFSI; and

- oversight of cyber security related items or components.

Based on the results of this Task Force, in October 2011, the USNRC issued their

agency-wide approach to CFSI, which details the actions that the USNRC is taking to further address CFSI in the U.S.

In addition, the USNRC is in the process of creating a CFSI knowledge management Web page to be the central communication tool for disseminating CFSI information.

CNSC staff have reviewed how the Canadian regulatory framework addresses CFSI.

The Canadian regulatory framework provides significant layers of defence against the introduction of counterfeit and fraudulent items.

First, the management system requirements specified in the CSA N286 Standard state that licensees must have programs in place to ensure that all procured items and materials meet the technical and regulatory requirements necessary for its use.

In addition, the N286 Standard has requirements pertaining to controlling non-conformances, ensuring only approved items are used, and also has requirements for the sharing of experience.

Next, the CNSC has reporting requirements for a safety-related systems that

have become degraded, which would have been caused by CFSI.

Another layer of defence is provided by the various requirements which ensure that all systems, structures and components important to safety are designed with sufficient quality and reliability. Two notable features of these design requirements are the use of redundancy and diversity in the design.

Another design requirement is equipment environmental qualification. This qualification ensures that the equipment continues to function under all anticipated environmental conditions to ensure safe shutdown, removal of residual heat, containment and monitoring.

Fitness for service requirements are the next layers of defence. The CNSC regulatory document for reliability programs for nuclear power plants, RD/GD98, requires that the systems important to safety meet a defined design and performance criteria at acceptable levels of reliability throughout the lifetime of the facility.

This reliability program is implemented through surveillance testing,

inspection and measurement of system structure and components' performance or physical characteristics in order to verify their reliability and their state of readiness to perform their functions.

These tests and inspections will reduce the impact of counterfeit items that may make it through those other layers of defence.

In addition to the overarching management system requirements for all components that are part of the pressure boundary of the power plant, authorized inspection agencies such as the TSSA, known as Technical Standards and Safety Authority, certify and inspect the equipment. These rigorous inspections reduce the possibility that counterfeit and fraudulent items are introduced into the nuclear-grade pressure boundary components.

There are two major initiatives that the nuclear industry is taking to address CFSI.

The first initiative that we'll talk about was started by the Electric Power Research Institute (EPRI), an independent, non-profit organization that conducts research and

development into the generation, delivery and use of electricity.

EPRI issued a report in 2009 that summarizes insights on techniques being used to address CFSI. It also provides guidance on implementing enhanced controls to reduce the risks of these items being installed in plant systems and identifies measures that suppliers and licensees can implement immediately to reduce their risk of CFSI.

EPRI also created a database that U.S. and Canadian members are asked to update to be able to track CFSI cases and to learn from those experiences.

Another industry organization that is working to combat CFSI is the Nuclear Procurement Issues Committee, also known as NUPIC.

NUPIC was formed in 1989 to evaluate the performance and quality assurance programs of nuclear suppliers to U.S. NPPs.

In their audits of nuclear suppliers, NUPIC uses specific criteria to evaluate the suppliers' program for the prevention and detection of CFSI.

Canadian power plant licensees are

members of both EPRI and NUPIC.

Some of the measures adopted by the Canadian NPPs include:

- using audited, qualified and reputable suppliers;

- incorporating contractual requirements for suppliers' Quality Assurance Programs for the prevention, detection and disposition of CFSI;

- carrying out inspections from the receipt of an item to pre- and post-installation and to periodic inspections and surveillance testing during operation.

They have introduced CFSI Awareness Programs for their procurement personnel. They receive notifications of CFSI cases through the experience-sharing network and take appropriate preventive measures. In turn, they share internal experiences back to the network.

NPPs are members of both NUPIC and CANDU Procurement Audit Committee, known as CANPAC.

Similar to NUPIC, which we discussed earlier, CANPAC's role is to audit the

quality programs of CANDU suppliers to ensure that the nuclear supply chain is robust. In September 2010, CANPAC started auditing each supplier's process for preventing and detecting CFSI.

Currently, the CNSC is involved in a number of activities to address CFSI.

First, the CNSC participates in the NEA Working Group on Operating Experience and on the NEA CFSI Task Group. CNSC staff actively participated in the development of the reports issued by these groups.

The CNSC also participates in the NEA Multinational Design Evaluation Program Vendor Inspection Cooperation Working Group. That is known as MDEP.

The CNSC is an observer at the semi-annual CANPAC Steering Committee meetings and at NUPIC meetings in the U.S.

The CNSC staff have inspected the materials management/supply chain programs at each NPP and also recently started liaising with the USNRC to benchmark strategies and to share information.

As we have seen earlier, the existing Canadian regulatory framework contains a

number of different requirements that also act as barriers against the introduction of counterfeit and fraudulent items.

The first line of defence is to ensure that there are proactive measures implemented to detect and prevent the intrusion of counterfeit, fraudulent and suspect items. In the unlikely event that the first line of defence is breached and CFSI are installed in the NPP, the inspection and testing prescribed by the Fitness for Service Program will form the next line of defence to identify and remove those items from service.

In addition to these preventive and detection programs, there are multiple layers of defence by applying conservative design and construction with large safety margins, design redundancy and diversity and the use of multi-barriers -- multiple barriers. This defence in depth makes the CANDU design less susceptible to the effects of counterfeit items.

In summary, the primary defence against safety issues associated to CFSI is the fact that all failures have been accounted for in safety analysis and the design assures safe

operations or shut-down for any failures whether caused by CFSI or other reason.

To address the potential threat of CFSI in Canada as it pertains to the supply chain, CNSC Staff plan to take the following actions. Staff have added specific objectives and criteria and inspection guides to enable the evaluation of licensee's program for preventing and detecting CFSI.

Staff have engaged with industry on the subject and it has been very constructive so far.

Staff will continue to monitor CFSI initiatives nationally and internationally through participation and observation in CANPAC, NUPIC and the various NEA groups.

Staff also intend to reach out to federal and provincial regulators and agencies overseeing other high reliability industries.

Staff have added a specific reporting requirement on CFSI to the new proposed regulatory document on reporting requirements for NPPs, REGDOC 3.1.1. This REGDOC is currently undergoing a consultation process.

This concludes our presentation.

Staff is available to answer questions.

Thank you.

THE PRESIDENT: Thank you. Before we open up the floor for questions, maybe I would like to hear from industry what's happening in the real world with all you just went through, refurbishment with all kinds of thousands of new components.

Did you run into this problem?

MR. SAUNDERS: Frank Saunders for the record. Yes, I think -- I mean, we have certainly a lot of experience with this, we literally use millions of these things over a 10-year period. We have done a lot of work. I think as Staff presentation indicated, that probably the most important aspect is to realize it's a multi-layered approach, right, starting from the initial prevention from the supplier on through inspections and so forth.

Some of the biggest changes over the last two or three years is a lot of the work with EPRI where we were actively involved, as were most utilities and not just the nuclear utilities, utilities in general, to identify ways of making sure we can find these things better in audits and

how to specify the requirements better, we have adapted our audit procedures to be able to do that.

We have also done a lot of education on receipt inspectors, the guys that our place to look at the equipment when it arrives and the amount of inspection again of course varies with the significance of the equipment, but an awful lot of work with these people to educate them on what things to look at, and then Staff indicated one example there of a valve which has the maker stamp on it, but it's traced on with arc weld versus actually, you know, part of the moulding that formed that thing. And, you know, I have here about, you know, probably 25 pages of those kinds of examples.

So we educate our people extensively to do that. So when you look at the sort of big changes, that's it.

The other bit is, of course, a lot better reporting now than we used to have, so any suspicious items we find we have reported, there is OPEX on it so people can look.

We have better reporting out of the field for early failure so that we can go back

to the manufacturer and say, you know, was this the right part or did we get fooled? And our actual activity level, which I think is the question you are getting at, is how many times have we found items that we think might have been suspicious?

And really the last item we have had that we were suspicious, we were never able to actually confirm whether it was counterfeit or not, was back in 2009 of any consequence, and it was an integrated control circuit that failed early in the field. We could not confirm exactly with the manufacturer that it was indeed theirs -- now, there is a little bit of self-protection there, right, sometimes, you don't know whether the manufacturer is telling you the truth or not -- but we were a little suspicious on that one.

But, in general, we find very little of this on the quality components, you find more of it on the lower quality stuff, you know, office supplies and other things, that tends to be a little harder to check, but in terms of the QA and the quality components, we really don't have a history of finding major faults in the stuff we

are bringing in. Sometimes manufacturing defects, I would say that's actually more common than the counterfeit here in Canada.

But certainly a lot of work with suppliers to make sure they have a rigorous program, how do they know, how do they test. If you are bringing in some items like metal composition and that, of course, it's very hard to tell on a physical inspection so, you know, if you are importing it from somewhere on the other side of the world, how do you know, right? So our demands on their programs are much higher than they were.

We are in the process actually of updating some of the standards through CSA and that to reflect the -- you know, to make sure we have a common approach in all that in Canada.

So I think that's my update to that extent.

THE PRESIDENT: Okay. I'm sure we will have lots of questions, let me start with Dr. McDill.

MEMBER McDILL: Thank you. I very much enjoyed the presentation. On your slide 9 you have a CFSI worldwide and there is United

States, Japan and the others.

With respect to the others, Canada isn't mentioned here, so I don't know where we fit into this, but I'm assuming from the report we just had that there is some.

Is it possible that these countries are reactive, not proactive, or they just never found something?

MS HEPPELL-MASYS: Of course this comes from DoE and we do have people in the room that were at that meeting, but I will ask Paul Wong to provide some answers.

MR. WONG: The report actually was quite detailed from the responses from the various countries. They do indicate that they don't actually have an active -- the majority of them do not have an active CFSI program.

So in response directly to your question, yes, I presume they are reactive in that sense because they do not have a proactive program.

MS HEPPELL-MASYS: I just realized that Monsieur Ben Poulet is here with us and I think he has participated in those meetings, so maybe he would like to add a comment.

MR. POULET: Thank you. My name is Ben Poulet, I am the Director of the Gentilly-2 and Point Lepreau Regulatory Program Division. I am also the current Chair of the CNRA Working Group on Operating Experience.

The survey that was circulated that's been referenced to here specifically requested to the member states to look into the event reporting databases to see if there were any events that actually were reported to the regulator. Now, the instances that are presented in the presentation -- included in the presentation, are those countries that actually had events reported to the regulatory agency.

In our case we did not have any and no events were reported to the CNSC under the current regulatory framework S-99 because of, or as a cause of counterfeit or fraudulent items.

This is in line with what Mr. Saunders has said, it's true, there have been instances where -- and we are aware of those -- where counterfeit parts were, either through inspection or through self-discovery by the licensee staff, there have been some instances but they did not result in an official report or a

mandatory report. We picked those up because we have site on staff, those have been picked up and we are aware of them through our regular surveillance and monitoring activities.

So that's the nuance, if you like.

THE PRESIDENT: I'm told that we have somebody here from New Brunswick and I'm curious whether -- if memory serves, some such piece of equipment was detected in New Brunswick, I'm just curious whether anything was found during the refurbishment of Point Lepreau?

MR. DAVIES: Terry Davies, for the record. We have no reported CFSI events during the actual refurbishment itself. Obviously we did replace a lot of critical equipment through the refurbishment process.

With the kind of the equipment that we replaced it is stability critical, therefore, there is a lot of focus that goes into the supply chain in the actual purchasing of those products.

Also, there is a lot of factory acceptance testing that's done at the manufacturers and also a lot of testing is done actually on-site during the commissioning process.

So there is a lot of rigour in place for those critical items that were addressed during the refurbishment project.

The CFSI is focused on low-cost, high-volume items and that is where the most common CFSI events occur. In the last six months at Point Lepreau we have identified for occurrences of suspect items and that means that they are suspect, not confirmed counterfeit or fraudulent. We are going through the process of working with the manufacturers to understand how these items got into the actual supply chain and those investigations are ongoing currently to determine how best to move forward.

But those items, they are low-cost, high-volume items, they are also a low-risk item. We have a rating system of A, B, C and no-risk, "A" being the highest risk, and these items would be Category C, which is relatively low-risk.

So the threat to the industry is really those items that are low-cost and high-volume, and that really needs to be -- we have room for improvement as regards to the oversight in those areas. Certainly we work with

our utility partners to share that OPEX and obviously these four events we will -- no, we have shared them with our peer utilities and certainly as our investigations bear some outcomes, we will also share that as well.

THE PRESIDENT: Thank you. Dr. McDill? Ms Velshi?

MEMBER VELSHI: Thank you. So if we looked at what is the residual risk -- by the way, thank you, this is extremely informative and it's great to hear from the licensees and what they are doing about it.

If we looked at what is the residual risk, is this something that you feel confident that it's being well managed or is this like hacking where the hackers are always a step ahead of the good guys?

MS HEPPELL-MASYS: Well, as we mentioned in our remarks, there are multiple levels of defence that we feel are good, but one cannot -- we also need to be remaining vigilant. Some people are very creative.

But our intent with our next steps is to go through the oversight with our criterias and objectives of the licensees and then they will

be in a better position to really say -- you know, we will verify those programs and then we will be able to come up with where are we with respect to the benchmarkings that we will have done, conducted also by then.

So what we are hoping, though, we are confident that we should not find -- after the conversations we have had with licensees and listening to them adopting the EPRI guidance that pertains to the nuclear supply chain, and we also hear from them that they are working together, but there is also a little bit more room there for more consistency in the approach, but I think we are on the right path.

MEMBER VELSHI: Thank you. I seem to recall that I recently read that I think it was GE Hitachi that pled guilty to doing something along these lines recently in the States, maybe in the last couple of -- maybe in the last month.

Does that ring a bell, anyone?

MS HEPPELL-MASYS: I'm sorry, we don't know about that case and we do have people that participate through NUPIC and CANPAC and they have not heard, so...

MR. JAMIESON: For the record,

Terry Jamieson, Vice President of the Technical Support Branch. So that recent media report was actually related to the design certification of the ESBWR of GE Hitachi and it related to some differences in the documented design on the steam dryers. So not for an operating reactor, a reactor undergoing certification process.

THE PRESIDENT: But it was falsifying information; was it not, or something of that nature, or withholding information? I can't remember the exact --

MR. JAMIESON: It was a difference between the documentation between the design as submitted and intended to be built.

MEMBER VELSHI: Okay. And in this EPRI database that Canada contributes to, how many cases would be reported? I mean we have heard four and nothing really since 2009. Is it hundreds, is it a handful?

I think I should ask industry to see if they have reported anything to the EPRI database?

MR. DAVIS: For the record, Terry Davies. From an industry perspective we haven't shared any confirmed CFSI items into the EPRI

database. We certainly have some suspect items currently, but they haven't been confirmed. Once they are confirmed, we can actually share that information.

THE PRESIDENT: Yes. Is the database -- it seems to me again that I was told that it is kind of in the club, it is not being published, you guys don't blacklist.

So let me ask you specifically, Korea, we know about the Korean issue on cables and a couple of other things. Did they actually identify the source, and that is the source, is the intention to blacklist and is the intention that you publicly will stand up and say, if we find any one of those ever supplying us we will never, ever buy anything globally? Are you guys into this kind of a space?

MR. SAUNDERS: I think the shorter answer is yes, although we do it a slightly different way, right. What we have is an approved suppliers list, right. We don't have a blacklist, we have a list of those we will buy from.

And, of course, this is part of the equation, right, so if you have provided fraudulent materials to somebody else, then

obviously you are not going to be on our approved list unless you can really demonstrate to us that you have fixed that problem and that's part of what the audits and the other things are about.

This is not actually new, this has been around for quite a long time in the supply business where you do it -- I would say we have gotten a lot more sophisticated about how we do the approved supplier list now, the technology today allows you to manage that much better than you have in the past.

So yes, and are we aware, we do -- and we do share the information ourselves. The NEI work, in my view was, you know -- or the EPRI work in my view was much more about how you find it. I mean, that was really the value we get out of it; databases are fine, but the real issue was how did it slip by other people, so how do you need to manage your audit program, and so forth, to make sure it doesn't slip by you.

And that's really what that working group is about and that's really the use we make of it.

But certainly even if -- you know, it doesn't take a whole lot to get you off the

approved supplier list and a lot less than fraudulent activity, but fraudulent activity would certainly do it, right. Just the simple issues like not delivering on time and not, you know, being cost competitive and other things get you off the list, too.

So I think companies, all companies are very active in that. I invite Lepreau to have the --

--- Off microphone / Sans microphone

MR. DAVIES: The actual example quoted with regards to the South Korean fraudulent CFSI items, the actual -- the people who were actually involved, or the causes of the CFSI were a number of what they call brokers and we call distributors here in Canada.

Those brokers were unique to the South Korean market. We don't do ourselves business with those brokers ourselves as utilities. There was a lot of lack of control in the approval of those workers and I think that's one of the things that came out from the regulator's investigation into those CFSI items.

Certainly a lesson learned -- the lesson we learned is that the robustness of the

supply chain is very important and is really the first barrier to preventing CFSI items getting through and actually installed in our plants.

So for us it was a learning opportunity, but with no real action necessary as regards to stopping to purchase products from them or anything of that nature.

THE PRESIDENT: But the Korean experience is a really good example about the global issues. So here we are, we are all worried about global incident and Korea now is selling plants globally, so how can we make sure that when they build one somewhere else the whole Korean supply chain is okay?

You see, that's why I think there's got to be a global look at and disqualification of suppliers, all the way from the actual NPP bill to all the supply chain that goes behind it. I don't expect an answer, I'm just making a statement. This is the kind of thing that has to be discussed at a global level, in my view.

MR. DAVIS: I think I can offer some information with regards to what we do may be a little different from the South Korean example.

Now, Canadian utilities are active members of NUPIC and CANPAC, we also share a lot of information through the COG OPEX realm, we are also expanding inspections ourselves. Because the actual manufacturing takes place in remote locations like China and India, so what we are doing as an industry, we are moving a lot of our -- sorry, a lot of our inspections were really North American, but we are moving those inspections to where the actual manufacturing is taking place today.

THE PRESIDENT: Thank you. Ms Velshi...? M. Tolgyesi...?

MEMBRE TOLGYESI : Merci. You know, when you were looking -- I still believe that a kind of blacklist will be much more dissuasive in this disqualifying on your proposed suppliers, because somebody who is not necessarily on your list doesn't mean they should not be on the blacklist, should probably. Have you --

MR. SAUNDERS: Yes. I think the issue is there's always all fairness in competition, right, and we do have to meet those kind of requirements.

So as a supplier you can apply to

us to be on our Bruce supplier list and if you can meet the requirements, you know, and assuming there just aren't too many for us to manage, you can get on there.

I think that's an opportunity you need to provide the people, however, you do have to have a way of distinguishing between those that you don't accept, right. But in a sort of fair and competitive world it's harder to do something as simple as a blacklist, although it sounds very inviting, and even if you made a mistake once it doesn't mean you are on the blacklist forever, right, so what do you do to fix it and were you effective at that.

So I think -- you know, I think the way we've approached it is to say we need to be convinced that you can supply the material and the requirements vary of course depending on the nature of the material. And if we are convinced and our audits support it, then you are on the list.

If there was a counterfeit item that was attributed to a supplier we're using, we would of course look at that very closely and decide whether that ought to be withdrawn.

So yes, I take your point, it's nice to send a message by having a blacklist, but there are some legal and fairness things in trade that you also have to deal with.

MEMBER TOLGYESI: And my last one is, how do you -- to introduce a new or equivalent product, should it receive a certification or general acceptance or whatever? How you do that?

MR. SAUNDERS: Yes. Frank Saunders again, for the record. There actually is an engineering process that we have to go through to evaluate new products. This happens frequently actually in the electrical and the IC area because you never seem to be able to buy the same one you bought last time, it's already outdated.

So we have an equivalency process in engineering and IT that goes through that design review and make sure that what you are buying is actually equivalent to what you had before and whether you have to make any other changes to accommodate it of course.

So it's a very necessary thing these days, you couldn't get along without that process. So yes, that is well-established and it's part of our programs that we commit CNSC to

have.

MEMBER TOLGYESI: And that was my question. CNSC, how do you react? What's your involvement when these new products or similar or equal products are implemented or introduced?

MR. LAHAIE: Pierre Lahaie, for the record. As part of our baseline compliance program we conduct inspections on our NPP licensees' supply management processes and in the event that -- part of that inspection follows the criteria in our management standard and the criteria detail what a licensee should do should they come across non-conforming product, and typically we have not had any findings or issues with that part of the supply management process as the regulator.

THE PRESIDENT: Thank you. Dr. Barriault...?

MEMBER BARRIAULT: Thank you. Just a few brief questions for me. First question, is there a downside to a company producing CFSI parts other than not being purchased from it; in other words, is there a penalty imposed on these companies for producing this kind of a product? I don't know who would

care to respond to that.

MR. SAUNDERS: I think there are penalties at various levels -- Frank Saunders -- we can talk about anything. From a corporate level of course we would pursue, you know, financial action against companies that do that.

There generally are rules and laws of the land that prevent you from doing counterfeiting, right, and that would make you subject to legal action. Of course it's not -- as a company we don't do that, but I'm sure that there are jurisdictions that would pursue it in an obvious case. In our case we would seek the appropriate financial compensation for that.

MEMBER BARRIAULT: Thank you. My next question really is, do you have a problem at all with recycled items coming through as new parts? I know in the aviation industry that can be a problem.

MR. SAUNDERS: Part of our non-conforming part is to look for evidence of recycled parts. I mean in some cases, of course, we actually buy recycled parts, right, but again there are standards around how they need to be retrofitted and what it all looks like.

Like, you don't just want to get a recycled one as a new one, it's both an economic issue and a technical issue. If it's recycled and properly fixed, you know, then that's okay, but usually there is a definite price difference and that's why you want to know what it is.

So it is part of the objectives. We don't actually -- we haven't had an issue with it in terms of finding it, but it is part of what the inspectors look for.

MEMBER BARRIAULT: Thank you. Thank you, Mr. Chairman.

THE PRESIDENT: Dr. McEwan...?

MEMBER McEWAN: Thank you, Mr. President. Again, a very interesting and eye-opening talk.

We have talked today about the NPPs. Is this an issue for the large number of accelerators that we are responsible for licensing? Is there something that the operators of those should be aware of as they move forward? The risk of harm seems to me to be great.

--- Off microphone / Sans microphone

MR. LAHAIE: Sorry, I'll repeat that.

Pierre Lahaie, for the record. We also conduct procurement and supply management inspections for all our Class 1A and 1B licensees, including the TRIUMFs and the CLSIs of the world, and as far as I know we do not have any issues of procurement, however, we have not specifically looked at the issue of CFSI with these facilities and so that's something we should consider going forward, because I would identify with the problem that you have mentioned that some items that are fraudulently built, non-conforming, could cause some issues with the operation of a high-energy cyclotron.

MR. JAMMAL: It's Ramzi Jammal, for the record. We have a certification process in the CNSC where we certify the design of the equipment with respect to its safety. However, as the purchase of the equipment takes place at the hospital, the hospital itself is part of the commissioning process to include the verification of the circuitry boards, is it CSA approved, is it stamped. So there are requirements on the licensee that they must carry out their own activity with respect to the inspections of, is it medically qualified or not and was it build

according to its design?

So the commissioning testing that we ask our licensee to put in place to verify the functionality of the equipment and part of the commissioning will indicate if the machine has received or had any fraudulent equipment. To date the CNSC has not received such information.

At times they discover, on non-safety end of the equipment, boards or any other components that are not probably CSA certified or not and then the hospital's biomedical engineering will stop that procedure and then request on other elements of the machine to have it properly certified and properly approved.

So we start from the certification process of the CNSC that looks at the safety elements. The commissioning testing by the licensee and our inspections as a result of the commissioning indicates if there are any components of the device or certified equipment that does not meet our requirements, we get these reports.

And then there is the other elements that is beyond the operation safety which

is an electrical installation on the site itself and that is the hospital's responsibility.

MEMBER McEWAN: What about post-commissioning replacement parts? If you have to replace the widgets on a linear accelerator, is there any check or balance on that?

MR. JAMMAL: Ramzi Jammal, for the record, one more time. As we issue the CNSC for -- if we are talking about accelerators, we issue a licence to service such equipment and as part of the licence to service is the qualification of the -- no one can service a prescribed equipment unless they are licensed by the CNSC.

As part of a review of the issuing -- for example, a company, to license an accelerator, they will have to put in place procedures and elements to do two things: verification that the components will function as designed; in addition to that, they will report to us if there have been any elements that do not meet the requirements.

On the testing, no machine can go back in-service unless the service provider has certified and assured the fact that the machine

will be -- the parts that were replaced on that unit meet the existing design perspective and will function accordingly.

So the installation takes place through certified and licensed service personnel, the testing of the machine is done according to the specs as certified by the CNSC and then no machine can be put back into, for example, clinical work unless it's commissioned by the physicist and signed it off.

MEMBER McEWAN: So CFSI awareness is formally part of the process?

MR. JAMMAL: Ramzi Jammal, for the record. I cannot give you a precise answer. I will look into it and I will make sure that it is part -- it will be part of the process, but there are procedures in place that probably will address the CFSI process, but I cannot say yes or no unequivocally on that.

THE PRESIDENT: Go ahead.

MEMBER McDILL: A follow-up question to that. I'm thinking back to the radiation therapy device that was a bit of a hiccup between us and Health Canada, so is this something that would be done jointly between

Health Canada and CNSC?

MR. JAMMAL: Ramzi Jammal, for the record. Based on the lessons learned from the event that did take place, now Health Canada does not certify a unit and the CNSC will not certify a unit unless both organizations have received in writing that the certification process has been addressed and has been closed, so there will be no gaps.

So, in other words, the CNSC will not certify prescribed equipment until we obtain a certification from Health Canada that they have certified the unit, the components, the elements of the unit have been certified by Health Canada and then we will continue with our certification.

MEMBER McDILL: So there will be a responsibility on the part of Health Canada to look for counterfeit/fraudulent suspect items as well?

MR. JAMMAL: It's Ramzi Jammal, for the record. A quick answer, the answer is yes because the components that Health Canada is responsible for are integral part of the certification. It should be yes and I can definitely say yes, but I will look into it and

give you back an answer on this.

THE PRESIDENT: Anybody else on this?

Well, all I can tell you on a personal note, this is my nightmare scenario because some of those fake stuff, I have no idea how you guys can actually tell one from another and you can spend all your time trying to check on a circuit, there are so many components in it.

It reminds me on way, way back where -- you know, when I was in Hong Kong this little kids come to me and say, "Hey, Mister, would you like to buy this genuine fake Rolex."

--- Laughter / Rires

THE PRESIDENT: Yes, that's the way, it was so cute. But all of you I'm sure came across Prada bags, right, very difficult to tell apart. So you can imagine bringing this down now to a component.

In the example you gave here, I have no idea how one can tell one from another really, it's really tough. So I don't know what the answer is, but it's the whole of government. It's not only nuclear, it's aviation, it's transportation, it's -- you know, practically

everything we do. You have to be vigilant.

And my final remark is, you thought components were difficult, what about software and hacking into the software. So I don't know what the answer is, but I think that being in close-knit kind of committees I'm not sure that's the right answer, you have to actually namely shame, and not to mention the penalties and all the rest of the stuff.

But any time there is an incident it has to be really publicly dealt with, that would be my kind of opinion about this. But I think this is -- I can tell you in our discussion amongst regulators, we really are worried about what we don't know in some of those very complicated machinery, I'm sure just as you do, and we don't know what kind of regulatory scheme we should kind of devise, if anything.

So any final remarks that anybody wants to make?

MS HEPPELL-MASYS: I might take the opportunity in this case to talk a little tiny bit about the activity that we take part to address some of the global concerns you mentioned.

I would like to point out that the

CNSC does participate in the multi-national design evaluation program, MDEP, and there is a working group that is focused on vendor inspection co-operation and Pierre could probably break down a little bit more about the kind of activities they do where they go around the world looking at various suppliers and conducting inspections there and they share, as regulatory authorities, that information among themselves too.

So did you want to add anything?

MR. LAHAIE: Sure. Thanks, Kathleen. I don't actually have to add a whole lot because you said a lot, which is good.

So this committee looks at what standards various countries use to verify vendors and I think the important thing here is just to mention that they have started looking at the issue of CFSI in the supply chain from a global perspective.

No answers obviously yet, but they are looking at it.

MS HEPPELL-MASYS: They actually plan on hosting the next meeting in Korea.

MR. LAHAIE: In June.

THE PRESIDENT: Okay. Thank you.

Thank you very much.

--- Pause

THE PRESIDENT: We now will move to the approval of the Minutes of the Commission meeting that was held on December 9, 10 and 11, 2013 in Toronto, Ontario. The Minutes are outlined in Commission Number CMD 14-M10.

CMD 14-M10

Approval of Minutes of Commission Meeting held December 9, 10 and 11, 2013

THE PRESIDENT: Any comments on those minutes? Ms Velshi...?

MEMBER VELSHI: I do have a comment that I have passed on to the Commission Secretary and it is to better reflect the evidence that was presented at the meeting around potential risk regarding alpha contamination in air.

The minutes don't fully reflect the evidence received and the Commission Secretary has my comment on that.

THE PRESIDENT: Okay. Dr. McDill...?

MEMBER McDILL: Thank you. As

part of the meeting I asked if the emergency plans were well communicated to the community and in number 100.100 it's clear the plans are communicated to City of Toronto, the Toronto Fire Department and medical services, but I wonder if the staff could review the transcript to see if there is an action item or a commitment by GE Hitachi with respect to the communication of the plans to the community.

THE PRESIDENT: Okay. Do you want to say something about that?

MR. JAMMAL: No, just confirm -- it's Ramzi Jammal for the record -- that we are taking this into consideration. We just got the Minutes this morning, so...

MEMBER McDILL: Yes.

THE PRESIDENT: Okay. Any other comments?

So with those additions we will approve those Minutes. Do I have concurrence for that?

Okay, thank you.

MEMBER BARRIAULT: I wasn't there.

THE PRESIDENT: No, that's right. You were not at this particular wonderful session.

--- Laughter / Rires

THE PRESIDENT: Thank you. We are now moving into an in-camera.

MR. LEBLANC: In fact, this closes the meeting, we are moving into a technical briefing session that is outside of the Commission proceeding process, but yes it will be in-camera here in this room.

So I will invite Claire and her crew and Denis to approach us. We were first going to do it in the back room, but we just thought there may be too many people and it was as comfortable to do it here.

--- Pause

THE PRESIDENT: So the webcast is finished?

THE SECRETARY: Yes.

THE PRESIDENT: The webcast is finished? Good.

So now we can be very informal. I'm with you, let's go and get coffee.

--- Laughter / Rires

--- Whereupon the hearing adjourned 11:54 a.m. /
L'audience est ajournée à 11 h 54