Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Public meeting

Réunion publique

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Le 12 octobre 2017

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

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

Commission Members present

Dr. Michael Binder
Dr. Sandy McEwan
Dr. Soliman A. Soliman
Dr. Sandor Demeter
Mr. Rob Seeley

Commissaires présents

M. Michael Binder
Dr Sandy McEwan
M. Soliman A. Soliman
Dr Sandor Demeter
M. Rob Seeley

Assistant Secretary:

Ms Kelly McGee

Secrétaire-adjointe:

Mme Kelly McGee

General Counsel:

Ms Lisa Thiele

Avocate générale :

Me Lisa Thiele

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Ottawa, Ontario / Ottawa (Ontario)

--- Upon resuming on Thursday, October 12, 2017
at 9:03 a.m. / La réunion publique reprend
le jeudi 12 octobre 2017 à 9 h 03

Opening Remarks

MME McGEE : Bonjour, Mesdames et Messieurs. Bienvenue à la continuation de la réunion publique de la Commission canadienne de sûreté nucléaire.

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

We have simultaneous interpretation. Please keep the pace of your speech relatively slow so that the interpreters can keep up.

Des appareils pour l'interprétation sont disponibles à la réception. La version française est au poste 2. The English version is on channel 1.

To make the transcripts as complete and clear as possible, please identify yourself each time before you speak.

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

I would also like to note that these proceedings are 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.

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

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

President Binder.

THE PRESIDENT: Thank you, Kelly.

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. Welcome to all of you who are joining us via the webcast.

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

On my right is Dr. Soliman A. Soliman; on my left are Dr. Sandor Demeter, Dr. Sandy McEwan and Mr. Rob Seeley.

We have heard from our

Assistant-Secretary, Kelly McGee, and we also have with us here Ms Lisa Thiele, Senior General Counsel to the Commission.

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

The agenda was approved yesterday. Please refer to agenda CMD 17-M40.B for the complete list of items to be presented today.

Thank you.

THE PRESIDENT: We are going to start today with an information item to provide us with the 2016 Regulatory Oversight Report on the Use of Nuclear Substances in Canada, as outlined in CMDs 17-M42, M42.A and M42.B.

The public was invited to comment in writing. The Commission received four submissions. Three intervenors requested to make an oral presentation and were permitted to do so.

I will now turn the floor to CNSC staff.

I understand, Mr. Moses, you will make the presentation. Over to you.

CMD 17-M42/17-M42.A/17-M42.B

Oral presentation by CNSC staff

M. MOSES : Bonjour, Monsieur le Président et membres de la Commission. Je m'appelle Colin Moses et je suis le directeur général responsable de la réglementation des substances nucléaires.

Je vous présente mes collègues :

- Mrs. Sandra Mortimer, Program Officer within the Transport Licensing and Strategic Support Division;

- Mr. Henry Rabski, Director of Operations Inspection;

- Mr. Mark Broeders, Director of the Accelerator and Class II Facilities Division;

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

- ainsi que M. Sylvain Faille, directeur des autorisations de transport et du soutien stratégique.

On est également joint par d'autres membres du personnel de la CCSN qui sont présents dans la salle en appui à l'équipe.

Nous vous présentons aujourd'hui le rapport annuel de surveillance réglementaire sur

l'utilisation des substances nucléaires au Canada pour l'année 2016. Ce rapport constitue le septième rapport produit jusqu'à maintenant par la CCSN, le précédent rapport vous ayant été présenté en septembre 2016.

Production of this Regulatory Oversight Report continues to be an achievement for the Canadian Nuclear Safety Commission and a mark of best practice internationally. Following the presentation today, the report will be finalized and published on the CNSC external website.

The CNSC regulates the nuclear industry in Canada through a comprehensive program of licensing, certification, compliance verification and enforcement. The safe use of nuclear substances in Canada is a reflection of licensees' compliance with the *Nuclear Safety and Control Act* as well as its associated regulations and specific conditions set out in CNSC licences. The *Nuclear Safety and Control Act*, its regulations and the licence, require that licensees implement and maintain appropriate programs to ensure the safety of nuclear activities, minimize doses to workers and the public, and minimize any potential consequences of events.

Licensees are always responsible for the safety of their operations and activities. For each

nuclear industry sector described in this report, CNSC staff conduct inspections, assessments and reviews to evaluate each licensee's programs, processes and safety performance.

Pursuant to the CNSC's mandate for the dissemination of objective regulatory information, and consistent with our commitment to transparency in our activities, the CNSC publishes a series of annual regulatory oversight reports covering all main sectors of CNSC regulated activities. You have already heard about the CNSC's regulation of nuclear power plants and today we will be presenting the CNSC's regulatory oversight report on the use of nuclear substances.

Before proceeding any further, I would like to note four corrections to the report, which are outlined on this slide. These errata do not impact any of the conclusions in the report and the corrections will be made to the report prior to its final publication.

You will see here an overview of the presentation, which will provide an introduction to the CNSC's regulatory approach to regulating nuclear substances in Canada, a summary of the comments received during the consultation period, and outline the 2016 performance of the industry in four key safety and control areas. We will

conclude the presentation highlighting our progress on certain key initiatives underway in 2017.

So to start with a brief introduction of our work.

The nuclear substances industry in Canada continues to operate safely in 2016. CNSC oversight activities, including licensing reviews, technical assessments and inspections, confirm that licensees in the sector have appropriate safety programs in place in order to protect the health and safety of Canadians and the environment. Further, CNSC staff verified that licensees continue to maintain adequate measures to implement Canada's international obligations.

Despite the generally strong performance in the industry, there were two events reported in 2016 that involved exceedances of regulatory dose limits, both of which had been previously reported to the Commission. In one case, a Nuclear Energy Worker exceeded the regulatory dose limit for extremities as a result of contamination during the administration of a therapeutic nuclear medicine treatment. The second involved a member of the public exceeding their effective annual dose limit as a result of non-compliances with transport regulations. No adverse health effects were observed in either case and

we will be discussing these events further later in the presentation.

CNSC staff remain committed to continuous improvement and have made a number of improvements to the report from previous years. Further to a suggestion from the Commission last year, the 2016 report includes preliminary information on repeat poor performance of a licensee. In addition, in the interest of continued transparency, we have included a list of all inspections conducted by CNSC staff in this area as an annex to this report. Finally, consistent with our objective of disseminating information on operational events, CNSC staff have included a summary of events related to the use of nuclear substances in Canada in 2016, along with information on significant events that have occurred elsewhere in the world.

For the third year, the CNSC posted the draft report for comments prior to presenting the report to the Commission. The report was posted on the CNSC website and pushed out to subscribers to the CNSC subscription service, which includes all licensees regulated and that are covered by this report. In addition, this was the second year that the CNSC made participant funding available to support the review of the report. Funding was

awarded to the Canadian Radiation Protection Association, the Canadian Industrial Radiography Safety Association, the Canadian Environmental Law Association, and the Algonquins of Ontario.

CNSC Staff are particularly pleased this year to have reached a broader span of interest in our regulation of this sector, and the commenters raised questions in several areas, summarized on this slide. This was an excellent opportunity to provide additional information on our regulatory oversight activities, and it resulted in a number of opportunities to further enhance future editions of this report.

Because of the breadth of comments received, CNSC Staff prepared supplemental CMD 17-M42B, which provides CNSC Staff responses to all comments received.

To summarize the themes that came out of the comment period, regarding planning and prioritization of compliance activities, the Canadian Environmental Law Association noted the decrease in number of inspections in 2016. CNSC Staff have developed a risk-informed regulatory program that considers the nature of the regulated activity and assigns a baseline inspection frequency that is commensurate with the relative risk of that activity. This

serves as the foundation of our annual inspection plans. But we layer on top of this a wide variety of reactive inspections triggered by different factors such as inspection results, compliance history, events, whistle-blower calls, and sector performance trends.

As a result, the number of inspections and person days dedicated to compliance activities can vary substantively from year to year and should not be taken as either an increase, a decrease, or increase for that matter, in overall regulatory oversight. In 2016, all high-risk inspections were completed as planned and there were no substantive changes to our overall regulatory program.

CELA also commented on the limited information on environmental protection that was included in the 2016 report. It is important to note that the majority of the activities that we regulate have no impact on the environment. There are no operational releases from a double-encapsulated sealed source within a radiation device that goes through a rigorous certification process and is subject to annual leak testing.

When licensees work with unsealed nuclear substances, we expect stringent work control measures to minimize doses to workers and the public. Although this

has never happened since we have started preparing our regulatory oversight reports, if there were ever to be a failure of these barriers, it would trigger an event report that would be discussed in detail in our regulatory oversight report.

As a result, CNSC Staff do not agree that there is a need to introduce an environmental protection SCA chapter to further editions of this report. We do, however, recognize that there is an opportunity to better describe these measures and will include this information in future editions of the report.

Regarding the transport of nuclear substances, CELA raised questions on requirements for labelling, shipping documents, and emergency response. Our detailed responses are included in the CMD; however, I would like to note that CNSC's regulatory framework in this area follows the IEA transport regulations which are widely adopted internationally and includes, amongst other things, risk-informed requirements for packaging design and testing and requirements for shipments while in transport. Our regulations also incorporate transport of Canada's Transport of Dangerous Goods Regulations, which are applicable to movement of all dangerous goods in Canada.

Both the Canadian Radiation Protection

Association and the Canadian Industrial Radiography Safety Association suggested different means of presenting dose information in the report. The current format is aligned with the type of information currently collected from licensees and is only one indicator CNSC Staff use to assess adequacy of the radiation protection programs that are in place. This format has proven the most effective at identifying meaningful trends in the industry, although we continue to explore different ways of extracting and presenting the wealth of data that we collect from our compliance activities.

The CRPA and CIRSA also recognize the importance of outreach and engagement activities, and CNSC Staff remain committed to this as one vehicle to communicate and engage with our stakeholders. In addition, CRPA and CIRSA noted the importance of sharing information on events reported to the CNSC. Staff have made a number of improvements in that regard, and will continue to explore means to share this information with licensees.

Finally, the Algonquins of Ontario requested additional opportunities to engage with the CNSC on our regulatory activities. CNSC Staff will continue our engagement with the AOO providing information on our regulatory framework and exploring which specific

facilities and activities within their traditional territory are of interest to their membership. The CNSC's participant funding program is flexible and can assist the AOO to meet with Staff, participate in CNSC reviews, participate in monitoring programs, and to conduct Indigenous knowledge and traditional land use studies that will bring value to the Commission.

Before turning the presentation, I would like to note that CELA suggests that our report presents an overly optimistic picture of industry performance. I can assure you that is not the case. Our report presents the facts of our oversight. The data collected from inspections are presented as they were observed in the field, and the full list of all events reported to the CNSC is included. Our report objectively discusses the trends that we have extracted from this data. The conclusions are borne out when you look at the year-over-year performance of the industry and the totality of our regulatory oversight. In particular, the dose data clearly shows a gradual reduction in occupational doses received by nuclear energy workers. Taking into account the totality of our regulatory oversight activities, with due consideration to the trends presented in this report, Staff are confident in the conclusions presented.

I'll now turn the presentation over to Ms Sandra Mortimer to provide an overview of the industry we regulate.

MS MORTIMER: Good morning. I am Sandra Mortimer, a program officer in the Transport Licensing and Strategic Support Division.

In this section of the presentation we provide an overview of the different activities covered in the report.

Nuclear substances and prescribed equipment are used in a broad range of applications that can be grouped in four sectors: the medical sector, the industrial sector, the academic and research sector, and the commercial sector. The written report provided detailed information for compliance statistics and doses to workers down to the level of subsectors; however, in today's presentation the information will remain at the level of the sectors.

In 2016, there were 470 licences in the medical sector. There were over 9,800 individuals working in this sector. Two-thirds of these workers are designated as nuclear energy workers or NEWs. Nuclear substances and prescribed equipment are used in the medical sector in nuclear medicine for both therapeutic treatments and

diagnostic procedures as well as research studies, for radiation therapy, and veterinary nuclear medicine.

The industrial sector is the largest of the sectors covered in this regulatory oversight report, both in terms of the number of licences and the number of workers. Fifty-eight percent of the licences held for activities covered in this report are in the industrial sector. In 2016, there were over 43,000 total workers. Nuclear energy workers represent only 28 percent of workers in the industrial sector. Many industrial applications of nuclear substances do not require workers to be considered as nuclear energy workers. Only those with the potential to receive doses above 1 millisievert must be registered.

Activities in the industrial sector are varied. They include, for example:

- the use of portable nuclear gauges which are gamma- and neutron-emitting devices for measuring density, compaction, and moisture in civil engineering;

- fixed nuclear gauges in manufacturing facilities and refineries where sealed sources and radiation devices can monitor process flow rates and pipes, fill levels in bottles, or thicknesses of materials being manufactured as examples;

- industrial radiography using

gamma-emitting sealed sources in devices for non-destructive testing of materials such as welds on pipes or concrete in buildings;

- and finally, oil well logging, which lowers specialized gamma- and neutron-emitting devices into drill holes to map out geological characteristics.

The academic and research sector involves the use of nuclear substances and prescribed equipment in teaching and research applications. In 2016, less than 10 percent of all licences for the use of nuclear substances and prescribed equipment were in this sector. Over 7,200 workers worked in the academic and research sectors, 37 percent of which were designated as nuclear energy workers. The academic and research sector includes laboratory studies which primarily involve the use of unsealed nuclear sources for academic and biomedical research. It also includes licences for consolidated use of nuclear substances that are granted to institutions such as hospitals and universities where both unsealed and sealed nuclear substances may be used and which have in place an internal system of permit approvals.

In 2016, there were 247 licences held by users in the commercial sector. This was 11 percent of all licences. In this sector, there were approximately 1,900

total workers, of which 73 percent were designated as nuclear energy workers. The commercial sector encompasses a number of licensed activities related to the production, processing, storage, and distribution of nuclear substances, the calibration of radiation detection equipment, and the servicing of radiation devices and Class II prescribed equipment.

The CNSC maintains regulatory oversight of the use of nuclear substances and prescribed equipment by licensees in all Canadian provinces and territories. This slide shows the location of licensees in all four sectors. In 2016, there were over 2,000 licences held across the country. For clarification, as it's difficult to discern on the slide, in the Yukon, Northwest Territories, and Nunavut, the licensees are all from the industrial sector.

Forty-two licences were held by companies based outside of Canada. These are primarily servicing licensees that come to Canada to perform work on devices owned by Canadian licensees.

The number of licences issued by the CNSC for the use of nuclear substances and prescribed equipment continues to decrease. This is primarily due to consolidation of licensees' business activities, economic conditions, and advancing non-nuclear technologies. In

2016, there were 2,233 licences held by 1,584 licensees.

Doses are monitored for all workers involved in activities authorized by the CNSC. In 2016, there were over 62,000 persons working in the areas covered by this report, the majority of whom worked in the industrial sector.

A worker who, in the course of their occupation, performs duties that may result in a dose of greater than 1 mSv per year must be designated as a nuclear energy worker. In 2016, 36 percent of all workers were designated as nuclear energy workers.

Similar to how licensees are located across Canada the CNSC has staff located in different regions of the country to provide regulatory oversight and support to licensees in all parts of Canada. The Directorate of Nuclear Substance Regulation has staff located in offices in Calgary, Alberta; Mississauga, Ontario; Ottawa, Ontario; and Laval, Quebec. In 2016, the CNSC conducted 1,452 inspections of licensees using nuclear substance and prescribed equipment.

Last year, more than 12,600 person days were dedicated to the core of CNSC activities of licensing, certification and compliance for nuclear substances and prescribed equipment. The breakdown to each activity is

shown on the slide.

When a request for licensing or certification is made to the CNSC; staff review the application and perform a technical assessment of request to verify that all regulatory requirements have been met, and that the applicant has in place adequate measures to protect health, safety, security and the environment. A peer review of the assessment is conducted. Once the peer review is complete, the designated officer makes a decision on each request for licensing or certification activities based on staff's evaluation and recommendation, and ensures that all requirements of the Nuclear Safety and Control Act and its regulations are met.

CNSC staff continue to lessen the administrative burden on licensees and improve our efficiency through consolidation of licences where appropriate, and by reviewing our internal licensing processes.

Industrial radiography involves the use of nuclear substances in exposure devices for the non-destructive examination of materials. Under the Nuclear Substances and Radiation Devices
Regulations, licensees are required to only allow CNSC-certified personnel and supervised trainees to

use exposure devices. In 2016, the CNSC certified 115 new exposure device operators and renewed the certification of 340 exposure device operators.

Licensees have the primary responsibility for safety. All licensees must have in place radiation protection programs. These are evaluated by CNSC staff during the application stage or when changes to the program are made, and are assessed during compliance activities throughout the course of the licence.

Radiation Safety Officers, or RSOs, are individuals responsible for the implementation of the radiation protection programs. Licensees that operate Class II nuclear facilities or that service Class II prescribed equipment must have a certified RSO. A detailed presentation on radiation protection programs and the role of RSOs will be presented later today in CMD 17-M44.

Most decisions related to the regulatory oversight of the use of nuclear substances and prescribed equipment are made by designated officers.

As you can see on the slide, designated officers made a total of 2,805 licensing and certification decisions in 2015. Licensing decisions accounted for majority of these.

Looking at the decisions on the

Certification of Prescribed Equipment, compared to 2015 there was a notable increase in the number of decisions related to the certification of prescribed equipment. This was due to an increase in the number of expired certificates that were originally issued in the early 2000s. This trend will continue into 2017 before returning to normal levels by 2018.

Turning now to the Certification of Exposure Device Operators, or EDOs, the number of decisions related to the certification of exposure device operators continues to increase. The number shown on the slide, the 455, includes both new certifications and renewals. While the number of new EDO certificates has remained stable, the increase in the number of certification decisions in 2015 and again in 2016 is attributed to the CNSC's gradual implementation of a new expectation for EDOs to renew their certification every 5 years. It is expected that the number of EDO certifications will remain similar to the level in 2016 for the coming years.

Now we move to the topic of packaging and transport. Every year approximately 1 million packages containing radioactive material are transported safely in Canada. The packaging and transport of nuclear substances is regulated jointly by the CNSC and Transport

Canada. Transport activities and any packages that are used for transport must comply with:

- CNSC's Packaging and Transport of Nuclear Substances Regulations, 2015;

- Transport Canada's Transportation of Dangerous Goods Regulations and;

- The International Atomic Energy Agency's Regulations for the Safe Transport of Radioactive Material.

References to packaging and transport made within this presentation or in the regulatory oversight Report itself, for example in reference to reported events, are made in the context the activities covered by this report, namely the transport of nuclear substances and prescribed equipment.

The CNSC compliance program is risk-informed, planned and responsive. CNSC inspectors conduct inspections of licensees at defined frequencies over the period of the licence. Inspections that are planned but not performed are tracked for inclusion in the next planning cycle. Most inspections of nuclear substance and radiation device licensees are Type II inspections.

Type I inspections may be conducted for licensees that operate at multiple geographic locations or use a combination of unsealed or sealed nuclear substances

and radiation devices. These Type I inspections are above and beyond those performed at Class II facilities, which form a part of the baseline inspection program for Class II licensees.

The nuclear substance and radiation device licensees subject to Type I inspections are determined for each year based on a risk-informed process taking into account the nature of the activities performed by the licensee, the nuclear substances used and past compliance history. For all other licensees, Type II inspections are the default inspection type, and are inspected on a risk-informed inspection frequency. A complete list of all inspections conducted in 2016, and whether or not they were Type I or Type II is included in Appendix E of the Regulatory Oversight Report. This was a new feature of the 2016 edition.

Compliance activities include more than just inspections. The CNSC compliance program also involves reviewing of submissions from licensees including the review of annual compliance reports for each licensee, assessment of procedures submitted by licensees, for example servicing procedures, and the review of events reported to the CNSC and their corrective actions.

The results of all compliance activities

are documented and non-compliances are tracked until they are addressed by the licensee to the satisfaction of CNSC staff. Repeated performance below expectation leads to increased regulatory oversight, which could include reactive inspections or an increased inspection frequency. Of the 1,452 inspections conducted in 2016, there were 48 cases where licensees who received an SCA rating of below expectations or unacceptable, had also received ratings below expectations or unacceptable on the same SCA in their previous inspection.

Enforcement actions are taken by the CNSC to compel licensees to comply with the regulatory requirements. When CNSC staff find a licensee in non-compliance, they use a graduated approach to bring the licensee back into compliance and deter future non-compliance. CNSC staff have a range of tools available to them including orders, administrative monetary penalties, and licensing actions. The most appropriate enforcement action is selected and applied based on risk-informed decision-making.

In 2016, CNSC staff issued 14 orders and eight administrative monetary penalties, or AMPs, to licensees covered by this report to address concerns for safety and security. Consistent with previous years, most

enforcement actions were issued to licensees in the industrial sector. Concerning the orders issued, once CNSC staff were satisfied that the licensees met all terms and conditions of the order, the order was closed. All 14 orders issued in 2016 have been closed. All eight AMPs issued in 2016 have been paid.

In 2016, the designated officer refused to renew four licences, refused to authorize the transfer of one licence, and in another case, changed the terms and conditions of the licence to be more restrictive.

CNSC staff continue to engage stakeholders through outreach activities held across Canada. This slide shows the sectors targeted by different outreach activities through the year 2016. Activities included information sessions and webinars for all users of nuclear substances and radiation devices, the DNSR newsletter, participation in working groups such as the CNSC/CRPA working group, and the CNSC industrial radiography working group.

CNSC staff gave presentations at conferences and industry meetings, for example, at the Canadian Organization of Medical Physicists Annual Meeting, and the British Columbia Funeral Association Meeting, and it included workshops focused on particular sectors or activities such as the portable gauge workshops. Outreach

activities are one venue the CNSC uses to inform licensees of regulatory requirements and expectations, and are also a venue for sharing operating experience.

In addition to outreach with the licensed community, CNSC staff continue to engage and connect with their peers in the federal government, including counterparts at Transport Canada, the Public Health Agency of Canada, the National Energy Board, Health Canada and the Community of Federal Regulators.

Furthermore, CNSC staff continue to be engaged at the international level on matters concerning the use of nuclear substances and prescribed equipment.

At this time, I will pass the presentation over to Mr. Rabski.

MR. RABSKI: Good morning, members of the Commission. My name is Henry Rabski, Director of the Operations Inspection Division in the Directorate of Nuclear Substance Regulation.

Through the following slides, I will be providing an overview of the safety performance of nuclear substance licensees for 2016.

For the purposes of the reporting in the Regulatory Oversight Report the following four safety and control areas, or SCAs, have been selected, as they provide

a general overview of licensees' performance: management systems, operating performance, radiation protection and security.

Overall, licensees continued to demonstrate adequate performance within all safety and control areas as the majority of inspected licensees in 2016 were found to be compliant in the four SCAs covered in this report.

More details on these safety performance measures is provided in the following slides.

Overall, doses received by nuclear energy workers remained low in 2016 with most workers receiving less than .5 mSv per year. In 2016, no nuclear energy workers received whole body doses above the regulatory limit of 50 mSv.

Note that the data from 2012 was obtained by a sampling of workers. Data from 2013 and '16 used all the information that was submitted through the ACRs, the Annual Compliance Reports, by licensees.

The management system SCA includes the processes and programs put in place by licensees to achieve their safety objectives and that foster a healthy safety culture. Overall, 97.8 per cent of all inspected licensees showed a satisfactory rating for this safety and control

area in 2016.

The most common non-compliances in this SCA included: conducting activities contrary to a licence condition, failure to comply with regulatory requirements related to having records at work locations and a failure to notify the CNSC of changes in contacts for licensed activities.

Please note that two licensees received unacceptable ratings for this SCA and both received an order as a result of the inspection performed.

It is too early to speak to trending for performance within the management system SCA at this time as 2016 marked only the second year this SCA was reported on as part of the Regulatory Oversight Report. CNSC staff will continue to analyse the compliance data for this SCA in future years to monitor for any emerging trends and report them.

Moving now to operating performance, which refers to the licensee's ability to perform licensed activities in accordance with pertinent operating and safety requirements defined in the *Nuclear Safety and Control Act,* its associated regulations and licence conditions.

Licensees are expected to demonstrate that

they comply with the operational and safety requirements by providing workers with appropriate procedures for the safe use of nuclear substance and provide prescribed equipment by ensuring that workers follow procedures and by maintaining records that demonstrate compliance. Eighty-seven per cent of licensees inspected received grades that were satisfactory or fully satisfactory in 2016.

As shown in the table, this year five inspections conducted within the industrial sector resulted in an unacceptable rating for this safety and control area in 2016. In all cases, an order was issued to ensure that corrective actions were taken immediately. The majority of non-compliances in this safety and control area included: failure to comply with regulatory requirements related to the retention of records, worker obligations and sealed source leak testing. In all cases, licensees addressed these non-compliances to the satisfaction of the CNSC.

Overall, compliance in this SCA dropped slightly in 2016 compared to the previous year, but remained within the range observed over the last five years. The one sector that showed a year-over-year improvement in 2016 was the academic and research sector.

Moving now to radiation protection, which

requires licensees to establish programs to ensure that contamination levels and radiation doses received by workers are monitored, controlled and maintained below regulatory limits and kept at levels that are as low as reasonably achievable, social and economic factors being taken into account.

Licensees are expected to monitor worker doses, post-radiation warning signs, plan appropriately for radiological emergencies, manage oversight of operational activities, institute effective workplace practices that emphasize the use of time, distance and shielding to minimize exposure to radiation and use appropriate protective equipment.

All sectors demonstrated adequate performance within this safety and control area, with 84.5 per cent of inspected licensees who received a satisfactory rating.

In 2016, for the second year in a row, a decrease in the performance by the medical sector has been observed.

In response to relatively lower compliance in this SCA, staff started a project to review the oversight processes for radiation safety officers who are appointed and the radiation protection programs put in

place to identify factors that may lead to greater success in implementing effective radiation programs.

This initiative will be described in more detail in a presentation later today.

The majority of non-compliances reported involved survey meters not being calibrated, inadequate implementation of measures to ensure that doses are kept as low as reasonably achievable and improper posting signs at boundaries and points of access. In all cases, licensees addressed these non-compliances to the satisfaction of the CNSC.

As we see in this slide, four licensees, all in the industrial sector, received unacceptable ratings for this SCA. Note that these same four licensees also received unacceptable ratings for the operating performance SCA and all received an order.

Finally, security, which requires licensees to have in place physical security measures, practices and programs to prevent the loss, illegal use, illegal possession or illegal removal of nuclear substances during their entire lifecycle including while they are in storage or during transport.

The extent of security measures required depends upon the type of nuclear substance being used and

activities performed by each individual licensee.

All sectors show satisfactory rating for this safety and control area in 2016, with 93.6 per cent of inspected licensees having ratings of fully satisfactory or satisfactory for this SCA, a small decrease from last year's report.

One inspection was given an unacceptable rating and resulted in the issuance of an order to ensure that corrective actions were taken immediately.

Licensees, as a whole, addressed and corrected all non-compliances related to security identified during inspections to the satisfaction of the CNSC.

Performance in this safety control area decreased marginally in 2016 compared to previous years. This is attributed to a decrease in the rating in the medical sector.

As mentioned earlier, the extent of security measures required is commensurate with the activity of the source.

REGDOC-2.12.3 provided further requirements and guidance for licensees with regards to their security programs. The first phase of implementation of this REGDOC affected licensees with Category 1 and 2

sealed sources. For these licensees, the expectation for security programs outlined in the REGDOC came into effect in May, 2015.

As a result, during inspections of licensees with Category 1 and 2 sources, CNSC staff verified compliance against requirements described in the REGDOC. Seventy-nine per cent of licensees inspected against these requirements were compliant with all requirements in 2016.

The non-compliances cited were primarily administrative in nature and did not impact the immediate security of sources.

The second phase of implementation of REGDOC-2.12.3 will occur in May, 2018, impacting licensees in possession of Category 3, 4 and 5 sealed sources. CNSC is proactively reaching out to licensees and clarifying expectations under the REGDOC that will be coming into effect.

For the third year in a row reported events have been ranked using the International Nuclear and Radiological Events Scale, INES, a tool for communicating the safety significance of nuclear and radiological events to the public. As described in previous years, this tool allows the establishment of a proper perspective of an

event's safety significance. The scale has been used to classify events at nuclear power plants since 1990 and has been extended over the years to apply to all nuclear installations. By 2006, it had been adapted to all events associated with the transport, storage, and use of radioactive sources and nuclear substances.

Note that the scale is not a tool to compare safety performances among facilities or organizations, but rather to effectively communicate the safety significance of events.

The use if the INES scale provides a consistent approach to reporting the safety significance of radiological events. Under this scale all events are classified on a scale that includes seven levels.

Examples of events that could be rated as Level 1 include exposure of a member of the public in excess of the public dose limit or a loss or theft of a radiation device such as a portable gauge.

Examples of events that could be rated as Level 2 include exposures to the members of the public in excess of 10 millisieverts or exposure to a nuclear energy worker in excess of the annual dose limits.

CNSC staff review, assess and track all events reported by licensees. In 2016 there were 139 events

reported to the CNSC by licensees in the sectors covered in this report. Of the 139 events, 136 events were ranked as Level 0 or no safety significance under the INES scale: one including where a worker sustained an injury note related to the use of nuclear substances; two events were ranked as Level 1 or anomaly on the INES scale due to the quantity of nuclear substances involved and the type of event reported; finally, we had one event that ranked as Level 2 or an incident under the INES scale.

Note that the events involving missing or found sealed sources are also incorporated into a report that is available on the CNSC website and updated on a regular basis. More information on the three events which obtained an INES rating above 0 is provided in the next slides.

Two events related to lost or stolen radiological sources ranking above INES Level 0. There were two instances of theft of a portable gauge where the gauge was subsequently not recovered. For this reason, these two events were ranked as Level 1 under the INES scale. These events remain open and CNSC Staff will continue to track any future developments on the identification of sources.

In 2016 there were two events of dose exceedances, both were reported at Commission meetings in

December 2016.

In the first event a member of the public received an effective dose that exceeded the annual limit of 1 mSv. The individual received the dose after receiving a ride in a vehicle that was also transporting packages containing nuclear substances. CNSC Staff estimate the person received a dose of 1.62 mSv. An administrative monetary penalty was issued to the driver of the vehicle. The event was ranked as a Level 1 on the INES scale.

The second event occurred when a nuclear energy worker from a hospital received a dose above the regulatory limit of 500 mSv for extremities. The equivalent dose to the hand was estimated by the CNSC Staff to be 1,100 mSv. Corrective actions were put in place by the licensee and accepted by the CNSC. This event ranked as Level 2 on the INES scale because a worker received a dose above the regulatory limits.

No health effects are expected in either case.

Now, I'd like to turn the presentation back to Mr. Moses.

MR. MOSES: Thank you. So before Staff conclude the presentation, we would like to provide an update on some of the industry trends that we continue to

monitor and highlight some of the work that we currently have underway in 2017.

In order to continue to maintain a regulatory program that is robust and effective, the CNSC monitors trends in the nuclear industry and developments in the economic space that may influence the use of nuclear substances and prescribed equipment.

Trends of note include industry changes as a result of economic developments, which led to the consolidation of a number of licensees who operate in the oil and gas sector, and increased infrastructure funding, which may lead to the increased use of devices used in construction activities.

We've also seen continued interest in new applications of nuclear technologies or improvements to existing technology. For example, with the recent publication of Health Canada's regulations permitting the sale of irradiated ground beef there's a potential for new irradiation facilities or repurposing existing facilities. There has also been an interest in leveraging this tool for other food or consumable products.

Developments in industrial radiography are also of interest. In particular, the industry is exploring the use of small controlled area radiography technology,

which mitigates some of the risks associated with industrial radiography.

In addition, in the medical field there's consideration for the construction of proton therapy facilities in Canada as well as the development of new equipment, such as the GammaPod that has been developed for the treatment of breast cancer. This is on top of the continued development of new probes and labels for medical and research applications.

Finally, some applications are finding alternate non-nuclear tools to meet their needs. For example, the academic sector is adopting alternatives to the use of nuclear substances in research, such as phosphorescence. Also, some low-risk devices are being replaced with technologies that do not require the use of nuclear substances.

CNSC Staff will continue to monitor these developments in order to ensure that our regulatory framework and oversight remain suitable for the wide variety of applications regulated by the CNSC.

While the industry continues to evolve, so does the CNSC. In 2017 we have launched several initiatives to enhance our regulatory oversight, including the development of initiatives for oversight of radiation

protection programs for nuclear substances and radiation device licensees, which we'll be discussing in more detail later this afternoon, and enhancements to the Type 1 inspection methodology.

In addition, as noted in Staff's supplemental CMD, we continue to explore opportunities to better share information and lessons learned from events that have occurred in the industry.

Finally, we continue to modernize our regulatory framework and have several related projects underway, including the development of documents to enhance our licence and certification application guidance, outline reporting requirements for the sector, and provide expectations in technical areas such as the design of fixed radiography installations and guidance for the safe handling of the deceased.

So in conclusion, both as a result of a rigorous licensing and certification reviews and our comprehensive and risk-informed compliance approach, and as evidenced by the continued low levels of exposure across the industry, CNSC Staff conclude that the use of nuclear substances in Canada is safe, with adequate protection for the health and safety of persons and due consideration to the security of nuclear substances and prescribed

equipment.

Thank you for the opportunity to present this report, and we remain available to answer any questions you may have.

THE PRESIDENT: Thank you. So as per our normal procedure before opening the floor for Commissioners' questions, I'd like to hear from the oral presentations, the oral intervenors. The first submission is from the Canadian Industrial Radiography Safety Association, as outlined in CMD 17-M42.1.

I understand that Mr. Brady will make the presentation. Over to you.

CMD 17-M42.1

Oral presentation by the

Canadian Industrial Radiography Safety Association

MR. BRADY: Good morning, Members of the Commission. I'd like to introduce myself, I'm Allan Brady, I am a past President of the Canadian Industrial Radiography Safety Association. I currently still sit on the executive. I'm involved with the working group and the PCP-09 Scheme Committees, amongst other things. I'm also the Compliance Director and the Radiation Safety Officer

for Team Industrial Services, an industrial radiography company here in Canada.

With me is Mr. Tom Levey for support. He is the Director of Radiation Safety for the Acuren Group.

So moving into this, the purpose and scope of this presentation is to provide feedback and comment on the regulatory oversight report on behalf of the industrial radiography industry, specifically members of the Canadian Industrial Radiography Safety Association, otherwise known as CIRSA.

The scope here is limited to the subsector of industrial radiography within the industrial sector, and those are outlined specifically in sections 3.4, 3.9.1, through 3.9.1.3, and sections 5 through 5.8 and section 7.

So the Canadian Industrial Radiography Safety Association, just a brief history here. We are an advocacy group representing those industrial radiography companies that choose to be members in Canada.

We have objectives. Radiation safety is our prime objective. We work to influence the industry and change the culture, improve working relationships with the CNSC, and between the industry and the CNSC. We promote exchange of information on health, safety, and the environment, and related topics between industrial

radiation companies, CIRSA members and any allied industries. We provide representation to government bodies for any of our members. We conduct ourselves according to our mission statement.

This is our mission statement, quickly:

> "To be the leading radiation safety advocacy group and source of communication for the industrial radiography industry. This is achieved by promoting a strong radiation safety culture, member support, radiation safety awareness. We provide direction in fostering cooperative working relationships with regulatory bodies while, at the same time, we maintain a common voice for the industry." (As read)

This slide here that you're seeing just shows the different stakeholders that have been identified, all stakeholders with one common goal; radiation safety.

The common goals between CNSC, CIRSA and the industry, the stakeholders believe that a good safety culture is important. We're constantly working on making improvements to safety culture.

The industry goal is a safer environment, reduce environments and improve compliance.

There is a vested interest for continuous improvement, reduction in incidents, improvements in performance and, ultimately, an improved safety culture.

The Industrial Radiography Working Group -- briefly on this, the Industrial Radiography working Group resulted from a 2008 Commission meeting. We believe the decision that was made by the Commission at that time was a good one because it resulted in this working group.

And since 2008, Tom and I have both continued to be members. And it has resulted in a positive group with multiple stakeholder representation.

CIRSA is just one of those representatives in that working group, but others include, but are not limited to, individual non-CIRSA member companies, industrial radiography equipment manufacturers and various applicable CNSC Directorate representatives.

The working group has had a very positive impact and improved the relationship with industry. Meetings in the spring and fall with outcome towards general industry meetings in the east and west -- so we do have meetings in the east and west.

There has been good attendance and good feedback for them.

The outcome -- or one of the outcomes, anyways, has been improved -- improvement in compliance dose reduction and reduction in incidents. And I'd like to add communication to that as well.

So the report feedback.

The report appears to be thorough and accurate. The industrial radiography industry performance results remain steady. We recognize through this report and we're able to recognize areas that we need to improve on, so we appreciate seeing this report and that it is accurate in that way.

CIRSA would like to have seen a bit more information on the initiative, the current status and future plans of the CSA PCP09 certification, exposure to vice operator personnel certification guide.

The guide currently is in revision.

I'd like to just add to this that we had a working group meeting yesterday and we did get an update, so we are satisfied. However, it would have been nice to have seen a bit more of that detailed information in this report.

Section 3.4 of the report is the CSA PCP09

CEDO standard and has been influential on industry performance. We set out to build a better operator, and we believe that that has been the case so far.

Any other remaining concerns at this time include Section 3.5R certification. I believe this might be brought up later on as well.

We agree -- the industry agrees with Section 3.6 regarding RSOs not requiring certification in our industry. Industry agrees that a guide developed by CNSC would be beneficial.

We also have some concerns over possible future costs for renewals of CEDOs, and that may include RSOs in the future as well.

Section 5.1 on security.

Security non-compliance is -- they say were high because it always takes time to implement new measures that industry is unfamiliar with, so this started in 2015. We believe we've maintained -- you know, worked towards and met our compliance requirements in this area, but it's an ongoing improvement process. And security will be the focus, I believe, in the near future here.

Effective doses to works in Section 5.8.

The industry would like to see industry reports that provide average radiation dose to workers in

each industry category.

Currently, the report only shows how many workers were within a specific range. Of course, this comes from our annual compliance.

Each individual company would know what theirs was, to a point, but they wouldn't know what the industry average is.

So in summary, we would like to close by requesting that the Commission continue to support the stakeholder engagement programs outlined in Section 3.9 of the report, specifically, the outreach meetings, newsletters that the DNSR puts out and the CNSC working groups.

These initiatives have made a lot of improvement in communication and overall compliance.

Thank you for your time, Commissioners.

THE PRESIDENT: Thank you.

So questions.

Let me start with Dr. Demeter.

MEMBER DEMETER: Thank you very much for the presentation.

I wanted to pick up on sort of slide 10, we said we recognize our areas that need improvement. And based on the previous description of all the orders and

non-compliances, they were, as I understand, all in the industrial sector.

Maybe you can help me understand what the issue is relative to the industrial sector. Is it a safety culture, is it a training? What's -- what sort of -- given the number of orders through time and your comment about needing an improvement, how does that fit?

MR. BRADY: Well, I'll speak to specifically the sub-sector.

In my opinion, it's either -- not either. It can be resources, the availability to, you know, have enough resources in place to continually make sure that people aren't -- are able to keep up with the compliance.

A lot of these that I'm seeing here are administrative, reporting. These things can be easily forgotten.

So it's just a matter of keeping an eye on the ball and not being so busy that we forget to slow down, stop and focus on what we're doing.

MEMBER DEMETER: Thank you.

Maybe for staff, if you look at graded responses to non-compliance, an order is one level, and they were all given to this sector.

What do you see as sort of the potential

solution on a go-forward basis?

Is it a resource issue for this sector, is it a training issue? Is it that it's such a small part of their practice that it gets easily forgotten, or...?

MR. MOSES: Colin Moses, for the record.

So first, I'll be careful in how I answer that question because the industrial sector does cover a wide variety of activities that aren't industrial radiography.

So you made reference to the escalated enforcement actions. Two of those in the industrial sector were issued to the industrial radiography. The others were other activities within that sector, generally the portable gauge sector.

So I will note back in 2005 and 2008 we reported to the Commission with significant concerns with the overall performance of the industrial radiography sector and launched a number of initiatives to drive improvements in that area, most notably of which were the creation of annual meetings with the industrial radiography association as well as the working group that was referenced by Mr. Brady.

We found that those have been particularly effective in driving -- sharing lessons learned and

informing on future regulatory initiatives and engaging on important initiatives, most notably the introduction of renewals of CEDO certifications that led to the publication of PCP09.

And I think those tools have really driven improvements in the industry, and so the concerns that we outlined to the Commission back in 2005-2009 don't remain today.

We have seen significant improvement in that area of the sector, but industrial radiography is a high-risk operation and that's why we do inspect those operations every year.

In addition, the activities in the industrial radiography sector are generally -- are often done in the field, so workers operating remotely and so a big part of our focus is looking at the oversight mechanisms that licensees have been put in place to ensure that their workers are following procedures.

So I think those are things that need to continue, and we will maintain communications with the industry. And --

THE PRESIDENT: Can I piggyback on this?

So is there a -- what's a good benchmark? You know, you got many, many licences, so

we would like to see 100 percent compliance, obviously, but is there international benchmark comparison? Does it make sense to compare with, you know, other countries in terms of performance?

Is 90 percent good enough? I mean, is there a number, a magic number that you look for?

And while we're at slide 10, was -- what's the issue with the CSA PCP? I'm not sure I understood what the concern here is.

MR. MOSES: Colin Moses.

So I'll let Mr. Brady speak to the concern with PCP09 and then we also have staff that can speak to activities in that area.

So yes, there is a benchmark that we can set, and I think the only thing I can say is absolutely 100 percent; we want full compliance by all licensees, and that's a benchmark that we target and that's what we work towards.

But we do have a risk informed regulatory program, and that looks at the performance of each of the different use types that we regulate and looks at, you know, generally performance trends, looks at the potential -- the risks, the hazards associated with those activities and assigns a different inspection frequency to

determine how often or how extensive we do to oversee that part of the sector.

In terms of benchmarking internationally, that's very difficult.

So the one thing that we did include this year and we are monitoring is reports on international events. So these reports are tabled through the International Nuclear Event Scale, and a number of countries report on significant events that are incurred in those countries and this is the first year where we have included those in this regulatory oversight report.

We also want to communicate those proactively to the industry and so one of the DNSR newsletters that we put out in 2017 outlined all these international events as well as the lessons learned to share that kind of operating experience with the industry. So those are the kind of activities that we would like to continue.

I will let Mr. Brady speak to the concerns around PCP-09.

MR. BRADY: So again, we did get an update at the Working Group meeting, but regardless, when you read through it, it gives you a little bit of information on what it is but it wasn't really up to date. We were

looking for a current status and perhaps that just might not -- this report may not have been the place for it, I'm not sure, but we needed a status update and it could have stated what the plans or the future plans were for this particular guide. So right now it's being revised but we don't know where it was going or when it was going to be completed and that kind of thing, when was the new revision coming out and questions like that. That's all that meant.

THE PRESIDENT: Maybe I interrupted you.

MEMBER DEMETER: I'm good.

THE PRESIDENT: Mr. Seeley.

MEMBER SEELEY: Thank you for the presentation. Maybe just a couple of questions for background and it goes to maybe the question of resources. I note that we have roughly 76 staff I think within CNSC regulating all of the 2,200 roughly licence holders in Canada and I don't know how many field inspectors we would have. How many field inspectors would we have out of the 76 total staff?

MR. MOSES: I'll let Mr. Rabski speak to -- so we have two groups of inspectors in DNSR. One group regulates the industrial medical, the uses of nuclear substances radiation devices, of which industrial radiography is included. The other group of inspectors

regulates the accelerator applications in Class II facilities. So I will let Mr. Rabski speak to his current team of inspectors and then Mr. Broeders speak to those that regulate the accelerators.

MR. RABSKI: Henry Rabski for the record.

In the reporting year 2016 we had 11 full-time dedicated inspectors in the regional offices that were performing inspections and participated in delivering those over 1,400 inspections. This year we're at 11 and we have been actively recruiting some replacements and putting them in the flow to train new inspectors. So from the field inspection office perspective, that is to say Calgary, Mississauga, Laval, and we have one based in Ottawa, those are the ones that are doing the field-orientated ones.

The ones for Class II I will leave to my colleague Mark Broeders to speak to how many inspectors he has.

MR. BROEDERS: Mark Broeders for the record.

At the time of the report there were 12 qualified inspectors and one in training that serviced all the Class II licences.

MEMBER SEELEY: Okay. Thank you for that.

So we have 11 and 12 type IIs. On the industrial side we have 1,300 licences. And I guess sort of the point I'm coming to is then the role of the RSO becomes more important as you have, you know, 10, 11, 12 inspectors and so then you go to implementation of the regulations and requirements at each site and for each licence holder. So the role of the RSO becomes an important role and you made some recommendations around that that you were -- how many RSOs would we have in the industrial sector? Do we know that? We wouldn't have one per licensee, would we?

MR. BRADY: Alan Brady for the record.

I don't know what the number is for the whole -- all the licensees. I don't have that information. I mean I can tell you, for example, a company like ours that's coast to coast and all the industrial radiography companies, ours would have -- I'm the main RSO but we would have Facility RSOs for example. A smaller company would as a minimum have one RSO of course and many of these RSOs will be wearing multiple hats, and again, a resource issue, trying to focus strictly on radiation safety and not being pulled in other directions.

THE PRESIDENT: Okay. You should be able to -- what is the number of RSOs?

MR. MOSES: Colin Moses for the record.

Every licensee is required to have an RSO in place to oversee their activities. Some licensees who have more complex operations, so locations in multiple locations, as Mr. Brady alluded to, have a team of supporting RSOs who oversee work at specific locations. So it's much larger than the number of licensees that we regulate but I couldn't give you an exact number.

MEMBER SEELEY: Right. Okay. So it's minimum one per company holding licences and it could be multiple numbers within a company if they have multiple licences, et cetera.

And then you made a recommendation with respect to a guide for an RSO. So I guess my question then goes to training the RSO. Do we have a standard training package or standard requirements for an RSO? We don't have certification, I saw that, and you're okay with that, but do we have sort of a minimum package of information and knowledge that this RSO individual needs to have? Maybe staff first.

MR. MOSES: Colin Moses for the record.

Yes, all RSOs are required to have a general understanding or expected to have a general understanding of regulatory requirements, a good understanding of the activities that they're proposing to

undertake, and a good understanding of the programs that they have provided to us as safety control measures to control those operations. And so we do evaluate that during the licensing phase and I will let Mr. Fundarek speak to that.

MR. FUNDAREK: Peter Fundarek for the record. I'm Director of Licensing for Nuclear Substances and Radiation Devices Licensing Division.

We do have a comprehensive program that's based on the risk-informed approach for the evaluation of RSO qualifications. All companies or all licensees are required -- as Mr. Moses indicated, all licensees are required to have at least one RSO and there is a provision for having persons in other geographical locations to provide radiation safety support to the main RSO as well.

During the evaluation of the RSO, as noted, it's a risk-informed evaluation, so we look at the type of licensed activity, whether it's a low-, medium- or high-risk activity, and we look at the type of activities that they're going to be undertaking, so if they're going to be working with unsealed sources or sealed sources and what types of radiation devices they're going to be working with.

So licensees are required to have a

Radiation Safety Officer, as noted previously, that is familiar with the licensed activity that's going to be authorized, they are familiar and understand their obligations as a licensee with the CNSC, and they have the sufficient education and training for the work that they're going to be carrying out. So we look to see that the Radiation Safety Officer has certain training for the area that they're going to be working in, and if not, we will ask them to supplement that training with a third-party provider to get the radiation safety training so that they fully understand their roles and obligations as a Radiation Safety Officer.

MEMBER SEELEY: Okay. So CNSC provides a list of minimum requirements for the RSOs, that's what I'm hearing. Yes. And it can be slightly modified per sector, it can be tailored per sector.

So coming back to your point then, which was, you know, okay, here we have on the industrial side the requirement for RSOs, but you're asking for a guide particularly for RSOs and knowledge training. You didn't provide -- provide a little elaboration on the guide that you're referring to in your recommendation, please.

MR. BRADY: Alan Brady for the record.

So, as you heard, there are minimum

requirements but they're broad and we would like to see something a little more specific. You can take examples of the CEDO guide, something like that that really gives us some specifics on how or what to focus on for the training, for example.

So to answer your question, there really is no standard other than the general guidelines really for us to work on. So everybody could do something different. What is the training standard? I don't see one. So we would like that also as opposed to certification in our sector anyhow. And then the challenge would also become trying to fit this information into the whole sector and include the differences within the industry as well. Ours may be different from the medical or something like that.

THE PRESIDENT: You heard that staff mentioned that they are going to present this afternoon some discussion about RSOs. They are going to study -- are you going to stick around for that discussion?

MR. BRADY: Alan Brady for the record.

I hope to. I hope that there's valuable information there that's specific to industrial radiography, though. If there's value there, by all means I will be here.

THE PRESIDENT: So we will revisit it this

afternoon.

MEMBER SEELEY: Yes. I guess my point here would be the RSOs are an important piece of the regulatory machine here, they're the boots on the ground for the licensees, and so maybe we need something a little more robust for these individuals to make sure that the company is meeting all their regulatory obligations. So hopefully that's what you're looking for in the guide. I tend to agree. Thank you.

THE PRESIDENT: Thank you.

Dr. Soliman.

MEMBER SOLIMAN: Thank you. Thank you for your presentation. It's a positive presentation and very valuable.

I have one question for the staff and another question for CIRSA.

On page 12 of the presentation the industry would like to see industry reports that provide average radiation dose to workers instead of currently a report showing how many workers were within the specific range.

So is staff receptive to this change and can it be accommodated in the next revision?

MR. MOSES: Colin Moses for the record.

No. The current information that we collect from licensees through their annual compliance reports ask that they provide the number of workers in each dose range and those are presented in our presentation on the regulatory oversight report. We don't collect specific information on individual workers and the dose that they receive. Those are submitted directly to the National Dose Registry.

So while we could run reports, I think the average dose could be influenced by, for example, the number of workers in a company. The number of workers at very low doses could bring an average down. And so we find that the way that we presented the average doses by group of dose is much more informative because our particular area of interest is where those doses are approaching regulatory limits, so in the 20 to 50 dose range.

I will let Mr. Jammal provide some additional details there.

MR. JAMMAL: For the record, Ramzi Jammal. Thank you for asking me to complement Mr. Moses' answer.

We would like to work with the industry. Mr. Moses spoke to the fact that the presentation of the doses is taken from annual compliance reports and there is always a question of inaccuracy, but since there is a

workgroup at the CNSC, I would recommend at this point that CNSC staff and the industry work with the National Dose Registry, in specific, for the NDR to produce a report to the industry that provides you with the average dose of the industry.

For most of us who are old-timers in the business, in the old days the National Dose Registry used to publish such information. They stopped doing it, but we should explore the fact that we can work with NDR, collectively, to provide you with that information.

But I fully support what our staff are doing. We are taking information from the annual compliance reports. The National Dose Registry has the proper evaluation associated with it, and they will give you the ranges with respect to the average dose.

I will recommend to the Commission that we work together, CNSC staff, CIRSA and the NDR, to provide you that information.

THE PRESIDENT: I must be missing something, but the way you presented those by classes, you can derive just from that a range of an average. What is the big deal? I mean you have the classes and the number of people in each class. You can actually calculate this. I thought you guys would be smart enough to do that.

MR. LEVEY: Tom Levey for the record. I would like to comment on that.

Two thousand and six was the last year that the CNSC published the annual report for doses to workers in each category and I agree with Mr. Ramzi Jammal on that topic as it was very valuable information. Later on the industry did contact the National Dose Registry and we got reports and it allowed us to be able to see an average dose to the worker, much more valuable, measurable for us because you can compare how you did one year to the next year and you can also get reports from your company as to how your average dose rate compared to other industry competitors.

MR. BRADY: Alan Brady for the record, quickly.

But I agree with you, Mr. Binder. Why, if they have all the information, can we just not do an average quick calculation. If we could maybe get an answer to that. What is the difference between that as opposed to going and spending all this time and resources trying to get a -- going to the National Dose Registry? Do we have the information or do we not?

THE PRESIDENT: I think Mr. Jammal made a suggestion that the industry with staff get together and

figure out what to do. I don't think it's a big issue, but not everybody is a fan of averages. Averages is -- you can go into medians, you can do all kinds of other statistical things. But if you find it useful, you know, I think you can be accommodated on that one would be my understanding.

MR. MOSES: Colin Moses for the record.

Absolutely, and I sort of alluded to it in the presentation. We collect a wealth of compliance data -- inspection results, dose information, reports through annual compliance reports -- and I think we do have an opportunity to leverage that kind of data and more sophisticated statistical analysis. And so that is something we're exploring. There's new technologies available to comb data and extract meaningful trends that go beyond human capabilities, and so we are exploring whether those kinds of tools will help with extracting some trends.

THE PRESIDENT: Dr. Soliman.

MEMBER SOLIMAN: I have another question. CIRSA is part of IRWG. What is the overall activity for the IRWG that maintain the -- or contributed to the compliance improvement dose and the incident reduction? So what is the activity, the main activity that is done by IRWG?

MR. LEVEY: Tom Levey for the record.

The Industrial Radiography Working Group, they've had a lot of initiatives and a lot of actions that the group has taken, along with the industry, to be able to monitor what type of compliances we're having problems with.

The focus of the group has been to arrange for some kind of training or bring it up at a general meeting, have a topic on it and discuss it with industry members who attend the meetings, so a very good avenue to provide knowledge and information to the industry. And then they go back to their companies, take the valued information and start to implement it as a licensee through their RSOs and through their workers and make improvements within their companies.

As an example, the CEDO PCP-09 was one of the initiatives, got us a better worker with more skills and more expertise. Transportation of dangerous goods issues that we had, we went to the experts within CNSC on the transportation side, got some information. Security, areas where we're having security, and even dose and incident reduction. Thank you.

MEMBER SOLIMAN: Thank you.

THE PRESIDENT: Dr. McEwan.

MEMBER McEWAN: Thank you, Mr. President.

Thank you for the intervention. It's very, very helpful. But I would also like to take a second to congratulate staff on an excellent presentation. That really was first-rate, very, very good. Congratulations. Thank you.

I would like to go back and just explore the RSO piece and the risk-informed inspections. The industrial sector, the whole report covers a huge range of activities. If you broke those activities down not by sector but by risk category, how many of our licences would fit into the high risk, the medium risk and the low risk and would that provide us with some better understanding of requirements for oversight of radiation safety?

MR. MOSES: Colin Moses.

I will let Mr. Fundarek speak to the different use types and how to categorize within the industry sector.

MR. FUNDAREK: Peter Fundarek for the record.

I believe the first part of your question was how the licences break down into low, medium and high risk. So according to the latest information we have, 14.1 percent of our licences are low risk, 65.7 percent are

medium risk and 10.4 percent are high risk. Industrial radiography, which we're looking at right now, represents 6 percent of the high- and medium-risk licensees. There is a total of 106 licences right now and they represent 5.1 percent of all of our licences.

MEMBER McEWAN: Can you go through that latter section one more time, please?

MR. FUNDAREK: Certainly.

Industrial radiography represents 6 percent of the high- and medium-risk licences in total, but they represent 5.1 percent of all the CNSC licences issued through the designated officer decision, and there is a total of 106 licences and they represent the high-risk category.

THE PRESIDENT: So would such a statistic be useful to put in a report like that -- and just thinking out loud -- and maybe show the correlation between the high risk and the kind of inspection you do? In other words, if you want to explain that it's truly risk-informed, there should be some correlation between the high risk and the number of inspections you do in this group. Does that make sense?

MR. MOSES: Colin Moses for the record.

Yes, I think that makes absolute sense and

I think that's something we can explore for future years.

In terms of the correlation of inspection numbers to the number of licensees, the proportion might remain consistent but it's the frequency of inspection that varies. So high risk is inspected every -- particularly industrial radiography is inspected every year and other activities are inspected less frequently. So the proportion may remain constant, but yes, there is a correlation in terms of inspection effort and the risk categorization of our activities.

MEMBER McEWAN: So the bulk of industrial radiography activities are high risk?

MR. MOSES: All are.

MEMBER McEWAN: All are. So I think this brings me back to the area of RSO certification and training.

If I look at benchmarks -- and this is getting into the questions we will be asking on the report as well -- the NRC, for example, are very much more prescriptive in the requirements for training than we are and I think we need to perhaps learn something for the high-risk and medium-risk groups. There is not a requirement for all RSOs to be members, for example, of CRPA. Is that true?

MR. MOSES: Colin Moses for the record.

Yes, that's true, there is no requirement for them.

MEMBER McEWAN: So I was a little concerned at Mr. Brady's comment that RSOs may not have time to do their appointed duties because they are busy doing other things. So again, that strikes me that it's an argument for more certification and more prescription at least in the high risk groups.

So Mr. Brady, perhaps you would like to comment on that.

MR. LEVEY: Yeah, Tom Levey for the record. I would like to comment on that, as per Al Brady.

One thing that we have in the industrial radiography industry is that we have taken the initiative to have educators that have thorough knowledge. They have good experience in our industry and they have conducted radiation safety courses that are specific to industrial radiography. We found that, you know, each of the licensees kind of has that option to go out to the -- out to different providers in Canada and find the best course for them. You know, we know who those best trainers are and we do use them.

So we have a pretty good guideline and,

you know, it's different in Al's company than it is in my company with Acuren group. We have different ways that we do things. You know, we have fulltime RSOs within our company. We have five of them that are fulltime and that's all they do.

However, you know operations and the economy always contribute to everybody wanting to steal our RSOs away to do other work. But you know we keep pushing, and I think the report that CNSC has provided today shows very good trends that the industrial radiography sector is performing very well. That is the success of the RSO in how they are conducting and carrying out, making sure that the training is adequate of the worker, making sure that maintenance is done properly, calibration of equipment, leak tests, inventories, tracking a sealed source's security.

There is numerous things. I think that a guide would be a very good opportunity for us to all be able to look at it from even the small company perspective to say what is it that we need to do and what do the educators need to do to make sure that they cover all the topics when they are covering the training for an industrial radiographer -- industrial radiography company that has an RSO.

Thank you.

MR. MOSES: Colin Moses, if I could just add too. I'll let Mr. Rabski speak.

So for lack of a better term, the proof is in the pudding. So when an RSO -- the true success of an RSO we evaluate for our compliance activities. And so I will let Mr. Rabski speak to how we evaluate that through our compliance --

THE PRESIDENT: Can we please save this for this afternoon; lots of our kind of additional information on this about not only how RSOs behave in a company, what's your role in the inspection to make sure that they have the adequate resources and training? It's a bigger topic than right now.

I would like to -- we are getting into a bio break.

So I would like to go through this round with CIRSA and then move on to the next intervenor and continue. Hopefully the next intervenor also will join this afternoon where we will talk about that.

So we are now -- anybody has an additional question? Go ahead, Dr. McEwan.

MEMBER McEWAN: So just following on, does staff have any comments on Mr. Brady's comment that RSOs

are dragged in multiple directions and find it difficult to fulfil their responsibilities?

MR. MOSES: Colin Moses for the record.

I'll let Mr. Rabski speak to that because that's what we observe through compliance inspections. He can speak to what we have observed.

MR. RABSKI: Henry Rabski for the record.

I know, Dr. Binder, you didn't want us to go into the other topic but just for clarification on high risk, operators of exposure devices and in the industrial radiography field, because it's high risk, it's also addressed in the regulations that those operators have to be certified. So that's a level of defence-in-depth in using high risk devices in this field. CNSC certifies, as you heard earlier, those operators.

I think it was a very interesting comment yesterday with the new PCP-09 comments from industry at that radiography meeting saying that they have noticed a change in the new operators that they are getting that they are much more aware of their obligations through these new requirements and the new training that has been instituted by the private sector or the outside trainers to address the change into PCP-09.

So that was very refreshing to hear from

the committee members that this is working and they have noticed that reflection and areas that have changed since the original G2-29. That's all been brought up to speed and it's reflected now in the new people that are coming and in new expectations for recertification and a practical test, are real positive things to raise the bar for people using those high risk sources.

So the role of the RSO in the radiography field, I think is recognized by that high risk factor by the comments you're hearing from industry that how serious they take that role, and the efforts that they are putting in to maintaining that oversight of the radiation safety programs. Sometimes there are problems and we work with those and we identify those in the field.

Our particular concerns when it comes to radiation safety officers would be in the industrial side and all the other ones where they are not dedicating, as companies have indicated, fulltime resources, where they are being challenged to balance other activities, and other responsibilities with the organizations. And those other very clearly picked up in our inspections. We take appropriate action when we see those, and I can speak to that if you wish.

THE PRESIDENT: No, we'll save you for the

afternoon.

--- Laughter / Rires

THE PRESIDENT: I would like to give the floor to final comments to CIRSA. Any final comments?

MR. BRADY: Alan Brady for the record.

We appreciate the opportunity for being here. Our point is that we do support the report as it is written.

And also for clarification, there are challenges with RSOs, no doubt, but we are managing. You know, training and education of course is good. So is certification to a point, but I don't think any amount of that is going to make any difference as to how people allocate their resources. So you know just keeping that kind of thing. We are managing and the results are so far good, and it is responsibility of the licensee to maintain compliance.

Thank you, folks.

THE PRESIDENT: Okay. Thank you.

We will take a 15-minute break. We'll get back here at 11:00. Thank you.

--- Upon recessing at 10:44 a.m. /

Suspension à 10 h 44

--- Upon resuming at 11:00 a.m.

Reprise à 11 h 00

CMD 17-M42.2/17-M42.2A

Oral presentation by the

Canadian Radiation Protection Association

THE PRESIDENT: The next submission is from the Canadian Radiation Protection Association, as outlined in CMDs 17-M42.2 and 17-M42.2A.

And I understand that Mr. Jeff Dovyak will make the presentation. Over to you, sir.

MR. DOVYAK: Good morning, Dr. Binder and members of the Commission. I am Jeff Dovyak.

Amongst other things I am the president elect of the CRPA.

And I have two associates with me today. Trevor Beniston is a member of the CRPA-CNSC Working Group and Ali Shoushtarian is the CRPA Director of External Affairs. For the most part, I will be doing the presentation along with Trevor. We brought Ali along to support us with any questions you folks may ask us that Trevor and I can't answer.

So who is the CRPA? Well, for over the

past 10 years we have operated a program for radiation safety professionals to demonstrate their knowledge and commitment to radiation protection through the Registered Radiation Safety Professionals Program. And by the way, the three of us actually are CRPA-Rs.

The CRPA strives to ensure the safe use of radiation by providing scientific knowledge, education, expertise, and policy guidance for radiation protection.

The CRPA was founded in 1979. Currently we represent approximately 280 Canadians involved with radiation protection. We are stressing that because the CRPA is a Canadian organization for Canadian activities. There certainly are other RP organizations around, not may are solely Canadian. A lot of our members are RSO. Some are not but many are.

Since last year, the CRPA has had the stakeholder hub for accrued radiation events, or SHARE program, available through our website. The idea behind the SHARE program was to provide radiation safety professionals with a venue to post radiation incident summaries so that their experiences can be used by others to mitigate potential incidents in other places.

So to put together our intervention, we talked to our internal stakeholders. So we went to our

members of the
CRPA-CNSC working group; we polled the members of the so-called CIII working group, and that is CRPA Class II division and Canadian organization and medical physicists working group. We talked to the executive of the Registered Radiation
Safety Professionals Executive Committee, and we let the board of directors know we were doing this and we solicited comments from them too.

So I guess our first main comment is CRPA membership and the CRPA board has certainly taken note of the notion of increased oversight of RSOs by the CNSC. As an organization we are trying to understand what the impact of that increased oversight may be. In terms of the project we keep hearing about for discussion this afternoon, several CRPA members are involved with that RSO evaluation project.

So we were as an organization somewhat disappointed in seeing the end of 2018 as the tentative publication date for that one REGDOC. And when we were reviewing the ROR, we wondered about, you know, were high risk activities the same as the high risk activities outlined in the licence application guide, and we understand now from staff that that's really the case. So

ideally, if the ROR referenced in Appendix B in the licence application guide that question would have gone away. So that's kind of like an editorial comment.

In terms of stakeholder engagement, our membership continues to find the CNSC outreach sessions that are held across the country very valuable and worthwhile. There is a number of CNSC staff that participated at our annual conference. That participation is priceless. The collaboration and the insight we can get at a meeting face to face with our regulators is excellent. Personally, I don't have an easy way of selling that back home to people I report to as a means of, you know, let me come to the conference. Some people think conferences are all fun and games, and maybe in other organizations they are, but there is a lot of work at the CRPA conference.

The DNSR Newsletter is another good tool for maintaining stakeholder engagement. It would be great if publication frequency could be increased.

A year and a bit ago, May 2016, there was an article regarding CNSC's expectations during skin contamination events. That was most useful. It really helped RSOs eliminate reports dealing with minor skin contaminations that were often less than 1% of the annual extremity dose limit. In other words, publication of those

expectations really decreased administrative burden to RSOs. Whether they belonged to CRPA or not it was a lower end of workload to RSOs.

The ROR mentions that there is a special outreach session held in Montreal for RSOs. As an organization we weren't aware of it. It could well be that RSOs in other locations would have been interested. We didn't know as a group that was going on. We understand subsequently, discussing with staff, that that was really driven by the RSOs in Montreal and not really driven by CNSC staff. But had it been made more well-known, maybe some other locals would have asked for that presentation too.

And at this point I'll turn things over to Trevor.

MR. BENISTON: Good morning. My name is Trevor Beniston.

With section 4.1 of the report, it talked about new licence conditions for NSRD licensees and, in particular, there was a change to the thyroid screening and thyroid
bioassay licence conditions. The change added Iodine 123 and 124 to the screening requirements. This did catch a number of licensees off guard.

We spoke with the human monitoring laboratory at Health Canada and we utilized their thyroid intercomparison program to establish its efficiencies and effectiveness of our screening process. The HML did not seem to be aware at the time that there is now a requirement for I-123 and I-124 for thyroid screening. With that, many RSOs looked for RD-58 for some guidance on the addition of I-123 and I-124. That document has not been revised or was not revised to take that into account. As a result, it has been a challenge for some sites to implement screening for these relatively new radionuclides without a written guidance document.

In the same section it discussed the introduction of REGDOC-2.7.3. This was published in August 2017. This is the guideline for deceased or descendants implanted with nuclear substances. This is a document that has been eagerly anticipated by some medical RSOs for some time, getting guidance on how to address the issue of implanted radioisotopes into patients that have left the hospital and then subsequently pass on afterwards, has been something that many RSOs are looking for. That document is currently open for public consultation until November and we have encouraged members to provide their comments before then.

With the reported events in section 5.7, while the summary of those reported events in the appendix is helpful along with the INES classification, many radiation safety professionals in Canada would find an online, CNSC-published event report, sort of similar to how the NRC does is it, to be even more helpful. We feel that providing as much communication and information as possible about events and spreading that along to the maximum number of licensees and radiation safety professionals is in everyone's best interest. The more information provided, the more useful that exercise is.

In particular the incident where the dose to the skin of a nuclear energy worker was in excess of the does limit was definitely an event that raised a lot of eyebrows and was of concern to a number of medical RSOs. This event was used to reinforce to workers the necessity of having a proper safety culture and to follow procedures. It was an excellent case study showing here is why we have the rules in place that we do. Here is an event where we have exceeded a dose limit.

Complacency is something that can set in and publishing and describing these events are very useful to our members. We can take this information back to our front-line users, to our organizations.

And sort of as a general comment, looking at the data that's collected and used to assess radiation safety across the board, some members have questioned and expressed, is there a better way to combine dosimetry results with other measures as an assessment of practice? Looking at strictly dose levels is one particular approach, but is there a way to provide some context to that?

So, for example, if we have an activity that works with a large amount of radioactivity, how does that compare to, say, another activity using a smaller amount of radioactivity yet receiving a similar dose? Basically, is there a better way to contextualize the information?

I would mention that NDR used to provide an Occupational Exposure Report. That would be something that we would definitely want to see again, or could see again.

And we also wanted to raise a commendation -- while it's not strictly speaking on part of the report -- the ability of interested parties to watch Commission meetings, to attend these hearings via -- either in person, to see them via the webcast is incredibly helpful. It allows professional -- radiation safety professionals to get an increased appreciation for CNSC

expectations, gather some insight into the workings of the CNSC and better understanding of how the entire system works.

With that, I'll turn this back over to my colleague, Jeff.

MR. DOVYAK: It's Jeff Dovyak, again.

So, in closing, we wish to acknowledge our appreciation for participant funding which allowed our involvement with reviewing the draft ROR and appreciation for CNSC staff's involvement with stakeholder engagement generally, but specifically the ongoing involvement in our annual conference, the willingness to be involved with CNSC industry working groups goes a long way to having much improved communications that are two-way.

So, with that, thank you for allowing us to do our presentation.

THE PRESIDENT: Thank you. So, let me jump right into the question session starting with Dr. Soliman.

MEMBER SOLIMAN: I have a question on the M42.2, page 3, the second paragraph. What level of the players you would like to be included in the report, in the event report from CRPA on to you?

MR. DOVYAK: Basically, everything that's

addressed in the NRC Reports that are available online. Maybe everything, except we don't necessarily need to know the identity of the licensee or where the licensee's located, it would be sufficient knowing the use type or licence type, knowing what -- being able to read what actually happened, what was the impact, what was the disposition or how was the incident mitigated.

MEMBER SOLIMAN: Okay. Staff?

MR. MOSES: Colin Moses, for the record.

So, the US NRC has an automated system for event reports. When an event report is received by the NRC it automatically gets posted up exactly as received and that information, you know, as they do the investigation if it becomes a non-event, it gets deleted if it doesn't. So, they really have an online system that maintains that kind of information.

It's certainly an area of interest I think I've discussed in previous meetings, but with the industry that the CNSC regulates in DNSR, we're in a unique position of receiving reports from sectors that wouldn't necessarily have a cause or reason to communicate amongst themselves.

So, for example, the same fixed gauge might be used in the oil and gas sectors that's used in the bottling sector.

And so, I think there is a role for the CNSC to play in sharing the kind of operating experience and events and we've made a number of strides in that regards. In particular, the 2017 edition of the newsletter focused on events that are of significance, that did have key lessons learned. As was discussed, the personal skin contamination event, that was discussed, both that one and the one that was reported to the Commission shortly thereafter in 2017, were discussed in details with an emphasis on the kind of protective measures that licensees need to put in place.

So, I think there's a lot of value in that exercise. This is the first year that we've included a list of all reported events and absolutely, you know, through our outreach sessions we include information on events, we talked with CIRSA earlier and we have annual industrial radiography meetings where we actually ask industry to present case studies on events that occurred in the industry.

So, we're trying to leverage as many vehicles as possible because I think it is really important to share that kind of operating experience as widely as possible across the industry.

MEMBER SOLIMAN: Is this okay, acceptable?

MR. DOVYAK: Yes, that would be great.

MEMBER SOLIMAN: Okay.

THE PRESIDENT: Thank you. Dr. McEwan?

MEMBER McEWAN: Thank you, Mr. President.

For the sake of disclosure, I should note that Mr. Beniston and I work in the same building, so...

A couple of questions. Thank you for this, it was very helpful and thank you for coming and, as the President said, I hope you will stay for this afternoon.

Two very simple questions to start with. Why was I-123 included and why was it included without discussion with users of a community?

MR. MOSES: I'll let Mr. Fundarek speak to that.

MR. FUNDAREK: Peter Fundarek, for the record.

The isotopes were added as a result of a review of the licence condition and the increasing use of iodine 123 and 124 and it was felt by our specialists within the CNSC that it merited adding those two isotopes to the licence condition.

The information about that was provided in a general information to licensees that we had the revised

licence condition available and we're implementing -- it was available to be added to the licences as they requested it or when their licence was renewed, so it was added at that time.

MR. MOSES: I'll just add to -- Colin Moses, for the record.

I take that feedback and I think that is really strong feedback. And, in fact, we launched an initiative to develop generic licence condition handbooks for different sectors that we regulate to revise the licence and also include additional guidance on how to meet the requirements that we're placing through our licences.

And so, we want to make sure that when we introduce new requirements, licensees are well aware that those requirements are coming and they understand what we're looking for within those requirements. And so, I think that feedback from CRPA was helpful.

MEMBER McEWAN: It's probably the thing that I've had the most phone calls about too over the last six months.

So, I still don't think I got my answer, the reason for doing it, other than the specialists said, I'd like to understand why.

Is it only I-123 iodide or is it all I-123

labelled ready pharmaceuticals?

MR. MOSES: So, Mr. Fundarek can speak to the specifics of the licence condition. I'll ask Ms Caroline Purvis, the Director of the Radiation Protection Division, to speak more specifically to that.

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

So, unfortunately, my technical specialist is not here today, but what I can tell you is when we looked at the increasing use of iodine 124 and 123 and then looked at -- working with our colleagues in DNSR, it was clear that we should set some conditions for screening, which is to look, to determine if your radiation protection program is working properly and that to identify criteria to when you would do further investigation to ascertain the dose.

The view is, certainly you'd want to do that for volatile iodines and, as we've seen so far, we're working on a case-by-case basis, recognizing that our guidance is catching up and it's a very fair comment from our licensees in this case.

We talked a little bit about REGDOC-2.7.2 yesterday and that is incorporating the legacy document RD-58 which currently only addresses iodine 125 and 131.

Our new document will be expanded to include the new iodine isotopes that are under discussion today.

I'm not sure I answered your question.

MEMBER McEWAN: How many I-124 licences are there in the country?

MR. FUNDAREK: Peter Fundarek, for the record.

I don't have that information at this time.

MEMBER McEWAN: Can we find it, please?

MR. MOSES: Yes, we can look into that and we'll get back to you on that.

MEMBER McEWAN: My second question away from that is, does CRPA have a view on RSO certification?

MR. DOVYAK: It's Jeff Dovyak speaking.

Well, we've had the RSO registration program now for over 10 years and we'd be delighted if that RSO registration program received more recognition from the regulator that it exists, that not everyone passes that attempts, that it's a real program, it's not just a rubber stamp thing.

So, I guess without knowing where RSO certification may be headed, we may or may not be supportive. So if one of the possible branches of RSO

certification would be, oh, if you have registration with CRPA as a registered radiation safety professional, that gives you one of the qualifications that we're looking for, yeah, we'd be happy with that.

But if we were told that our program isn't good enough, that our people with CRPA are -- still need to do even more, I guess we would go back to trying to find CNSC Staff from 12 or 15 years ago that suggested we develop this registration process. Because it wasn't -- we didn't do it out of thin air. We did it under some advice from CNSC Staff.

MEMBER McEWAN: Thank you very much.

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

Dr. McEwan, you ask a very valid question with respect to the comments from CRPA with respect to the -- I'm not going to beat around the bush -- surprises of the licence condition.

I would like to make two comments. Number one, clarity is very important to us. We do not know what we do not know. So in other words, the licence condition -- we do not impose requirements on a licensee that renders them to be non-compliant.

However, I would like to tell the CRPA

they do not need to wait 'til the end of the year and come to the ROR. They can always raise it up the line with respect to licensee.

I am the chief regulatory operations officer. I was not aware that a licence condition was amended and it was put into licences during renewal based on requirements: I-123 or -124. That's the point I would like to leave the intervenor and CRPA in specific. If there are issues, raise it up the line with respect to surprises.

Because that's not our policy. Our policy is compliance. And at the same time, if we're going to come up with an amendment, we will provide the licensee to be in compliance with respect to an implementation.

I just wanted to make sure that this process will be applied. And if CRPA -- I encourage CRPA if there are issues not to wait 'til the end of the year to raise them.

MR. MOSES: Colin Moses. Not to belabour the point, but that's where we find our outreach activities most helpful. In particular with the CRPA, we attend every year their annual conference. And we hold a Q and A session with the entire audience where any questions of regulatory concern, any questions on new requirements or

CNSC expectations, that's an opportunity for that community to raise that with us. And that happens at every outreach session we do hold.

THE PRESIDENT: Yet there was surprise here. So, you know, we have another policy which is no surprises. And therefore, you know, you heard me say it many times we promise never to stab anybody in the back. If we're going to stab you, it's going to be from the front, and you're going to see us coming for miles. So I thought that's something we adhered to. So I'm surprised that they were surprised by that.

Okay. Next is Dr. Demeter.

MEMBER DEMETER: Thank you, Mr. President.

For the sake of disclosure as well, I work in the same building and health authority as Mr. Dovyak, and I'm a general member of the CRPA without any governance appointments.

For CRPA, can you give us a sense of your membership by category. Because we talked about there's medical, industrial, commercial, and academic. And you represent radiation safety professionals. And I want to get a sense of the scope and breadth of your membership.

MR. DOVYAK: It's Jeff Dovyak. I don't have that data. Years ago we used to present that annually

in our membership handbook, which was a hardcopy thing. And to be green, the CRPA has gotten away from that. And we don't really publish where our members come from anymore that's easily retrievable. We could find that out and let the secretariat know on another day. So right now I can't give you that information. I know that generally most of the CRPA membership tends to come from medical or academic research sectors as opposed to industrial.

MEMBER DEMETER: Thank you. Yeah, it's helpful to understand who you represent from a stakeholder point of view.

Just as a follow up to Dr. McEwan's question about I-123 and I-124, it will be really helpful to have clarity as to whether this particularly applies just to volatile substances using iodine, whether it applies to any pharmaceuticals that incorporate iodine into their molecule and they are no longer volatile. And it would really be helpful to understand the risk-informed health basis for including I-123 to trigger a monitoring versus the historical I-131 which we know a lot about the risks to the thyroid versus a more diagnostic I-123 which is not used therapeutically.

I don't know if Staff have any comment on the health-risk-informed basis for adding I-123, volatile

or otherwise.

MR. MOSES: I'll ask Ms Caroline Purvis just to provide a preliminary answer, and I think there is an opportunity to provide more information to the Commission on this and we can get back to you with that.

THE PRESIDENT: I would argue -- or ask a question that until the REGDOC becomes in effect, you may want to consider some -- issuing some clarification -- I don't know if you use a newsletter or whatever -- about the history and the intention and the future of those new parameters.

MR. MOSES: Colin Moses. Absolutely. And I think the CRPA also referenced clarification on our expectations around skins contamination and that vehicle is something that we can definitely leverage in this case.

THE PRESIDENT: You want to add anything to that, Ms Purvis?

MS PURVIS: Caroline Purvis for the record.

I don't think I'll add anything to that. Certainly what I will say from a risk point of view is that iodine -- well, screening programs in general are to determine at what threshold level you would proceed with ascertaining a dose for the purposes of confirming whether

you're under a dose limit or not. So it really is not related to risk to the thyroid in the sense that the other nuclides present more of an issue in that regard. It really is -- it's linked to other regulatory documents such as G91 about ascertaining and recording doses to individuals. And I believe that was the sense of your question.

MEMBER DEMETER: Okay, thank you.

MR. MOSES: Colin Moses. Just we had a question earlier on the number of licences that use the different iodine isotopes. So there are 101 licences that use iodine-123, and there are six licences that use iodine-124.

MEMBER DEMETER: Thank you.

THE PRESIDENT: How did you get this number so fast?

MR. MOSES: We have databases on all isotopes that are used by all licensees, and so we just had to refer that back --

THE PRESIDENT: I'm impressed.

MR. MOSES: I should add too that not all of those licensees are required to implement the monitoring program. It really does depend on the actual quantities that they manage within their licence.

THE PRESIDENT: So you could actually search the data to find this?

MR. MOSES: We've got people back home combing the data as we speak.

--- Laughter / Rires

THE PRESIDENT: Terrific. No, that's great.

MEMBER McEWAN: Can I just go back to the unanswered question, and that is is it only iodide, the volatile, or is it I-123 labelled radiopharmaceuticals?

MR. MOSES: We'll look into that and we'll get those people to comb the data for that answer as well.

THE PRESIDENT: Okay, moving on to Mr. Seeley.

MEMBER SEELEY: Right, maybe just a question/comment related to the type of data used to assess radiation safety across the licensees. This is a bit of a theme in that we heard the industrial sector also talk a little bit about this business of average dose per worker per industrial site versus number of individuals at given levels of dose. So they're coming at the same theme. Hey, we should be looking at some other metrics.

And so this group, my understanding, is looking at -- they refer to low activity dose results

versus high activity doses, maybe another type of measure. So my question is to the CRPA is this something you are asking -- it's the old story careful what you ask for. So are you asking for more, you know, regulatory requirements in terms of how that would be reported to improve the data? Or are you suggesting maybe your group could come up with some guidelines and/or metrics on how this information -- what kind of information you'd like to see and provide that to the regulators. Just trying to get at how do we get to the point you've raised here. What's the process and what's the next step.

MR. DOVYAK: It's Jeff Dovyak. Commissioner Seeley, I guess we would prefer the latter, not the former. And we could discuss that within CRPA and certainly discuss it at the CRPA CNSC working group.

MEMBER SEELEY: Right, because I -- yeah, exactly. I'm thinking it's a good discussion that has to happen, and perhaps rather than just leave it as something that's on the presentation, maybe take an action around it as was done with the industrial group this morning taking an action around that average dose piece, how do we get to that with the least amount of work in the most efficient way. Yeah.

THE PRESIDENT: And that goes -- you know,

you may want to also use the CSA to set up some standards of measurement. The point here is that if you come up of course with a way to describe the organization and the sector in the different metrics, it should help CNSC. We can help also if there's agreement about how to do this. We can actually put some resources to try to develop that. But we're always looking for ideas. We are not necessarily a lock on all ideas.

Okay, back to the top of the list here. Dr. Soliman? Dr. McEwan?

MEMBER McEWAN: So you said that most but not all of your members were RSOs. What do the other members do?

MR. DOVYAK: Some of our members are research scientists, so they're using radioactivity every day to further their research. Some of our members work in government for CNSC, for Health Canada, for provincial governments that look after X-ray safety provincially. Some people are in management in radiation protection administration and other kinds of health care management, because maybe they used to be RSOs five jobs ago, but they still have an interest in radiation safety. So it's fairly diverse.

MEMBER McEWAN: Thank you.

THE PRESIDENT: Okay, Dr. Demeter.

MEMBER DEMETER: Just a clarification. There was interest on managing deceased who have either radioactive implants or unsealed sources that have biodistributed, and there was discussions about guidance for cremation. And I wanted to get a sense whether it was broader than that, whether it dealt with cremation, autopsy, embalming, open casket, closed casket -- is that project going to include the broader spectrum of handling and managing deceased?

MR. MOSES: Colin Moses for the record. So the shorter answer is yes, but I'll let Ms Adelene Gaw, who is leading the development of that document, speak to that.

MS GAW: Adelene Gaw, for the record. I work in the Radiation Protection Division.

So yes, REGDOG 2.7.3, which is a guide for handling of decedents who have received radioactive implants and also treatments for radiotherapy. It will include -- it does include all the items that you mentioned. So it does provide guidance on cremation and embalmment and safe handling during autopsy, et cetera, and also guidance for family members as well.

MEMBER DEMETER: Thank you very much.

THE PRESIDENT: Is CRPA going to comment on this document? It's now in consultation mode.

MR. DOVYAK: It's Jeff Dovyak. We were actually talking about that this morning, Dr. Binder, before the session began. I know I've comment for my health authority, I think some other people are. We're not sure if the CRPA is going to comment or not because our mechanism to comment on things, our Position Statement Committee seems to be rather unwieldy how it operates. So by the time the committee has actually come to consensus, it's usually months beyond the deadline for comments. So --

THE PRESIDENT: And you're complaining about CNSC being slow?

--- Laughter / Rires

THE PRESIDENT: I think that you should do something about ---

MR. DOVYAK: I'm just telling it like it is.

MR. MOSES: Colin Moses. I'm not sure if it's even worth adding, but we do welcome comments at any time. So if it is months after, don't hesitate to provide them to us. If we can't address them in that edition, then we do regularly review the documents that we put out.

THE PRESDIENT: Okay. Mr. Seeley? Anybody else?

Okay, any final comments you want to share with us?

MR. DOVYAK: Sure. So it's Jeff Dovyak again. As I said, I'm a medical RSO. So are Ali and Trevor. So I wasn't particularly surprised when the new thyroid screening conditions appeared on our licences for iodine-123 and iodine-124. What I was surprised with is that we were told it applied to all forms of those radioiodines, not just unbound or volatile.

I tried clarifying that with my licensing specialist, who I believe went to whoever the licensing specialist speaks to, and the answer that came back, that now covers all forms of radioiodine, whether it's volatile or not. And that was a surprise to us. But within my health region, we didn't think of it as being a showstopper such that we needed to elevate it higher. We weren't happy with it, but I guess we accepted it.

And I think some other health regions were more unhappy than we were, because I think maybe one of Trevor's colleagues has been working with NSRD licensing to try to look at some particular cases for I-123.

But other than that, thank you once again

for allowing us to be here today due to participant funding and the opportunity generally to comment on the ROR.

MEMBER McEWAN: Sorry, you've just set me on train for a question. And I guess this could be either CRPA or Staff. How many facilities had to buy new probes because of this change in the licensing condition?

MR. DOVYAK: It's Jeff Dovyak. I'm not aware of hearing that any had to buy new probes. I was speaking with Trevor much earlier this morning, and I said that we had in my health region had to get our medical physicist involved to figure out how to properly program the existing probes. The newer probes tend to be very automated, and unlike probes 30 years ago, it's not easy to just dial in a particular gamma ray energy and set a window around it. You need to understand what the software is doing.

So I'm not aware of any licensees having to buy new equipment to be able to do the screening, but CNSC Staff may be more aware.

MR. MOSES: Colin Moses. I can certainly be corrected, but I don't believe that's the sort of information that we would have.

MEMBER McEWAN: So I'm certainly aware of one site that's considering stopping doing I-123 work

because of this requirement, because they would have to buy a probe. So I think as we do introduce this, we need to be aware of the administrative and cost burden that this might be placing on users.

THE PRESIDENT: And just to add, my understanding is when we introduce such a new requirement, we normally worry about transition period, and negotiate sometimes transition period with the licensees. So I'm not sure if this is now in effect, this is mandatory, or yet to come, or just -- even though it's in the licence condition, I don't know if there's a transition period associated with it.

MR. MOSES: Colin Moses. I don't know that there's a specific transition period that was developed associated with the introduction of this, but it was based on an application and renewal process, so it was gradually introduced across the industry. But I think -- absolutely I think this is the kind of feedback that we need to look at and make sure that we're effectively introducing new requirements and that we're engaging with the industry before we do that.

THE PRESIDENT: Okay. Thank you. Thank you very much for the intervention.

And I'd like to move on now to the next

submission from the Canadian Environmental Law Association as outlined in CMD 17-M42.3 and M42.3A. I understand that Ms Blaise and Mr. Siersbaek -- I don't know if I'm pronouncing it correctly -- will be presenting. Over to you.

CMD 17-M42.3/17-M42.3A
Oral presentation by the
Canadian Environmental Law Association

MR. SIERSBAEK: Good morning, President Binder, Commission Members. My name is Morten Siersbaek. I work as counsel for the Canadian Environmental Law Association. And as you noted with me today is co-counsel Kerrie Blaise.

I would like to start by saying that CELA's review of the draft report has been made possible by the participant funding program. We received funding specifically to review environmental effects and related impacts on health and safety. We appreciate this opportunity and hope that our comments can contribute to ensuring the best possible protection of the environment in this field.

We believe that this annual report is an

important mechanism to review performance of the entire sector and look forward to constructive dialogue.

So who is the Canadian Environmental Law Association? CELA is a non-profit public-interest organization funded by Legal Aid. And our objectives include protecting the environment and advocating for environmental law reform. We provide access to justice to those unable to afford it. We also work for long-term sustainable solutions to environmental concerns and resource use and we advocate for the use of precautionary measures to prevent harm to humans and the ecosystems.

CELA's approach when reviewing this report, we basically started by identifying environmental issues that we found in the report. And in doing that, we considered both what I would label actual and perceived issues. We then moved on to make recommendations to address these issues.

The reason why we included both actual and perceived issues, there's a couple of reasons for this. First of all, it ensures that less obvious issues are not left unaddressed. It also provides an opportunity for the CNSC to explain why a perceived issue is not in fact an issue. And on that, I know that there is a document posted on October 6th that does address a number of issues that

Staff also mentioned. So that is what I'm referring to, that type of feedback. And finally, it helps highlight areas where CELA has found a lack of clarity in the draft report. And this approach is by design slightly over-inclusive, but we believe that it provides greater certainty and ensures that no issues are left unaddressed.

In taking this approach we are guided by and ensure the support for the implementation of the precautionary principle. This is the principle that includes the duty to prevent harm, even when all the evidence is not in. We believe that all regulators acting in the public interest should embrace this principle.

So the contents of CELA's submission contains both specific comments, recommendations, and requests, and more general comments such as the proposed inclusion of an environmental chapter. In total, CELA has provided close to 100 comments that deal with a wide range of topics related to the environment and human health.

And we will now provide a brief summary of those findings. And of course all these findings are described in our submission in greater detail.

So on inspections and reporting, we note that there is a significant drop in person days spent on compliance verification. We also note that compliance with

operating performance SCAs is at 87.4 per cent and, to us, this suggests a need for increased compliance verification to increase the overall level of compliance.

While the CNSC has stated that these noncompliance issues are generally addressed once licensees are contacted by CNSC Staff, CELA still believes that this initial compliance rate could be higher. We find it not entirely satisfactory that the regulator has to remind licensees to comply in what we think is a significant number of cases.

On compliance, we find that the newer compliance rating levels are somewhat misleading, combining the old compliance levels C and D into the new compliance level below expectations, in our opinion, may lead to an overly optimistic image of compliance compared to the past compliance levels. The performance of all licensees is averaged in the report.

So a certain percentage may have made adequate provisions, some may have done better than adequate, and others may have performed unacceptably. Yet, the report concludes that overall licensees made adequate protection provisions. We find that such averaging, it tends to be a bit misleading. The data is in the report, but those more qualitative descriptions could be

misleading. So you need to read into the details to see what is really in the data.

So overall, we find that this new rating level system and averaging of protections leads to conclusions that are perhaps too optimistic.

On protection standards and regulatory requirements, we find that there is a lack of information on environmental protection programs. It's mentioned on page 4 of the report, these programs, but no further details are provided on that. We also see a need for further clarification of some aspects of the use of ALARA standards. One thing we would like to see in this area is perhaps a summary of how licensees typically implement ALARA standards just to make it a little bit more clear to the reader how is this done in real life.

We also find that there is a lack of specific references to individual provisions within the *Nuclear Safety Control Act* and its regulations. Our issue here is that without these references it's harder to determine if the regulatory requirements are actually being met. It's easier if you have the information and the provisions, and you can pair them in the text.

So specific references there, we believe, would help, and that includes specific references to the

relevant REGDOCs as well.

The draft report includes some sample worksheets that we have reviewed, and we find that these worksheets contain little to no mention of environmental protection. We also find that there is a lack of detail on page 11 of the report, dealing with how licensees demonstrate protection of the environment.

To sum up on protection standards and regulatory requirements, we believe that the report ought to include further information on the standards and the regulatory requirements, and on how these standards and requirements are applied to licensees.

On environmental risks and exposures, we also see that there's some lack of detailed information. Again, we are advocating for the environment, so that is our focus. So we will drill down and look for those particular issues, and we have found there is a lack of information there for us to determine whether there is an issue or not. It is very possible that risks and exposures are actually low, but we feel that more information is needed to fully demonstrate this.

We have also reviewed past versions of the report from 2011 to 2015, and what we found is that little appears to have changed in the review of environmental

protection over the past several years. The reports look quite similar. What we've also found is that the CNSC appears to have found no impact on the environment for the past six years.

Again, with the lack of information, we find that it's difficult to support this conclusion and we would have to reserve our judgment for a possible future version of the report with hopefully more information on environmental protections.

We've also looked at climate change and recommended that the report consider climate change and its effects on the integrity of stored and in-use nuclear substances. With an increasing frequency of catastrophic weather events, the climate resiliency of licensees should also be considered.

On the transport of nuclear substances, we've noted that 1 million packages of nuclear substances are shipped on an annual basis in Canada. We feel that there is a need to consider how transportation, shipping documents, and emergency plans can be improved to increase protection of human health and the environment.

We also find that the draft report ought to include greater consideration of the human health and environmental ramifications of transport, and discuss how

procedural improvements can be made in light of reported accidents.

Finally, CELA recommends that an environmental chapter be added to the report. There's a number of reasons for this. First of all, section 24(4) of the *Act* requires that all licensees make adequate provision for the protection of the environment.

Furthermore, several of CELA's findings involve a lack of clarity regarding environmental protection, and the current report's focus is almost exclusively aimed at radiation protection and safety.

Because of all of this, we found it difficult to determine if sufficient environmental protection measures are currently in place. This issue is found in the draft report and it's also mirrored in past annual reports. Overall, it has made it difficult for us to determine if improvements in environmental protections have occurred in 2016.

We feel that a dedicated chapter would provide an opportunity to include an explicit assessment of the environmental protection SCA in the report. We also think that an environmental chapter would ensure a more focused and more detailed review of any potential environmental issues. The environmental topic, as a whole,

we find that it would provide an efficient way of addressing many of the issues that CELA has identified and help improve the protection of the environment overall. Finally, it would help demonstrate compliance with section 24(4) of the *Act*.

So what's next? Well, we welcome a dialogue about the implementation of CELA's recommendations and we look forward to hopefully review a new chapter on the environment in next year's draft report or at least an expanded review of environmental protection throughout the report.

To conclude, I would like to point out that CELA's submission is available on our website at cela.ca/publications. On cela.ca you'll also find a vast collection of our past work. With that, thank you for your time.

THE PRESIDENT: Thank you. So let's start the question session, starting with Mr. Seeley.

MEMBER SEELEY: Maybe with respect to the need for more information on environment in the report, maybe Staff, did you want to comment on the risks to environment due to the use of nuclear substances? Maybe just some general comments and information for the room?

MR. MOSES: Colin Moses, for the Record.

Before I get into that, I did want to say that we really did appreciate CELA's review of the report. We do our best to provide a report that outlines all our compliance data and clearly describes our activities. I think it was very helpful to have sort of a third party have a look at that and provide some feedback on how we can improve the clarity.

CELA's submission was also a large driving reason behind the development of the supplemental CMD, because I think it identified a number of areas we can clarify regulatory oversight activities.

So with regards to your specific comment, we describe in the supplemental, but the vast majority of the nuclear substances that we regulate have no impact on the environment. They are gauges that include double encapsulated sources, so the nuclear material is included within a source, an encapsulated source, that ensure that there's no releases there, they're within radiation devices, and those are certified by the CNSC to assess adequacy of shielding. We have measures in place for licensees to monitor, to ensure that the integrity of those devices remain.

Any instances where those barriers are compromised are required to be reported to us. So we

include information on event reports and would explore if there are any potential environmental impacts.

There is a small subset of licensees that do deal with unsealed nuclear substances, and those, our focus of oversight is on the radiation protection side to ensure that workers aren't receiving unnecessary doses, to ensure the doses remain ALARA, and to ensure that they have appropriate worker protection measures, that there is no releases of those nuclear substances. So our focus on radiation protection, by definition, protects the environment.

As I alluded to, I think we do concur that there is an opportunity to better describe how the environment is protected in our regulatory scheme, and so that is something we'll be looking at including in future editions of the report.

MEMBER SEELEY: Thank you. No further questions on that.

THE PRESIDENT: Dr. Soliman.

MEMBER SOLIMAN: Thank you very much.

Thank you for that presentation. You put many recommendations and it's a very good report. I have a question, besides on the environment my colleague asked, you suggested that we should take the climate change into

consideration. I would like the Staff to elaborate on that, and if the climate change is applicable to this type of study or this type of report?

MR. MOSES: Colin Moses, for the record.

The requirements that we establish require the licensees to identify potential risks and potential emergencies that they need to manage, and have measures in place to respond to those.

Typically, the dangers are more localized than sort of climate change effects. So fires in a facility that has nuclear gauges, potential disconnects of sources during the operation, and so we require the licensee to have those emergency measures in place to ensure that they can mitigate any potential impacts of that.

So those measures are more than capable of dealing with anything that nature might throw at us. But there are areas where we do increase our oversight. So we reported last year to the Commission on our response to the Fort McMurray fires, because Fort McMurray is a location where there are many oil and gas servicing companies, there is inventories of nuclear substances within Fort McMurray.

So in those cases we do monitor situation reports that are developed by the Government of Canada on the development of any significant events; earthquakes,

fires, significant weather events, and proactively reach out to licensees to ensure that they are undertaking those appropriate measures, reminding them of their obligations.

In many cases the licensees that are in those locations are mobile, so they have portable gauges, and it's as simple as moving those out of any danger zones. So that's very quick and easy.

But, as I mentioned, the emergencies that they need to prepare for will address any potential climate effects that may come in the future.

MEMBER SOLIMAN: Is this answer satisfactory or addresses your comments?

MS BLAISE: Thank you. This is Kerrie Blaise, for the record.

I do appreciate that follow-up. I think our point was just as catastrophic weather events become more frequent, if this could be explicitly referenced in the licence condition handbook or even in a REGDOC that might overview these considerations of climate resiliency.

We do go into detail about flooding and the impact of flooding, on the integrity of stored devices, and also on the impact of wildfire with Fort McMurray being the example we gave. So I do appreciate that, thank you.

MEMBER SOLIMAN: Thank you.

THE PRESIDENT: Next is Dr. McEwan.

MEMBER McEWAN: Thank you, Mr. President. Again, thank you for both, for the presentation which was really good and for the submission.

Have you actually observed, do you know the activities that are performed in each of the different sectors within DNSR?

MR. SIERSBAEK: Morten Siersbaek, for the record.

We have only written descriptions of the different activities, and I would say that maybe not every single activity, as has already been alluded to by Staff, not every single activity is perhaps a clear and direct risk -- posed a clear and direct risk to the environment. But from our understanding, some of them could, under the right or wrong circumstances, pose a risk.

Beyond that, we found that there is a level of uncertainty. Maybe I should add that we also review these documents from the perspective of the general public, and so a lot of our comments are aimed at ensuring that a document is clear when there's no risk. So part of what we wanted was also to have that made clear wherever that was the case, and simply to point out where there are risks and where there aren't.

Thank you.

MEMBER McEWAN: So it seems to me that there's almost a two-stage process: the first stage is an educational process so that you actually understand the elements of the activities in each of the sectors; and the second, is using that knowledge that you gain from that educational process in the reviews that you do. Then I guess the third stage would be in the interventions that you then make.

So perhaps actually a question for CELA, maybe even for CRPA and for Staff, would it be helpful if we put on, if you like, an education 101 in the activities within each of the different sectors so that we actually had clear definition of the activities that are performed in the medical sector, in the industrial sector, with an indication of the tools that we used for those activities and for the potential risks that might come out of the use of those tools?

Would that be helpful in providing you with background, but would help in future reviews?

MR. SIERSBAEK: Morten Siersbaek, for the record.

That would definitely go a long way towards maybe diffusing some of our concerns and questions.

So I think that would definitely be helpful. Thank you.

MEMBER McEWAN: Staff, do you think that would be possible?

MR. MOSES: Colin Moses, for the record.

Absolutely. I think it would be a wonderful opportunity to speak to some of the different activities that we regulate. So we'd be happy to do that.

MS BLAISE: Just to add to that, Kerrie Blaise, for the record.

That would be a wonderful idea, because I'm not sure the forum today provides that opportunity for that dialogue and extended Q&A, so we would --

THE PRESIDENT: Yes but, you know, that's a bit too precious. You know that you could have asked for a little -- DNSR, this is a group here, 101, we do 101 on any subject across the whole country on demand. It would be a lot more useful if you actually add this. So to be helpful to us is a deep understanding of the activity before you do the analysis from a legalistic perspective.

When I read this here document, it was purely a document review from a legal perspective. You'll always have this kind of uncertainty associated with an annual report that presents the activity to the public, you'll always have this thing. It would have been useful, I

think, if you would have asked and had this kind of discussion with Staff before you come here. That would be my two bits on this.

MR. JAMMAL: Mr. President, it's Ramzi Jammal, for the record here.

I just want to make sure we're not going to end up with a regulatory oversight report that's going to be voluminous in numbers. So I would like to finish the fact, that we accept the fact, that CELA is looking for assurance to the public on what the activities are.

We will take that into consideration so that -- we already have a phenomenal amount of information on our website that we will provide linkages to the activity that is being overseen by the CNSC so that the public can use that link, in order to educate, with respect to, what activity is going to be done. Because it's a regulatory oversight report, we will be more than happy to educate the public, and we have other mechanisms to do so. I just want to make sure that -- the information's already existing, and we provide linkages to that --

THE PRESIDENT: I think Dr. McEwan was talking about a presentation right here, in the Commission, in the public. Bring some of the equipment. You know,

people talk about the radiographer. I remember that the last one, we've done it here, many of us didn't know what one of those equipment that measures oil and density, et cetera, look like. It would be useful to bring it in. You can take a look and you can see what can go wrong with them, what's the environmental impact.

So I think we should maybe do it periodically, particularly in six months this group may look completely different and you may want to do this again to explain and educate the new members about some of the activities. Some of the activities are not obvious. People don't run into radiographers in day to day life, and we should spend some time trying to explain what they do and the risks associated with them.

So I interrupted you, Dr. McEwan.

MEMBER McEWAN: I had no intent that this would go into the ROR, it would be a separate educational session, please be assured.

Just one other comment for Staff. As I read through your responses, I was struck by the terminology you used in the description of the Staff response, recognizing you did not have a lot of time to turn this around. But I think certainly if I look at some of the CELA requests for information, you've just put a

generic "not accepted."

I think it would be helpful to actually reflect the question -- if it's a recommendation and you want to put not accepted, I fully accept that. But if it's a request for information, I'm not sure that that's the most helpful response to put in, recognizing the caveats that this document has.

MR. MOSES: Colin Moses, for the record.

I think that's wonderful feedback and, you know, we sort of qualified those "not accepted" by "additional information provided", and I think there's different ways we can characterize that, and I appreciate that feedback.

THE PRESIDENT: Dr. Demeter.

MEMBER DEMETER: Thank you, Mr. President. I have just a quick question for CELA and then I'll get into the more substantial question. On your report and in your presentation on your title page you have a picture of a semi truck carrying containers. What that told me is that there's a definite need for you to have better insight as of the scope of practice for this ROR. I couldn't find a connection between that transportation of non-fissile or fissile-exempt or radon of low-specific activity based on the placard to that kind of activity.

So maybe I'm wrong, but I couldn't make a connection between that picture, which sends a message, and this ROR. So maybe you can explain where that picture came from and why it's there?

MS BLAISE: Kerrie Blaise, for the record.

That's actually a personal photo. So when CELA does reports we are very cautious about copyright, so the photos we use often come from our lawyers. This one was actually one I took, and that was purely based on -- we did have significant comments on transportation and shipping. As one of the points highlighted in the report, was there's 1 million shipments of nuclear waste in Canada. That's where that link came from.

MEMBER DEMETER: Okay.

MR. MOSES: Colin Moses, for the record.

You're correct, that is a picture of a transport of nuclear substances that aren't covered by this report, but I think that is an opportunity to clarify again --

THE PRESIDENT: Yes. But for pure disclosure, you should have said this is a transport of material which is not covered by this report. It's for a different type of waste.

MEMBER DEMETER: So the question I wanted

to talk to Staff about that CELA raised is the difference between the categorization, previously the A to E, to the current categorization, and where C and D were previously categorized as improvement or seriously compromised, and that's been merged to below expectation.

From a risk communication, seriously compromised sounds like a really big deal, and below expectation doesn't sound like as big a deal. So help me understand the transition and how seriously compromised got merged into the below expectation category.

MR. MOSES: Colin Moses, for the record.

So maybe I'll just step back for a second and speak to -- so the CNSC traditionally used A, B, C, D, E to report on performance and, based on feedback from the Commission many years ago, we adjusted to what you see reported in this, so fully satisfactory, satisfactory, below expectations and unacceptable. And so with that comes a mapping.

The only reason we included in this report the A, B, C, D, E is the systems that are wonderful for extracting the number of licensees that deal with iodine-123 are also -- there's a lot of maintenance effort and a lot of effort to maintain those systems and to address them, and so one of the things we haven't gotten to

yet is adjusting that system to accommodate these new ratings.

And so when we produce inspection reports out of that, we still categorize it A, B, C, D, E and provide that information to licensees.

So about two years ago, we heard comments and suggestions on this report from the licensee who wanted to better understand how what they're seeing on their inspection report compared to what's reported on in the presentation, and so that's the information that we're including here.

The -- part of it is the mapping, but "seriously compromised" and "unacceptable" is very different in our eyes. "Unacceptable" results in immediate enforcement action. "Seriously compromised" results in increased scrutiny, required corrective actions and increased oversight but may not result in an enforcement action such as an order to require -- to address an immediate health and safety concern.

So a "seriously compromised" needs correction, but there's no immediate health and safety risk associated with that.

MEMBER DEMETER: Thank you.

And if I may direct to CRPA, who practises

in this field, does this communicate with you that you understand and, from an operational point of view, can work within these parameters? Does it make sense to you?

MR. BENISTON: For the record, it's Trevor Beniston.

The rating system that is used does work, it does make sense. The work sheets that are provided as part of the inspection process does fully and comprehensively explain what the rating system means.

MEMBER DEMETER: Okay. That's good to hear. Thank you.

THE PRESIDENT: So -- but I still think CELA is right here. There's some work to be done on clarity, and I'm a fan of giving examples that you go -- if you're going to use the old model and then transfer it to the new one, you've got to take us through a live example all the way from inspection down up the line.

And we've done it -- you've done it a couple times in other NPPs, I think, we -- and I think it could -- it's still not clear how we migrated from the C and Ds into some of the rating now.

So if it's going -- if it's going away, fine, but you still got to clarify how you do the rating and come up to -- and maybe if you also marry it with the

high, medium and low risks.

So something which is non-compliant and a high risk gives me a different kind of comfort level than non-complying in a low risk.

So we got to find a way of actually explaining better the risk and the compliance that goes with it.

MR. MOSES: Colin Moses, for the record.

I think that's good feedback, and that's something we can look at in future editions of the report.

And I'll also note that we do have a commitment to staff writ large to present to the Commission on how we arrive at our ratings and our different rating schemes, and that will cover all our different oversight activities from nuclear power plants to DNSR regulated activities. And I believe we've scheduled that in early 2018 for the Commission.

THE PRESIDENT: Thank you.

Back to the top of the list here with Mr. Seeley.

You're good?

Dr. Soliman.

MEMBER SOLIMAN: Thank you.

In the presentation, page 9, it specifies

the need for further clarification of some aspects of the use of ALARA.

What, exactly, do you want to be explain in the report concerning these aspects?

MR. SIERSBAEK: Morten Siersbaek, for the record.

So the -- we tried to exemplify -- like I can only give it in some sort of example of how ALARA is applied at the level of the individual licensee, and I understand that you cannot provide an overview of every single licensee, so perhaps some sort of summary of what does it really mean, how do you achieve ALARA because it's something that needs to be put into effect on the ground, practical ways of -- like methods you -- how do you perform your tasks, how do you ensure that there's like minimal risk, how do you do that in a day-to-day setting when you use these different nuclear substances.

So just a summary or some examples of how it's implemented just to make ALARA a little bit more, you know, easy to understand.

Thank you.

MEMBER SOLIMAN: (Inaudible - off mic) to illustrate the use of ALARA so you can meet the requirement -- you can meet the question, you can answer

the question.

MR. MOSES: Colin Moses, for the record.

I actually was just chatting with Ms Mortimer on potentially in the future editions including, you know, and "making it real" type component to the report so that people can really see how the requirements are put in place in practice.

And it's a good way to emphasize best practices that we see in the industry.

But I would like to note that G-29 is a regulatory document in our scheme, and it gives quite wonderful guidance to the regulated community on how to really implement a concept that's more philosophical in nature, you know, As Low As Reasonably Achievable.

And so that guidance document lays out a very systematic approach to analyzing your work practices, analyzing your work controls, analyzing your protective measures and assessing the impact that those may have on dose and adopting other mechanisms to keep that dose ALARA.

MEMBER SOLIMAN: Thank you.

THE PRESIDENT: Dr. McEwan.

MEMBER McEWAN: Thank you, Mr. President.

A couple of very -- well, one simple question.

So again, you heard us earlier discussing the risk rating for the different elements within DNSR regulated industries. Would it be helpful for your review if we had a little more emphasis on that in it so that you could stratify your comments against those areas of DNSR which were a higher or a lower risk?

MS BLAISE: Kerri Blaise, for the record.

I think that detail would be very helpful and even just the mentioning of that G129 provides a description of ALARA, if that could be referenced right in the document, we'll go to it. So that would be helpful.

And also, many of our comments of areas that there was gaps or we didn't know the answer was responded to by CNSC staff quite well in their CMD 17-M42.B, but again, that was released on October 6th and we haven't reviewed it fully because of the timeline, but there is detail that could be added. And so we recognize -- and it was provided, and I think that could just be integrated into the report.

So if that style could be adopted, then that would -- that would frame our arguments and our comments.

THE PRESIDENT: Actually, that's a very good suggestion. I thought in the references you would

reference all the licensing basis or regulatory basis you put in.

If you comply with -- even if you don't go on all 14 safety and control area specifically, you can -- you can make reference to where the licensee actually does take a look at all of them.

MR. MOSES: Colin Moses.

That's something that we definitely can look at doing in future editions of the report.

MEMBER McEWAN: So I'll just finish with this one and then -- so CELA slide 6 resonated with me, particularly the operating performance of 87.4 percent. And we'll get into this in detail when we just look at the document itself.

But as I looked at it, and particularly in the medical sector, there is a fall in performance ratings.

If I use our experiences with the NPP sector, that is usually associated with failures in the management system as well, and yet in your review you say the management systems are just fine.

So I'm interested in -- I don't necessarily want an answer now, but I will be raising that when we get to the more general discussion unless you want to answer it now.

MR. MOSES: Colin Moses, for the record.

Maybe I'll let -- Henry, would you like to -- Mr. Rabski to -- well, or maybe -- we'll get back to you on that.

THE PRESIDENT: Okay. Dr. Demeter?

Everybody is good?

Okay. You're the final say.

MS BLAISE: Thank you.

I just want to thank you once again for this opportunity and for providing the participant funding. And again, I just want to reiterate that we do appreciate the response we received from the CNSC Staff in their CMD, and if it could be appended to the current draft ROR that would be appreciated because there is detail in there that goes beyond general education about the sector, and I think it would be beneficial to include.

And we look forward to next year's report where we hope there will be a designated environment chapter.

THE PRESIDENT: Okay. Thank you.

We are going to take a lunch break, and we will return at 1:30.

--- Upon recessing at 12:23 p.m. /
Suspension à 12 h 23
--- Upon resuming at 1:34 p.m. /
Reprise à 13 h 34

THE PRESIDENT: We are back and we will proceed to the next intervention, which is a written submission from the Algonquin of Ontario as outlined in CMD 17-M42.4.

CMD 17-M42.4
Written submission from the
Algonquins of Ontario

THE PRESIDENT: And we will start our question session with Mr. Seeley.

No questions.

Dr. Soliman.

If you're not ready, you can pass and we'll go to the next one, whoever is ready.

Dr. McEwan.

MEMBER McEWAN: Thank you, Mr. President.

So I mean, my comments on this is, again, I think it's a helpful intervention in that it does bring

up some important areas and important questions.

I'm not entirely sure that the DSNR report is perhaps the most appropriate area for some of these comments, but again, I think it's an opportunity for the educational process that we discussed with CELA just to help the intervenors understand what the different components of this sector.

So I think as we build it, it's probably going to be important that we build an outreach component for that educational session, whatever it might look like.

MR. MOSES: Colin Moses, for the record.

I agree. And one of the things we have done is we do offer the CNSC 101 presentation.

We hold sessions in different countries, but I think there's an opportunity to leverage that tool and develop it to targeted audiences.

The Algonquins of Ontario, we do engage with them on other files, and so we can leverage those communications to speak to the type of activities that we regulate and help inform them on our oversight and the use of nuclear technologies in Canada.

THE PRESIDENT: So could you update us, what -- what was done with them on this particular file? Did staff met with them, talked to them?

I see Kim in -- do you want to share with us?

MS NOBLE: Sure. Kim Noble, for the record. I'm the Team Leader for Aboriginal Consultation in the participant funding program.

So we're already engaging with the Algonquins of Ontario on other environmental assessments that are ongoing in their territory. And when we found out that they were interested in this, we have offered to meet with them to go over our regulatory framework.

There's a lot of activities and facilities within their traditional territory they're not familiar with, so we've let them know that we're ready to talk with them any time. We can go through it. It will take more than, potentially, one meeting.

They're very busy right now. They're -- it's harvesting right now in October and there's other things coming up in November, but they definitely appreciate our approach.

They know that we're committed to more than one meeting to talk about this. We will build this relationship. And they really appreciate our approach and will let us know as soon as they're available for us to meet to talk about this and other facilities in their

territory.

THE PRESIDENT: Okay. Thank you.

Dr. Soliman, are you ready now?

MEMBER SOLIMAN: I have the same questions, so it has been answered already.

THE PRESIDENT: Thank you.

Dr. Demeter?

MEMBER DEMETER: No questions. My question's been answered.

THE PRESIDENT: Yes?

So the only thing I would add is I'm not sure that this particular sector is of great interest because I think that it would be useful to actually put the geographical facilities in their territories and go through them and then try to see if there's any particular interest because I just don't see any facilities that would be of particular interest to them aside from other issue like Chalk River, for example.

So the end of the table, we discuss what really is of interest to them, but I'm not sure there's anything interested in here unless they're interested in some nuclear medicine in hospitals in the medical sector.

MS NOBLE: Kim Noble, for the record.

I agree with you, sir. I think there's a

big learning curve here for the Algonquins, and it's our responsibility to help them through that. And we'll -- and it could just be also information about radiation protection and how we regulate that, and education on those sort of things.

So we will work with them and find out what is of interest to them and we will address these concerns, and we can report back.

THE PRESIDENT: Okay. Thank you.

So we now open the floor for question in general on any subject just has been raised with staff, and I'll start with Dr. McEwan.

MEMBER McEWAN: So do you have any further thoughts on my question from before lunch may be a good place to start.

MR. MOSES: Colin Moses, for the record.

Yes, I do. I'm not sure if it would be helpful, but a lot of the differences in performance and different control areas are a nature of where we've binned, the different requirements that we look at.

So you're absolutely correct in that some of our observations and the non-compliances that we see in the operating performance area are related to management system, and it's ultimately how we report and how we bucket

those.

So for example, in the operating performance, one the primary areas of focus is procedural adherence. And so it's no surprise, given that we're moving to a much more performance-based oversight approach where we're actually observing the activities in the field and assessing their alignment with the procedures and practices that they put in place, that we do find those non-compliances.

And you're also correct that it is related to the management system.

In a management system, the dichotomy of the different -- the findings and the performance in that area, typically the non-compliances that we see in the management system, we're looking at their adherence to our administrative requirements, so have they notified us of changes in personnel, have they updated the procedures, are they following the procedures that are referenced in their licence. And often, those non-compliances are the lower risk categorizations, so it may not necessarily result in a below expectations, but it would result in a corrective action so, you know, update the reference, update -- make sure you fill out the RSO notification form.

Not that those are acceptable. All

non-compliances need to be followed up. But in terms of the risk significance that would result in an overall rating below expectations, they don't fall in that same level as something like procedural adherence, which is a very critical component of the overall safety of the operations.

MEMBER McEWAN: So again, my concern is large university systems and then these consolidated health care systems.

The sharp end is divorced from the overall management system support infrastructure that's in place for the sharp end, whether that's the RSO or the technologist in the field.

How do you actually ensure that there is structured support in place as we require in the guidance documents?

MR. MOSES: Colin Moses, for the record.

So for that, I'll turn the question over to Mr. Broeders, who regulates our Class II facilities.

MR. BROEDERS: Mark Broeders, for the record.

So to answer that question, if I could just clarify that when we do a Type 1 inspection, it generally includes interviews. It's a much more involved

process, so we will interview what we call applicant authority, so the senior manager, typically a vice president or higher, who is accountable for the licence activities and represents the licensee.

We also interview the Radiation safety officer and interview a good cross-section of staff.

What we're looking for is evidence that there's a governance structure, so we may hear what we want to hear from the applicant authority, but we want to hear it from the staff as well that that's actually what's happening.

Those type of investigations or type of analysis is limited to Type 1 inspections, which is difficult to do without interviewing the staff in a Type 2 inspection.

So it's less frequent than we might otherwise do with the Type 2 inspection.

In terms of your question about guidance, the licence application guide gives some direction as to what we're looking for in terms of specifying the role of the applicant authority and we verify that they understand the responsibility both in writing and in person when we do an interview during inspection.

We also look at the role of radiation

safety committee in terms of their governance structure. We look at making sure that there's no conflicting priorities, especially in a hospital, as you mentioned before, between patient throughput and safety. It can be at odds sometimes.

So we're looking to make sure that there's some independence in reporting lines there as well.

And finally, we're looking at making sure that the staff -- it's related to what we talked about earlier in the industrial sector, but it's making sure that the RSO has sufficient time to perform his or her responsibilities.

That's not quite a science -- it's really more of an art than a science because they are typically a shared responsibility -- but it is an area we look at.

We look for evidence that they don't have the time required to perform their duties.

MEMBER McEWAN: So if you look at the radiation safety committee that we heard about when we discussed the incident in Vancouver, that radiation safety committee as it was described to us was, in my mind, not fit for purpose.

It didn't have what I would consider the required expertise on it.

How do we address that?

MR. MOSES: Colin Moses, for the record.

So you're correct, and I would agree with that assessment.

The radiation safety committee is a governance function, and what was described in the event initial report by the licensee is more of a -- sort of a management function, so there was an RSO and they have a team of site RSOs and they had a structure to ensure oversight of their activities.

That's not a radiation safety committee, and so we're treading into territory on the next agenda on the item (sic), but that is one of those areas where we want to flesh out our expectations and be more explicit.

Currently, we require a radiation safety committee for consolidated uses. We strongly encourage it in other areas, and I think one of the areas that we want to look at is whether that kind of governance needs to be in place as licensees are turning to more complex operations, and so that is something we want to address.

MEMBER MCEWAN: And finally, just an observation on the structure of the report, it would have been very, very helpful, again, on the sort of risk understanding to have separated out the central radio

pharmacies and the cyclotrons that are manufacturing radio pharmaceuticals or research tracers because it seems to me those are a particularly high risk area because of the volume of product that is going through, and I think it would be helpful to see that as a separate grouping to understand doses, to understand management structures and things like that.

THE PRESIDENT: I wonder if that would come up naturally if we also divide -- sub-divide them by risk of high, low, et cetera because just to add, I -- no matter how we like it, the medical sector will get a different attention than all the other sectors.

The word "medical" conjure all kind of things, rightly or wrongly, so we got to make sure that we understand the risk associated with the medical sector very well, if nothing else, for public consumption.

So I'd like to move on to Mr. Seeley.

And let's see if we can actually stay away from the next version. I was thinking about stopping the questioning, have the staff doing the deck, and then we can open up for both. But let's see if we can go in order here.

MEMBER SEELEY: Yeah. I had a question on the performance ratings here in the document, so whether

we're -- I think we're on page 54, 17-M42.

But we look at management performance based on inspections and radiation protection performance based on inspection ratings. But I guess my point here is I would note that, for medical, we're at 80 percent being fully satisfactory or satisfactory, and 20 percent being below expectations in the medical sector performance as it relates to radiation protection.

So question 1 is, 20 percent below, does that meet your expectations? It seems like a lot. And I noted from the other sectors: industrial, academic and commercial, they were more around 10 per cent below expectations on average between those other three sectors, where the medical sector is 20 per cent below.

So, question one is, why is this sector significantly different and not performing as well? Maybe there are some underlying reasons around the type of activities they're doing, or is it really performance? Because I guess it raises a flag for me that if it's performance, then we need some performance improvement initiatives for this sector.

MR. MOSES: And so, I'll let Mr. Rabski speak to that.

MR. RABSKI: Henry Rabski, for the record.

Just as you alluded previously about the classification of risk, we consider this, you know, a risk significant area of use in nuclear substances and particularly because you're involved in patient care, patient therapy and so on.

The evaluations that we are conducting on our site inspections focus on radiation protection and much more so in that hospital or that treatment environment because, number one, you're using open sources, you're also using fixed sources, you're also providing therapeutic and diagnostic work.

There's a lot of activity there, hence, the oversight is really focusing on radiation protection of the workers, the patients, the public.

When you look at the individual assessments, and we have what we call worksheets, I did a quick verification for the preparation and we do almost double the amount of verification, that means we look at a hundred per cent -- double the amount of items or issues when we go to inspect those facilities because we're looking for that level of conformity, expectations for radiation safety.

So, with that level of scrutiny we should be seeing and we should be identifying more areas for

improvement and that's what we're striving for.

So, yes, we're not satisfied either with 80 per cent and I don't believe the sector is, but it shows that there's a lot of improvement there and we're working with the industry.

You heard earlier today as well of outreach that focused in an area in Montreal, Montreal region that actually reached out and spoke to our staff and said, hey, we want to approach, we want to dialogue and work on and talk about the things that are challenges for us and what you're seeing and have that dialogue and work towards improvements.

So, we do that, we identify those flags, we communicate that back to the medical field and we're working with them to address those things that we're finding in the field and work towards that improvement.

THE PRESIDENT: Is it because in the medical sector the actual activities, or the intensity of the activities and the frequency of the activities and the complexity of the activities is more than any other sector?

I'm just trying to understand, because you heard -- I think we heard from the intervenors that they would look for not only the dose, but some sort of context. So, I'm trying to understand does some of the work in

hospital, medical activities, et cetera, involve a lot more intense use and that's why you get more observation of kind of maybe non-compliance?

MR. RABSKI: Henry Rabski, for the record.

I may ask Mark to supplement that, but what we're seeing -- what we know for a fact is that the application is involving patients and a lot of care needs to be taken when you're interacting with patients or the public with nuclear substances. So, that interaction is right with humans. There are a lot more procedures that have to be followed, there's a lot of handling that has to be taken into account and there are a variety of isotopes that are being utilized.

In the industrial sector they're in devices, they're in tools, they move them, they don't vary. Those tools have been in operation for 30 years.

The medical field is dynamic and it has to be flexible for the clientele. So, it is much more complicated in terms of delivery and adherence ultimately.

THE PRESIDENT: So, it sound like a yes, that the nature of the thing, and not unnecessarily there should be a zero intolerance for infraction when you're dealing with a patient, but in terms of the procedures, storage, forms, reporting and all that, I could see that

maybe the intensity is more than anywhere else.

MR. MOSES: Colin Moses, for the record.

I'll let Mr. Broeders add some context, but the short answer is yes, in some areas, but as Dr. McEwan alluded to, the volume, the nature of the activities and cyclotrons that are producing isotopes and handling and preparing in the commercial sector is equivalent and the volumes that they're dealing with is generally much higher than a hospital.

So, there's different risks and different complexities with different activities that we're regulating.

MR. BROEDERS: Mark Broeders, for the record.

I just wanted to add to what Mr. Rabski said earlier about the complexity and really it comes down to the pace of change.

So Mr. Moses explained some of the developments in the medical sector with respect to new devices. So, for example, the GammaPod, first of a kind in Canada -- the only one in Canada, in fact, is being installed here in Ottawa this year. Last year there was one of a kind accelerator installed in Vancouver.

So, we're always changing our regulatory

framework to adapt to that new technology, but so does the licensee and, as a result, some of the procedures that they have to modify to keep up with the pace of change I wouldn't say lags, because we wouldn't allow them to proceed with a licence until we're confident the procedures are appropriate, but it's inevitable that some people are a little slower in taking up the changes in the procedures and adhering to them when a new machine is first introduced.

So, I think it's indirectly related to the complexity and the pace of change in this sector.

THE PRESIDENT: Thank you. Dr. Soliman?

MEMBER SOLIMAN: Thank you. The ROR Report is very professional and it's very easy to read. I really appreciate very much the report and, please, to tell you the truth to do the same thing, it's very, very professional and a good report.

I have a question about the four SCAs which we have chosen in the report which is management system, operating performance, radiation protection and security.

There is one SCA which is packaging and the transport. This is identified in the 14 SCA, but we address it in the report under reported events. So, is

there any reason for that; why we didn't globally highlight packaging and the transport as one of the SCAs and address it exactly like the other SCAs?

MR. MOSES: Colin Moses, for the record.

So, we chose those SCAs really to be representative of the entire industry that we regulate. Not all licensees are necessarily involved in packaging and transport activities.

But I'll let Mr. Sylvain Faille speak to our oversight of transport.

MR. FAILLE: Sylvain Faille, for the record.

As Mr. Moses mentioned, not all licensees are involved in packaging and transport and that's why it's not covered as a separate SCA, but within the report we're trying to capture all of the elements where there could be some non-compliances and where you can see some -- that's why we have a section on certification of radiation devices and transport packages.

For example, there's also the section about the -- when last year we had the new regulation that came into effect that was also reflected in the report. And all of the events that are reported are also communicated. So, that's where you can see more of the

information on the packaging and transport would be on events and how those -- if there's any effect on the environment or the people as opposed to an SCA indicated for all of the regulated licensees under the report because it's only touching some of the industry sectors.

THE PRESIDENT: But I think, again, that was like still observation, when you said you're going to focus those four, you could have put transportation with a little asterisk on it.

But I think that you should then maybe have one, at least, paragraph with all the references to why you don't think it's material and explain that if you want to know what the requirements are, go to the -- what is it, G-122 or whatever the number was, I can't remember -- but you should have an explanation why you're not actually reporting on all the rest of the sectors of the SCAs. I think that would be kind of an improvement, in my mind.

Dr. Demeter?

MEMBER DEMETER: Thank you. A couple of questions on portable gauge devices.

There were a number of incidents where they failed to operate within specifications, the shutter remained open, so forth.

I was curious about, in other industries there's a root cause analysis as to why a device didn't work that may have caused undue exposure or harm.

What's the usual follow-up if a device doesn't work properly to both the operator of that device and to the supplier of that device, because I suspect there's regulatory oversight on both sides, and how often do you sort of go that full cycle of investigation for an inappropriately operating device within portable gauges?

MR. MOSES: Colin Moses, for the record.

I'll let Mr. Fundarek speak our review events and follow-up on those corrective actions.

MR. FUNDAREK: Peter Fundarek, for the record.

So, when the CNSC gets an event, and there are specific requirements for licensees to report to the CNSC on specific situations and including damage to a gauge or failure of a gauge to maintain its shielding configuration, those are mandatory requirements and they have to immediately report to the CNSC the occurrence of such an event.

And that is funnelled through our Duty Officer Program so that we maintain a centralized reporting system so that licensees can reach the Duty Officer at all

times, and the Duty Officer passes it along to the appropriate person within the CNSC for follow-up.

So once we receive the initial report on such an event like that, the licensing specialist will categorize it and put it into our internal database system and discuss with the licensee any specific information we would be looking for in the subsequent follow-up written report that is required.

The written report is required generally for most events within 21 days of the occurrence of the event. So at that point the licensee has to provide information regarding the circumstances that led to the event, probable cause as to why the event occurred, what steps the licensee is intending to undertake to prevent recurrence of that event, and any consequences to either the persons or the environment as a result of that event.

So, for example, in the case that you cited there with the gauge open, if there was a malfunction of the device, that would be a damaged device, and there is also a provision in the Regulations requiring that the device be serviced before it can be returned to use. So the licensee would be responsible and we would be looking for that as part of the event report follow-up. And if it was inadvertently left open, then again, we would be

looking for corrective actions by the licensee to ensure that they are properly closed when they are being transported.

MR. MOSES: Colin Moses.

I'll just add too that we also certify all those devices. So we have connections with the manufacturers and we trend events. So we look if there's repeated occurrences of any incidents with radiation devices, we track the make and model of those devices, and we have opportunities, if there are sort of recurring issues or there are issues that tie back to the design, to follow up with the manufacturer to encourage design changes which would go through that certification process.

MEMBER DEMETER: Okay, thanks.

And then the second question. The NRC -- as of very recently it was open to the public but now just to registered users -- has a portable gauge database that's mandatory. If you get a portable gauge, you put it on the database, it becomes like a registry so they can keep track of within the whole country all the portable gauges in case one gets lost or misplaced in inventory. Is there such a database in the Canadian system? How do you keep track of all your portable gauges that are out there, other than just having licensees, but is there a portable gauge

database?

MR. MOSES: Colin Moses for the record.

I will let Mr. Sylvain Faille add some additional details, but we do require active monitoring of all high-risk sources and that includes all sources contained in devices. So anytime they move anywhere, we're required to be notified and licensees are required to update through our system the current location of those. We also maintain inventory information of all our licensees which includes a list of all the devices that they have in their possession in the inventory and that's reported to us on an annual basis.

I'll let Mr. Sylvain Faille speak to the operation of the system.

MR. FAILLE: Sylvain Faille for the record.

Just to complement what Mr. Moses indicated, we do have a tracking system for all high-risk sealed sources and those are mostly in industrial radiography cameras. In terms of portable gauges that you were referring to, those are Category 4 sources and the information that we receive is on the annual compliance report that every licensee has to submit on a yearly basis. So we have a mechanism that we track all of the inventory

of each licensee on a yearly basis and so that's where we have all the information on all the sealed sources that are in Canada for all of the licensees.

MR. MOSES: If I could, I would also like to ask Ms Lucie Simoneau to speak to the verifications that we do during our inspections of inventory as well.

THE PRESIDENT: While she is coming to the podium, I thought that you were going to put all level 4 and 5, everybody, on the same sealed sources database. Would that include the portable gauges?

MR. MOSES: Colin Moses for the record.

Yes, that will. That is a system improvement and that is planned in the near future, to upgrade our system to be able to accommodate that.

THE PRESIDENT: So is that equivalent to what the Americans are doing or they're doing something different?

MR. MOSES: I can't give a definitive answer on that, but meanwhile, I'm sure Ms Simoneau has come up to the microphone.

MME SIMONEAU : Lucie Simoneau pour l'enregistrement.

À ce que je sache, il n'y a pas de registre où tous les utilisateurs de jauges portatives vont

s'enregistrer, mais le travail en tant qu'inspecteur, généralement, ce qu'on va faire durant une inspection c'est de vérifier l'inventaire physique que le titulaire possède. Donc, on a une copie de leur inventaire via le rapport annuel de conformité. On demande si l'inventaire qu'ils ont actuellement est à jour, et par la suite, on va vérifier physiquement si les appareils qui sont inscrits sont présents au niveau de l'entreposage du titulaire de permis.

LE PRÉSIDENT : Alors, maintenant c'est toujours manuel, n'est-ce pas?

MME SIMONEAU : Oui. On fait des vérifications qui sont manuelles, donc visibles. L'inspecteur va sur site, on confirme l'inventaire.

MR. JAMMAL: Just to complement Lucie's answer, there is a database. So every source and every device that is licensed in Canada is in our database. So they are in our database. What Lucie is mentioning is the compliance verification against the inventory of the licensee is done in the field. So we do the tracking of Category 1, 2 and 3 sources. So, in other words, every time the source is moved from one place to the other, they must inform the CNSC.

On the lower categories such as portable

gauges, which is Category 4, we do the verification based on the inventory of our database, that the possession of the licensee they have is matching, and that's the conformity we carry out. So we have a registry of the device and the sealed source in the device, and we verify against it in the field. We do not track it at the same level. So we track it on an annual basis, but the registry does exist with respect to the database that we have.

THE PRESIDENT: So just share with us -- you remember when the B.C. fires happened and we wanted to know where all those gauges were. How difficult was this to find them?

MR. MOSES: Colin Moses for the record.

So just to confirm, Mr. Jammal is entirely correct, all the inventory is recorded in our databases. And what I was alluding to is we have one particular system that tracks Category 1 and 2 and another system that maintains the inventory of all other categories of risk sources. So when Fort McMurray or the B.C. fires happened, we looked at both of those databases to collect and identify any licensees.

We also -- sorry, I'm getting off track, but we geotag also the locations of all the licensees that have activities in the region so we can identify what

regions are affected, we can identify what licensees are in that and we can extract any inventory that they have, and so we can extract all that from our database.

THE PRESIDENT: Thank you.

Dr. McEwan.

MEMBER McEWAN: Whilst I think about it, would it be possible for staff to come back to us at the next meeting with some answers to our questions about the I.1, .2, .3 LCH changes?

MR. MOSES: Colin Moses for the record.

Yes. I already took that as a personal action, but we can absolutely brief the Commission on the analysis that was done to support those changes.

I would also like to add. I checked, Mr. Fundarek was at the CRPA annual meeting, and we have an open Q&A session, so he can speak to whether that issue did come up as an issue or through the Working Group.

MEMBER DEMETER: And just to add to that. Based on the rationale for adding other iodine products based on not particularly health risks but risks to internal contamination which would add to personal dose, just to add that once that compound is linked to another molecule which no longer makes it volatile, then the risk to dose is all external, like all the other

radiopharmaceuticals. So once an iodine compound was linked with MIBG or other molecules, it doesn't have that risk of being internalized, and if the purpose of this is to look for internalized dose that might have been missed, then it's only volatile iodinated compounds. That would make sense.

THE PRESIDENT: So to piggyback on those two, if you look at your page 23, we see at 4.1 the three bullets. LC 2600, LC 2601, I assume -- I assume, I don't know if it's true or not. What I want to know is now that the thyroid issue came up, did any one of those licence conditions come as a surprise or they were consulted properly and industry understands the why of all of this?

MR. FUNDAREK: Peter Fundarek for the record.

The changes to the licence conditions for the thyroid bioassay requirements came about in July of 2016. At that time three licence conditions that were associated with the thyroid monitoring program were changed to include iodine-123 and -124, and this was based on CNSC staff's request to our internal specialists to review the applicability of those conditions to more than just iodine-125 and iodine-131 that they previously had been concerned with. CNSC staff were seeing more medical

institutions adding 123 and 124 to their licences and so we were concerned that there was an opportunity here for potential for uptakes that were not being properly monitored. So we asked our internal specialists to do this review. They conducted an assessment that was quite detailed and very comprehensive and identified that yes, there was a potential for an uptake if materials were being handled and so it was prudent to add iodine-123 and -124 to the licence conditions in the way that they did so.

There is also Regulatory Guide GD-150 on designing radiobioassay programs and it talks specifically about these areas. It considers these as pseudo-sealed sources because they have short half-lives, typically less than seven days, which both of them have; they are more or less uniformly handled throughout the year; the material is not aerosolized or boiled or held in open vented containers; and it's basically in a dilute liquid form and it's generally handled through syringes.

In those cases, GD-150 says that there is not much of a requirement for a bioassay program. And so that was -- when one of the licensees pointed that out or asked questions about that to CNSC staff, we were able to respond back to the licensee and say, yes, that is something that we don't require. If you're handling these

isotopes in those quantities, then you're not required to have a bioassay program for 123 and 124.

We should have done a better job of communicating this more widely to other licensees. We failed in that respect because we neglected to do a more comprehensive assessment of the impact of this change. We need to do a better job of that.

However, I would also point out that we hadn't heard of any feedback from licensees regarding the addition of 123 and 124 to the licence condition and we've had a few meetings with the CRPA and our Working Group since the licence condition was implemented and certainly we heard nothing during the open session at the CRPA conference. So this was relatively a bit of a surprise to us, but it's true we should have done a better job in terms of communicating these requirements and making them more clear.

THE PRESIDENT: And I think we're not -- there's two issues we're debating here, the rationale for doing it and then the consultation and the implementation, and it should always be a two-key system, you know, the rationale and then how do we implement it. So this is the kind of things that we would like to see, I think that Dr. McEwan was asking for. But I was asking if we ran into the

same issue on LC 2110 and LC 2583. I'm just trying to verify because I don't understand the nature of -- it's only important I understand. What I want to know is was there sufficient consultation done on those two other LCH amendments?

MR. FUNDAREK: Peter Fundarek for the record.

As we do most times, we try to bring this information out to our licensees either through information sessions or through our working groups or through directed information to the licensees that are going to be affected by these potential changes, sending them an email advising them what the potential change is and how they could meet the requirements.

Again, with those other licence conditions, the answer is no, we have not heard any feedback from licensees regarding any challenges associated with implementing those. So we have to assume that that information we've provided is sufficient at this time.

THE PRESIDENT: You see, what I'm worried about is what we've heard: Yeah, they issued it, we decided not to fight that. I hate that kind of an attitude. If we do something that is maybe not as efficient and they decide not to fight you for that, that's

not a good outcome either. You want a formal process of consultation and I'm not sure even an email will do. You need a normal kind of consultation on a particular new condition you impose and you should have a challenge internally in our organization, whether it's really required and what is it you're trying to do. Especially our licensing people should both exercise the mandate.

MR. MOSES: Colin Moses for the record.

I entirely agree. In fact, your statements reflect the conversation we had over lunch with respect to that issue. I think there is an opportunity. We have a robust internal control over the licence conditions and internal approvals, but I think there's an opportunity to improve in terms of how we engage the licensees before we roll out those changes and there's always opportunities to improve how we regulate the sector.

THE PRESIDENT: Mr. Seeley.

MEMBER SEELEY: Maybe I'll just finish up on the performance measures. So we were talking previously about the medical sector and that they had 20 percent below an acceptable on the inspection ratings of radiation protection. Now, I know that the inspections are an early indicator. Clearly, you want to have other measures in place, including the top events, where you actually have

exceedances for either workers or public. And we did see one exceedance I think in the medical sector on extremities. It was the only one we had for 2016. So I guess this goes back to my question, which is 20 percent of inspections for radiation protection were below expectations or unacceptable. In fact, I noted below that, nuclear medicine it's 25 percent of inspections didn't meet fully satisfactory or satisfactory. So it's a lot. It's not one or two. I understand that of course if that happens you're going to make a list of recommendations that need to be undertaken to get them into compliance, but it starts to become a lot of recommendations if 25 percent of your licensees are not meeting the requirements and so there's a long list of recommendations for everyone -- or 25 percent involved.

So it brings me to the point. Is there something more systemic or something broader you should be doing in the medical sector to bring that group up to where you want it? Because it just feels to me like it's -- maybe it is more complex and maybe there is more rigor in those inspections, as was described, but it feels to me like it needs improvement.

MEMBER McEWAN: I'll just add a number to that. Figure 23 on page 51, the management system for

radiation therapy dropped to 65 percent.

MR. MOSES: Colin Moses for the record.

I'll let Mr. Broeders speak specifically to the radiation therapy, but that's exactly what I was referring to when I talked about tracking and monitoring trends in performance. And so this report is useful in that we package it together and we provide it out. There's also a lot more analysis that goes behind that. So we record all the inspections in a single system. We're able to run reports by use type, by subsector, by type of activity by licensee to look if there's trends in performance, repeated non-compliances, and we use that kind of information to inform how we engage, how we prioritize our inspections, what kind of communications we put out to licensees, what we choose to highlight in our communications in our outreach sessions. So yes, when we see any kind of performance or trends in that, that changes how we oversee the sector.

On top of that, on a quintennial basis we review our risk rankings that inform our risk-informed regulatory program. In that too we look at trends over several years in the sector to see whether we need to adjust our risk rankings and also whether we need to adjust our inspection frequency and our inspection focus and our

inspection priorities.

MR. BROEDERS: Mark Broeders for the record.

There was a drop in management system performance in radiotherapy largely related to administrative non-compliances. For example, a licensee accepting an upgrade to equipment and not reflecting that in their licence. So that speaks to the lack of oversight in terms of procurement and management oversight with respect to how that equipment is being upgraded. There were a few instances of that in 2016, so that's an area of review for the current year. We will be working with our management system specialists to do sort of a wholesome review of the management system expectations, including procurement, which wasn't historically a large area of focus.

THE PRESIDENT: I assume you keep track of repeat offenders, so to speak?

MR. MOSES: Colin Moses for the record.

Yes, we do. We track compliance history for every licensee. And maybe I'll let Mr. Schmidt speak to how we review that as we prepare for inspections.

MR. SCHMIDT: Jonathan Schmidt for the record. I'm the Regional Site Inspector Coordinator out of

the Mississauga office.

So as part of the preparation for every inspection, we look at the compliance history of the licensee. So we pull previous inspection reports going back from the previous inspection as well as the whole history of the licensee over its period of having a licence and we look to see what were the non-compliances and how the licensee addressed them in the past.

Then when we complete the inspection, we follow up on those areas to ensure that they're still in compliance. And if there's any non-compliances in the areas that we've seen previously, we then ask the licensee to take additional measures. What we might do is talk to the RSO and the applicant authority and actually call them into the regional office and have a discussion to say: We are seeing repeat non-compliances from year to year or from inspection to inspection -- it may not be annual. How are you going to address this?

We have gotten good responses from applicant authorities and RSOs by approaching them in this way and it seems effective in resolving those repeat areas.

MEMBER SEELEY: So according to these statistics you might have 25 percent of your licensees in your office for that discussion?

MR. SCHMIDT: It's a little complicated. The areas where we see repeats might not be the same people or the same locations. So, for example, in the medical sector there might be four or five hospitals that are under the same licence. So we might see a non-compliance in the areas of radiation protection, for example, not doing their swipe checks, at one hospital and then we might see it again two years down the road when we repeat the inspection at a completely different hospital. So there is an indicator that perhaps the program isn't functioning, but in and of itself, they did correct the issue at the one hospital, it's just showing up in a different area, which explains the complexity that we're dealing with with these larger institutions.

THE PRESIDENT: So think about this for the next presentation. In about maybe half an hour we'll get into the next session. Because the question is -- so you have under one licence four hospitals but there's only one, if I understand correctly, applicant authority. So where do we put the accountability scheme at the end of the day? I understand the RSO but I never understand the applicant authority and what is that applicant's responsibility for making sure that everything is working properly. Don't answer it now but keep the answer there

for the next session.

I would like to move on now to Dr. Soliman.

MEMBER SOLIMAN: Thank you.

Some of the licensees are based outside Canada. They come to Canada to perform work. What is the process in place to deal with a licensee in terms of an inspection and non-compliance?

MR. RABSKI: Henry Rabski for the record.

For companies outside of Canada coming in to do servicing of specialized equipment and replacement of sources and so on, we know because they hold the licence with the CNSC, we know who they are. On an annual basis, we send them a notification with our expectation that they notify us in advance of coming to Canada to provide a service. So there is an expectation there. It's very clear.

We get a lot of calls back when they get that letter to specify what we are looking for, because in most cases they want to comply and they want to be in good standing when they are coming in to do these services for their clients.

So we get those notifications. They are directed to the regional offices like the two staff members

that I have here today. They will get those notifications and we will look and see if those servicing companies have been inspected. We will make every effort to observe the work that they are going to do, so we will come out. The notification is given to us and then it becomes an unannounced inspection. We know where they are, but we don't necessarily have to be there on that day.

We can also contact the individual licensee to verify time, place through another mode to make sure that the timing is correct, and we make every effort to go and see those licensees. Sometimes they are only in Canada once a year, sometimes even less frequent. They are also in different regions across Canada.

So it provides a challenge. Wherever possible that's one of our priorities is to inspect servicing companies that come in to do these special jobs and haven't been inspected in a reasonable period of time, say within the last 18 months.

MR. MOSES: Colin Moses. I will just add too that we did do inspections in other countries. And so Mr. Broeders can speak, for example, to the one we recently did on a manufacturer.

MR. BROEDERS: So we use a similar strategy, as Mr. Rabski explained, for foreign service

providers. So it's a combination of requiring the licensee to submit their plans for servicing in Canada, so we can plan our schedule accordingly to be sure we're on site when they conduct their servicing work so we do the inspection.

In some cases it's opportunistic. If we are on site say in a hospital doing an inspection and one of the vendors happens to be there doing servicing, we'll do a Type II inspection on the spot. We are prepared for that at all times. All the inspectors carry the necessary information they need and the forms they need to be able -- electronically to be able to generate those reports in the field and give it to the licensee on the spot.

In rare circumstances we'll go to the licensee's headquarters to do inspections. So as Mr. Moses alluded to, there is one particular licensee where we had a concern about their management system and their organizational behaviour, if you will. And so we drew together a team from class II, from the management system group and from the human and organizational performance division and went to Atlanta and conducted an inspection.

As it turned out, there were some concerns that were uncovered as a result of that inspection. So it was a worthwhile exercise to do it, but it's used rarely in the case where we see there is evidence of a significant

and systemic problem.

MEMBER SOLIMAN: Okay. How do you deal with non-compliances?

MR. BROEDERS: Mark Broeders for the record.

Just like any other licensee. So these are licensees just like the operators. So the Class II regulations require that anyone performing service on Class II prescribed could also be licensed. So if they wanted to do -- perform licensing activities in Canada, they must have a licence with us. So we follow through the same way we would with any other licensee through to completion.

MEMBER SOLIMAN: Thank you.

THE PRESIDENT: Thank you.

Dr. Demeter...?

MEMBER DEMETER: Well, thank you very much.

There was a very interesting story in the ROR about the driver and the passenger who got $1.6 milliSieverts. So it raised a number of questions. One, was the driver authorized to transport nuclear substances? Two, was the package appropriately for nuclear substances and was the driver new? Or do we know if the passenger got a dose of $1.62, I think, milliSieverts, was it because of

proximity to the package or that was a short trip with this -- well, it wasn't short like with the number of hours, but it didn't mention the driver's dose versus the passenger's.

So it raises bells about how much dose is this driver getting? This may not have been his first trip with a nuclear package. It just -- it raised a bunch of questions in my mind.

MR. MOSES: So I'll let Mr. Sylvain Faille speak to specifically how doses are managed in transport situations, but to brief, it really was a proximity. So in fact there were other members of the public who did receive unnecessary doses as a result of that non-compliance. The worker had received the appropriate training. They were authorized to do that transport. The packages were adequate.

And in that case we issued an administrative monetary penalty because there was clear intent behind the non-compliance, for lack of a better term, to make that extra money by carrying passengers along with those shipments.

MEMBER DEMETER: Thank you. That answers my questions.

So the dose received was the expected dose

at the surface for that type of package and product that was in the package and everything else was appropriate, relative to training certification. It was just someone literally sitting beside a box they shouldn't have been sitting beside then.

Okay. That answers those questions.

THE PRESIDENT: Thank you.

Back to the top of the list, Dr. McEwan...?

MEMBER McEWAN: Thank you, Mr. President.

Just a couple of minor questions: So on slide 10 when you were discussing public consultation, you said that you actively pushed the report to a number of organizations. Did those organizations include the Canadian Association of Radiation Oncology, Radiology and Nuclear Medicine?

MR. MOSES: Colin Moses for the record.

No, they did not. In fact, I think that was one thing that we did take away and we've requested updates to our subscription service to ensure that those organizations are included so they get that proactive notification.

MEMBER McEWAN: Thank you. And the second thing, it would be helpful to separate the AMPs and the

orders by sector so that we actually, if you like, have two columns and the sectors. I think it would just be helpful to see where the sectors are performing, and particularly if we look at it in terms of some of the subsector sectors -- sector subsectors. Thank you.

T**HE PRESIDENT:** Thank you.

Mr. Seeley...? Dr. Soliman...?

MEMBER SOLIMAN: I have a question about the compliance -- the non-compliance penalties. There are four enforcement actions for non-compliance. This is order, administrative monetary penalties and decertification of exposure device operator, and RSO. The action taken is commensurate with the risk.

What rules govern the non-compliance risk? That's the first part of the question. The second one is how we determine the AMP.

MR. MOSES: So maybe I'll ask Ms Lucie Simoneau who can speak to the considerations that an inspector goes through in determining the appropriate response to a non-compliance.

MEMBER SOLIMAN: The risk, how we evaluate the risk and how the risk value will be -- will lift any of this for non-compliances.

MME SIMONEAU : Si je comprends bien, vous

voulez savoir c'est qu'est-ce qui détermine le fait entre émettre un ordre ou des sanctions administratives pécuniaires? C'est quoi?

MR. MOSES: So just what Lucie was looking for is just a bit -- so maybe I'll give some context.

So we do have internally, we have processes and procedures that govern all our work including our compliance oversight. We have inspection procedures, and we have one that's particularly relevant to your question called the select and apply enforcement tool. That process outlines the different considerations that need to be taken when determining the appropriate enforcement response to a non-compliance.

So again, no non-compliance with our requirements is acceptable and all of those require corrective actions. But our regulatory response to those non-compliances can vary, and they vary on a number of factors including compliance history of the licensee, previous non-compliances, the risk significance of the non-compliance which we have gone through all the requirements and assigned a risk associated with the different requirements, the extent of the non-compliance, so Mr. Rabski spoke when he gave their presentation to there are instances where unacceptable ratings were given

in multiple SCAs and all of those resulted in escalated enforcement actions.

So all those considerations come in when designing the appropriate response and that's why we have a very robust inspector training qualification program because it is that inspector who is authorized to take that immediate action and determine the appropriate compliance response.

You spoke to administrative monetary penalties, and so the regulations for the administrative monetary penalties actually lay out the factors that are used in determining both whether or not to issue an AMP or determining the amount of the AMP. And those again include compliance history, intent or negligence, significance of harm or potential for harm, and a number of other factors that are laid out in those regulations.

And so if you do look on our website, we post all enforcement actions and the notices of violation that are issued for the administrative monetary penalties; go through all of those considerations, assign a rating associated with each of those factors, which is then used to calculate the total amount of the penalty.

MEMBER SOLIMAN: I think it will be better to have an appendix which explains the process to evaluate

the risk and from there how we assign the risk to the non-compliance. I hope that this can be incorporated in the next revision or something.

MR. MOSES: Colin Moses.

Thank you for that suggestion. We do have a section where we speak to enforcement and determinations and they can look at those opportunities to improve and clarify that.

MEMBER SOLIMAN: Okay. I have another question on --

THE PRESIDENT: Why is there -- but we do have something called graded approach and I don't want for a second for everybody to believe that there is not some judgment associated at the end of the day where the inspector decides whether they are going to move from just an observation, a report, to an order, to an AMP, to prosecution if need be. There is a range of a graded approach that has all the history and all the factors that Mr. Moses described to reach a proposal to do something just to go through the lines. So it's not kind of check the list, all the lists, and then it becomes -- there is some subjective opinions here.

MEMBER SOLIMAN: On the report on page 14, figure 2, what is this figure? What would you like to say

by this figure?

And I would like to ask if there is something wrong in that figure, because it's not understandable really.

MR. MOSES: So as I look at it I do note that the title of the figure has been cut-off so that's something we can definitely correct.

MEMBER SOLIMAN: No, not about the cut-off. It is what this figure means. I don't see this figure. For example, there is a percentage and you say a number of licenses. So is the number of licensees can be expressed as a percentage? That's number one.

Number two, I think the black indicated all sectors and the green is industry, and the yellow is the hospitals. So the figure does not indicate -- does not go with the numbers.

MR. MOSES: Sorry, that's good feedback. So that figure is actually the result of Commission feedback from previous Commission meetings where there was some curiousity in terms of the number of licences held by individual licensees.

So if you look at the data, the total number of licences issued by the CNSC is greater than the total number of licensees through -- that we regulate. So

this figure is really just showing the distribution of licensees that hold multiple licences.

Generally, where you find that is in the medical sector and where -- in some cases in the industrial sector where they may be engaged in different use-type activities. So for example, industrial radiographers may also have other tools that they use that are different use types and have a different licensing scheme or licence requirements.

So really what we are just trying to communicate there is just the distribution of licences for those who hold multiple licences.

MEMBER A. SOLIMAN: But why the all sector is less than the industrial sector in terms of presentation, the black and green?

THE PRESIDENT: So do you want us to explain to you the graph?

MR. MOSES: No, I was listening to Dr. McEwan's answer and he is entirely correct. It's a percentage of the number of licences within that sector who hold one or two or three or greater licences. So the percentages are representative of the number within that group. So, for example --

THE PRESIDENT: Is it percentages or

numbers?

MR. MOSES: So 80 percent of all sectors hold one single licence. Approximately 90 percent of the industrial sector hold a single licence.

THE PRESIDENT: That's in the graph.

MR. MOSES: The graph, yes.

THE PRESIDENT: That's in the graph. I'm looking at the table. The table is the numbers.

MR. MOSES: Yes.

THE PRESIDENT: Right. The actual table is the numbers?

MR. MOSES: That's correct.

THE PRESIDENT: So you have 1252 organizations that hold one licence, 262 organizations that have between two and three. And what really struck me is 12 organizations that have seven to nine licences. Why would we allow that to happen? You have an organization -- one organization has nine licences. Is that because of regional distribution?

MR. MOSES: It can be regional distribution. It can be the nature of the activity. It can be -- so some licensees are involved in multiple different businesses. Some licensees are very complex in their operations and have licences both for academic and

commercial.

THE PRESIDENT: And four hospitals have 10 or more?

MR. MOSES: And so I spoke earlier to one of the initiatives that we have to develop sort of enhance guidance along with those licence conditions. Another piece of that initiative is to look at how we have divided the work into use types which is driven for historical reasons and embedded in our regulations, and opportunities to provide for more consolidation if there is no logic or no sense and no safety benefit to requiring those separate licences.

MEMBER A. SOLIMAN: I think this needs to be explained. This is not very clear and it doesn't go with -- when you read the whole chapter in section -- subsection 3.2.1, and you say this graph is -- you just refer to the graph but there is no explanation and really it is very confusing.

THE PRESIDENT: It may be misplaced. It maybe should be in a different section when you talk about the trend and you talk about merging licences. You may want to talk about the governance and particularly after you have done the study that we will talk about in a minute.

Right, okay, we'll move on. Dr. Demeter...?

Back to Dr. McEwan.

MEMBER McEWAN: So then just in terms of setting the scene for the next discussion -- we're going to keep going on at this -- which again is a really concerning graph, figure 12 on page 33, and the fact that again the medical sector is distinguishing itself by failing in the security area as well. So I would be interested to know what those -- some of the security findings were, again because it just seems to me to be continuing this trend.

MR. MOSES: I'll let Mr. Broeders speak to that one specifically.

MR. BROEDERS: Mark Broeders for the record.

So indeed, it is a concerning trend. One of the realities is that REGDOC 2.12.3 was introduced in 2014 and the first implementation was in 2015 for Calgary 1 and 2 sources. We learned from that experience with the struggles that some licensees had.

And so for the next phase in the implementation which is due in May of next year, we have been targeting those licensees specifically that we know are going to be affected by the next phase and doing more

security inspections there than we would do otherwise at a higher frequency to make sure that they are prepared for the implementation to meet the additional requirements. It's not to say there aren't already security requirements. They must be secure but there is more specific expectations that are tied to this regulatory document. So it's unfortunate that the numbers are lower than we like but the point is we want to get in and make sure that they are prepared for the full implementation of REGDOC 2.12.3 May of next year.

To answer your question, what is a typical issue that we find, these are often -- they are called remote-controlled off loader devices. So they are iridium-based sources that are used for brachytherapy. They are portable devices so they are concerning from a security point of view. We do expect them to have intrusion detection, two physical barriers, trustworthiness and reliability checks, a full security plan, and that security plan is adequately protected, and so on.

The most common non-compliance we find in this area is a lack of robustness with those two physical barriers. It's not to say they don't have barriers; we're not satisfied that the barriers are robust enough given their response times. So the principle is always detect,

delay, and then respond. If the response time is very good they can have a less robust barrier. If it's a longer response time, we expect a more robust barrier.

And so we're finding as we go into the sites and see it live and actually verify the response time, we're finding that in some cases it's not adequate. So that's largely what we are seeing.

To be perfectly transparent, I expect that the results will improve slightly but probably won't be where we want them to be until 2018.

THE PRESIDENT: But that's a combination of two things, if I understand correctly. One, there was a slightly new requirement of guidance. And secondly, the security or responsibility was transferred to you people from another shop and you integrated it into your own oversight. They had to get used to it. Am I getting it right?

MR. BROEDERS: Mark Broeders for the record.

It's true that the responsibility for conducting these inspections was transferred. I like to think they were all consistent in application of the regulations and the expectations. I think this is more to do with the change in expectations rather than the transfer

of responsibilities from one division to another.

It is true we are doing more frequent inspections because we are there, and so we are taking advantage of the fact that we are there to do another inspection to do the security inspection at the same time. So you do more inspections you're going to find more non-compliances.

THE PRESIDENT: Yeah, I think that's right. Thank you.

Mr. Seeley...? Dr. Soliman...? Dr. Demeter...?

So I got two quickies. First of all, how does it go with a five year cycle with EDOs? You know they have to renew the cycle. How is that transition going?

MR. MOSES: I will let Mr. Sigetich -- Justin Sigetich manages the certification shop, and I will let him speak to that.

THE PRESIDENT: I am surprised we don't get a lot more noise about that kind of process. This is not -- is it Year 2 or 3? I can't keep track of the time. When did you introduce it?

MR. MOSES: As Mr. Sigetich gets settled -- Colin Moses -- I'll just add too that this is a change that was also asked for by industry. And they were

supportive of that. They wanted to ensure that their workers maintained those qualifications. And so I think that's part of the reason we don't get more noise because it's delivering and it's giving them [indiscernible - multiple speakers] --

THE PRESIDENT: So nobody is failing on the recertification?

MR. MOSES: But I'll let Mr. Sigetich speak to the specific performance of the CEDOs through that process.

MR. SIGETICH: Justin Sigetich, for the record, director of the Personnel Certification Division.

The CNSC implemented the program for renewal of exposure device operator certification in 2015. So we've been performing the renewals of these certifications for the last few years. Over those few years, we've been gradually implementing the expectations for that program. So the industry is able to understand exactly what's expected of them, and we've gradually ramped up those expectations.

So currently we are implementing the full expectations that are in the CSA group document that's called the Certified Exposure Device Operator Personnel Certification Guide. It was mentioned earlier that's this

PCP-09 document that was discussed. That document expects that people are -- that certified individuals must perform continuous work and continuous training. So they are maintaining their knowledge and skills to safely operate their device over this five-year period of their certification. The other expectation we have is to be able to renew their certification they are to complete a practical examination, which is a final check-out to verify that they do continue to have the knowledge and skills to safely perform their duties.

We're finding that the applications that we're getting indicate that individuals are following these expectations. People are maintaining their knowledge through continuing training and through continuous work, and people are passing these practical examinations. So we definitely have confidence that the individuals that we are recommending for -- well, we are renewing their certification, that they do in fact have the knowledge and skills to safely perform their duties.

THE PRESIDENT: But the majority of them have not yet come against the wall of five years. Did I get it right? I mean, how many of the CEDOs now went through a cycle, a full cycle? Not if you started two years ago, a lot of them are still on their first five

years; right? So I think you're going to get noise coming up very soon.

MR. SIGETICH: When we implemented the expectation for renewal of certification, we anticipated that. So when we started issuing -- when we started issuing cards with expiry dates starting in 2013, and so any new certification after 2013 was given a five-year validity period. All the people who were certified prior to 2013, what we did was we staggered the expiry dates of those certifications over a five-year period starting in 2015. And so what we did is made sure that the population of certified exposure device operators was going to be staggered over that period, so we don't have a large number of people who all need renewal of certification at the same time.

THE PRESIDENT: Thank you.

So my last comment, I really love the geographic distribution map of -- on your page 5. And you know me by now. I would like to see this on our website so people can click on it and get the names of every facility, what they do. At one time we were planning to do the location of some of those facilities, where they are, the licensees. Is that feasible to do?

MR. MOSES: Colin Moses for the record.

So first of all, thanks for that feedback. I also really appreciate that, and I can take no credit. That was a brain child of Mr. Fundarek behind me in terms of how to represent the distribution of licensees.

But I think it really does give a clear indication of the diversity of the activities and the diversity of the geography that we regulate.

We do already have information on all licences that are issued by DNSR on our website. That's a searchable database. So you can look by licence type, licensee name, and licence location by city. So that information is available.

We did at one time have live Google maps that could do that kind of search as well visually. It was a challenge to maintain. These things change every single day. We have licence amendments, we have consolidations, we have new additions, new licensees, we have new locations. And we so we haven't been -- gotten efficient yet at keeping that kind of graphical information alive. But that's definitely an opportunity for improvement.

THE PRESIDENT: But nowadays I think you're more sophisticated. If you already have a database, the database should create this map and update it automatically. Just wishful thinking, I guess.

Any other observations? Okay. This concludes. We're going to take a break or what?

Okay, thank you. Thank you very much. We're going to take a 10-minute break. I think you guys are going to stick around for the next one. So we'll be coming back at 3:00.

--- Upon recessing at 2:53 p.m. /
Suspension à 2 h 53
--- Upon resuming at 3:06 p.m. /
Reprise à 3 h 06

THE PRESIDENT: Before we start, I understand that -- who's going to -- CRPA has some information for us.

MR. DOVYAK: Thank you, Dr. Binder. Jeff Dovyak, CRPA.

This morning Dr. Demeter asked about the membership breakdown, and I said I would try and get it. Unlike CNSC, we don't have an army of support people working in our headquarters. We have an army of one. So it took a little while to get the information.

So in terms of full and associate memberships, 13.6 percent of our members say they're

consultants, 17.9 percent of our membership identifies as government, medical is 23 percent, industrial is 8, national laboratory is 7 percent, power utility is 5 percent, university is 20 percent, uranium mines and mills is 4.3 percent, uranium refineries are 2 percent.

So another way of looking at that, that top five would be medical, university, government, consultant, and industrial.

THE PRESIDENT: Do you charge any fees?

MR. DOVYAK: Yes. Our annual fee is I believe somewhere around $250, $275. And then if people have the CRPA (R) credential, there's another fee on top of that.

THE PRESIDENT: I think you need to consider getting more than one backup. If you want help with the new thinking about some of the regulatory oversight and help us, you may need to consider a different financing model. Anyhow. That's my free advice here.

MR. DOVYAK: Thank you.

THE PRESIDENT: Okay, thank you for that.

Let's move on to I think this is the final item on our agenda. And this is an information item on the oversight of radiation safety officers and radiation protection programs for nuclear substance and radiation

devices licensees as outlined in CMD 17-M44 and M44.A. And I understand, Mr. Moses, the floor is still yours.

CMD 17-M44/17-M44.A

Oral presentation by CNSC staff

MR. MOSES: Thank you. And before I get into the presentation, I would just like to note that there's clearly a lot of synergy between the item we discussed this morning and earlier this afternoon and this item. And originally we had planned on blending our response to the action item into the report on the regulatory oversight report, but this is a substantive enough and important enough topic that we felt it really did warrant a separate discussion, which is why we have separated it out in a different agenda item.

So as I said this morning, my name is Colin Moses and I am the director general of the Directorate of Nuclear Substances Regulation. With me today are Mr. Peter Fundarek, the director of Nuclear Substance and Radiation Device Licensing Division, Ms Natalie Ringuette and Mr. Paul Matthews, licensing project officers in the same division, Mr. Keith Dewar, director of the Regulatory Research and Evaluation

Division, and Ms Geneviève Boudrias, senior evaluation officer. And we're also joined by other CNSC Staff supporting this initiative.

So we are here today to report to you on CNSC staff's initiative to enhance oversight of radiation safety officers and radiation protection programs in the Nuclear Substances And Radiation Devices Sector, as outlined in CMD 17-M44. This topic has been discussed at previous Commission meetings during presentations of our regulatory oversight reports, as well as event reports, and is in response to Commission Action no. 8816 to report back on our progress in this area.

With over 2,100 licences across 51 different use-types, the CNSC have adopted a risk-informed regulatory program to effectively oversee the large variety of applications within this sector. As we've demonstrated through the regulatory oversight report, the use of nuclear substances and radiation devices in Canada remains safe. Licensees are responsible to put in place safety and control measures to control their operations through the implementation of a radiation protection program. These measures are reviewed during CNSC Staff's assessment of licence applications and verified through our compliance activities.

CNSC Staff are closely monitoring trends in the operational structures and performance of certain licensees. In particular, in the academic and medical sectors, many licensees are trending towards more centralized and complex governance structures. These transitions must be effectively managed with due attention to the critical importance of nuclear safety.

In a few cases, licensees have struggled with these transitions triggering the need for regulatory interventions. Further, performance trends and reported events have at times revealed licensee program weaknesses. While these issues have been resolved to the satisfaction of CNSC Staff, they do highlight an opportunity to improve licensee programs and regulatory compliance.

Recognizing the critical importance of radiation protection program design and implementation to ensuring the safety of licensee operations and the key role of radiation safety officers in this work, CNSC Staff have launched an initiative to both enhance guidance to licensees and to evaluate the key success factors needed to ensure an RSO can adequately perform their duties. We will leverage these activities to share lessons learned and best practices with licensees.

I'll now turn the presentation over to Mr.

Paul Matthews.

MR. MATTHEWS: Good afternoon. For the record, my name is Paul Matthews. I'm a licensing project officer in the Nuclear Substance and Radiation Device Licensing Division in the Directorate of Nuclear Substance Regulation.

In today's presentation, CNSC Staff will demonstrate plans being undertaken to strengthen CNSC's regulatory oversight of radiation protection programs, including the role of the radiation safety officer for nuclear substance and radiation device licences. The strategy chosen will strengthen the regulatory framework as well as increase our understanding of the role of a successful radiation safety officer. Through these planned enhancements, CNSC Staff will ensure the use of nuclear substances remain safe for the future.

Today CNSC Staff will provide background on the CNSC's current approach to the regulatory oversight, how CNSC Staff is planning on enhancing this regulatory oversight through strengthening of the regulatory framework and by conducting an evaluation of radiation safety officers in the medical, academic, and research sectors to identify factors that may lead to success for those persons in the role of radiation safety officer.

Before a licence can be issued, an applicant must demonstrate they are qualified to undertake the licensed activity. REGDOC 1.6.1 is the Licence Application Guide for Nuclear Substances and Radiation Devices. This document outlines regulatory requirements for this sector and provides guidance on meeting CNSC expectations. In particular, REGDOC 1.6.1 outlines the duties and responsibilities of radiation safety officers, recognizing that this will vary with the magnitude, diversity, and complexity of the uses of nuclear substances.

Through the application process, applicants must demonstrate to CNSC Staff that they are qualified and that they have the necessary policies and procedures to ensure safety of their operations.

Once a licence is granted, the radiation protection program forms part of the basis of licensing and is monitored through licensee internal audit programs. CNSC Staff monitor compliance with their programs through compliance activities.

The radiation protection program is an essential component to the safe operation of licensed activities. A radiation protection program consists of a number of key elements including management control over

work practices, personnel qualification and training, control of occupational and public exposure, and planning for unusual situations.

CNSC Staff see the radiation safety officer as being critical to the effective implementation and oversight of the radiation protection program.

There are a number of people who have key roles in the radiation protection program. The applicant authority is the person that holds overall accountability for the licence. Generally this person holds a role in senior management and has the necessary authority to direct human and financial resources. The applicant authority is accountable and is required to complete and sign the applicant authority form, and by doing so attests and certifies that they are aware of their obligations and responsibilities under the Act and that the contents of the application is binding.

The radiation safety officer is appointed by the applicant authority. The radiation safety officer has the delegated responsibility for the functioning of the radiation protection program, including the ability to stop unsafe work practices.

As part of the process to designate a radiation safety officer, the applicant authority must

submit the following necessary information: details of duties to be undertaken by the radiation safety officer, copies of curriculum vitae of the prospective radiation safety officer indicating relevant experience, and copies of any training certificates.

A licensee must have at least one person designated as a radiation safety officer.

CNSC Staff continue to see changes to the structure of licensees. Many of these changes are driven by financial or business decisions. In the medical sector, there is a trend to move from a single hospital and single licence to multiple hospital, single licence across the city, region, or even a province.

In the industrial sector, CNSC staff have observed consolidation of licensees through amalgamation where a licensee acquires another licensee or a licensee that possesses multiple licenses of a single use-type amalgamates under a single licence. When a licensee amalgamates or consolidates, the result may be a more complex licence that requires greater resources to manage and implement the radiation protection program.

CNSC Staff expect that a licensee undergoing such a transition to prepare for a suitable implementation in situations where the licensee is

combining different radiation safety programs. A licensee must have a robust governance and oversight of licensed activities to ensure that all sites meet their obligations. Regardless of the organizational structure in place, licensees must have a radiation protection program that safely manages their licensed activities.

If a radiation protection program is not effectively managed, a licensee may face implementation challenges that, if not addressed, can lead to non-compliances. Weaknesses that have been identified during compliance activities include limited or lack of engagement by senior management, including the applicant authority; inadequate resources provided to oversee the program; insufficient or inadequate program oversight, including limited internal audits; and poor procedural adherence across different sites.

CNSC Staff have addressed these weaknesses through our compliance program, ensuring that licensees maintain effective programs through any transition. When licensees are undergoing amalgamation to a provincial structure, CNSC Staff will engage with a licensee to ensure they give due consideration to nuclear safety through the transition. In addition, CNSC Staff will increase regulatory scrutiny to ensure effective implementation of

the radiation protection program within the new structure.

While effective on a case-by-case basis, there is opportunity to share lessons from previous challenges and best practices of successful licensees more broadly. In order to inform this initiative, CNSC Staff have benchmarked our regulatory framework against the US Nuclear Regulatory Commission's with particular focus on their requirements for radiation safety officers, including educational, professional, and experience requirements. Taking into account the different regulatory schemes, this exercise confirmed that US expectations for radiation safety officers are generally consistent with the CNSC's regulatory framework. The review did, however, identify potential opportunities to enhance guidance for radiation safety officer training and qualifications and provide additional guidance on radiation protection programs, governance, and oversight.

To enhance CNSC oversight of nuclear substances and radiation device licensees, CNSC Staff have launched a two-stream initiative which will proceed in parallel. CNSC Staff will provide additional guidance to licensees through the production of a comprehensive REGDOC related to radiation protection programs. And to ensure we've captured the necessary elements, we've initiated an

evaluation to identify factors leading to success for radiation safety officers. Although CNSC Staff will approach the question of radiation safety officer success and radiation protection REGDOCs separately, they are closely related and any resulting solution will incorporate both streams.

I will now pass the presentation over to Madame Natalie Ringuette.

MS RINGUETTE: Bonjour. Mon nom est Natalie Ringuette. Je suis Agente de projet des permis de la Division des permis de substances nucléaires et d'appareils à rayonnement de la Direction de la réglementation des substances nucléaires.

In the next four slides, I will provide an overview regarding the development of a new regulatory document for nuclear substances and radiation devices licensees, provisionally titled Oversight of Radiation Protection Program.

Nuclear substances and radiation devices licensees have been asking for practical and detailed guidance on how to develop and oversee a radiation protection program that is appropriate to their licensed activities and that takes into consideration their unique structure and governance framework.

Currently, the expectations with respect to an effective radiation protection program can be found in a number of CNSC publications. In particular, REGDOC 1.6.1, the Licence Application Guide for Nuclear Substances and Radiation Devices. In addition, Regulatory Guide G-121, published by AECB. This document provides information to medical, academic, and research licensees on how to design and implement radiation protection programs. And finally, Regulatory Guide G-313, which provides guidance to licensees for developing radiation safety training programs for workers.

CNSC Staff are developing a new regulatory document for nuclear substance and radiation device licensees that consolidates all guidance under one comprehensive document. This is to facilitate and clarify expectations applicable to the development and implementation of an effective radiation protection program for these specific licensees. Where appropriate, the document will reference other applicable documents, such as documents on radiation protection, safety culture, and management systems.

In addition to consolidating information, new content will also be added in the document for the purpose of providing greater guidance to licensees. With

the publication of this document, nuclear substances and radiation devices licensees will find in one document all applicable information as well as licensing expectations for developing their radiation protection program. The document will accommodate the wide variety of governance structures seen in the industry and will incorporate pertinent information obtained from operational experience of radiation protection program implementation.

The purpose of this regulatory document is to provide practical guidance on the elements to be incorporated as part of an effective radiation protection program for nuclear substances and radiation devices licensees.

Licensees are responsible for safety and designing and implementing a radiation protection program commensurate with the licence activity. This shall be in accordance with the ALARA Principle established in the radiation protection regulations.

As mentioned earlier, the applicant authority is an individual within senior management level with authority to direct financial and human resources. These resources are necessary for maintaining compliance with the licensee's established radiation protection program.

The applicant authority must remain actively engaged in overseeing the radiation protection program by allocating necessary resources to improve compliance or correct non-compliances to regulatory requirements.

The applicant authority's engagement can also be achieved by setting a direct line of communication with the radiation safety officer on all aspects related to radiation safety.

The regulatory document will provide expectations on the roles and responsibilities of the applicant authority to ensure it is clearly understood by this individual that he or she is ultimately accountable for the radiation protection program.

The radiation safety officer is delegated by the applicant authority for day-to-day operation of the radiation protection program. This qualified person is selected based on the combination of his or her experience and training. This individual must have full authority to enforce the radiation protection program and the authority must include the ability to stop any unsafe work practices.

The radiation safety officer is the primary liaison between the CNSC and the licensee. This individual is responsible for managing the radiation

protection program along with the support of qualified persons at other licence locations where more than one geographical location is authorized by the licence.

In addition to details on the roles and responsibilities of the radiation safety officer, the regulatory document will provide some suggested competency requirements to fulfil this role such as knowledge, training, experience and education.

The regulatory document will provide additional guidance and clear expectations supporting the information requested as part of the licence application process. The guidance will be tailored to address the challenges identified with the design and implementation of an effective radiation protection program for nuclear substances and radiation devices licensees.

The regulatory document will describe the necessary elements of a radiation protection program, including policies and procedures. The document will also describe expectations for program oversight, including a licensee's internal audit process.

A radiation protection program must include a clear organizational structure which defines the authority and responsibility of each person involved in overseeing the radiation protection program. These

individuals are mainly the applicant authority and the radiation safety officers.

The radiation safety officer, including his or her designates, must have sufficient authority for overseeing the radiation protection program. The licensee shall ensure that the management structure of the radiation protection program aligns with the organization being licensed, which can be unique to each licensee due to their governance structure.

The role of the Radiation Safety Committee is to act as an advisory committee and to provide advice and direction to the radiation safety officer on the development and implementation of an effective radiation protection program. The regulatory document will provide guidance on its roles and responsibilities, the recommended membership and meetings' frequency for those licensees that would benefit from a Radiation Safety Committee.

An important factor to consider when establishing a Radiation Safety Committee is to have representation from groups involved with or impacted by the licence activity, essentially, there should be a representative from each impacted group occupying a seat on the Radiation Safety Committee.

I will now turn the presentation to Mr.

Keith Dewar to describe the evaluation process.

MR. DEWAR: Good afternoon. For the record, I'm Keith Dewar, Director of the Regulatory Research and Evaluation Division. I'm here today with Geneviève Boudrias, who is the Senior Evaluation Officer and will be lead evaluator for this evaluation.

I'll begin by noting that although evaluation is a relatively common word, program evaluation has a defined meaning within the Government of Canada. In essence, it is a systematic approach to assessing the performance of programs, policies and processes.

Performance in this context means whether and under what conditions a program is effective in achieving its desired impacts or is efficient in delivering. To arrive at these judgments it uses research methods that are similar to those of social science and uses tools such as the ones described on this slide to generate multiple lines of evidence from which to draw its conclusions.

Although many factors contribute to the success of licensee radiation protection programs, this evaluation will specifically try to assess the contribution of RSOs to radiation program success and it will specifically try to understand those RSO-related factors

that are important to or barriers to program success. These include such things as the hard and soft skills possessed by the RSO, organizational structure and governance factors and the institutional support that the RSO receives, amongst other factors.

The evaluation has been scoped to focus on the medical and academic research sectors as has been described. These sectors were chosen primarily as they're the most complex and similar in RSO functioning. Adding the industrial and commercial sectors would increase, of course, the evaluation effort and time.

In undertaking the evaluation, we propose to conduct extensive engagement with the RSO and related stakeholder community. We are planning an electronic survey of the entire RSO population of the medical, academic and research sectors, the 380 members shown on this slide.

We'll conduct a large number of semi-structured interviews with over 40 people, including RSOs, applicant authorities and nuclear energy workers, researchers, et cetera. And in this case, semi-structured means that the questions will defined in advance, but the interviewees will also have a chance to give us open-ended responses to the questions.

We will also undertake a detailed comparison between the RSO approach and the work that's already been done to compare the U.S. and Canada, but we'll look at other international practices such as the U.K. and, as possible, other similar roles in Canada like the Occupational Health and Safety Workplace Safety Advisor.

We've already engaged a number of RSOs who've been actively working in these sectors to help us design the evaluation and to make sure the questions the evaluation will examine are valid.

The evaluation Terms of Reference are in draft and will likely be approved by a high level advisory committee later this month.

I'll now turn the presentation back to Mr. Colin Moses.

MR. MOSES: Thank you. As mentioned, the regulatory document development and the evaluation project are proceeding in parallel.

By the second quarter of 2018-19, the results of the evaluation program will be known allowing us to incorporate information from the evaluation into the draft REGDOC and release the document for external consultation in the third quarter.

Feedback from the consultation will be

considered and incorporated into the document, as appropriate, with publication of the REGDOC currently planned for the second quarter of 2019-20.

As you heard in this morning's Regulatory Oversight Report for the use of nuclear substances, the use of nuclear substances in Canada is safe. This is borne out by observation from the licensing and compliance verification activities and the CNSC has a strong regulatory framework backed by an effective risk-informed licensing and compliance program that can address non-compliances in situations where a licensee deviates from regulatory requirements or CNSC expectations.

Where problems have been identified, the CNSC has managed the licensee on a case-by-case basis using existing regulatory approaches. However, the licensee landscape has and is changing and, when not effectively managed, this transition can expose weaknesses in licensee programs.

Using the experience gained through our regulatory oversight activities, CNSC staff will enhance guidance provided to licensees on the design and implementation of radiation protection programs, sharing and emphasizing best practices with the industry and ensuring licensees put in place a framework that supports

the success of the radiation safety officer.

We remain available to answer any questions you may have.

THE PRESIDENT: Okay. Thank you. So, let's jump right into the question session starting with Dr. McEwan.

MEMBER McEWAN: Thank you.

Just a couple of general comments and then I'll step back for more questions later.

I don't think you can do this exercise excluding central radiopharmacies and accelerators producing medical isotopes, I just don't think that is a group that cannot be included in this exercise. It's not a large number.

And I think as you look at skill sets for RSOs, I think we have to bear in mind the other high risk group, which is the industrial radiography, and I think we need, as we do this exercise, to see if the learnings are applicable to that group as well.

Second thing. As you reach out to people to do this interview, I would suggest there is probably value in talking to the associations that represent the end users. So, CAMRT, CANM, CARO, CAR, COMP, because they bring the skills.

And I will just make an observation again at this stage, and I'll ask for a response, but I will respectfully disagree with slide 12. Your benchmarking does not show that CNSC is comparable to NRC. They are prescriptive, but they are also very risk-informed in that prescription, in that the requirements for the different sectors have quite different requirements for the skill sets of the RSOs.

I mean I just happened to pick out one, which is an RSO who's involved in medical and is very prescriptive as is, by comparison, very laissez-faire. So if you will allow me at this stage, a disagreement with slide 12.

THE PRESIDENT: Anyone want to react to that?

MR. MOSES: Colin Moses, for the record.

So your first point was in the scope of the evaluation. In fact, I completely agree with you. We just had a discussion, that I think there is benefit in bringing some of the more complex licensees from some of the other sectors, within reason, because some licensees are much simpler, and the sort of organizational, governance that we'll be exploring really doesn't add value there. But I think there is certain activities that should

be included.

MEMBER MCEWAN: Bear in mind that many of the pharmacies or cyclotrons belong to the hospital academic sector anyway.

THE PRESIDENT: Again, by the time you value it, you understand what RSO is, you'll want to take advantage of the knowledge gain to see if you can get into other sectors, not only the medical. I particularly think that you need to look at the large organizations, that are multiple licences.

It's always the complexity of the governance model that should dictate where you should put attention on. Because human nature is such that it's competing priorities, you know, and radiation protection may not be the highest priority in a particular corporate structure.

So you heard from our industry friends that they would like some clarification on that too. So you've got to pick the area where you can get most beneficial results to inform the REGDOC.

MR. MOSES: To your second point with regards to the benchmarking, you're entirely correct. Generally, our structures are consistent in terms of expectation, but there are areas where they really do delve

into detail and they provide extensive guidance. So you mentioned RSOs. Another area is an entire document that the NRC has released on the structure, the composition of the Radiation Safety Committee. There's extensive guidance on the selection of the chair for that committee.

That is the kind of information that we want to leverage to help enhance and flesh out the kind of information that we provide in our regulatory framework.

THE PRESIDENT: Thank you. Dr. Demeter.

MEMBER DEMETER: Thank you. A bit more philosophical here. There's always a tug and throw about regulatory frameworks and comparison to other authorities like the NRC. So the NRC is a very prescriptive regulatory framework; you do it like the way we tell you and you'll be okay. The Canadian framework is much more risk-informed; they say, tell us what you do and we'll tell you if it's okay. There's always a tug between those two philosophies.

I think there's an opportunity to reach a happy compromise where the certification or the credentialing of RSOs and of committees, you get a baseline and then you can add to that. I want to also avoid credential creep in a sense that you don't want, you know, all your RSOs to be PhDs, you know, the risk to escalating the credentialing beyond what is reasonable.

So I guess I want to get some sense of how you -- if you're going to benchmark to the U.S., which is a very prescriptive system, very different than the Canadian approach to regulation, how do you marry those two so that you get a happy compromise?

MR. MOSES: Colin Moses, for the record.

So it's a bit of a tough question to answer now, because part of the evaluation is really doing that kind of analysis on the different schemes, the different legislative frameworks, the different structures that different regulators use. You're correct, in that the U.S. does tend to take a much more prescriptive and specific approach. I guess the other comment I'll offer too is that's one thing we're very sensitive of with this REGDOC, that we want to design a framework that provides useful and constructive guidance to licensees, sets clear expectations, but is also suitable for the different types, nature, structures, the relative importance of the regulated activity to their own structures.

So it is a bit of a push/pull, which is why I think the consultation piece of the REGDOC development is so critical.

But our focus is really, as Dr. Binder was alluding to, on those licensees that do have those complex

structures and complex governance. The principles that will be described in this REGDOC are universal, they're not specific to the particular application.

The other piece that we alluded to in the benchmarking is looking at other regulators in Canada, because they are much more consistent in terms of the legislative framework, they way they're structured. We talked about occupational health and safety, for example.

Another area that I want to explore is in the health area, there's requirements for labs, and they have biosafety officers. So what are we setting as requirements for biosafety officers versus radiation safety officers? What are the qualification and training requirements?

So those are the kind of things we want to explore to make sure when we put out a document it's suitable, useful, and really has the desired effect.

THE PRESIDENT: We probably could describe the CNSC differently than the U.S. We are a performance-based organization, which means that we like our cake and eat it too. We can be prescriptive when it's required, and give us a safety case and we'll decide.

I think that's a better model, in my opinion. But we should not forget that the driver here is

safety, and you've got to work backwards from that concept. So whatever model that people will argue is acceptable, and there may be more than one model, the bottom line should be still safety is never compromised.

MR. MOSES: Absolutely.

THE PRESIDENT: Mr. Seeley.

MEMBER SEELEY: Thank you for that presentation. Yes, I think in general, definitely on the right track with some of these major initiatives. In this space, roughly the improved guidance document, so the new REG document, really pulling the pieces together, providing that clarity for licensees. Then the second element is around the resourcing side of it, the RSO. Let's get underneath that and make sure the role's clear and what the requirements of that role are and are clear as well. So very happy to see that.

I guess my question would be more around timing then. So these are the big pieces of what I would call program improvement. I've been hitting on the program improvement and the need for it earlier in the day, talking about the 25 per cent that doesn't meet expectations in the medical sector on RPP inspections and whatnot.

But I guess my question would be there is a bit of an increasing trend there in terms of inspections

not meeting the expectations for the last few years. So this program is going to take two more years to implement, as I see on your timeline. So that's a very long time.

I guess my point is, you know, if I'm looking for improvement in performance in the next year when we're sitting here and we're looking at the 2017 report and, you know, and this particular sector continues to go up, then I won't be very happy.

So are there any other initiatives or what I call near-term initiatives? So maybe call it sub-milestone. You've got the big milestones, we're going to get that new REGDOC out, going to get the clarity on the RSO role, and their accountability and their qualifications. But is there anything you can do in the interim to actually turn this around and try to steer the improvement earlier so you're not waiting two years for those documents and those requirements to be clarified? So that's my question to you.

MR. MOSES: Colin Moses, for the record.

In fact, there's things we are doing today to address some of those issues. We heard earlier from one of our regional coordinators, Jonathan Schmidt, who spoke to how we're changing the way that we engage with the applicant authority, we're changing the way that we engage

with the senior management and the organization, and being more proactive and to highlight the concerns that we have if we are seeing more systemic issues, or if we have any concerns with the way the RSO is managing that program.

That's proven every effective, because in many cases the applicant authority accepts that accountability but delegates the responsibility and they have many other concerns to concern themselves with and have been giving due attention to the importance of radiation safety.

That's why engagement with them and bringing them in and being clear about some of sort of the systemic issues, we've seen strong improvement in individual licensees just through that simple step.

The other thing we're doing, the administrative monetary penalty program is also very effective at that. It's a good way to send a signal if there are sort of concerning developments that warrant escalated enforcement. One of the pieces I actually do, because I'm the issuing authority for the administrative monetary penalties, is engage with the applicant authority when I issue that to make sure that they understand, they're aware of the concern, they're aware of the issuance, and they understand the significance of those

non-compliances, which has triggered that enforcement action.

Aside from that, we're adjusting our compliance oversight approach in sort of two main ways. The first is adopting more of a performance-based approach, because we saw trends in industry in terms of the way that licensees are performing that weren't adequately being captured through inspection processes.

So over the last three years we've been increasing the import of performance-based inspections where we're actually going out in the field and we're observing the compliance at the worker level with the procedures that are put in place, as opposed to focusing on the compliance with the record retention requirements and the documentation requirements. That's proven particularly effective. It does mean that we are discovering more non-compliances, but I think it means we're being more effective as a regulator.

Although those types of inspections are more resource-intensive, more travel for the inspectors, I think there is really value in those kind of activities.

The second piece that we're doing in the compliance oversight is transitioning to more what we refer to as Type 1 inspections. So Type 1 inspections are

really designed for those complex licensees where we take a step back. A Type 2 inspection gives us indicators on the performance, so instances of non-compliance that show that there is an effective program oversight. A Type 1 really delves into specifics of how a licensee is implementing a program and speaks to the effectiveness of that program that is put in place.

Generally at large, when we do those Type 1 inspections, one of the findings is that they need to improve their program governance and they need to improve their program documentation.

So all the information that we're gathering through those regulatory oversight activities, we're now embedding in this regulatory document so that we can share that more broadly with licensees and we can be more proactive.

MEMBER SEELEY: I like that informal approach where, you know, if a licensee is struggling, you just have the meeting with them and we're just going to talk this through about what's not going well and what you can do better.

I noted from the report that the radiation I think it was -- yes, nuclear medicine was one that was the highest proportion that didn't meet expectation, 25 per

cent of them.

So I guess my suggestion is there maybe there's room for more of that where you're bringing in whatever it is, the management or the managers or management teams or individuals, senior management responsible, and just having that talk with a number of those in the interim and let them know what's coming down the pipe in terms of regulatory documents and RSO clarification, but work with them to try and make those improvements happen now.

Thank you.

THE PRESIDENT: I think you're doing it in parallel, developing the REGDOC in parallel, because you know what you need to do already. You're looking for some of the evaluations to give you evidence, if you like.

So I'm with Mr. Seeley here, particularly on the application, the AA, let me put it this way. I thought after every inspection in a hospital let's say or in a medical facility, you meet with an AA. I think if that's part of the process, that'll go a long way to deal with some of the issues that we're observing.

MR. MOSES: Colin Moses, for the record.

I know I'm answering all the questions, and my apologies to my staff for that, but I'll just speak

to a very real experience. I try to get out and accompany inspectors on inspections from time to time. One of the most recent ones that I did was accompanying a Type 1 inspection at a local hospital. Part of that inspection is to sit down with the applicant authority.

I mean, that's a very telling discussion. For one, it helps us get a feel for how aware they are of the activities that are happening in their hospital, of the importance of radiation safety. It gives us an opportunity to get their feedback on how they view our regulatory oversight, and if there's opportunities to better enhance that, and it gives us an opportunity to really highlight and push where we feel that there needs to be changes in the program.

So in this particular case, they had recently been subject to a compliance inspection in one area where we did have concerns with how they were managing that program. So our inspectors did sit down with the applicant authority to emphasize those concerns.

So when I went back and sat down with the applicant authority on this next inspection, it was very clear that they took that to heart and they're implementing a number of different program changes, they're introducing governance, they were creating a radiation safety

committee, and they were giving consideration.

In fact, they were leveraging that experience to oversee other hazards that they regulate that are outside of our regulatory oversight. For example, laser and x-ray safety. They're bringing that under one governance structure. So I think there is value to engaging with the applicant authority.

THE PRESIDENT: Dr. Soliman.

MEMBER SOLIMAN: Thank you. Concerning the RSO licence, what is the current practice and what are we proposing, and what is the situation in the U.S.?

MR. MOSES: Colin Moses, for the record.

So if I heard you correctly, what is our current practice for oversight of radiation safety officers and how does that compare with the U.S.?

MEMBER SOLIMAN: (off microphone) proposing to -- not to issue a licence for an RSO? Because I heard this morning that we are planning to remove the licence requirement for RSOs. Is this correct?

MR. MOSES: Colin Moses, for the record.

I believe you're referring to the potential for certification of radiation safety officers?

MEMBER SOLIMAN: Yes.

MR. MOSES: So currently, we do not

require it for this sector. We do certification of radiation safety officers for the Class 2 licensees, and that really is based on, I alluded to it this morning, a risk-informed regulatory program. So we looked at the risks of the relevant activities and determined that it was necessary and appropriate to certify Class 2 RSOs.

When we did that assessment, there weren't evidence of systemic issues that would warrant that kind of regulatory intervention for this community. But part of the reason we're launching this evaluation is to see whether that approach has merit for this sector, different pieces of that sector, or particularly for those more complex licensees.

Our current approach is analogous to a certification. There isn't an exam, but there is a detailed assessment of the qualifications of the RSO and the suitability of them to take on that role. I'll let Mr. Fundarek speak to that.

MR. FUNDAREK: Peter Fundarek, for the record.

During the licence assessment process we look at two parties fundamentally. The first is the applicant authority. We get them to sign a form that indicates that they understand their obligations, that they

are willing to direct human and financial resources as necessary, and they understand their obligations as a licensee because the ultimate licence authority is the applicant authority, and we will engage with that person as the time requires if the situation demands it. So we do use that avenue of discussion.

Our primary discussion, our primary liaison point is the radiation safety officer. When we're faced with an application we look at the radiation safety officer's education, their training, their experience, and their general knowledge in the activities that they're proposing to oversee.

So, for example, if a licensee has got a fixed gauge operation we wouldn't necessarily look at somebody who has unsealed nuclear substances qualifications as favourably as we would at somebody who has extensive experience in dealing with fixed gauges, because the two properties are different and we want to make sure that the person who's undertaking the work understands what they're doing.

We're also looking at that they understand the CNSC obligations and what it means to be a licensee, the reporting requirements particularly, so that they can report to us in a timely and effective manner when

situations happen that require reporting under the regulations. We want to make sure that they're capable of implementing the program.

So through our compliance verification, whether it be on-site inspections or annual compliance reports or just general conversations with our licensees, which we do from time to time, if we get indications that the radiation safety officer doesn't have the necessary resources to undertake the program or is unable to implement the program as they've described in their licence application, that's when we then engage with the applicant authority and remind them of their obligations and enforce the fact that they need to provide the necessary resources to get this program functional in the way that it was described in the licensing basis.

So we do have a circular approach, we do go through a roundabout approach in terms of coming back to the applicant authority, because they are the ultimate authority.

THE PRESIDENT: Okay. Technical question. So how in a very complex multinational organization, how do we assess whether there's enough resources to do the job? Not to mention in a very complicated hospital structure, a provincial structure. You're not likely to get the RSO to

blow the whistle on the AA for not giving them enough resources.

Can we, on our own, determine where the adequate resources are going on using some, I don't know, performance indicators, volume of required jobs, incidents of non-compliance? How do you assess?

MR. MOSES: Colin Moses, for the record.

So what Mr. Fundarek spoke about is our preliminary assessment on the adequacy of the individual to take on that role. I'll let Mr. Rabski speak about -- because it really is quite evident when we're in the field and we're doing our inspections, when there are program oversight issues. There's, you know, minor non-compliances, inadequate documentation, and those are indicators that the RSO isn't performing that role adequately.

I'll let Mr. Rabski speak about how we respond to that.

MR. RABSKI: Henry Rabski, for the record.

The role of the inspector is to do the verification in the field of what has been committed to and the role of the RSO is evaluated through the performance of the individuals using nuclear substances in the licence and how they comply with the expectations in their licence and all the regulatory requirements.

So it's quite evident to us through our worksheets and what we call our Type 2 inspections when there is degradation of the program and when expectations are not being met.

We also combine that with other observations that we see. So we'll also look at events that have occurred. We'll do follow-up on their ACR, their annual compliance report, and all that information comes together very nicely when you can see and when you start to tell where an RSO is failing to meet those obligations for the applicant authority or the licence that they're operating.

We take different approaches. Some of my colleagues have alluded to meetings with the applicant authority. When we know that there is already a history there, that's the direction that I give my staff. So even though they might be doing a Type 2 inspection, they make an appointment beforehand to meet with the applicant authority at their departure and, in some cases, they provide the preliminary report directly to the applicant authority to bring that message back as to what they're seeing in that facility and what are the issues and what some of the challenges are for that particular licensee.

In addition to that, we take also those

observations and we assess all our complex or higher risk licensees, we put them through an assessment when we're planning and we look for opportunities to lever age a Type 1 inspection. The Type 1 inspection then actually integrates, as my colleagues have said before, interviews with staff throughout the organization and they provide us the evidence that we need to show that the program is not meeting expectations and the failure of the RSO to manage those programs.

So we take -- we take different approaches, but we're looking seriously at the indicators and using what tools we can to initiate changes in the RSO performance.

And last -- one of the other options we talked about was bringing in -- applicant authorities in, and RSOs, to a meeting with our staff and we'd talk specifically about resources and we'd talk about what we're seeing.

So we're very blunt about those observations and we're looking at providing them the evidence they need to stand up and take account for a licence and for that safety of that facility that they're responsible for to ensure that the radiation protection program is meeting our expectations.

So there are a number of different ways to do it, but leading all back to the RSO, who is the key person that is the instrument through which the operational procedures, the performance continues to be positive through their guidance and their oversight. And when we don't see it, we have to take them -- any one of those steps to change that -- that situation and reverse potentially unsafe work conditions or an unsafe environment for workers and whoever's going through that facility.

THE PRESIDENT: Okay. Thank you.

Do you want to add something?

MR. BROEDERS: Mark Broeders, for the record.

I just want to add to Mr. Rabski's explanation.

So if we took out a list of the adequacy of the resources available for radiation safety, it's at the front end and the back end. So with the licensing submission, we look at the job description to make sure that enough time's been allocated in that job description for radiation safety function.

As I said before, many facilities, the RSO, because it's a part-time responsibility -- may not be full-time except for the larger centres. But for the

smaller centres, it's a part-time responsibility so we've got to make sure they have sufficient time allocated to that responsibility.

And we have a tool -- we developed based on the cost recovery fee regulations that uses -- that determines the amount of time required for us to support that licence, so we use the same model for them.

It's a -- it's a bit of an estimate, but it gives us a good feeling for whether or not it just seems like a reasonable amount of time allocated for that RSO duty. So that's at the front end.

We actually do the inspection and ongoing through the year through other techniques like the ACR.

If we're seeing that the ACRs are late, if the quality of the licence application submissions are poor, if they're submitting those applications at the last minute and then call us frantically saying "We have patients booked for Monday, please, please, you know, get this processed", those are indications that they're short staffed. And that would either trigger a Type 2 inspection or it may escalate and accelerate the inspection cycle to do Type 1 sooner than we might otherwise do to investigation.

THE PRESIDENT: Okay. Thank you.

MEMBER SOLIMAN: Thank you very much for identifying (inaudible - mic failure) inspections. But I searched all over the documentation. I cannot find that definition. I spent lots of time looking for it.

Isn't this a very good addition to the documentation we have?

MR. MOSES: Colin Moses, for the record.

Sorry. I was just conferring with my colleague because I believe in the supplemental we actually did commit to add that to the regulatory oversight report just because there was a question raised by one of the commenters in the difference between the Type 1 and Type 2, but I could stand to be corrected on that.

But if we didn't commit in the supplemental, I think that's something we have and could very easily be added to the documentation.

THE PRESIDENT: Back to the top of the list.

Dr. McEwan.

MEMBER McEWAN: Thanks.

So can a large, complex organization have more than one applicant authority?

MR. MOSES: Colin Moses, for the record.

So each licence requires a single

applicant authority, but in some cases, particularly if you look at radio oncology and nuclear medicine, often they're very different structures, different funding mechanisms, different personnel involved. And so in those cases, sometimes there may be a different applicant authority for each of those individual licences.

MEMBER McEWAN: And the second question, so again, for some of these large, complex structures, B.C. -- and again, I'm going back to B.C. because of the experience we had.

How do you ensure that if you like the corporate RSO who is managing the RPP across the region, whatever size organization that might -- how do you ensure that they're appropriate supported in the individual hospitals by a local RSO or somebody fulfilling a local RSO function and reporting back to them?

MR. MOSES: Colin Moses, for the record.

So we do that both in the licensing assessment -- we look at the organizational structure and we do that through our compliance activities because our Type IIs are done at different locations and they help assess whether the individual locations are complying to the corporate policies.

THE PRESIDENT: No, I'm still stuck on the

first question.

So in a given hospital, you can have two AAs.

MR. MOSES: Colin Moses, for the record.

Yes. And maybe I'll let Mr. Mark Broeders speak to sort of how different the governance structures can be and the different types of activities that we --

THE PRESIDENT: But I'm not -- the hospital has one CEO. That's ultimately the person who allocates resources. But if there is -- is there any overlap at all between such two AAs in one hospital competing for resources?

MEMBER McEWAN: And the corollary of that is, can one hospital have two RPPs.

MR. BROEDERS: Mark Broeders, for the record.

So really, the most granular it can be for a license is the radiation safety program or radiation protection program, if you prefer. And with that is associated application authority and a radiation safety officer or radiation safety officers, plural, in some limited cases.

So in the case of a hospital you're referring to, yes, they share the same campus, but they

are -- beyond that, the differences are fairly broad.

It's a different physician group, different staff and completely different profession. We have nuclear medicine technologists and radiation therapists. Yes, they're both members of CAMRT, but they're different professions, a different funding model.

And until recently, in some places like in Ontario, the funding came directly from Cancer Care Ontario. Although they shared space -- they rented space from the hospital, they are completely independently funded.

So if we follow where the money flows and the governance structure, it makes sense to have a separate applicant authority, separate RSO and a separate radiation safety program.

Even in a hospital like University Health Network, which have a cyclotron and radiation therapy, we keep the two separate because of that reality.

We don't want to force two radiation safety programs together artificially where they don't belong together because then you have problems with people pointing fingers and not really aligned with the overall goals of the organization.

So Dr. Binder, to your point of the CEO,

yes, indeed, there may be one CEO, but we try to find the right balance between having someone that has the ultimate authority, the CEO, where someone is not too far removed from the day-to-day operations that they can fully appreciate the nuances of what's happened in the program and be accountable for the performance of that program.

So typically, we're at the vice president level in a large organization, but in smaller centres, for sure, it'd be the CEO.

THE PRESIDENT: Well, you live it. Jump right in.

MEMBER McEWAN: I think this is a good example of why this review is so important because I think, at the sharp end level, it doesn't work.

I'm aware of a hospital, for example, where a patient with an unsealed source therapy, if they vomit on one side of the door, it's one RSO looking after it; if they vomit on the other side of the door, the other RSO is looking after it.

And to me, that doesn't allow a seamless application of the principles of radiation protection.

THE PRESIDENT: So look, we're not going to have all the answers. That's why we're doing this particular study. But you may want to think about area

where it may make sense to have two if it's really, really separated, et cetera. If they reside in, I don't know, one location, et cetera I'm starting to lose faith because I could see they're competing for resources, location, parking, all the good stuff that people fight about.

So it's an opportunity for us to take a good look and, at the end of the day, when you put some guidance, in the guidance you'll have to explain what our preference would be and then why.

So if you do allow for two, that should be a one off for really separation of duty, resource allocation. You've got to make sure there's no possible duplication of effort.

So that's the kind of evidence and wisdom that we will look for to get back to us not only from the -- from the study, but also from the advisory committee.

You know, if you're going to have a good advisory committee with experienced people who actually live it on a day to day, we probably can get some pretty good insightful information about what needs to be done.

MEMBER McEWAN: And in fact, talking about the advisory committee, I would urge you to include an end user on that, so a radiation oncologist and/or a nuclear

medicine physician.

I think you really have to have somebody who understands the clinical operational impacts of the regulatory framework.

THE PRESIDENT: And just to jump on that, at the end of the day, how prescriptive do we want to be eventually in the -- in the committee that's being set in a particular facility to have the right composition and the right authority because, really, that would -- that would colour the kind of -- the RPP process.

Does that make sense?

MR. MOSES: Absolutely. That does make sense.

And Dr. McEwan, to your comment, I think that's something we can definitely look at.

THE PRESIDENT: Dr. Demeter.

MEMBER DEMETER: Thank you.

First a comment. I'm glad that there's mention of a formulaic approach to deciding what the appropriate time for a radiation protection officer is because we have one-camera departments, we have five-camera departments, and we don't want to over-staff or under-staff. And that's an appropriate approach that gives you some guidance and gives us some guidance from a funding

point of view.

The question I have for you to consider in your -- you talk in your -- you talk in your document about amalgamation creating larger structures.

One of the concerns that may happen with larger radiation protection committees is it gets so dilute with individuals from so many different sectors that you lose that focus. Like if you get a radiation protection committee that includes x-ray and laser and nuclear -- clinical nuclear medicine and brachial therapy, it just -- the people around the table, the focus is not on that particular sector.

So one of the risks of making the animal larger is it becomes more diffuse versus focused on that.

So that's just one of the -- again, the thresholds of if you have these amalgamated licences, how much do you permit a committee to grow to the point where it becomes disengaged with the reality of the majority of the members except maybe one who may be not be able to come to the meeting that day.

That's one of the concerns I have about these larger committees if they're multi-stakeholder that you may actually dilute the experience such that it becomes less engaged.

MR. MOSES: Colin Moses.

That's also a very good point. I think that's the delicate balance that we'll have to work on, and that's where the evaluation and taking a very evidence-based approach to this project, I think, will be particularly helpful.

THE PRESIDENT: Mr. Seeley.

So any kind of final remarks?

MR. MOSES: Colin Moses, for the record.

No. Only that we certainly appreciate all the feedback we received today, and that's the whole purpose of going through this exercise, to make sure we take into account all the diversity, so appreciate that. Thank you.

THE PRESIDENT: I think the industry wanted to fast track all of this, so I'm not sure -- I think you alluded to this, that you're not going to wait until the very last, you know, year, 19, 20, to put in effect some improvement that you know what to do right away.

MR. MOSES: Colin Moses.

That's correct, yes.

THE PRESIDENT: Okay. Thank you.

So this concludes the public meeting of

the Commission. Thank you for your participation.

MS McGEE: If you borrowed interpretation devices, please remember to return them at the reception and claim your identification card.

Thank you. Bonne fin de journée.

--- Whereupon the meeting concluded at 4:16 p.m. /
La réunion s'est terminée à 16 h 16