

Canadian Nuclear
Safety Commission

Commission canadienne de
sûreté nucléaire

Public meeting

Réunion publique

May 7th, 2014

Le 7 mai 2014

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

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

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Ottawa, Ontario

--- Upon commencing on Wednesday, May 7, 2014
at 4:15 p.m. / La réunion débute le mercredi
7 mai 2014 à 16 h 15

THE PRESIDENT: Let me start by first welcoming you. We know how busy you guys are and really it's a privilege to have you here and listen to your story. And I don't know how long you've been in the room watching all of us in the regulatory business. We may get into that with you too. But in the meantime, so I'm going to skip right into the business at hand and they -- what we are -- for the audience on the webcast, the next item on the agenda is a presentation on radiation therapy in Canada as outlined in CMD 14-M26 and this is presented by the Canadian Partnership for Quality Radiotherapy. I understand that Dr. Milosevic will be making the presentation.

Please proceed.

CMD 14-M26

Oral presentation by Dr. Milosevic

MR. MILOSEVIC: Thank you very much. I'm Michael Milosevic. First of all, thank you for the opportunity to come and speak today to talk about radiation therapy, quality and safety really from a patient perspective in Canada. And I think that what we want to talk about today really very much complements the activities of CNSC in relation to worker and public safety around the therapeutic use of radiation to treat cancer.

I am a radiation oncologist at University Health Network and the Princess Margaret Cancer Centre in Toronto.

I am joined by two colleagues today. Radiation therapy is very much a partnership in terms of how we deliver care. The doctor doesn't do it in any way on -- by himself or herself and we require the integrated efforts of a large team. John French, on my extreme left, is a radiation therapist by training. He is now a senior director at the British Columbia Cancer Agency in Vancouver. And on my immediate left is John Schreiner, who is a medical physicist. He is the chief of medical physics at the Kingston General Hospital and also the Radiation Safety

Officer at the Kingston General Hospital.

The Canadian Partnership for Quality in Radiotherapy really embodies the three professional organizations in Canada that are involved in the delivery of radiation, treatment to patients with cancer, radiation oncologists, medical physicists, and -- and radiation therapists.

And the organization was formed about five years ago as a grass roots endeavour by members of those three organizations, recognizing that although there were very, very well thought out and organized activities at the level of individual cancer treatment programs across the country to -- to provide high-quality care, there was no overarching organization, there was no harmonizing affect across the country to be sure that the quality of care provided to patients in Vancouver was the same as Toronto, was the same in Charlottetown.

And members of the three organizations, of the three professions came together and they said we think we can do this in a better way, we think there's a real opportunity right now in Canada to do this. And we were

fortunate at the same time to be talking to members of the Canadian Partnership Against Cancer that was also very interested in quality and safety issues, and we had some seed funding from them to move this activity forward and that has recently been renewed.

So the Canadian Partnership for Quality in Radiotherapy really embodies the three professional organizations with strategic and financial backing from CPAC, and -- and it's been a very rewarding experience and I think very positive for the treatment community across the country.

So just a word about cancer burden in Canada, which is something that is growing. It's growing in a number of different ways. First of all, we have an aging population in Canada and the incidents of cancer is, therefore, projected to rise over the next several years. So we're going to see more and more people with this disease and we'll need to address that as a broad community in Canada.

Not only that, we're diagnosing tumours more readily, more frequently. We're -- our treatments are becoming more effective for

these tumours. So more and more people are surviving their diagnosis of cancer and are around for many years afterwards, hopefully free of side effects of their treatment but sometimes with side effects. So, the concept of -- of cancer as a chronic illness and the need to consider survivorship issues in patients with cancer is something that's very important.

Now, radiation therapy is an important treatment for cancer. There are three main treatments for people with cancer: surgery, radiation treatment, and chemotherapy. Radiation treatment plays an important role in at least half of all patients who are diagnosed with cancer. There's strong evidence from multiple lines of evidence to suggest that. And it's used both to cure cancer and it's used to help with symptom management. Patients who may not have a curable disease but have pain or bleeding or other problems, radiation is extremely effective in palliating those symptoms.

Probably about 40 percent of patients who eventually will be cured of their cancer have radiation treatment at some point along the way and often integrated with surgery or

with chemotherapy. And one of the trends we see now in going forward is that radiation is not used as standalone treatment. It is more often than not integrated with these other forms of cancer treatment in some kind of way that makes sense from a patient perspective.

There are about 40 or so radiation treatment centres in Canada. We're -- we're a very close-knit community and an organized community and we all know each other, and that makes moving these kinds of activities in quality and safety forward much easier than in some other medical specialties.

About a hundred thousand courses of radiation are administered annually in Canada, typically as fractionated treatment. So one course might consist of many, many fractions of radiation, maybe 20 fractions, 15 fractions on average, given usually on consecutive days.

The future of radiation. Radiation is evolving as we speak and it has actually come a long way over the last 40 years and the real focus right now is on very much individualized care, what can we do for the patient that's in front of us that -- that

personalizes their care, optimizes their particular outcome. As I have said previously, there's a real focus on integration of treatment modalities, surgery, radiotherapy and chemotherapy. We're often driven by technology advances. So our technology is moving forward, radiation treatment moves forward with it, but we also try not to be solely driven by technology, that we try to be driven by medical evidence to suggest a benefit of a new treatment in a particular patient or a benefit of some technological innovation in a particular patient population.

Our technology is getting more complex. We're able to deliver more precise conformal treatment to tumours and keep the radiation away from normal tissues and normal structures that contribute to side effects. And the future is also going to be about how we adapt changes in how we deliver radiation treatment to how the tumour changes over a course of fractionated radiation, something that we have -- we're talking about in determines of adaptive radiation.

There are very well-defined lines

of accountability, I think, for some of the issues that come up in terms of quality and safety, certainly from the patient quality of care and safety side of things that really at this point rests primarily in the hands of the medical team involved in delivering care to an individual patient, and that team, as I have said, consists of physicians, radiation oncologists, it consists of medical physicists -- not "medial physicists", as I have written there, I apologize for that -- and it -- and it rests with radiation therapists. And it's the integrated activity of those groups of people that are -- are important in that.

And all of those groups have national and provincial certifications and licensing bodies that are involved in -- in certifying their qualifications and assuming that -- assuring that we have competent teams of people working for the benefit of our patients.

I have mentioned briefly here, in -- in a very simplistic way, the main responsibilities of the radiation treatment team. The oncologist has the role primarily of integrating with other medical disciplines, prescribing the treatment, and defining the

treatment plan, the volume to be treated, in other words, the -- the target tumour volume as well as the critical structures around the tumour, and supervising all aspects of the medical care of that patient through treatment. Our -- we could not, however, do our jobs without medical physicists, who are involved in maintaining the equipment performance at a very high level so that we know the equipment is doing what we want it to do, and also helping us design and implement radiation treatment plans. And the radiation therapists are really the people who run the front lines. They're the people who every day see the patient when the patient comes into the clinic and actually delivers care to that patient. So they're the folks who -- who see the patients probably most often.

As I have said, these roles are they simplistic, as they're identified here. These roles are also evolving and changing as how we deliver care changes over time. But what is key and what we all recognize is that interdisciplinary engagement across the team is important at every step of the radiation treatment, planning, and delivery process if we

want to deliver the highest quality care and the safest care to our patients.

And we talk a lot, as I know CNSC does, about a culture of quality and safety and how fundamental this is at a particular clinic level, at a programmatic level to being sure that care is always of the highest quality. And this is something that comes from a document that was published by our American colleagues ASTRO, the American Society for Radiation Oncologists [sic], which really emphasizes the fact that this culture of quality and safety, we -- we believe, has to come from the grass roots level, from the people who are actually delivering care in the clinic, not from program leadership. Program leadership can support and nurture that and monitor the culture of quality and safety, but it really has to be driven at a grass roots level. And I think building this culture in relation to patient safety really compliments the culture of quality and safety that's important in maintaining worker and public safety as well.

So the Canadian Partnership for Quality and Radiotherapy integrated a lot of potential areas where we thought quality and

safety could be improved and -- or harmonized, I guess, on a national level, and there are five main areas that you will hear about today.

One was to develop a set of guidelines and indicators of performance in relation to how each individual radiation treatment program across the country was -- was functioning and performing.

The second was in relation to the technical performance of the radiation equipment, to be sure that it was optimal at all times.

The third is relating -- is -- is relating to an ongoing initiative to develop a national incident reporting system for radiation treatment, incidents that relate to patients.

We also believe, we believe that -- that patient and family engagement is essential to what we do, that we're there to benefit patients, we're there to benefit their families. So as we move forward with these initiatives, having feedback from -- from that -- from that stakeholder group, which is so fundamentally important, is key to our success and we've actually engaged patients and families, and you'll hear about that. Education and advocacy,

of course, is also very important.

And finally, we're beginning to look at not just what happens at a programmatic level, which -- which many of these address, but -- but also how we think about medical indicators of radiation quality. So at the highest level how do oncologists, how does the medical team decide what kind of radiation is appropriate, when radiation is appropriate and how it should be used and integrated with other therapeutic modalities.

CPQR is consultative in nature. It's not top-down. We -- we -- everything we've done and will continue to do is based on broad community consultation with key stakeholders, the radiation treatment, our partners in the community and other key partners. And also we believe that -- that we should capitalize on existing investments in areas in Canada that we -- that we can work with to strengthen our mandate. And so, you'll hear about some of these partners with other national organizations that have furthered our objectives as we go forward.

I'm going to turn it over now to Dr. Schreiner, who will talk about some of the

technical issues in relation to radiation treatment of patients.

MR. SCHREINER: So we thought it would be helpful for you to see a little bit of how we are trying to implement the treatments and the complexity that's involved in the care we try to take for that.

Tumours are sometimes very complex in shape and in the 25 years of my career we have gotten much better at carving the doses around the treatment areas that we wish to treat. So if you look at a CT scan perhaps of a treatment of a prostate, we are actually trying to treat some target to some dose. And just to give you some idea of the dose, we would be giving on the order of 200 Sieverts, to that red area to the prostate every day for those fractions that we are doing through the treatment, and obviously we have to do a lot of work to make sure that the rest of the tissue is not receiving those kinds of doses. So a lot of our work is to try and carve that dose so that we are hitting the target and sparing as much normal tissue as possible.

There is quite a bit of technology that's come into the clinic, again, in the last 20

years. We have CT simulation that enables us to image the -- the patient, for example, in many cases. Most of our cases now would go through the simulator. This gives us anatomical data that allows the physicians to contour the areas they wish to treat and, very importantly, the areas that they wish not to have receive radiation. It also gives us a map of the X-ray attenuation properties that we can then insert into a treatment planning computer and that can then predict, if we are coming from certain directions, what the doses are.

So then we go to a treatment planning system. That system would have had all the data from the radiation properties of all the radiation beams available on the devices input into the system, and then we can predict, if we are shooting from various directions with different types of beams, what the dose distribution would be, and we can individualize that treatment and try to give the best treatment, again, sparing the normal tissue and -- and hitting the target. And eventually that will go to the -- that information, that whole set of instructions of how to control the machine will be

sent to the -- the treatment unit, the linear accelerator, and then that treatment will be implemented.

Just to give you an idea of -- of what that would look like, if you look at the centre, the patient would be -- would be positioned so that the target that we are trying to treat is at the centre of rotation of this unit, and that's a very precise centre of rotation. And then what we can do is we can bring the beam in from one direction. If we just were treating with a single beam, the maximum dose would be just below the surface of the patient at some distance and we wouldn't be getting most of the dose to the target. So what we do is we bring in another beam from the other direction and then we can homogenize the dose over a different region. And if we do that a couple more times, we can actually -- we cannot focus the dose but we can add the dose to the target that's at the centre of rotation. And as we normalize that, the dose to the rest of the -- of the patient is diminished. And one more time. And so we can start to build up that dose.

If I look at the port that that

radiation is coming out of, it actually has collimation, so blocking, that is a number of individual nearly fingers that are all under computer control. So each of those fingers is -- is on a motor and I can shape that radiation port essentially to cover the target that I'm trying to treat, and, again, to shield the normal tissues that we are not trying to treat. And if I just shoot radiation out of that beam, out of that port, I'll have a uniform intensity of beam across that port.

And then I can actually plan my radiation delivery from different directions and get a dose distribution that would have to follow some protocol for that particular case or site that we're trying to treat. If you just do that kind of treatment, though, it's sometimes hard to carve the dose to the target. So, an additional term that we would do is actually use the fact that I can control those fingers, those collimators, in the multi-leaf collimator individually, to stay at that position and move those, that collimation, so that I can actually have a variation of the intensity of the beam shaping as it comes out from that particular

direction. And what that enables me to do is to carve the dose much more exquisitely. So I can now, for example, if you look at the bottom, there's a little bit of a C there now where I have brought that high dose area up off of the rectum, I'm not going to give dose to that sensitive tissue and I'm still treating the target.

The paradigm for this is a little bit different on how we plan in that what the physician will do is contour all of his or her targets of interest and the area she's -- he or she is trying to avoid and we give that dose distribution to the computer and we ask the computer to optimise how the -- the leaves should be positioned and -- and what position we -- we should be coming out of. So we actually have an optimisation that optimises that treatment for that particular patient. And often that involves this modulation of the intensity across the beam.

And so if we look at how things have moved over the last few years, we've gone to this intensity-modulated radiation therapy, that's the IMRT, acronym that we're using there, which is a lot of information that's going between the treatment planning system and the -- and the

treatment unit, and there's a lot of quality assurance to ensure that all of that happens appropriately.

In fact, we can be even more sophisticated by increasing the number of angles we shoot from. And with modern -- some of the modern units from all of the manufacturers that make these machines, we now have the ability to, in fact, have that modulation occur as the machine is continuously rotating around the patient, with the dose rate coming out of the machine varying. So there is a lot of control variables and parameters that we can adjust to try and do this carving as well as we can -- we can do.

And so, inherent with that, of course, is that we have to make sure that these machines are -- are working appropriately. So there is a lot of work to -- to actually ensure that the calculations are appropriate, that the machines are appropriate. Whenever a new unit comes in, the physics department will usually spend two to four months testing that machine before it ever is used on a -- on a patient. In all of that we assure that we are -- the facility and -- and the first set of safety that we do is

to ensure that workers and the public that are using this machine are in the rooms and the waiting rooms around this machine are safe. There are technical indicators of how these machines should work. And we have really been working as a community to now not only do that well at each of our individual centres but actually to have, as Mike pointed out, a set of quality standards that are coming from right across the nation.

So, the next.

So, in the last few years the CPAC, with the Canadian Organization of Medical Physics and the Quality and Radiation Safety Advisory Committee have issued a number of documents that actually specify how various testing, frequency of testing, standards of testing, tolerances and such should be adopted for each of the units that we are using and different components of the work we do. And the community has actually had a set of experts design these documents and then we go through a process where the documents have gone out for essentially beta testing in the clinics so that we get feedback from the users, and then those documents have become standards of care that we expect all

quality assurance programs in our profession to be -- to be adopted.

And if you can see, right now we are working on also a radiation safety systems, a system that's in development, and that was initiated, in fact, by my colleagues in -- in medical physics in discussions with -- with various folk at the CNSC who are helping us to -- to make sure that we stick to the specifications on the expectations of the regulator.

This is a national endeavour and there has been participation from across the country both in generating the work and which documents we wanted to bring out, getting the initial documents generated, and then having expert reviewers look at this. And these -- the intent is that these will be living documents that will come up for regular review to make sure that they stay current with the technology that's delivered and we're not looking at policies and procedures that become out of date. So, we're really trying to make these living documents that are readily achievable.

And I ...

MR. MILOSEVIC: Mike Milosevic for

the record. Thank you, John.

So -- so the technology that we have available to us now is very complex and -- and capable of -- of performing some amazing feats in terms of allowing us as physicians to target tumours very, very precisely in patients and -- and to avoid normal structures. And the end result of that is that we as physicians are able to use higher doses of radiation. And in many tumours, the higher the radiation dose to the tumour, the greater the likelihood is of tumour control as a fundamental principle.

And we see this coming out now in many randomised clinical trials, which is the best source of evidence that we have available to us, the strongest evidence of medical efficacy that's available to us. And this is an example of four trials in prostate cancer radiation treatment that have been published over the past few years. And the message here is -- is simple, the -- the higher the radiation dose to the prostate gland, the better the outcome for patients. And so, this is very strongly supportive of the fact that these kinds of technological advances are very, very important.

And if I were to summarize as a physician where I think things are right now, we have amazing radiation treatment technology that's continuing to evolve at a very rapid pace. The equipment that we have available to us now is extremely effective and reliable, thanks in no small part to our medical physics community that has gone to the extent that John has talked about to develop these quality control procedures to assure equipment performance. And from my perspective and I think from many in the community, the biggest challenge right now is not necessarily in terms of equipment performance, it's in the challenges associated with how we integrate that technology into the routine clinical care of patients with cancer, integrating advanced technology into clinical practice, and we'll talk a little bit about that over the next little while.

And this is shown here, it's just highlighted here, these are data that were published a few years ago from the Ottawa Cancer Centre here, Ottawa Cancer Clinic, looking at radiation treatment incidents that affect patients. So these aren't safety incidents

necessarily in terms of the public or workers, these are things that happen unexpectedly to patients in the course of their routine care, and these are root causes for these things from the group here in Ottawa. And you can see that equipment malfunction or performance problems really account for less than 5 percent of all of the things that affect patients in our clinical practice. Most of the errors, most of the incidents really come back to policies and procedures, failure to follow policies or procedures, or a lack of a policy and procedure in place to describe a particular scenario.

Radiation treatment, as -- as we have alluded to previously, is becoming very much more complex as we speak. Our patient populations are more complex. We're seeing patients with different medical problems. Radiation treatment itself is a complex multistep process, from -- from the decision to treat with radiation until the last radiation treatment fraction is delivered. There are very, very real professional interdependencies that I've talked about.

We're also in an era right now where things are evolving quite quickly, so

research and innovation is always a constant aspect of what we do, and -- and integrating clinical care with -- with research and innovation can be a challenge.

And of course we're always under pressure to see more. The -- the problem of cancer is not going away. Radiation treatment is effective. And so, our volumes are rising all the time. So we're always under pressure at almost every centre across the country to see and treat more patients.

This is an example of some of the clinical problems at that we now face. The technology is there; the technology works, and we can target very precisely, but some of the things we're struggling with as -- as professionals is where is the tumour that we want to treat? One would think that would be a very straightforward thing to answer, but in reality it is very, very challenging sometimes. This is an MRI scan of a woman with cervical cancer and you can see a large cervical tumour here, but the question of whether -- where the microscopic disease is, whether there's little bits of cancer extending beyond the big lump that we can't detect with

current imaging is a real challenge. PET studies are also becoming more and more useful in this regard, but the issue of target identification is very real.

Once we can see the target, there's also not a lot of agreement among expert radiation oncologists -- I'm sorry, if I can go backwards here. Whoops. If we can even ... Here we are.

In the middle there, if we can even see a big lump of cancer, there is not agreement among radiation oncologists as to what constitutes a relevant volume. The slide in the middle there are from 20 world experts in the treatment of gynaecologic cancer who were asked to just identify what they would treat in a particular patient with cervix cancer and you can see the degree of variability. So despite our ability to target these tumours very precisely, the uncertainty rests more with clinical understanding of how to integrate that technology into practice.

And finally, tumours move around inside the body, they're not fixed in one spot. So we can target something precisely, but if we

target it today and tomorrow it's in a different position, we've lost the battle potentially and we need to account for those kinds of uncertainties.

This is a process map of a typical radiation treatment delivery stream and it shows just the complexity and the number of steps involved in delivering care from the first decision to treat with radiation until the last fraction is delivered. And -- and obviously a lot of points along the way where problems can happen that can directly affect the quality of care that we deliver to patients, and this is the kind of thing that the radiation treatment team addresses and deals with every day.

At the end of the day, if we had multiple resources, infinite resources available to us, we would deal with this without any challenge, right? We would actually throw money and people at it and the problem would go away. At the end of the day we don't have that. We're always balancing priorities. We're balancing clinical workload with quality and safety, and with complexity and innovation. And if you tug too hard in any one of those directions, sometimes that's when we get into problems in terms of

quality and safety.

And this is illustrated here. We often think of quality and safety as errors, problems that happen that can be quite extreme that sometimes make the -- *The New York Times* for example, but the quality issues in relation to radiation are much more subtle than that. And this -- these are patient survival curves from a study of patients receiving radiation, curative radiation for head and neck cancer. The three curves on the top that are very tightly clustered together are curves from patients who had high-quality treatment, "high-quality" defined by peers who looked at the radiation treatment plans and either found a problem and saw that the problem was fixed or the plans were good from the start. The red curve, where survival of those patients is significantly impaired, is from patients who had some kind of problem with their treatment plan from the start. And you see there is a 20 percent difference in this case local control, the ability to control the disease with radiation.

So these kinds of issues that we struggle with around target identification and

planning issues are very, very important and they really are -- to my mind really are the challenge these days, not so much equipment performance as we move forward.

So the Canadian Partnership for Quality Radiotherapy as one of their initiatives came together a few years ago and put together a document of quality guidelines for radiation treatment programs that really summarize what we think are important measures that should be in place at all programs across the country to assure high quality and safe treatment. Not only are there guidelines, there are indicators associated with these guidelines that programs can use to measure their own performance in relation to others, for example. These guidelines incorporate CNSC safety guidelines as part of this. There was a strong attempt to do that. And it's been through a couple of iterations now with community consultation. Version 2 was released back in September. It's now available in French and English, and it's available on our Web site and on the CARO and COMP Web sites as well.

It really addresses all of the steps at a programmatic level and a

patient-specific level that are involved in -- in high-quality and safe radiation treatment, including radiation safety, as you can see there. And it's meant to also be compatible with other things that are going on internationally. We're not here to reinvent the wheel. We want to -- we want to build on other international activities and really develop something for Canada that is best practice based on those and unique to the Canadian environment.

This is an example of one of the quality indicators that -- that really speaks to the requirements of -- of CNSC and other regulators in the country to maintain a radiation safety program and there are other indicators like this in the document.

And there are other higher level indicators that really focus on patient-specific quality of care. In -- in this case the concept of peer review, the concept that I as a radiation oncologist can develop a treatment plan for a patient in conjunction with my medical physicists and radiation therapists. But if I identify the target incorrectly, if I make an error upfront, it propagates through the system and the patient can

be treated incorrectly. So now, across Canada, there is a very strong thrust for radiation oncology peer review, so all of my treatment plans that I define are reviewed independently by a colleague. At our place, we do this in the context of a rounds every week where we sit down and talk about these plans.

And I actually think that this has really elevated the level of care that's provided to our patients.

And as I've said, it's being rolled out nationally across the country.

It is not so much about finding errors. We know that major errors in this context are about five percent, things that really are wrong and need to be changed before the patient is treated.

It's really about a culture of discussion and learning and growing our understanding of how best to provide care to patients in a changing environment when technology is changing and how we work as a team is evolving.

One of the things that we've been looking at is how to make this sustainable going forward, and we have developed a partnership with

Accreditation Canada.

Accreditation Canada has a program that accredits hospitals and cancer programs across the country, and there are cancer-specific accreditation modules that Accreditation Canada has.

At the present time, there is actually nothing specific to radiation treatment embedded in Accreditation Canada Qmentum program, and we've been in discussions with them and now have an agreement to move forward with Accreditation Canada to actually build a radiation treatment specific Qmentum module that will address some of these concerns and really take them to the next level in terms of sustainability going forward.

We're hopeful that this will be in place, or at least a beta version of this will be in place, within the next 18 months so that cancer programs going through accreditation after that will have this -- will be subject to this kind of scrutiny as well.

And I now would like John French to talk about the next section.

MR. FRENCH: John French, for the

record.

So despite best efforts, occasionally mistakes do happen in health care. This is an illustrative example, and you can see here where a patient received a high radiation dose to a part of the body that was not actually impacted by cancer at all, okay, so obviously that's an unfortunate thing to happen.

And occasionally, we see these incidents break out in the news, and these are all headlines that came out in the "New York Times" two or three years ago -- actually, four years ago now.

So there's increased awareness about radiation therapy incidents and the danger they pose to patients. One of the ways that we are trying to address that is actually by developing a national incident learning system so that we can all learn across Canada from mistakes that happen at any cancer centre.

Some of the benefits of this is that we'll be able to learn from our mistakes on a country-wide basis as opposed to currently what happens, which is we learn on a centre-by-centre basis, okay.

That learning will lead to, actually, hopefully, preventing similar incidents happening elsewhere. It provides an opportunity to harmonize practice across the country, okay. Learning about the incidents that we face can help drive improvements in technology, it can build system resilience in terms of our understanding of how to make the system less error prone, okay.

It helps promote collaboration around the country between our various practitioners, okay, and also fosters transparency. We need to be open about things that do go on in medicine, and this is one means of doing that.

It's not actually an easy thing to do, and there are certain challenges that we face in doing this. One is in terms of defining the actual scope, what constitutes the type of incident that should be reported and learned from nationally.

A second is taxonomy in terms of how do we actually describe the incidents that occur in a language that is understood by everybody in clinical practice.

Another issue is in terms of

establishing how we classify the severity of incidents, okay, and this can be challenging in radiation therapy because some of the side effects in patients may occur early on or in an acute phase, some may occur many, many years after the radiation has been delivered and in a late phase.

There's issues around privacy and confidentiality of patients, but also of providers and people in the system. We need to create a system that's compatible with systems that are used at the local level so data and information can be transferred both ways.

There's issues around who owns the data and how people access that data, okay. And we need to foster a culture of trust and disclosure which will mean that people will actually disclose incidents as well.

There's many, many efforts going on internationally around this, so consistent with what we're trying to do in Canada.

In the U.S.A., national incident learning system is part of the ASTRO Six Point Action Plan and they've actually tested a prototype using their taxonomy.

In Europe, there's systems like

ROSIS, SAFRON, which has been developed by the International Association of Atomic Energy, PRISMA from the Netherlands.

There's a reporting system in the UK and a reporting system in Australia.

Efforts have been based around collaborating with CIHI, and we've had actually some very, very good and productive discussions with them at this point in terms of constructing a national incident learning system, okay. That's well on the way to fruition, and we're optimistic that it will be in place either by the end of this year or early next year.

We also know, of course, that incidents have an impact on patients, and through organizations like the Canadian Patient Safety Institute, we understand what patients want when an incident happens, okay.

And what patients actually want is they expect their health care providers to explain what happened, apologize that it happened, help us, the patients, understand how and why it happened, explain what will happen next and enable us to contribute by including us in the fact-gathering process.

This really speaks to the need to actually engage patients in the process of care, not just when incidents happen, but during the normal pattern of care, okay.

And that's another area that CPQR is working on, is looking at how we can best and better engage patients within various elements of radiation delivery, okay, and that includes the point of care, which is patient involvement and participation in processes where they integrate information and professional advice about their own needs and their preferences and abilities to optimize their own health on a personal level.

It also speaks to the patient's informational needs, the need for informed consent and what that requires in terms of information and understanding, how best we can communicate with patients, the concepts of shared decision-making.

There's an ethical element, too, to this. There's issues around disclosure and how we tell patients and to what extent we tell patients the things that have happened during the course of their care, how we handle patient complaints, how we measure and evaluate patient satisfaction with care and how we look at the

outcomes of care, particularly from a patient perspective.

Patient engagement also happens at a programmatic level, okay, and that's the extent to which patients are involved and able to participate in designing health care facilities and programs.

An example of this is work that is going on at Princess Margaret Hospital, where they use patient focus groups and surveys to actually help design part of the facility there.

And then we need to involve patients more at the national or the systems type level, okay, and that includes work that's going on in the CPQR in terms of involving and participating patients on national committees and in various working groups that we have, so at the moment in the CPQR, we have patient representatives on our CPQR steering committee, but we also have a patient advisory group, okay.

And adding that voice to the work that we do, I think, has really informed us and helped us grow in terms of what we've been doing.

So part of our patient engagement initiative is to incorporate a patient perspective

as an integral component or part of all of our CPQR activities, to develop and validate patient engagement indicators that will actually guide radiation therapy programs nationally in terms of how best to engage patients both in the immediate process of care, but also in developing their programs, okay, and conduct and uptake and gap analysis to determine how feasible it is to actually implement these indicators, okay, and what the difference is between what we believe we should be doing and what we're currently doing nationally.

MR. SCHREINER: So back to me, John Schreiner, for the record.

We thought after we've explained some of what we do to make sure that the patients are safe, we want to also have a bit of discussion with you that we do maintain a safe radiation safety environment for the workers and for the general public in the hospital.

So it pretty well works out if that if you are looking to do high quality optimal care for the patient that that's usually consistent with making sure that you keep workers and the public safe.

And we -- as we've explained, we think that there are ways that we can improve the radiation treatment quality and safety in Canada and the community is engaged in that work.

From a regulatory perspective, everything that we've explained to you up to now is done in an environment that is -- has been designed to ensure that it's safe for workers and for the general public, and this has been able to be done by a long-standing collaboration between clinic licensees and the regulator and the teams that we work with, especially in cancer centres with a Class 2 division that we work very closely with.

And generally, we do quite well. We do adhere with most of the radiation safety program initiatives that we are working with, but -- and we do maintain a safe environment. And I wanted to indicate that to you now.

Just an example of that interaction and communication was something that came up about a week ago where the CNSC was made aware of a potential contamination issue with a particular radiation device in an incident at one centre. Something had been observed that was a

little bit out of the ordinary.

Before any official notice was made, I received three emails from colleagues at the CNSC saying this is the flag that there's something out there and we might be coming back to you very quickly and asking you to do something.

And within less than a day, I think, we received a set of procedures that we were asked to run very quickly on this equipment, essentially swipe tests to make sure that there was no contamination on the units that we had in our centres. And within a morning of that request, we had responded very quickly.

So there is very good communication between the licensees, I think, and the licensing officers at the CNSC.

Next. Another thing I just want to point out here are some TLD badge readings for workers in the clinic.

And these are lifelong readings. You might not be able to read them from that distance. But we have people here that have been working for 25 years in the clinic, and they're getting less than a millisievert lifelong reading.

I can vouch for my reading. One

of the readings on there is actually my record after 27 years of being in the clinic. All of that dose that was on the record actually was previous to me coming in to a cancer clinic.

I have never had anything added to my dose in all my years of working in the clinic, and at one time I did a bit of brachytherapy, so I was actually clinically engaged.

Next slide.

Are we always doing as well as we can't? No.

And there was a very nice article by one of the officers from the Class 2 division, Mike Heimann, in the recent newsletter of the Canadian Organization of Medical Physics where he gave a little bit of a breakdown of things that sometimes do go wrong when we are not in compliance.

And the one thing I just want to point out is something that Mike indicated earlier is the big orange breakdown is, again, breakdown in using procedures or not having procedures and varying from the radiation safety procedures that you have and that we have in our licence. And those things do happen occasionally.

So again, we believe that because we are trying to maintain a high standard for the -- for our patients that we are inherently doing -- maintaining a high standard of care for the workers and for the public.

But as I hope you will appreciate, sometimes some of our attention is at patient-specific care. We are very focused, at times, on the delivery of high standards of care to the patient, particularly because if there are incidents, they can have severe ramifications.

And so it might look, occasionally, like our concerns diverge from the concerns of the regulator. I don't think that is really a case.

Occasionally, we are not focusing on some of the regulatory aspects as much as you would care for us to do, but I think we do a very fine job and I think how we can strengthen our work together is that we continue to collaborate and we continue to have licensees, radiation safety officers in the clinic and members of the Class 2 division interacting continuously to see how we can continue to work well together so that we assure that the patients, workers and public

are safe in our facilities.

MR. MILOSEVIC: Thank you, John. Mike Milosevic, for the record, just to finish off.

As John said, I think almost in 95 percent of circumstances, a focus on patient safety equates to a focus on public safety and worker safety, and vice versa.

We do sometimes see apparent divergence, and I think one of the ones that is really being discussed a lot now is this concept of prostate brachytherapy, interstitial seed brachytherapy. This is extremely effective treatment for selective men with prostate cancer where radioactive seeds are inserted into the prostate gland and, typically, 100 seeds or thereabouts in a pattern that delivers dose in a very uniform manner in a very high dose to the area of concern and very low doses to tissues around it.

You can see on the right-hand side there a typical disease control curve for over 1,000 patients treated in this manner, and it's very, very high. It's extremely effective treatment.

The seeds remain there. They're permanent seeds implants. They decay over time, you know, with a half-life of a couple of months. And patients go about their business in a very straightforward manner.

What's emerged, though, is an interesting controversy around what happens to these men if they die, and when they die, and whether or not they can safely be cremated.

And there's now a policy in Ontario, a legislation in Ontario that basically says that any man that's had a prostate seed, a permanent seed implant or other implanted radiation source, cannot be cremated.

So you know, treatment that might be administered to a man for their cancer many years earlier which, from a radiation safety perspective 10 years later is irrelevant, is then influencing their end of life wishes and how they're managed at that -- at the end of life, and their family's wishes.

So I think this is just an example how we, in the medical community, need to work very closely with CNSC and other groups to actually resolve these issues so that the patient

perspective is always maintained, and we need to keep that front and centre.

We need to protect the public, obviously, and workers, but there are ways of perhaps dealing with this problem and other, similar problems that don't compromise any of the relevant outcomes for patients.

Again, it's very important, I think, going forward, for us to work together. This is a great opportunity today to come and speak to you.

I think that that's something that we would wish to further and have more opportunities in the future.

And the last thing I would say is that for anyone who would like more information about the kinds of things we've been talking about today, it's available on the CPQR web site. It's available on each of the professional web sites for radiation oncology, medical physics and radiation therapy, and you can speak to any of us here on this panel personally or any of the other members involved in this at any point.

Thank you for your time and for listening today.

THE PRESIDENT: Thank you. Very interesting presentation.

I wonder whether CNSC staff that organized this little gathering, are there anything -- say anything before we open up the floor for questions?

MS MURTHY: Kavita Murthy, for the record.

The purpose of this presentation was to provide the Commission with information because it has happened in the recent past that the Commission has asked us questions about how the radiation safety of patients is controlled in Canada, so we thought rather than us telling you what is being done, we were aware of the initiatives going on in the industry and so that's why we wanted the practitioners to come and tell you.

Thank you.

THE PRESIDENT: Thank you.

I understand also we have Mr. Daniel Yoon from Health Canada who's available here if we want to ask them -- Health Canada some questions.

So we'll start with -- can you

hear me, Mr. Yoon?

MR. YOON: Yes, I can.

THE PRESIDENT: Okay. Thank you for being with us.

Monsieur Harvey.

MEMBER HARVEY: My first question would be addressed to staff, just a quick answer.

You monitor the radiation everywhere in Canada, but do you have something to do with the equipment itself, I mean, to the nature of the dose, the -- what part of the regulation touch that point because I heard that the doses are sometimes important, so how do you monitor that?

MS MURTHY: So all radiation therapy equipment that is approved for use in Canada has to first have a medical device licence that is issued by Health Canada.

The part of the process that -- part of the review, I believe, includes how the machine is going to deliver the dose and how, exactly, it is going to work.

We do have a role to play in the certification of the equipment as well, but the primary -- if your question is related to patient

dose delivery, that would be under the mandate of Health Canada.

I'll ask my colleague from Health Canada to add to this, if anything.

MR. YOON: Yeah. So as was mentioned, all machines that deliver doses do need to be licensed by Health Canada. The data that is submitted in the application, the manufacturer must show that they comply with the safety and effectiveness requirements laid out in the medical devices regulations.

And our scientific staff review that data, and if it's acceptable, then we will issue a licence and the device can be sold in Canada.

MEMBER HARVEY: Thank you.

Okay. I will turn to you.

MR. MILOSEVIC: May I supplement that just by saying that, in addition to the manufacturer's specifications and assuring that the machines are designed to perform in a particular way, there's a lot of effort ongoing to assure that they maintain calibration and maintain performance over the lifetime of the equipment.

One of the -- and John can comment

on this much more knowledgeably than I can, but one of the quality indicators, for example, is that machines, on a periodic basis, have independent testing of their dosimetric output to assure that we're delivering doses that we believe we're delivering in individual situations.

MEMBER HARVEY: What is the variation in the dose, maximum and minimum or average?

MR. SCHREINER: So when we calibrate our units, we ensure and then we have -- John Schreiner, for the record.

Then we have tolerances and action levels. But in our primary calibration, which is -- has to be traceable to a standard slab, we make sure that the doses that we are delivering are within one percent of the -- that the output of the machine is set to one percent. In fact, we go better than that, to about half a percent.

So the doses throughout Canada are all referenced to outputs that are -- can be traced to the National Standards Lab.

As Michael said, we also have -- annually, we do our -- periodically, and I'm just going blank on the second at this time -- we

independent checks where we have a body, in this case from the United States, who send us dosimeters that we irradiate to standard configurations and then we bring those dosimeters back, and they ensure that we are delivering doses.

Because of the nature of the dosimeter that they're setting, they set a limit of about five percent, but we actually -- most centres in Canada do much better than that limit, if that is what you're asking.

MEMBER HARVEY: Okay, thank you.

THE PRESIDENT: Just to follow, I want to -- so Health Canada approved the device, right, what does CNSC then does? Is Health Canada come first; right?

MS MURTHY: Absolutely. Health Canada's requirements kick in before the machine can even be advertised in Canada. So they have to have medical device licence. Even to bring it to trade shows here, they have to get an exemption from Health Canada to bring them in.

So there's a pre-market requirement that Health Canada has, and then a medical device licence that is required in order

for that equipment to be allowed to be used in Canada on human beings.

The certification of the equipment that we do looks at a small part of the device's operation and looks focusing specifically on the safety interlocks and aspects of the unit that can affect operator and public safety. So there is a little -- there's a little part of it that we are responsible for.

And our requirements -- the CNSC requirements are that in -- if an equipment is to be used in a clinic, it has to number one, have Health Canada licence. Number two, have CNSC certification, and a licence to operate. The licence to operate is not given to the manufacturer. It is given to the operator.

So, basically, a review of the facility itself into which the equipment is going to be installed, to make sure that the facility is constructed properly, that all the safety systems function, and that there are procedures in place to make sure that it will continue to be operated safely.

THE PRESIDENT: I always worry about, when there's too many regulators around. I

want to hear from you guys whether it's working well because, I assume, somewhere along the line, Ministry of Health come into play somewhere. And I don't know who else is overseeing this part of the treatment.

MR. SCHREINER: John Schreiner, for the record. The provincial ministries of health often have radiation groups associated with them and inspection bureaus, and in Ontario we have HARP, the Healing Hearts and Radiation Protection group.

They are more concerned with radiation devices and diagnostic imagining, the imagining x-ray units and such.

The purview of linear accelerators under the regulatory oversight is from the CNSC, partially because the energy of these units is sufficient that there can be some activation of the units, and so, historically, the high-energy units that we use in the cancer clinic are mainly under the direction of the CNSC.

One thing I also wanted to point out is, the community has set a number of guidance documents that direct what kind of precision to dosimeter that we need and what kind of quality

assurance we have to do to ensure ourselves that the machines are operating correctly, that they're giving the doses correctly.

And there are -- in our guidance documents that we were referring to earlier, many of them are machine-specific guidance documents that specify the tolerances; the frequency for the test; the type of tests that we are expected to do, to ensure ourselves that the machines are giving the doses that they are intended to give to the patient.

So that was on -- in the past, often loose guidances through task groups and from the American Association of Physicist Medicine; guidance documents from the IAEA.

But in our community now, part of the drive for these technical quality assurance guidelines was to, actually, as a community come together, have an accepted standard of what we said the community has to achieve, and maintain that standard.

And so all cancer centres now are expected to do -- have their quality assurance activities and their tests according to these guidance documents.

THE PRESIDENT: Okay. Ms Velshi.

MEMBER VELSHI: Thank you. Thank you very much for a very informative presentation.

Do you see opportunities for learnings between industries, so radiotherapy to others, or from other nuclear industries to you, whether it's in dosimeter, whether it's in incident reporting, or investigation, or training, things like that, and do you share that?

MR. MILOSEVIC: I think the answer is yes to that. And a good example of that is the COMP Winter School on Quality and Safety, which has been running now in Canada for the past several years.

It's organized by the Canadian Organization in Medical Physicists, and it brings together experts not only in radiation treatment, but they bring experts in from other disciplines to talk about quality and safety issues; so from the airline industry, from other aspects of the nuclear safety industry.

And it brings a different perspective on what we do. It brings a different perspective to our discussions about things.

And I think that series of

meetings was started, five or more years ago now, with the intention that it would run for a finite period of time. And these meetings often have a lifetime associated with themselves.

This thing has just grown over time as the community has found it incredibly valuable.

And so, I think, that's an example of how we are working to learn from people in other industries to strengthen what we do as users of radiation.

MR. SCHREINER: John Schreiner, for the record. Just to give an indication of the success of these meetings, we are actually now getting attendance from industry to these meetings, and also, attendance from colleagues in other countries, who have now seen this as somewhat of a unique venue where safety and quality assurance is discussed.

And the attendance is actually blossoming way beyond what we had dreamt of in the early days when we thought it was a small Canadian meeting, where we were discussing something that we all felt strongly about, into something that a lot of our colleagues in the industry and in the

clinics worldwide are seeing as a unique event.

MS MURTHY: And if I just may complete that. Because this initiative has received funding support from the CNSC consistently since it started -- it continues to do so -- we have recognized the value that it has brought to the sector in general, and with the philosophy that an improvement in safety culture in one part of the industry is going to have a ripple effect on the parts that we are most interested in, we have supported this mission.

MEMBER VELSHI: Thank you.

Do you do any epidemiological studies on your patients, not so much on their survival for their -- whatever treatment you're giving them, but because they're getting these high doses to perhaps other parts of their body, and for the impact of that?

MR. MILOSEVIC: Mike Milosevic, for the record. We would like to follow all of our patients as long as we possibly can. And that's an aspirational goal that CPQR has identified. And we follow them in relation to cancer control. And we follow them in relation to side effects of treatment which can happen many

years afterwards.

And one of the side effects that we are particularly concerned about, particularly in young patients who receive radiation, is the possibility of second cancers developing within the irradiated volume or close to an irradiated volume.

And there are well-defined studies that identify that as a risk. And it varies as a function of many, many factors, including the primary diagnoses; pre-existing circumstances in relation to a particular patient; how radiation is delivered and whether it's delivered in combination, for example, with chemotherapy. And patients are advised of these risks in advance.

The risks are relatively small over time. And, of course, someone with a life-threatening illness today, first of all, has to survive their cancer diagnosis right now in order to be at risk of having those kinds of situations develop down the road.

There is also ongoing work and an ongoing interest in developing new strategies for mitigating those sorts of issues as we move forward, for mitigating the risk of second

cancers, for example.

That work is in its infancy, but is really being done in conjunction with some of the work that -- and some of the interest in radiation protection in general around exposure to radiation in other circumstances.

THE PRESIDENT: I'd like to follow-up because there's an irony here, particularly since you also are concerned with some of the misinformation circulating about radiation.

We are always facing with a view that background radiation is killing the population. Maybe that explains -- some people like to believe that the increase in cancer is because of background radiation. And Fukushima, of course, is now poisoning everybody.

Do you have a comment about this, because the one community that still has institutional trust by the public is the medical profession; you haven't lost that yet?

So I'm just wondering whether you take upon yourself to try to rebut some of the misinformation, because the level of, you know, of ignorance about some of the radiation is really

amazing, even though you are in a completely different place with the high dose, which interesting, the public accept as an instrument for their benefit, whereas the low dose, they don't accept at all?

MR. MILOSEVIC: Yes, I think you're quite right. It's an interesting dichotomy in some regards.

And as oncologists, most often we're not in a position to talk about those sorts of things. We're talking about the side effects of high-dose radiation, with the exception of the second cancer story.

It actually -- it did come up around the time of Fukushima in relation to why we can use therapeutic radiation in patients. Why some patients are cured of their cancers. Whereas, you know, there's this concern around that time about low-dose exposure and the development of cancer.

So it was an interesting discussion that we had with members of the media, for example, at that time, around how that works out, and risk benefit to patients, those sorts of things.

I think, in general, our community needs to do a better job of educating patients and their families and the public in general about radiation, the benefits of radiation, and how radiation can be used in a very safe manner if it's controlled appropriately.

And that's, generally, how we have positioned this.

MR. SCHREINER: As a radiation safety officer in a clinic, I often get asked by a physician to have a chat with a patient who might have a concern that their cancer was because of something they had heard about some exposure in Deep River or whatever location they are at.

I've also had the opportunity a few times to correct a misperception that the Canadian Nuclear Safety Commission doesn't take their role seriously, and have been able to state that, as a regulator, I know that I am held to very high standards by the regulator, and that I believe that you take radiation safety quite seriously.

So in some of my advocacy it's not just been about radiation safety because of exposures, but it's also been to assure the public

that the Canadian Nuclear Safety Commission takes their role very seriously, and regulate our hospital, at least, to extremely high standards.

THE PRESIDENT: Thank you.

Mr. Tolgyesi.

MEMBER TOLGYESI: Merci, monsieur le Président.

On the slide -- I am sorry, which one was that -- when you were mentioning what's the rate of -- here -- radiotherapy incidents, you were mentioning that it's less than 5 percent, which is due to equipment.

But could you tell us, what's the proportion of incidents compared to the total treatment, because, you know, 80 percent is policies and procedures, but what's the proportion? I mean, it's -- these incidents are 10 percent of total treatment, 5, 25? I don't know.

MR. MILOSEVIC: Mike Milosevic. Probably 1 percent of patients who come through our centres, maybe a little bit more than that, experience either a near miss or an incident.

We define a near miss as something that -- an error that has happened that is

detected by our normal quality control measures before it actually reaches the patient. And so the consequences of that are minimized.

Things that actually reach the patient, for the most part we classify as minor. In other words, they have no consequences to the patient at all.

The proportion of incidences that actually reach the patient and have some kind of medical significance either today for that patient, or the potential for something happening down the road in terms of late complications or late side effects, is actually extremely small.

And, roughly, in our clinics, about three or four -- the near miss to incident rate is about three times, four times. So we try to learn from those near misses and build system resiliency to prevent errors from happening and propagating through to patients.

MR. SCHREINER: John Schreiner, for the record. And I'd also like to say, although we've told you today about a relatively new initiative for this national incident reporting structure, incident reporting has been inherent in radiation programs since as long as

I've been in my career.

So in our centre we have had a technical quality assurance committee that meets quarterly, that reviews all incidents that have happened to patients in our centre. And we've been doing that for the 20 years that I've worked in that centre. So it's just inherent in our culture.

The incident reporting structure is a no-fault reporting structure. Our staff are very cognisant of the importance of making sure that all incidents are reported because we all know that people do make mistakes.

We learn from our mistakes, and we have actually changed some processes and some procedures in our clinic based on these incident reports, where we were able to identify that some corrective action should be taken.

THE PRESIDENT: Are you required to report such incident to Ministry of Health?

MR. SCHREINER: John Schreiner, for the record. Cancer care Ontario has an incident reporting structure now, and we are required to report all incidents of a certain level. And these are reviewed, actually,

provincially, also.

THE PRESIDENT: Mr. Tolgyesi.

MEMBER TOLGYESI: When you're looking -- you know, you were talking about these surgery, radiotherapy and chemotherapy. To what extent the radiotherapy as such is sufficient as a primary treatment or, eventually, as a part of a treatment, because, I suppose, you do a surgery and you could do after radiotherapy, and what's success?

MR. MILOSEVIC: Radiation treatment factors into the care of about half of all cancer patients, patients who are diagnosed with cancer, either immediately or at some point over the course of their illness.

Sometimes it's radiation treatment alone. Although, increasingly, it's radiation treatment -- if surgery is not appropriate, it's radiation treatment often combined with some form of chemotherapy.

So head and neck cancer, cervical cancer, lung cancer, bladder cancer, a number of tumors of that ilk are treated with a combination of radiation and chemotherapy with curative intent.

And the other advantage of radiation treatment, in some of those circumstances, compared to surgery, is that radiation offers the potential of preserving normal anatomy and function.

So in situations where there is equally -- where surgery and radiation treatment sometimes have equally good outcomes for patients, we will defer to the option radiation treatment, for example, where we can preserve normal anatomy, normal function for the patient, always realizing that we can fall back to surgery if we need to.

The success rates vary a lot depending on how advanced the cancer is when a patient presents.

And it varies in some tumors from success rates that are quite low, if they've got very advanced cancer, to success rates that are 80 percent, 90 percent in situations where the tumors are detected at a very early stage and are quite localized.

So there's a number of patient-specific and tumor-specific factors that come into play and modulate that.

THE PRESIDENT: I'm sorry, I got

to do a time check because I'm told one of you has a train to catch at 6:10.

You are -- this is a high-risk move now. If you're going to make it, you better move now.

MR. FRENCH: (Off microphone) taking the time to meet with us. We appreciate it.

THE PRESIDENT: You're welcome. Feel free, we can keep you here the whole night, I'm sure.

Anybody --

MEMBER TOLGYESI: I have just one last, you know --

THE PRESIDENT: Please, go ahead.

MEMBER TOLGYESI: Here we are talking about technology. You know, technology is progressing, evolving. And we are looking the number of cancers -- the cancer rate in Canada is increasing, like worldwide.

What you foresee as a need, because you have a workforce? First of all, you need somebody like you, gentlemen. Other one is facilities. And third one is, what do you expect as a technological development, you know, what you

foresee to improve -- to speed up processing treatment?

MR. SCHREINER: John Schreiner, for the record. I wouldn't be able to predict that at all because we are doing things today we didn't even have words for five years ago or six years ago.

The technology moves extremely quickly. I mean, there are all kinds of technologies out there; proton therapy, carbon therapy. They have their roles. They are sometimes very expensive.

Will they be throughout all of Canada? I suspect that would be a struggle.

But to really try and put a crystal ball and tell you where we're going to go, I don't have that expertise. I've only been in the field 25 years, so I don't know where I can tell you where we should be going.

And the other thing I've learnt is never to say that will never be done because we are doing things today, for example, image guidance immediately before we treat the patients, and on some machines, image guidance while they're treating the patient, that we didn't even -- we

thought that was foolishness when we talked about it years ago.

So, sorry, I can't give you an answer there. And that was a long answer for saying I don't know.

THE PRESIDENT: Can I try one more time to put you on the spot, because the government did invest in cyclotron for producing isotopes. I don't know if you guys are getting involved in this.

But you have any views about some of the using isotopes for targeting, tracing, all of the above?

MR. SCHREINER: I think there's a lot of future there, and I think the excitement of using new approaches to making some of the isotopes are very, very exciting.

I do hope, though, that we continue to support the NRU, which makes one isotope that I still think is important worldwide which is Cobalt-60. And I am hoping that we always will have a source of Cobalt-60 to continue.

I think one of the -- actually, to go back to my last answer to you -- one of the

things I think the community will do is start to find ways to make radiation therapy more available throughout the world.

And that is a big challenge for the whole world, but I think it's a challenge that many of us are beginning to think of here in the developed countries because we do believe there is a role for radiation therapy.

And if you look at the amount of people worldwide who do not have access to this treatment modality, it's very concerning.

MR. MILOSEVIC: If I may just supplement that. Mike Milosevic. I think that, first of all, as we move forward, there's the technology side of it. There's also how we integrate that technology into practice.

And from a physician perspective, from a software perspective, how we actually develop smarter tools to allow us to use that technology in an optimal way at a patient-specific level.

So things like automated identification of organs that we are concerned about in terms of radiation toxicity, and automated identification of tumor targets, will be

something that will be very valuable, particularly if we want to try to begin to adapt treatment over time to changing target volumes or changing anatomy as radiation progresses over the course of several weeks.

PET tracers, radionuclide tracers that can be used for imaging targets, I think, is very, very important going forward.

One of the things that we always have to remember is, when we use radiation, we're actually using a very potent biologically targeted treatment. We're killing cancer cells because of their inherent sensitivity to the effects of radiation relative to normal tissue.

So at the end of the day, it's a biological effect that we're capitalizing on. And understanding the biology of radiation response will be increasingly important to us going forward, and why tumors respond differently than adjacent tissues, normal tissues around the tumor.

And some of these new biological imaging modalities that are coming out, molecular imaging techniques with different PET tracers, I think will be very informative, coupled with laboratory studies of radiation response

assessment that are ongoing.

THE PRESIDENT: Thank you.

Any further questions?

Okay, thank you.

You have the last word and you may want to use -- if there's anything you want from the regulators, two of them, there's Health Canada and us, now's your chance.

MR. SCHREINER: John Schreiner, for the record.

I think what I would like is that we maintain a strong desire to continue to communicate together.

Over my career, I've seen the interaction between the regulator and licensees in the clinic improve considerably and I think it's in part because I believe the CNSC has done a lot of work to make the people that interact with us aware of the pressures and the environment that we work in, in health care, and I think that's extremely important, and they recognize some of the challenges that we have and they want to work together with us.

I have surprised older Radiation Safety Officers sometimes because I will

communicate with my officer at the CNSC with a silly question, and they've always said to me, "You should never ask the regulator a silly question, you look silly." And I've always thought it's part of my trying to understand what the CNSC expects of me and I've always appreciated that my officer has not berated me for my questions but has been willing to answer and work with me.

So, what I would ask of the CNSC is that they continue to work with our community.

THE PRESIDENT: Thank you. Thank you very much. And keep asking those questions please.

MR. SCHREINER: Okay.

--- Pause

THE PRESIDENT: Okay. While we are setting up for the next presentation, let me go through some housekeeping.

CMD 14-M21.A

Adoption of Agenda

THE PRESIDENT: The first thing is I'd like to call for the adoption of the Agenda

for the meeting. Do I have concurrence?

Okay. For the record, the agenda is adopted.

CMD 14-M22

**Approval of Minutes of Commission Meeting
held March 27, 2014**

THE PRESIDENT: And I'd like now to call for the approval of the Minutes of the Commission Meeting held March 27, 2014, as outlined in CMD 14-M22.

Any comments, additions, deletions?

Okay. So, for the record, the Minutes are approved.

And I'd like now to proceed to the Status Report on Power Reactors, which is under CMD 14-M23.

Mr. Rzentkowski, the floor is yours.

CMD 14-M23

Status Report on Power Reactors

MR. RZENTKOWSKI: Thank you very

much, Mr. President. It's nice to be back.

Members of the Commission, good afternoon.

My name is Greg Rzentkowski and I am the Director General of the Directorate of Power Reactor Regulation at the CNSC.

The Status Report on Power Reactors before you provides the operational status of Canada's fleet of nuclear power plants that may be of interest to the Commission and the public.

It can be seen that the operation of all reactors is very stable and there were no events of regulatory concern.

Worth noting is that several units, including the Point Lepreau Station, are shut down for planned maintenance outages which are typically scheduled for 45 days. The frequency for these outages is every two years. During these outages a wide variety of maintenance and inspection activities are conducted.

I would also like to update the Commission on events that occurred since noon yesterday.

As reported in section 1.1 of CMD

14-M23, Bruce A Unit 2 was in an unplanned maintenance outage to repair a hydrogen leak of the turbine generator. Bruce Power has now completed the repair and reactor power is currently at 2 percent.

Pickering Unit 1 was manually shut down due to issues in a liquid control zone as per Standard Operating Procedures. As reported in section 1.5, Unit 1 was returning to full power after the manual trip due to loss of moderator level indicator. The event had no impact on the safety of the workers and the environment. The event was promptly reported to CNSC staff.

At Point Lepreau, approximately 100 litres of demineralized water was spilled on the roadway located insider of the protected area. New Brunswick Power staff took action to stop and contain the spill as soon as it was discovered. Samples showed that the water contained approximately 1 mg per kg of hydrazine. This event has been reviewed and determined to be not reportable. CNSC staff is providing this information to confirm that there was no releases to the environment and no impact on worker safety.

I have no further updates today to

the Status Report on Power Reactors presented in this CMD.

CNSC staff are now available to answer any questions the Commission may have. Thank you.

THE PRESIDENT: Thank you.

So, let's get into the questions with Ms Velshi.

MEMBER VELSHI: I have none.

THE PRESIDENT: Monsieur Tolgyesi?

MEMBER TOLGYESI: Nothing.

THE PRESIDENT: That's a first.

--- Laughter / Rires

MEMBER TOLGYESI: It's a challenge.

You were saying that --

THE PRESIDENT: Micro.

MEMBER TOLGYESI: Oh, I'm sorry.

There's a note that at Gentilly-2 there was flooding but there is -- because of a stoppage on December 2012 --

M. LEBLANC : Pour Gentilly-2, posez la question en français.

MEMBRE TOLGYESI : Ah! O.K. Bon, je reprends.

Considérant qu'il y avait une crue des eaux autour de la centrale nucléaire de Gentilly-2 et aussi dû au fait que le réacteur est en état d'arrêt depuis décembre 2012 et tout combustible a été retiré, quelles sont les conséquences, est-ce qu'il y en a, ces crues d'eaux ont envahi certaines installations souterraines qui pouvaient contenir certains contaminants?

M. RZENTKOWSKI : C'est clair. Merci beaucoup pour votre question. M. Benoit Poulet, le directeur de la Division de réglementation de Gentilly-2 va répondre à cette question.

M. POULET : Merci, Dr. Rzentkowski.

Pour l'enregistrement, Benoit Poulet, directeur du Programme de réglementation de Gentilly-2 et de Point Lepreau.

La crue des eaux a été causée par une rivière qui était située tout près de la centrale. La zone touchée visait plutôt la route d'accès et n'a nullement touché les installations de Gentilly-2.

Donc, c'était la route d'accès.

Il y a des mesures qui ont été prises pour faciliter le transport du personnel de la centrale, et aussi, il y a une digue permanente qui a été construite autour de la centrale, et cette digue n'a jamais été touchée.

MEMBRE TOLGYESI : Et ma deuxième touche encore Gentilly-2.

Cet incident avec l'électrisation de l'employé d'un entrepreneur qui, à l'extérieur du site, a touché la ligne, qu'est-ce qui est arrivé?

M. POULET : Benoit Poulet pour l'enregistrement.

L'incident s'est produit dans un camion. Alors qu'un employé déplaçait un contenant métallique, le contenant a été déplacé pardessus le fil électrique, qui a électrisé le contenant métallique, et les conséquences sont décrites là. L'employé a été transporté à l'hôpital pour une évaluation et a été retourné à la maison un peu plus tard la même journée, et il est retourné au travail à son prochain quart, à sa prochaine journée de travail. Donc, il n'y a eu aucune conséquence majeure sur l'employé.

MEMBRE TOLGYESI : Vous dites qu'il

a manipulé le contenant métallique sur le camion et il a touché le fil. C'est-à-dire qu'il était quelque part tout près des fils ou c'est le camion qui a touché le fil?

M. POULET : Non. Non.

MEMBRE TOLGYESI : C'est le contenant qui a touché le fil?

M. POULET : C'est le contenant qui a touché le fil. Le fil était... le fil d'alimentation était sur le plancher du camion, et le contenant a été tiré dessus. Ceci a brisé l'isolation du fil et a électrisé le contenant.

MEMBRE TOLGYESI : Le fil d'alimentation électrique qui est sous courant traverse la boîte du camion sur lequel on travaille. C'est quoi les procédures de travail? C'est supposé être comme ça ou...?

M. POULET : C'était un fil qui était... C'est essentiellement une rallonge électrique qui serait du même type qu'une rallonge qui serait utilisée dans un domicile, et puis le fil était là pour alimenter un chargeur de batterie qui était situé à l'intérieur du camion pour recharger les batteries.

MEMBRE TOLGYESI : Merci.

MEMBRE HARVEY : Ma question, c'est juste pour savoir quelle est l'importance de rapporter ça ici pour nous. Ça eu lieu à l'extérieur du site. Ça n'a rien à voir avec le nucléaire.

M. POULET : Benoit Poulet pour l'enregistrement.

L'importance, c'est que cet incident a été rapporté dans les médias locaux. Donc, nous voulions informer la Commission, donner de l'information à la Commission pour s'assurer que les faits étaient clairs.

MEMBRE HARVEY : O.K. Merci.

THE PRESIDENT: Anybody else?
Questions?

I just have one question on Pickering, on Unit 1. What I was wondering is the manual shutdown, so do we get a root cause? What's the root cause here?

MR. RZENTKOWSKI: Mr. Miguel Santini, Regulatory Program Director for Pickering, will respond to this question.

MR. SANTINI: Miguel Santini, for the record.

The cause for the first event, the

one that is reported in the Status Report, was determined it was a failure of a couple of valves on the relief valve -- sorry -- yeah, it's a relief valve. The valves were replaced and after this was corrected, the Unit was again set to critical on the -- started increasing power.

The second event, the one we just reported, occurred late yesterday. It's an unrelated event and has to do with a liquid zone, and that event, we don't know the root causes yet. We just have been informed about that. Perhaps OPG has more details.

THE PRESIDENT: OPG?

MR. PHILLIPS: Bryce Phillips, for the record, Senior Vice President, Pickering Station.

The event that occurred yesterday, yesterday afternoon, we had an indication problem with one zone in liquid zone system.

To set the context around that, liquid zone is what we use to control reactor power, both bulk power, you know, from zero to 100 percent and back, and also spatial power.

In one zone, Zone 1, indication went irrational, it went irrational low, and the

control system put water into that zone, thinking it was low in water level.

That indication is in the Control Room. The operators have procedures that they follow based on that.

So the Control Room certified staff performed as expected. They manually set back the reactor to shut down and as they got to about 2 percent power, which is the endpoint of a setback, they noticed that another zone was at anti-flood limits and they made a conservative decision -- because in front of them they could say that zone's normal operating, so I'm okay, or they could say, no, that's related to the Zone 1 problem.

They made the conservative decision and said it could be related, so they tripped the reactor, took the Unit to a guaranteed shutdown state.

And we're currently investigating to find the root cause. It's around instrumentation for that one zone. We have not yet got the root cause but I expect by the end of day today we will.

THE PRESIDENT: So we're going to

be informed of the root cause, right?

MR. PHILLIPS: Absolutely.

THE PRESIDENT: So I'm still -- on the first event, I was told just now that the first event is an independent event, right? So what was the root cause for the first event?

MR. PHILLIPS: You're correct, the first event is independent of the second one.

In the first event we were doing maintenance on some helium skids behind the station. That helium is used for many different applications. The one that it's most sensitive to is measuring calandria level.

When we were doing -- we replaced the PRV, the main supply, finished that successfully. We were moving to the backup PRV. When we did that, a valve did not fully open, it was stuck partially open, and the emergency supply PRV did not open and that caused low helium pressure in the system. And that gave indication to the Control Room of dropping calandria level.

Control system responded to that, operators saw that response, knew that that was outside normal operating conditions, so they manually tripped the reactor per their procedures

and their training.

The direct cause are the two valves, the manual valve that did not fully open, so it restricted helium flow, and then the backup supply PRV did not open to supply helium. That's the two direct causes.

THE PRESIDENT: So did you replace them, the valves?

MR. PHILLIPS: Both those valves have been replaced.

THE PRESIDENT: And the thing is working now?

MR. PHILLIPS: They are working.

THE PRESIDENT: Okay. Thank you.
Ms Velshi.

MEMBER VELSHI: So if that was the first event, and what I'm reading here was that the Unit was manually shut down following the loss of moderator system level indication, is that different?

MR. PHILLIPS: That's the event from a week ago. It was not manually shut down, it was manually tripped.

MEMBER VELSHI: Right, but it was manually tripped -- what you're saying is the PRV

not closing and the other valve, that's a separate event?

MR. PHILLIPS: The event yesterday was separate, that is correct.

The event I described on the helium supply, two valves on that supply didn't operate properly. That's all the one event from a week ago. A manual valve did not fully open and a backup PRV did not open.

MEMBER VELSHI: Right. So I know that was the event from a week ago.

MR. PHILLIPS: Correct.

MEMBER VELSHI: The one yesterday was on the liquid zone control one.

MR. PHILLIPS: That is correct.

MEMBER VELSHI: But the one reported here on loss of moderator system level indication is something different?

MR. PHILLIPS: No. That's the one from a week ago.

MEMBER VELSHI: Okay. So the week ago with the PRV not closing is the same one as this one?

MR. PHILLIPS: Correct.

MEMBER VELSHI: Okay.

THE PRESIDENT: Anything else?

Okay, thank you.

Are there any other information that you want to share with us because I see there is no Event Initial Report?

M. RÉGIMBALD : Oui, Monsieur le Président. Nous avons deux items à présenter. We have two items to present.

THE PRESIDENT: Okay.

MR. RÉGIMBALD: Can you give us just a minute or two so we can get organized? Thank you.

--- Pause

MR. RÉGIMBALD: Good afternoon, Mr. President. Again, my name is André Régimbald. I'm the Director General of the Directorate of Nuclear Substance Regulation.

This is in regards to an event that was reported to the CNSC on April 29, 2014, by a CNSC licensee operating a Flexitron High Dose Rate brachytherapy unit where the manufacturer (Elekta) service engineer detected removable contamination on the Flexitron unit while performing a routine source change. The licensee immediately suspended use of the unit.

I wish to emphasize at this point that this event is related to the equipment itself and has nothing to do with the safe licensed operations of the clinic where the problem was noted.

At this time, through analysis conducted at the CNSC laboratory, we have determined that the contamination is iridium 192, which is the same nuclear substance that is used in the unit. However, the manufacturer Elekta has yet to determine the cause of the contamination and where it occurred. A root cause investigation is under way.

As a precautionary measure, in the evening of April 29, CNSC staff sent an emergency notification by email to the licensees who have Flexitron units about this event, and on April 30th, the CNSC followed this up with a regulatory notice.

The regulatory notice was sent to all licensees who use this equipment and other similar equipment also manufactured by Elekta. It informed licensees of the event and required them to perform contamination checks on their units. None of these licensees have reported any

contamination.

CNSC staff has also notified Health Canada's Medical Device Bureau and the United States Nuclear Regulatory Commission about this event.

On May 1st, Elekta issued a notice to all their North American customers with the affected units to inform them of potential contamination problems with the units and provide them with instructions on how to deal with the problem if they encounter it.

On May 2nd, CNSC inspectors visited the clinic where the contamination was discovered and staff are satisfied that there is no contamination of the facility and that the contaminated equipment is safely quarantined.

All of this information is preliminary at this time. This is an Event Initial Report and staff will come back to the Commission in due course with more complete information on the matter when the exact causes and circumstances of the event will have been established and the manufacturer Elekta and licensee users will have put in place appropriate safety measures to prevent a similar problem in

the future.

Thank you.

We also have a short PowerPoint presentation to show you what exactly a Flexitron unit looks like and also a short video showing where the contamination actually occurred.

I'm assisted by Ms Kavita Murthy, who is the Director of the Accelerators and Class II Facilities Division, and Mr. Angel Licea, who is Senior Project Officer in Ms Murthy's Division.

Thank you.

So we'll go ahead with the video.

MS MURTHY: Kavita Murthy, for the record.

This fits in quite well with the presentation that we just heard from Radiotherapy because brachytherapy or brachytherapy is a type of radiation therapy.

Conventional radiation therapy, which is what our visitors were talking about a few minutes ago, is also called teletherapy because the patient is irradiated from the outside, with the source of radiation some distance away from the patient's body.

In contrast, in brachytherapy,

radiation is delivered to the tumour by placing a radioactive source in close proximity or sometimes inside the tumour site. The most common cancers treated with this type of therapy are gynaecological sites such as the cervix, the uterus, colorectal cancers, prostate and lung cancers.

Low dose rate, or manual brachy, uses low activity sources which are implanted into the patient permanently, and we also heard about that this afternoon.

So I just want to point out that anything that I'm going to be showing here are for the purposes of illustration only. It may not be exactly the same equipment that was affected in this incident.

In high dose rate -- what is high dose rate brachytherapy?

As I just said, in high dose rate brachytherapy, the therapy employs a very small but highly intense radioactive source, most commonly iridium 192, and uses robotics to remotely place the tumour at the treatment site. After the treatment, the source is removed and the patient is released.

A typical brachytherapy treatment source is about the size of a grain of rice. It has an activity of 10 mCi or 370 GBq and treatments typically last a couple of minutes.

So step-wise what happens is that the source itself is in a safe inside the unit, which is the unit you saw in the previous slide, which is what I have in Figure No. 3 on the slide.

So the patient is brought in, is positioned on the treatment bed, the treatment couch, an applicator is placed inside the cavity that is being treated and then using a transfer tube the equipment is connected to the applicator.

So in this case we are showing in Figure 1 what a cervical applicator looks like.

Figure 2 shows you the cervical applicator in place, and what would happen before treatment is that using a transfer tube the unit would be connected to the applicator. So when the patient is set up and the treatment is ready to go, everybody who is involved in the treatment itself leaves the room, the patient is alone in the room and they remotely turn on the machine.

The source stays in the positions that have been determined for treatment, and then

once the treatment is finished, the source is withdrawn, the room is safe to go and the applicator is taken out and the patient can leave.

Go to the next slide. So in this case what happened was -- in the case of this incident where contamination was discovered during a routine source change.

These sources are changed every three months and during the course of a source change, the service engineer from Elekta who was essentially taking out the source did a wipe test on the source that he had taken out and discovered contamination.

It is important to remember that there was no contamination on any patient, there was no contamination within the room; all of the contamination was contained within the unit itself.

And once the contamination was discovered, the service engineer immediately took out the source, made sure that the source was safely stored, that the equipment was safely stored. There was no spread of contamination to patients or persons.

The contaminated equipment has

been quarantined at this time. The licensee has performed a complete check of the room and the facility and there is no contamination anywhere and there are no restrictions on using the room.

So this picture shows you the place where the HDR unit itself is now stored and in the corner of that room the transfer tubes, some of which had a little bit of contamination, have been also quarantined and this is in a locked room, so it's not accessible by anyone.

The next slide is a video which should start... It should. So the video is not playing.

--- Pause

I'm sorry, it's not playing, but basically it was a video. This is actually a video showing the CNSC inspector's visit to the site. It has details of where the contamination was found, but I apologize we cannot see it at this point.

So anyway, the inspectors who did go on the site visit are here today, so if you want to ask them for further details they will be able to tell you.

Thank you.

THE PRESIDENT: Why can't we see the video, again? What's the technology challenges here?

--- Pause

MR. RÉGIMBALD: Perhaps we can show the video later after we go through the other event, we can show it after.

THE PRESIDENT: But in the meantime we want to ask some questions now. By all means.

MEMBER HARVEY: How can you say that there hasn't been any contamination? How can you say that, because some people didn't manipulate the...?

MS MURTHY: Because the service engineer, when he discovered the contamination did a wipe test of all the surfaces outside the machine that would normally come in contact with a person. No contamination was found on any of --

MEMBER HARVEY: It was inside the --

MS MURTHY: It was inside.

MEMBER HARVEY: Okay.

MS MURTHY: It was on some of the transfer tubes that are used, so a little bit of

contamination did get on the transfer tube, but these are not -- so there was no way a person could have gotten touched because you don't usually put your hands --

MEMBER HARVEY: I'm sorry, I didn't know that.

MR. RÉGIMBALD: This is all sealed material, it's all sealed inside. So the contamination was inside.

MEMBER HARVEY: I understand, yes.

MEMBER VELSHI: So is the contamination from the source like disintegrating or something?

MS MURTHY: Nucletron hasn't yet done a full analysis of where it was coming from. There is some speculation on their part, but they are not here today.

We will get a full report from them with the root cause analysis, but their initial assumption right now is that it is not the source that was leaking, that the contamination was on the actual cable that drives the source in and out.

MEMBER VELSHI: And would the service engineer have got any exposure?

MS MURTHY: No, we did verify that. The service engineer, in addition to a radiation badge, he also wears an electronic personal dosimeter. Nucletron tells us -- Elekta tells us that his dosimeter did not register any dose. He does wear a finger dosimeter also that has been sent for readings, so we don't know if he got any extremity dose from it.

In any case, we do know that his whole body monitor did not register any dose.

MEMBER VELSHI: And is this contamination that can become airborne and could he have inhaled and had some internal dose?

MS MURTHY: No, this would be very fine particulate.

MEMBER VELSHI: Thank you.

THE PRESIDENT: Mr. Tolgyesi...?

MEMBER TOLGYESI: Thank you. What you show in this picture, this is a room where usually it's stored the device and it's collected to the transfer tubes which are going to the surgery room or whatever?

MS MURTHY: No.

MEMBER TOLYGESI: No?

MS MURTHY: In fact the unit is

mobile and the unit actually does not leave the room, but it is usually close to the patient. So the transfer tubes in this case are one metre long.

MR. RÉGIMBALD: One metre, exactly.

MS MURTHY: One metre long. So it would be approximately less than a metre away from the patient.

MEMBER TOLGYESI: When you are saying no restrictions in using the room, is which ones; not this one, but where the source is usually?

MS MURTHY: The treatment room where the treatment would normally take place is a treatment room that usually has other diagnostic imaging equipment like a CT scanner. So that room itself is okay.

The equipment right now has been quarantined and it's in a different -- it's in a closet that is locked and interlocked, and so that, of course, nobody's allowed to go into that.

But the main room itself where the treatment couch was, where the treatment would have taken place is a room that is clean.

MEMBER TOLGYESI: But you are saying that the contamination was in a transfer tube. So normally the transfer tube is transferring, how you call it, the uranium to the device, but it's not supposed to be on the tube. If it's on a tube, it means that somewhere there was a leak.

MS MURTHY: I'm sorry, I guess I wasn't clear. The contamination is inside the tube. So they were able to put Q-tips and get some contamination inside the tube. So I don't know exactly what they put --

MR. LICEA: No. It's Angel Licea, for the record. We measure outside, outside the tubes and there was -- we scan it and there is a place where it shows that there is an isotope inside the tube.

When they did the swipes, nothing comes from the tube, it's inside the tube.

MEMBER TOLYGESI: So who is handling the source? The engineer who is delivering or the manufacturer who is delivering, he is licensed, he brings the source to the spot where it's supposed to be stored, nobody's manipulating them or somebody is using them,

moving them?

MS MURTHY: The source is transported in a source container, and so the source container -- the source transfer tube is connected to the source container.

Once the connection happens between the source transfer tube and the machine, the engineer leaves the room, and so it is transferred automatically into the machine. So at no time would the engineer be in direct contact with the source.

The way they found the contamination was, when they had it all set up, before the source was taken out and put into its container, the engineer wiped the cable and it was the cable that had contamination.

So the source was never touched by anyone.

THE PRESIDENT: Is that a normal procedure for them to wipe the -- what I am trying to figure out is, everything worked according to procedures and how did we get to know, the CNSC, how did CNSC get to know that, the inspector or the engineer phoned?

MS MURTHY: Yes.

THE PRESIDENT: What happened?

MS MURTHY: There is a requirement to report this in the general regulations, so both the licensee at whose facility this happened and Elekta report it to us.

THE PRESIDENT: You say two facilities?

MS MURTHY: No. So there's one facility which is where the incident happened, which is the clinic where brachytherapy treatments take place. They report it to us and separately Elekta service engineer, because they have a licence to do this activity, they also report it to us. Yes, so --

THE PRESIDENT: Go ahead.

MS MURTHY: Sorry. The service engineer is qualified and trained to do the source transfer and they have procedures to check for leaks and contamination, but because the source is welded to the wire they can actually hook it up and they don't really ever have to come in any close proximity to the source.

MR. REGIMBALD: I don't know if you'll remember, we had some time ago a demonstration of a radiography camera. So it's a

bit similar like that. The source cable travels inside this very small tube. This is very small in diameter.

So when -- as Kavita explained, when the patient is set up people leave the room, except the patient, and the source is protracted outside of -- it travels through inside the tube with a cable, and goes to the site of exposure and after the required time the source is retracted back. So it's very similar to a radiography camera, but it -- but in very small scale.

THE PRESIDENT: Anybody else? How many such devices are in production in North America, in Canada?

MS MURTHY: Today in Canada we have 50 brachytherapy units from different manufacturers. Elekta is the major manufacturer, and Nucletron, which is a company that Elekta bought. Thirty-one (31) out of the 50 units are Elekta Nucletron, out of which seven are Flexitron which is a type of -- which is another type of unit. So 30 -- out of the 31 Elekta units seven are currently in Canada that are of the type that were affected by this.

THE PRESIDENT: So are they

continuing to operate as normal?

MS MURTHY: Yes, we did send a notice to them right away to not do the treatments the next day and make sure that they were contacting Elekta before they did any treatments, which they did. We also sent a notice out to them detailing what the problem was and how exactly to check for contamination. We also asked them to acknowledge receipt of our communication and also to immediately inform us if, whether or not they found any contamination.

So all those notifications were received within one day of the event happening. And we did also broaden our -- the scope of our notification. We informed not only the licensees who had Flexatron units, we also contacted all licensees who had any Elekta unit to tell them that this had happened and asked them also to do the contamination checks, just in case it was a more widespread problem. And all of them reported back to us that there was no contamination found. So there was no real reason for us to tell them not to treat with that.

THE PRESIDENT: Is that the first time it happened?

MS MURTHY: To my knowledge, yes.

THE PRESIDENT: So you also mentioned that our lab, the CNSC laboratory played a role here, what was that?

MS MURTHY: So initially when the event happened there was some uncertainty around what exactly it was that was the contaminant. The equipment that the licensee had onsite was not able to accurately identify. So we requested the licensee to send some of the swipe samples. We contacted the lab immediately. My colleague, Angel Licea here, was responsible largely for that.

They were able to run the tests and get the spectrum out of the material that -- of the swipes, and identified that the material was iridium 192. So they played a pretty big role right at the beginning in helping us identify. And within -- of course, all this information was confirmed later on by Elekta. So Elekta did also do their own checks, but we were not waiting for Elekta to tell us what it was. We knew before they told us.

THE PRESIDENT: So it was nice to see some payoff for my investment in our laboratory,

MS MURTHY: Certainly.

Absolutely. Yes, it was.

THE PRESIDENT: That's good.

Any questions? Are we likely to see the video? While she's preparing, maybe we should start on the second event.

MR. REGIMBALD: The second event involves radioactive sources that were found at the Cross Cancer Institute in Alberta. So these sources were disused brachytherapy sources that were found in the machine shop at the institute. I believe you have already been notified of this by email from the Secretariat. But this gives a little bit more information, and again, this is the initial event report.

On April 2nd, 2014, while conducting a radio -- routine radiation survey, the radiation safety officer from the institute noticed an unexpectedly high dose rate, above 30 millisieverts per hour, in a clean area in the machine shop at the Cross Cancer Institute. Upon investigation the source of radiation were found to be two stainless steel pins, which are approximately four centimetres to six centimetres in length and they look -- they really look like

door hinge pins, but very small, like this. And they were inside a plastic box with a variety of small machine components, left on the corner of a workbench within the room.

The pins were immediately secured by the licensee and put into safe storage. The three individuals in the workshop, who are all nuclear energy workers, had radiation badges which were sent for immediate reading. The doses received by the workers are 11 millisieverts, 4 millisieverts, and 5 millisieverts for the three month, January to March 2014 wearing period. These are below -- the doses that they received are below the annual regulatory dose limit of 50 millisieverts for these workers.

The doses in the previous three month reporting period for the same individuals were between .5 and 2.5 millisieverts. And the highest annual whole body dose received by an individual in the workshop in the calendar year 2013 was 2.77 millisieverts.

A preliminary investigation by the licensee revealed that the pins were intrauterine preloaded tubes with cesium 137 sources, using in manual brachytherapy to treat gynecological

cancers. This type of treatment was used in the 1980s, but is not longer practiced anywhere in Canada. When the institute discontinued use of the IU tubes they were put into storage and have appear consistently on the inventory of sources reported in the annual compliance report submitted by the licensee.

It is not clear when, why, and by whom the sources were taking out -- taken out of storage from that room and moved to the machine shop. Based on a reading of the radiation badges of the three persons who worked in the machine shop, it is likely that the transfer took place in December of 2013.

We asked the licensee to provide more details and to re-examine the dose reports for other individuals who may have been in the vicinity of the sources and to estimate the doses that any individual could have received. The licensee has reported that no other individuals who are badged have any anomalous doses in their dose reports.

The licensee also reports that it is unlikely that any member of the public was exposed to the radiation. The machine shop and

the storage rooms are located in the basement of the center, in an area that is not generally accessible by, or used by, the public.

We also required the licensee to provide a root cause analysis of circumstances that led to the sources being transferred in this manner to the machine shop. All of this information is preliminary at this time. CNSC staff will come back the Commission in due course with more complete information on the matter, with details about the corrective measures that the licensee has put in place to avoid a similar problem in the future.

Thank you.

THE PRESIDENT: When do you estimate being able to come with a little bit more definitive story?

MS MURTHY: Right. We should have a pretty comprehensive review done in about a month's time. So I would say four weeks.

THE PRESIDENT: Okay.

Questions? Mr. Tolgyesi?

MEMBER TOLGYESI: You were saying that the source is not used anymore. It was used years back and it was always registered in

storage. So do we have a kind of facility or storage where all this old medical, or other sources which cannot -- which they are not used anymore but still radioactive, could be stored?

Because what we see here is in this facility, you know, you are saying that machine shop is in a basement, generally not accessible. I'll tell you something, machine shops are always accessible for all those who wants to access machine shops. That's my industry experience.

So do we have -- you don't -- we don't have any kind of storage where we could accumulate and store all these sources?

MS MURTHY: So just to be clear, the sources don't -- were not where they were supposed to be. So the sources are generally in a safe storage room that is at the licensee's location. So we still have to figure out -- the licensee still has to figure out how come they got out of that room without being detected, without anyone knowing that they were gone. So the fact that they ended up in the machine shop is really concerning to us. So we are looking into that.

These sources are generally in --

hospitals have to maintain a detailed inventory of what sources they have, and they generally, after they've accumulated a few sources, they will send them for disposal through standard methods that are available, companies that do this for a living.

These sources remained in the hospital for some reason and this is a cesium source. So it is not going anywhere anytime soon. The half life is 30 years. So they, you know, they were still active sources and some of our information, preliminary at this time, says that they were scheduled to have been disposed of in 2012 but they got missed and they remained in the hospital.

MEMBER TOLGYESI: So we don't have a kind of regulation, we're just saying that sources which are not used after so many years should be disposed safe away under some large storage areas. Because what's happened here in this hospital, as these doctors were saying, there is an evolution. That means probably the sources are the new sources, so the old ones, you don't use them anymore. But you store them in the facility or in hospital and you run a risk that it

will happen.

MR. REGIMBALD: There are -- sorry? Okay. There are controls in place, not in the regulations, but this would be through the licence, the licence conditions, and through the safety program submitted by the licensee when we assess their application and issue the licence.

So all the controls and procedures regarding inventory control, transfer of sources, disposal, acquisition of material, would be under those safety program. So now we're trying to understand what part of the program was not correctly implemented or missed, and this will come through when we receive additional information from the licensee.

THE PRESIDENT: Ms Velshi?

MEMBER VELSHI: How often are these routine surveys done, the ones that found these sources?

MS MURTHY: This was not a routine -- the machine shop is not a place where you would find a radioactive source. So it was very fortuitous that a survey was being done. The survey was being done routinely because of another activity that was taking place, which was

basically they had a collection of lead pots that they were moving from this source storage room to the machine shop so that they could be melted and recast, or done something with.

So the person who was transporting these empty lead pots from the storage room to the machine shop did a survey. This is the proper procedure. They did a survey of the lead pots in the storage room to make sure they were all clean. But then when the cart brought them to the machine shop, parked them luckily near the bench where these sources were, did another survey, picked up a reading. This was unexpected because this person had just surveyed it.

And so when we say routine surveys, that is the routine. That is the process that should be followed when you move stuff out -- in and out of radioactive storage room. So the person who was doing that was doing exactly what they were supposed to be doing. Luckily for the licensee and luckily for everybody, they were being done in the area where the source was. Otherwise, the source would not have been identified at that point.

Mind you, these people who were in

the machine shop, working in the machine shop, are all relation of nuclear energy workers. So when their badges would have been sent to be read, it would have raised a flag because they would have had doses on their badges. But fortunately it didn't come to that, it was discovered before.

THE PRESIDENT: I think we'll wait until we see the reports, but I sense that there is something that you may want to think about. It's not only there, there's the recent event in Sunnybrook Research, leads me to believe that some people don't pay enough attention to inventory of used radioactive material and we should find a way of -- because they have the inventory.

All they have to do is reconcile maybe annually, whether they need to keep the inventory. And I think we should become a little bit more aggressive, maybe is the word, to find out what happened here and to make sure that they don't keep old stuff. If they were a company they would pay licence fees on these, right? So a big hospital institution, maybe there's no costs to keeping old stuff and maybe that's what we're seeing here.

MR. REGIMBALD: Although they are

subject to administrative monetary penalties.

THE PRESIDENT: Which is a new concept. Maybe that'll focus the mind.

Okay. I think we're ready to see the video.

--- Video presentation

THE PRESIDENT: Thank you. Anything else on that? Okay. Thank you.

We'll take a five minute break here now.

--- Upon recessing at 6:35 p.m. /
Suspension à 18 h 35

--- Upon resuming at 6:43 p.m. /
Réprise à 18 h 43

THE PRESIDENT: The next item on the agenda is a presentation from CNSC staff on Controlling and Ascertaining Worker Dose as Part of a Radiation Program as outlined in CMD 14-M28.

I understand that Dr. Thompson will make the presentation.

Please proceed.

Oral Presentation by CNSC staff

MS THOMPSON: Merci, Monsieur le Président.

I just changed my speaker notes from bonjour to bon soir, so...

--- Laughter / Rires

But more seriously, mon nom est Patsy Thompson. Je suis le directrice générale de la Direction d'évaluation et de la protection environnementales et radiologiques.

With me today are Caroline Purvis, the Director of the Radiation Protection Division; Melanie Rickard, the Acting Director of the Radiation Health Sciences Division; as well as Tristan Barr, the Dosimetry Licence Specialist; and Bertrand Thériault, the Internal Dosimetry Specialist.

I should also mention that we have staff from Health Canada's Radiation Protection Bureau, Mr. Brian Ahier; Mr. Louis Marcotte; and Ms Mirela Tabra who are involved in the National Dose Registry in case you have questions on that for them.

Commission Members have asked a

number of questions about licensee dosimetry programs, dose records and the National Dose Registry. And in order to more fully address these questions we have prepared today's presentation to clarify requirements and practices related to these topics.

Almost three years ago, in June 2011, CNSC staff presented CMD 11-M29 entitled *Ascertaining Doses as Part of a Radiation Protection Program, Dosimetry Techniques, Practices and Applications*.

That presentation focused on the technical aspects of Dosimetry and we ultimately published the CNSC information document after that presentation entitled *Introduction to Dosimetry*.

The presentation today will build on the information provided in 2011 with a focus on how dosimetry fits within a radiation protection program, the different regulatory requirements, and the way in which doses are measured and managed.

Every licensee under the CNSC's jurisdiction must have a radiation protection program that meets the requirements specified in the radiation protection regulations. The

complexity of the program is developed to be commensurate with the risks of the licensed activities.

These radiation protection programs are reviewed by CNSC staff to ensure that the programs meet regulatory requirements, are appropriate for the licensed activity and associated radiological hazards, and are consistent with best practices.

Compliance activities such as inspections and desktop reviews are conducted to ensure that the radiation protection programs are adequately implemented. In order to ensure that CNSC experts remain up-to-date on best practices, staff are involved in many international activities with regard to radiation protection.

CNSC staff participate in the development of radiation protection, related international standards, recommendations and guides.

In addition to participating in the drafting and review of such documents, CNSC experts play a more direct role in various organizations. Some of these organizations are listed on the slide for your information and will

be described in more detail on the next slide.

CNSC experts are involved at the international level in various radiation-related organizations. These organizations have unique objectives and contribute differently to the science and framework of radiation safety.

Today we will briefly describe three key organizations that influence the radiation safety system.

Beginning with the United Nations Scientific Committee on the Effects of Atomic Radiation, or UNSCEAR, this committee was established by the General Assembly of the United Nations in 1955.

Its mandate is to assess and report on levels and effects of exposure to ionizing radiation. Governments and organizations throughout the world rely on the committee's reports as the scientific basis for evaluating radiation risk and for establishing protective measures.

The assessments conducted by UNSCEAR provide the scientific foundation used by the International Committee on a Radiological Protection, or the ICRP, in developing its

recommendations.

The ICRP is an independent international organization that advances for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionizing radiation.

The ICRP has developed well over 100 publications on all aspects of radiation protection, while most address a particular area within radiation protection, a handful of publications which are called the fundamental recommendations, describe the overall system of protection.

The ICRP system of radiological protection is based on the current understanding of the science of radiation exposures and effects and value judgments. These value judgments take into account societal expectations regarding the benefits of nuclear energy and acceptable risk levels, the use of nuclear substances, ethical basis, as well as experience gained in the application of the system.

Lastly, the International Atomic Energy Agency, or the IAEA, promotes and supports

the establishment of a global nuclear safety regulatory framework. One objective of this framework is to strengthen the transparency, openness, independence and technical competence and effectiveness of regulatory bodies of member states.

Central to establishing this framework are the IAEA safety standards. Documents such as the IAEA's basic safety standards for radiation protection are used by member states in the development of the regulatory framework for protection of workers.

This description of key international organizations is meant to provide insight on how the international radiation safety regime is structured and how the various organizations influence countries in the development of their regulatory framework for the protection of workers.

The CNSC actively participates in and relies heavily on these international bodies and considers their publications when drafting regulatory expectations in the area of radiation safety.

I will now pass the presentation

to Ms Melanie Rickard, the Acting Director of the Radiation and Health Sciences Division.

MS RICKARD: Good evening, Melanie Rickard, for the record.

Now that we have discussed the international framework, we will focus on the Canadian framework for radiation protection.

Under the *Nuclear Safety and Control Act*, the *Radiation Protection Regulations* set out requirements that speak to radiation protection programs, the ascertainment of dose, and other associated requirements.

Specifically, section 4 of the *Radiation Protection Regulations* sets out the high-level requirements for a radiation protection program. Each licensee must implement a program that ensures that doses are as low as reasonably achievable, the management control over work practices, personnel are trained and qualified, and there is control of exposure to radiation, and that responses to unusual situations are planned for.

Building on the fundamental requirements for all licensees the next two slides describe regulatory requirements for maintaining

dose records and the acceptable approaches for ascertaining dose.

Subsection 5(1) of the *Radiation Protection Regulations* requires that every licensee ascertain and record the doses of radiation that are received by persons who are present or who perform work in connection with licensed activities.

Subsection 5(2) of the Regulations states the manner in which these doses shall be determined. There are two methods prescribed. The first and preferred option is that doses be ascertained by direct measurement through monitoring.

If, however, the time and resources needed to perform direct measurements outweigh the usefulness of that method, then the dose can be estimated. Note that estimation includes indirect monitoring, and this term will be used throughout the presentation.

It is ultimately up to licensees to demonstrate if estimation is an appropriate method for the assessment of dose. The proposed method is reviewed by staff for acceptability.

In order to understand radiation

hazards and dosimetry it is important to know what the main types of radiation are and how they interact with matter.

The main types of radiation, ionizing radiation, are alpha, beta, photon, and neutron. The ways in which different types of radiation interact and the energy they impart to matter vary due to their physical properties.

Alpha radiation has a very short range and can be easily shielded. For example, by a piece of paper. However, when a source of alpha radiation is taken into the body the radiation can impart its energy to tissues and organs. Thus, alpha radiation is considered an internal hazard only.

Beta radiation has a longer range than alpha radiation. This diagram illustrates how some beta radiation will be absorbed by the skin, but will not irradiate to the deeper tissues of the body when the source is outside of the body.

When a source of beta radiation is taken into the body, the radiation can impart its energy to internal tissues and organs. Beta radiation is considered both an internal and

external hazard. Photon radiation is electromagnetic in nature and consists of gamma and x-ray radiation.

For the purposes of this presentation, the term gamma will be used exclusively.

Gamma radiation is very penetrating and is therefore considered both an internal and external hazard.

Neutron radiation is also very penetrating. Since neutrons are commonly associated with fission reactions, neutrons are typically encountered only as an external hazard. What is important to understand is that licensees must assess the risks present at their facility and must demonstrate that the methods for measuring and monitoring doses are appropriate for those hazards and exposure pathways.

Throughout the remainder of the presentation we will discuss different types of dosimetry, how dosimetry methods are chosen, and how dose records are managed.

First, what is dosimetry? Dosimetry is the act of measuring or estimating radiation doses and assigning them to individuals.

The magnitude of radiation doses that people receive is one parameter that can be used to assess whether the system of radiation protection is working and is effective in minimizing doses to workers.

There are two fundamental pathways of exposure that impact how doses are delivered and how they are measured. First, the internal exposure pathway. This is when a nuclear substance is taken into the body through ingestion or inhalation, for example.

As previously mentioned, alpha radiation is only an internal hazard. Photon and beta radiation are also internal hazards. Internal dosimetry largely consists of bioassay measurements that include in-vitro and in-vivo counting techniques.

The second is the external exposure pathway through which the body is exposed to a field of radiation from a nuclear substance that is outside of the body. External dosimetry typically consists of the use of personal dosimeters positioned on the body.

In both cases the results of the measurement device or technique itself is combined

with theoretical health physics information and models to determine the dose to a person.

As mentioned at the start of this presentation, info 0827, identified here on this slide, present a detailed overview of dosimetry methods and requirements.

As was mentioned previously, the regulations allow for two methods for ascertaining dose. The first and preferred method is direct monitoring often referred to as personal dosimetry.

The second is indirect monitoring that usually involves measuring nuclear substances in the environment and making certain assumptions to estimate doses to individuals or groups of individuals.

These methods will be discussed in more detail in a few moments.

It is important to understand that regardless of the approach, the ways in which doses are ascertained form a key part of the licensee's radiation protection program. Radiation protection programs are reviewed by CNSC staff prior to the issuance of a licence and the program is subject to compliance oversight if their

licence is issued.

Oversight activities include, but are not limited to, inspections, event reviews and review of licensee annual compliance reports.

A common and familiar way of ascertaining dose is to perform direct monitoring that is usually referred to as personal dosimetry. It involves measuring the dose to an individual with a personal dosimeter or involves measuring the amount of nuclear substances in the body or excreted by the body.

Shown on this slide are examples of measuring devices that are considered directed monitoring techniques. The picture circled in red are dosimeters that measure the dose associated with a field of radiation that is outside of the body, such as gamma and beta radiation emitted from a sealed source.

The one on the left is referred to as a passive dosimeter, meaning it requires processing to perform the measurement of dose while the one on the right is an active dosimeter, meaning it displays in real time the dose or dose rate.

The other devices shown on this

slide are used to measure dose from nuclear substances that are taken into the body, for example, through ingestion or inhalation.

Circled in blue is an example of the whole body counter, which is used to detect nuclear substances that emit gamma radiation.

By nature of the unique energy spectrum of gamma emitting radionuclides, the whole body counter can detect their presence and associated dosimetry software can be used to calculate the dose.

Circled in green is a liquid scintillation counter system that can analyze urine samples provided by workers for the presence of radionuclides such as tritium.

Each sample is mixed with the scintillation fluid in a vial like the one shown on the bottom left, and when placed in the counter is analyzed to measure the amount of nuclear substances in the urine.

In some cases dosimetry may be performed using indirect methods. Indirect dosimetry most commonly involves measuring radiation dose rates or airborne concentrations of nuclear substances as part of workplace

monitoring. Some examples of devices used for indirect monitoring are shown on this slide.

On the left of the slide is a portable sample counter used for radon progeny measurements in uranium mines. A pump, which is not shown the photo, is used to draw air through a filter, trapping alpha particles resulting from the decay of radon progeny on the filter. The filter is then inserted into the device and the alpha radioactivity is counted.

A technician uses a known formula to convert the number of counts to an exposure level which can then be used to determine a dose to a worker when the time spent in the area is known.

On the right is a neutron survey meter. The large ball contains a material that slows down fast-moving neutrons so that they can be detected by the device above it. Workers carry the meter and position it in a location of the highest neutron dose rate and keep it at that location for the duration of the work. The meter will display the total dose over the defined period of time. Once the task is complete, the worker will record the dose on a form and it will

be transferred to the dose management system.

It is also important to note that some indirect methods do not involve workplace monitoring using instrumentation but rely on known information about the radioactive source, along with health physics calculations to estimate the dose. This is normally done when doses are expected to be very low.

The choice of the dosimetry method or methods will depend on a number of factors, some of which are listed on this slide. I will discuss two of these factors for illustrative purposes.

In the case of internal dosimetry, the physical and chemical form of the nuclear substance determines its behaviour on intake and its subsequent biokinetics in the human body. Biokinetics describe how a substance is distributed to the organs and tissues of the body -- of the body following intake and the rate and manner in which it is eliminated from the body. Based on excretion routes and rates, decisions are made on the type of excreted sample to be collected and the frequency of the sampling.

Another factor is the cost, which

can vary dramatically for certain techniques. For an example, the analysis of a personal alpha dosimeter used the mining industry for the measurement of radon progeny and long-lived radioactive dust is far more expensive than a thermoluminescent dosimeter used for measuring doses from external exposure to gamma and beta radiation.

While all licensees are required to ascertain doses to workers, there is an additional regulatory requirement that specifies when it is necessary to use a licensed dosimetry method for ascertaining dose. Section 8 of the *Radiation Protection Regulations* requires that a licensee use a licensed dosimetry service to measure and monitor the doses of radiation for nuclear energy workers who have a reasonable probability of receiving a dose greater than 5 millisieverts in a one year dosimetry period. Requirements that apply to a dosimetry service or an applicant will be discussed later in the presentation.

This slide provides an overview of the requirements we have already discussed. Flowing from the box at the top of the slide, all

licensees are required to ascertain and record doses of radiation for all persons that are present or who perform work in a connection with -- in connection with a licensed activity. Taking into consideration the magnitude of the expected exposure, the licensee has two options. If the expected dose is less than 5 millisieverts in a one year dosimetry period, the licensee is required to meet the requirements to ascertain dose by either direct monitoring or through indirect monitoring, or estimation methods. The licensee may choose to use a combination of these approaches depending on the type and number of exposure pathways that lead to doses to persons. In some cases licensees may choose to use a licensed dosimetry service to monitor their workers despite the fact that it is not strictly required. If, however, the licensee determines that for some or all of their workers there is probability that their doses will be in excess of 5 millisieverts in a one year dosimetry period, the use of a licensed dosimetry service is required.

Now we will focus our attention on what it means to be a licensed dosimetry service.

A dosimetry service measures and monitors doses of radiation. There are two categories of these licences.

An in-house dosimetry service measures and monitors doses for its own workers, and a commercial dosimetry service is one that measures and monitors doses for other licensees at a cost. Under the Act and regulations, having a licence that allows the operation of a dosimetry service means that requirements of the regulations and regulatory standard S-106 must be met. S-106 outlines both technical and quality assurance requirements. This type of licence is issued by a designated officer of the Commission.

This table presents the 12 current dosimetry services that are licensed by the CNSC. The five licensed -- the five licensees that offer commercial dosimetry services are shown in red. The first three provide dosimeters that measure doses associated with exposure to radiation when it is received outside of the body. These companies provide service to many licensees, such as hospitals, universities, industrial sectors, and mines and mills. The Radiation Safety Institute of Canada is another commercial service

offering personal alpha dosimeters to all uranium mines for the measurement of exposure to radon progeny and uranium or dust.

Kinectrics has just recently obtained a CNSC licence for techniques associated with the measurement of alpha transuranics in urine and feces. The remaining licensees listed in blue font provide dosimetry only to persons monitored at their own sites. These are referred to as in-house dosimetry services. Other than SRBT, which performs only tritium bioassay sampling and dose assessment, most in-house dosimetry services utilize a wide variety of dose measurement techniques.

As was mentioned earlier, to obtain a licence that allows operation of a dosimetry service, requirements of regulatory standard S-106 must be met. Some of these requirements include those provided on the slide, such as the requirement to meet accuracy specifications, to participate in independent testing, and to meet a variety of quality assurance requirements, such as having a corrective action program. Desktop reviews, unplanned event reviews, and inspections

are some of the ways in which the CNSC monitor compliance with the regulations, S-106 and the licence.

An additional requirement that the -- that the dosimetry service must fulfil is that it must file with the National Dose Registry dose information for nuclear energy workers that it monitors. In addition to dose and exposure information, personal information, such as name, birth date and social insurance number, must also be provided for the individuals monitored. This information is collected to ensure data integrity and reliability.

The NDR currently accepts dose records from individuals monitored by licensed dosimetry services. The practice of archiving and collecting dose records for workers has been in place since 1951. While the database began, as what is now the National Dosimetry Service, it officially became the National Dose Registry in the mid-1970s. While the slide says that this database has dose records for over 500,000 workers, more precisely it has records for approximately 827,000 workers.

The NDR serves several purposes.

These include supporting regulatory bodies as needed, for example, notifying them when occupational dose limits have been exceeded; evaluating dose trends and statistics for information purposes; contributing to health research studies, and providing personal dose information to individuals upon request.

In order -- in order to control the quality of the data submission and to serve as a reliable source of information for regulators, individuals, and other interested parties, the NDR prescribes detailed input specifications to control the method and format of the data submitted. Acceptance criteria that is related to the input specifications must be met for each submission. Failure to meet the criteria will result in the data being rejected. To ensure that the data is being submitted as needed, the CNSC monitors this process through the review of statistics provided in the annual compliance reports from the dosimetry service and also through regular discussions with NDR staff.

Staff from the CNSC and the NDR interact routinely in a collaborative manner to ensure that areas of mutual interest are discussed

and followed up on. While much of this interaction is informal, regular NDR-CNSC liaison meetings are held and minutes and actions are recorded.

Staff also request data from the NDR on a regular basis. For example, in cases where we know that licensees use a licensed dosimetry service for dose assessment, staff collect data from the NDR to verify the data submitted by these licensees and also for dose trending purposes. Staff also request data for specific individuals when this information is useful in relation to events or in support of a dose change request.

As was mentioned, the NDR currently accepts dose records submitted by a licensed dosimetry service. There are, however, a limited number of agreed upon exceptions to this practice. The *Nuclear Safety and Control Act* requires every licensee to maintain dose records for the workers it is responsible for. As such, the licensee responsible for the activity that results in the exposure to radiation is the primary source of dose information. The maintenance of such records is managed under the

licensee's radiation protection program and is subject to oversight by CNSC staff.

Now we will provide some examples illustrating how doses are monitored and managed for different types of licensees.

Nuclear medicine involves the administration of nuclear substances for diagnostic and therapeutic purposes. Workers are primarily exposed to gamma and beta sources of radiation that are outside of the body. These exposures to workers are typically measured by use of passive dosimeters. The graph at the bottom of the slide presents dose statistics for this group of workers. During the years 2008 to 2012 the majority of doses received by nuclear energy workers in this sector are below 5 millisieverts per year. For example, the data provided for 2012, shown by the yellow bar, indicates that over 50 percent of nuclear energy workers receive less than 1 millisievert of effective dose, yet we know that the vast majority of these workers utilize a dosimetry service.

Internal intakes of most nuclear substances for this group of workers are mitigated by facility design and by effective contamination

control practices. However, the frequent use of volatile radioactive iodines in therapeutic medicine procedures introduces a risk to workers from the possible inhalation of these nuclear substances. A technique for measuring iodine uptakes in the thyroid, called in vivo thyroid monitoring, is used for the assessment of suspected intakes. This is managed as part of the licensee's radiation protection program and no commercial dosimetry service currently provides this option.

Moving now to a more complex example. Uranium mines present a certain unique radiological hazard to workers. This slide illustrates the various exposure pathways to workers. The boxes coloured in blue represent techniques for monitoring and measuring dose that are licensed as dosimetry services. On the other hand, the white boxes represent techniques for determining doses to workers that are approved through the licensee's radiation protection program.

Workers may be exposed to external sources of radiation from working in close proximity to the uranium ore. External exposures

of underground workers to gamma and beta radiation are determined using a CNSC licensed dosimeter. In this case the licensee has chosen to use a type of passive dosimeter called an optically stimulated luminescent dosimeter.

In addition, underground workers wear electronic personal dosimeters, referred to as EPDs. These devices are capable of measuring real-time exposure to gamma and beta radiation. The EPD is used primarily for dose control purposes.

Workers in uranium mines are also exposed to airborne radiological hazards in the form of radon gas, radon progeny, and long-lived radioactive dust. Radon gas is released into the underground mine atmosphere as a result of both natural processes and mining activities. The gas undergoes radioactive decay into other short-lived radionuclides that are collectively called radon decay products. In addition, airborne uranium or dust generated by the mechanical mining processes presents an internal hazard to workers when inhaled.

Worker exposures due to the inhalation of radon progeny and long-lived

radioactive dust are determined in two ways:

The first method involves having all underground workers wear a personal alpha dosimeter on their body. A picture of the personal alpha dosimeter, also referred to as a PAD, is shown on the bottom of this slide. The licensed PAD is a lightweight monitoring system which is comprised of a detector mounted inside a battery-powered air pumping system. Air is drawn through the dosimeter head at a specified flow rate so as to capture particulates, including any attached radon progeny and long-lived radioactive dust on a filter. The sampled air is considered to be representative of the air breathed by the individual who is wearing the PAD. When the dosimeter head is sent to the dosimetry service for analysis, the worker exposures to both radon progeny and long-lived radioactive dust can be determined.

For individuals who work underground on a more casual basis, an indirect monitoring method is used whereby the concentration of air -- in air of radon progeny and long-lived radioactive dust is determined and the time spent underground is recorded. Using a

health physics calculation, the radiation exposure is determined. This type of calculation method is approved through the licensee's radiation protection program.

Industrial radiography is considered a high-risk licensed activity. This is due to several factors, such as the high activity of the source contained in the device; the reliance on the individual for safe operation of the device; the potential for unplanned events, and the potential for relatively high doses to workers.

Given the potential for elevated doses to workers, specific dosimetry requirements for this licensed activity are included in the Nuclear Substance and Radiation Device Regulations. As specified in regulation, an exposure device operator must wear a dosimeter that, is issued by a licensed dosimetry service, has direct reading display capability, and emits an audible warning signal at a given dose and dose rate. At the current time there is no licensed dosimeter in Canada that meets all three requirements, and, therefore, each operator must wear at least two dosimeters on the trunk of their

body.

For the last example we will describe a nuclear power plant. The most complex example that we will discuss is shown on this slide. Similar to the uranium mine example, the boxes coloured in blue represent licensed dosimetry techniques, while the white boxes are techniques approved within the licensee's radiation protection program. It should be noted that currently all nuclear power plants in Canada hold an in-house dosimetry service licence, which includes the vast majority of their dosimetry techniques for ascertaining dose. Workers in nuclear power plants may be exposed to a wide variety of both external and internal radiological hazards, depending on the activities performed.

While this is a rather complicated slide, for the purposes of today there are a number of key items to discuss:

External exposures to persons can result from working in proximity to neutron, gamma, and beta sources. Typically workers wear thermoluminescent dosimeters to determine doses arising from exposures to external gamma and beta sources. Also worn by workers are electronic

personal dosimeters, which are used as dose control devices. Doses to workers as a result of neutron exposures are determined using an indirect monitoring method which was described earlier in the presentation.

The most common internal exposures to workers in nuclear power plants are due to intakes of Tritiated water. Measurement of tritium in urine samples is the most reliable and accurate method for determining doses from this exposure pathway. Contaminates, such as carbon 14, can also be determined using urine bioassay measurements.

Methods, such as thyroid counting and whole-body counting, measure the presence and quantity of radionuclides in a body. These methods are only useful for those nuclides which emit gamma radiation of sufficient energy and in sufficient numbers to exit the body and be detected by an external detector.

Radioiodines are fission products produced in fuel that could be released into the workplace as a result of maintenance activities. As described earlier, direct counting of the thyroid using an instrument placed against the

neck of the person is an effective method to ascertain doses from the inhalation of radioiodines.

Mixed fission and activation products are produced in CANDU reactors as a result of the fission process. The most commonly encountered contaminants include high-energy gamma emitters, such as Cesium-137 and Cobalt-60. These products are easily measured using whole-body counting of the person. Other mixed fission and activation products that are not easily detected in a person using an external method can be measured in urine samples using gamma spectroscopy methods.

Lastly, transuranics are produced in CANDU facilities from the activation of uranium in the fuel. These contaminants can then deposit within the heat transport and other related systems. Maintenance activities on these systems have the potential of creating an airborne hazard composed of transuranic contaminants. Depending on the radionuclide of interest, the doses due to intakes are determined through the collection and measurement of urine or faeces.

To recap, the last four slides

were meant to illustrate that with increasing risk to workers and increasing complexity of the radiological hazards for a given licensed activity, the dosimetry methods used to ascertain the dose will vary. In some cases the use of a licensed dosimetry service is selected -- is selected for practical reasons rather than specifically required in regulation, while in other situations specific dosimetry requirements are prescribed. In many cases the licensees will use a combination of licensed dosimetry techniques offered by a dosimetry service and approved methods for ascertaining dose captured within the radiation protection program.

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

MS THOMPSON: Thank you. Thus far in the presentation we have presented an overview of how doses are managed under this industry's regulatory framework. It is important to note that the Radiation Protection Regulations are currently under review.

The CNSC has chosen to move forward with proposals to amend the regulations as a result of three main factors:

Firstly, international benchmarks have changed since the regulations came into force in May 2000. For example, in 2007 the ICRP published a new set of main recommendations.

Secondly, the use of the regulations for the last 14 years has revealed areas that need clarification and also improvements based on experience using the regulations.

And finally, a nuclear accident in Japan, the Fukushima Daiichi Nuclear Power Plant led to the identification of lessons learned with regards to emergencies that need to be addressed in the RP regulations.

In the fall of 2013 the CNSC published a discussion paper describing the proposals to amend the Radiation Protection Regulations. Following the 120 day public comment period, CNSC staff are currently in the process of developing a What We Heard Report and further engaging stakeholders on key issues of concerns. While many changes have been proposed, I would like to provide some examples of the proposed amendments that relate to dose management that we have discussed today.

Currently the Radiation Protection Regulations only specify requirements relating to the use of a licensed dosimetry service for determining effective dose. The CNSC is proposing to add a new requirement specifying when a licensee must use a licensed dosimetry service for the measurement of equivalent dose to the skin and the hands and feet.

Another change proposed is to reduce the dose limit for the lens of the eye for nuclear energy workers. This particular change comes as a result of a recent ICRP recommendation which indicates that based on new scientific evidence the threshold for radiation-induced cataracts is lower than was previously believed.

Lastly, changes to the dose limits for persons involved in the control of an emergency have been proposed in response to the CNSC Fukushima Task Force recommendation number 8. We are proposing to use the updated requirements in the -- on the IAEA -- the recently revised IAEA Basic Safety Standard.

Following the outcome of the proposal to amend the Radiation Protection Regulations, there are several supporting

regulatory documents that are currently in the form of standards and guides that will need to be reviewed and perhaps revised. As part of that review these documents will be updated to the new regulatory document format of the CNSC.

In addition to review of the existing standards and guides, there will likely be a need to draft new documents as well. Two topics that may warrant additional documents are the application of the new dose limit for the lens of the eye and a clarification of overall expectations regarding methods and approaches involved in the estimation of dose.

As we conclude our presentation, we would like to emphasize the following points: According to regulatory requirements, it is acceptable for licensees to use methods for determining doses to persons either by direct measurement or by estimation if the expected doses are less than 5 millisievert in a one year dosimetry period. If the expected doses to workers will exceed 5 millisievert per year, the licensee is required to use a licensed dosimetry service for monitoring and measuring doses to persons. All methods for determining doses to

persons are included in the licensee's proposed radiation protection program. These programs are reviewed and accepted by CNSC staff. Compliance activities are designed to verify the methods -- that methods for determining doses to persons are implemented as per the commitment -- the commitments made by licensees and are appropriate for the hazards and the exposure pathways for the activity in question.

Finally with the four examples we provided, it is evident that all -- that not all licensees use licensed dosimetry services to measure and monitor those. In some cases other methods and sometimes a combination of methods may be used. It is important to note that only doses determined by licensed dosimetry services are submitted and retained by the National Dose Registry. This means that dose records maintained by the licensee are the primary source of exposure information. Those data in the National Dose Registry are used for many purposes, both regulatory in nature and for the support of epidemiological studies.

Finally, the relationship between the CNSC and the National Dose Registry staff is

well-established and there is effective interaction and communications on matters of mutual interest.

We are available to answer questions from the Commission.

THE PRESIDENT: Thank you. I feel after this positive -- you know, working as a team with Health Canada, we should give Health Canada a chance to -- do you want to add anything to this presentation?

MR. AHIER: Thank you. Brian Ahier for the record. In fact, the presentation was quite complete. Maybe I would just note that, as has already been mentioned, Health Canada does operate the National Dose Registry. I think it's worthwhile noting that it is Canada's official central repository for occupational radiation dose records, and that, as CNSC staff indicated, it does contain records for 827,000 workers. It's also worth noting that that also includes 34,000 employers and about 21 million discrete radiation dose records. So it's quite a comprehensive database and a very important tool.

THE PRESIDENT: Thank you.
Monsieur Harvey.

MR. HARVEY: The -- we saw in your presentation that there is different means to get the exposure and -- but all the data coming from all those means are sent to the National Registry?

MS RICKARD: So the -- the data is submitted through the licensed dosimetry services. So the table that showed the 12 licensed dosimetry services submit electronically the dose information to the Registry according to prescribed specifications.

MR. HARVEY: My sub-question is the -- that when there is some means or direct measurement and some others are like (indiscernible) counting, urine, BOSA, and whole body, so there is treatment to do before to -- to send the data to the -- I suppose there is some kind of treatment, some type of analysis to do before?

MS RICKARD: Yes, almost in all cases there is an analysis that needs to be done to actually calculate the dose, and then the dose information is sent, as I mentioned, according -- Melanie Rickard for the record -- according to prescribed specifications. So, for example, if we look at something quite detailed but familiar,

tritium, the tritium dose is sent in a certain way and it's captured that it is, in fact, tritium and who it was measured by, who -- who the dosimetry service was, for example, and that all of those details are documented in the input specifications, but of course there is analysis that needs to be done. Most of these instruments don't just spit out a value. There is some health physics knowledge that needs to be taken into account to calculate the dose.

MR. HARVEY: And the personal data, I mean -- and exposure, are they accessible to the worker? If the worker wants to know his own records, so he can -- he has access to the Registry?

MS RICKARD: Melanie Rickard for the record. I'll start. The licensee is required to inform, by regulation, the doses that are received to the worker. So the workers are informed as their dosimetry records are available. In addition to that, any person who has a dose record in the National Dose Registry can request that information from the NDR. There's a form that's available that they can fill out and request the information.

And if you need further information on how the licensee informs the worker, I'll ask Caroline Purvis to add if -- if you need further information.

MR. HARVEY: Okay then.

MS PURVIS: Caroline Purvis, Director of the Radiation Protection Division, for the record. I think -- I think it was well captured, section 7 of the Radiation Protection Regulations places obligations on the licensees to provide certain information to nuclear energy workers, and one of those items is their dose information. So essentially on -- on some periodic basis licensees must inform all NEW workers of what kind of exposures they're receiving.

MR. HARVEY: Okay. Thank you.

THE PRESIDENT: Ms Velshi.

MEMBER VELSHI: Thank you. Of the four sectors that you have presented here, just generally proportion of those by sector, can you -- can you give, you know, is it 50 percent NPPs versus whatever?

MS PURVIS: Sorry, just -- Commissioner Velshi, can you just clarify your

question? Do you mean -- I am just not certain what you mean by your question.

MEMBER VELSHI: If you took it by person sieverts or millisieverts, where does the greatest contribution of dose come from? From which sector?

MS PURVIS: Okay. In -- in comparison between the four sectors in terms of ... Certainly when we look at our nuclear medicine example, you can see that the sector is -- has relatively low doses, and typically the -- the doses for workers fall in the range of less than 5 millisieverts.

Uranium mines historically have -- have certainly higher doses in comparison to other sectors, but with new modern mining techniques their doses are coming down. Maximum dose is usually average about 10 to 12 millisieverts but a-- the average dose is usually around 2 or 3.

But if you looked at the collective dose, I would say because of the number of workers in the nuclear power plant industry as -- as an industry and compared -- when you compare it to the others, their collective doses are certainly higher. But if you looked at an

individual basis, the industrial radiography workers often have -- have high individual doses.

MEMBER VELSHI: Thank you.

You mentioned that with the new Radiation Protection Regulations the dose limit for the lens of the eye is going to change. What's it changing from to?

MS RICKARD: Melanie Rickard for the record. The current dose for the lens of the eye is 150 millisieverts per year. So that's to the eye only. And we're proposing to change it to 100 millisieverts over five years or 50 millisieverts in any given year. That would be in line with the current whole-body effective dose limit.

MEMBER VELSHI: And is eye dose measured separately or is it -- like, how is it even monitored?

MS RICKARD: It -- Melanie Rickard for the record. It should be moni-- no, I'm going to back up. It can be monitored separately. Right now because the dose limit is so high, lens of the eye doses have not been captured. It -- essentially lens of the eye has not been at risk due to the -- the former information. With the

new information, we now know that the doses that might result in cataracts are lower. So this is one of the pieces of work that we have ahead of us with the proposals is we need to clarify expectations with regards to how the dose will be measured.

In some cases reliance on the whole-body dosimeter will be appropriate but in other cases it will not. For example, with beta radiation -- beta radiation or low-energy photons, we're going to need to explore how those doses should -- should be assessed. And I have been involved in some work that was done at the IAEA for this, so there are some guidance documents available that we'll be relying on -- excuse me -- to move forward with this.

MEMBER VELSHI: Okay. Thank you.

At previous meetings and hearings we have often heard about the NDR, reconciliation between licensees' information, how current the information is in the NDR. Can you just bring us up to speed on -- on those two things, please?

MS RICKARD: The information -- Melanie Rickard for the record. The information in the NDR is -- is current. In terms of the

reconciliation of data, we have discussed that issue with the NDR. They already have some projects underway where they're sort of working on a data reflection process with some of our licensed dosimetry services. What that would entail is the NDR has received the dose information and this is exactly reflected back to the submitter exactly what was submitted. Now, this is highly detailed line by line. We have spoken to the NDR about some other ways that we feel it would be effective to do the reconciliation and I would ask the NDR to comment on -- on what we can do moving forward because certainly there are resource -- resource issues for them but I -- I don't want to speak for them. I'd like them to -- to answer that.

MR. MARCOTTE: Oui. Bonjour.

Louis Marcotte from NDR. So, section head. Yeah, we -- we're working on a project right now with our programmation informatique people to -- to produce maybe a report to look at a way to reconcile or cross-reference any batch file that is being processed on a delayed basis with every service provider.

So we're working on this, and the

main goal is to make sure that what is being submitted to the NDR is being registered properly to the NDR, and we can only inform the CNSC what has been submitted to the NDR.

So sometimes there are doses that are not submitted to the NDR, but we can only work onto making sure that the cross-reference can be developed and been provided by a special report.

So we're working on this and we're looking at some options with the CNSC to find out what's the best way because every batch file that is coming to the NDR can be very high level in terms of lines of information, so we need to make sure that we are efficient in producing quality assurance and a good cross-reference report on every batch file.

DR. THOMPSON: Patsy Thompson, for the record.

Ms Velshi, was your question also related to validation of the data that is being sent to the CNSC as well through licensees' annual reports and how it aligns or not with what is being submitted to the NDR?

MEMBER VELSHI: That's exactly correct.

MS RICKARD: Melanie Rickard, for the record.

Yes, I thought that's what you were getting at.

What I wanted to make clear was that we discussed this with the NDR and exploring some ways -- the most effective ways to do this because, as you've heard from the presentation, it is complicated. Not all licensees use exclusively dosimetry services, first of all, so their dose data will not be in the NDR, but certainly we think that it is valuable to do a cross-reference to make sure that large, or small, errors are not being made.

So we have identified the need to do this and we need to work with the NDR to ensure that they have the resources in place that they can meet the needs that we're talking about.

We foresee approaching this maybe by identifying one or two key licensees where we think this will be a straightforward process, seeing how that goes, and then moving from there. But we've certainly taken that direction and we'll be moving forward on it.

Certainly the NDR has to have the

resources available to do that, so...

THE PRESIDENT: Okay. Can I ask the NDR, do you have the resources to do that?

I can see some companies that will pay you to actually go online and make sure that there's instant confirmation by the data and the reconciliation and, you know, we are now in the online universe, government online.

I just want to make sure that if you need the resources, you've got -- you know, that you have them.

MR. AHIER: So in terms of -- Brian Ahier, for the record.

In terms of resources, we would certainly have to look at what would be required to deliver a specific project, and that's -- those are the conversations that are happening between Health Canada and CNSC as part of the NDR/CNSC liaison committee.

In terms of human resources, that's one issue. In terms of financial resources and IT resources, that's an issue that we would need to deal with internally through our own processes within Health Canada. I think as we go forward and I clarify what the actual requirements

are for a project, that will give us an idea, and what additional resources would be required.

THE PRESIDENT: All I'm suggesting is we can help you. We can actually -- I'm trying to be diplomatic here -- insist on the format that the -- if you want the data uniformity online, et cetera, we work in many, many areas of reporting requirement to try to streamline them, the kind of -- the way to make them online so we can help you in having the licensees produce the data that you need in the format that you need.

So I see there's room here for great cooperation and moving because we're really eager to make sure that we reconcile the data that we collect and you collect.

MR. AHIER: Brian Ahier, for the record.

Certainly any assistance that the CNSC can provide in providing direction to the licensees would assist the work that's being done by the NDR. Any changes that would be made have to be made to the NDR itself in terms of programming is something that we still need to go through our own IT processes, which is somewhat separate from the submission of data.

We are dealing with that and we will keep you informed of how that unfolds.

THE PRESIDENT: Ms Velshi?

MEMBER VELSHI: My last question was, one of the services that NDR provides you, you said, was if there was a dose limit that's been exceeded, then they'd let you know.

So has that happened where you've heard from NDR before the licensee?

MS RICKARD: Absolutely, yes.

I can't think of a specific example, but certainly that does happen.

In some cases, that makes sense because if the worker is mobile and they're working for different employers, the -- it would make sense that the NDR got the total dose faster and submitted it to us before any given licensee, particularly if the dose was received at a licensee where the worker worked previous.

And as I said, I'm not being able to come up with the specific example, but certainly from time to time licensees are not compliant with that requirement to let us know, so we do think it's a fantastic backup.

THE PRESIDENT: Mr. Tolgyesi.

MEMBER TOLGYESI: On your first slide, you are saying that radiation protection programs are submitted by licensee when applying for licence. But is the licence condition -- conditional to the submission or to the approval of radiation protection program?

That means if your program is not approved, you don't have a licence.

DR. THOMPSON: Patsy Thompson, for the record.

I'll start, and then perhaps Ms Purvis can complete.

An application for a licence has to have a proposed radiation protection program that meets the requirements of the radiation protection regulations.

The CNSC staff will review the proposed program for acceptability, and there is some back and forth if necessary to make sure the program is adequate.

From time to time, the licensees will make revisions of this program, and those are reviewed on a risk basis. And further to that, there are inspections to make sure that the RP program is implemented.

So there are several checks and balances to make sure that there is an RP program in place and it is effective.

MS PURVIS: Caroline Purvis, for the record.

I'm not sure I can add too much other than to say there's obligations for all licensees that are specified in the general regulations that mention that an application for a licence must be -- submit the measures necessary to show compliance with the radiation protection regulations.

Sorry; I'm paraphrasing. I don't have it memorized.

And also, of course, once accepted as part of the application for a licence, it forms part of the licensing basis, so certainly it is subject to, you know, proper implementation and enhancements as necessary.

MEMBER TOLGYESI: On the slide 7, you are saying that if the time and the resources required for direct measurements as a result of monitoring outright the usefulness of a certain amount of exposure, how do you define the usefulness? Where is that, when you stop to

measure and you do -- you do estimations?

MS RICKARD: Melanie Rickard, for the record.

Generally speaking, this paragraph 5.2(b) really refers to -- as we mentioned, in some cases, the ability to directly measure is quite expensive. We didn't go into details, but some of these methods are substantially costly.

And certainly if the doses are expected to be very low, one could make the argument that it is not warranted.

That's sort of the general sense of it, but it's looked at on a case-by-case basis.

And my last is when I look at uranium mines as an example, you say in the slide 25 that the measure external exposure two types of devices are used, the OSLD and EPD.

One is licensed, where the other one is not.

What's the difference in the measure that precision and when you require licensed measurements or not licensed? Is it five millisievert threshold or is something else?

MS PURVIS: Caroline Purvis, for the record.

I'll start, and then I'll pass the question about precision to my colleague.

Certainly there's a difference between those two devices. The passive dosimeter, the OSLD, of the Optically Stimulated Dosimeter, is similar -- has many similarities with probably the more well-known TLD. It's the official dose of record.

In other words, it's a dosimeter which you've probably all seen. It's a badge that you wear on your thorax, and it is monitoring the exposure to an individual over a period of time, whether it be a month or a quarter.

Because it doesn't have real-time display, there -- it's really not used for dose control purposes. It's more of a retrospective dosimetry.

So as I said, that's the official dose of record. It's also a licensed technique, and it -- inherent to being licensed, it has certain accuracy and precision requirements.

The direct reading dosimetry, the DRD as is -- or EPD, Electronic Personal Dosimeter, is a dose control device, for the most part, for this type of work.

It, in fact, is required in the uranium mines and mills regulations. For certain radiological environments, they must wear one.

But really, for all intent and purposes, this device is worn usually in a similar position on the body to the OSLD and it's pre-set for a dose rate and for accumulated dose, so it's controlling doses to workers every day in real time so that they would be alerted to out-of-normal conditions and they could back out and reassess.

And so with that, I think I'll pass it over to Melanie Rickard to talk a little bit more about the precision requirements for the licensed dosimeter.

MS RICKARD: Melanie Rickard, for the record.

Were you asking about the comparison between the results of the two devices specifically?

Okay. So it depends on the situation, but a general rule of thumb that's quite well accepted is that if the difference between the two devices is more than about 15 percent, then it needs to be investigated,

essentially.

So normally, they're quite -- in most situations, the values are quite similar, and if they're not, the licensee normally is required to look into why that difference has occurred.

MEMBER VELSHI: And is only the OSLD results are transferred to national dose?

MS RICKARD: Absolutely, yes. As the dosimeter of record.

And I'm just -- just if you're curious, I'm holding one just to show you sort of how big it is and what it looks like.

THE PRESIDENT: This?

MS RICKARD: This is the OSLD. This is a product that's actually offered by Landauer, which is based in the U.S. It's very popular.

TLD and OSLD are very, very popular. There are two passive dosimeters that are available from the --

THE PRESIDENT: So is that a licence that's --

MS RICKARD: Absolutely, yes.

THE PRESIDENT: So let me ask you, you know, this old saying about trust and verify.

You gave the licensee the ability to say I'm never going to have above five millisieverts or I'm not reporting any of this stuff. Does it happen that any of those people actually find, to their surprise, that they're above five millisievert and what are the repercussions?

MS PURVIS: Caroline Purvis, for the record.

I do have an example that just came to mind recently, and it's certainly been in front of the Commission as well.

It was a result of the errors at Chemical Fuel Manufacturing with respect to their spreadsheet for determining internal doses to workers.

That particular technique was not licensed by the CNSC. When the new Act and Regulations came into effect, there was certainly a review of how they ascertain internal exposures to uranium compounds and it was determined at the time that the potential for exposure was less than was required to license that technique.

However, recent evidence through the errors that were revealed in the spreadsheet

indicated that, in fact, those exposures were higher, historically, than had been reported.

And so when they did that reassessment and they presented the new data with the corrected spreadsheet, that was the time when myself and my staff started to question the licensee and actually said, you know, we needed you to go back and look and see whether it was appropriate to continue with that technique outside of a licensed dosimetry service.

Cameco did take that into consideration and they're proposing to license a technique now to ascertain dose for internal exposures to workers.

So that's one example. Of course, we always are watching.

And as I responded earlier to Mr. Tolgyesi, of course the program that's submitted and accepted is not static, and advancements in technology will change, new information will come to light, OPEX from other licensees will surface and will allow us to question some of those assumptions.

THE PRESIDENT: Mr. Tolgyesi?

Anybody else?

I got -- I hope that this deck will eventually find its way to our web site. I find it very informative, and there is a lot of misunderstanding about that, so I think that would be useful.

I wanted to ask the NDR, do you register also doses from x-ray work?

You know, we've been hearing about the medical community having a lot of x-ray, fluoroscopy, single dose nature. Do they get captured by you guys?

Do they have to report?

MR. AHIER: Brian Ahier, for the record.

The NDR accepts occupational radiation exposure records from essentially three groups of workers. One are the nuclear energy workers regulated by CNSC that use a licensed dosimetry service.

We also accept doses from occupationally exposed workers that are regulated by provincial authorities such as workers that are exposed to x-rays.

Then we have another category of occupationally exposed workers, but the NDR is

limited to the exposures to workers. We don't accept the -- we don't accept exposures to patients, for example.

THE PRESIDENT: Dr. Thompson.

DR. THOMPSON: Perhaps, Mr. Binder, the question you're asking is about whether the - in the measurement of doses from medical practitioners, for example, whether doses from fluoroscopy procedures are reported as such to the NDR.

And so Ms Rickard followed up with Health Canada staff yesterday, and because of the information that Mr. Ahier has just provided, there isn't a specific category called fluoroscopy. And so the doses from fluoroscopy procedures are being captured within what is called, you know, doses from x-rays.

So it's accumulated with other types of exposures and reported as a sum, and not specifically for fluoroscopy.

THE PRESIDENT: I think if I understand correctly on fluoroscopy, particularly, each procedure dose is low, but it's a cumulative effective, right. Those people have annual many, many procedures, so there's a cumulative effect

here.

So you may be under the five millisievert on each operation, but it's -- I guess it's the annual dose, right.

So I'm trying to figure out whether it's almost automatically they're using a licensed dosimetry service and, therefore, they automatically will get captured.

DR. THOMPSON: Patsy Thompson, for the record.

I'll start with some information, and then Ms Rickard will complete the information, and perhaps Health Canada will have something to add.

I've been Canada's representative to the IAEA's radiation safety standard committee for a number of years. The IAEA, the World Health Organization as well as other organizations have been looking at doses to medical practitioners because of the number of procedures and changes in techniques.

It has been recognized as an issue for practitioners. There's been a lot of committees and international work.

There's also guidance and

educational material being developed for medical practitioners, but it's recognized as a group of people who are difficult to manage, I guess, and there's essentially a requirement to do a lot of education to make sure that doctors are adequately protecting themselves as well as other staff involved in those procedures.

The information that Ms Rickard and her team collected from the representatives from the federal territorial -- federal provincial territorial radiation protection committee is that the provinces have -- many provinces have regulations in place to control worker exposures, but British Columbia is probably the only province to have moved forward with preparing of guidance material to educate doctors to the need to better -- to take better protection measures.

MS RICKARD: Melanie Rickard, for the record.

I actually don't have a lot to add to that.

As you're aware, we don't -- we don't have a mandate over fluoroscopy, so I certainly don't have any first-hand experience with the procedures.

But in preparing the information that we submitted to you -- well, actually, first, to just answer your question, if they are being monitored, which I do believe they are using dosimeters, the doses are cumulative, so those doses that are captured by the licensee's recordkeeping system, at a minimum, are entered into the NDR if they're submitting would be the total dose that they get from all exposure to ionizing radiation associated with their work practices.

And also, I just wanted to mention that the motivation -- or the fact that the dose limit for the lens of the eye is going to be reduced is actually very important for these type of workers because it's been recognized that their doses to the lens of the eye are actually quite high, so they've actually been looked at specifically for that hazard profile.

Finally, yes, some of these procedures can be carried out by the same physicians or workers hundreds or even up to 1,000 times a year, so bit by bit, the dose will accumulate. But as I mentioned, that would be handled under the provincial jurisdiction under

their regulations, not ours.

THE PRESIDENT: Does Health Canada wish to add to this?

MR. AHIER: Brian Ahier, for the record.

I think the important point is if they are being monitored, the information is going to the NDR and the accumulated doses are trackable.

THE PRESIDENT: Okay. Thank you. Anything else?

Okay. Thank you. Thank you very much, and thank you for being with us here a bit late.

And we're still not done.

We have one more item, and it's an update to the CNSC designated officer program as outlined in CMD 14-M24, 24.A and 24.B.

We are quite familiar with this, I expect, and given the time element, we all read the deck and the tables.

CMD 14-M24/14-M24.A/14-M24.B

Oral presentation by CNSC staff

MR. JAMMAL: Ramzi Jammal, for the record.

Encore une fois, bon soir, Monsieur le Président et les Membres de la Commission. I got your hint, so we can do it in two ways.

Well, first of all, I would like to introduce the work that was done by the team, and I will be amiss not to mention our colleague, Marc Leblanc, who's an integral part of this team.

Mr. Chamberlain will walk you through the presentation and, again, if you read the deck, we'll be more than happy to take the questions right off the bat. But for the record, we'd like to go quickly through the deck.

We'll take your advice, sir.

THE PRESIDENT: Well, just gallop through it very quickly, just bring in the highlight.

MR. LEBLANC: The first 10 slides are important and they won't do the other slides at the end.

THE PRESIDENT: Well, go ahead. The first 10 slides I hear are important.

MR. CHAMBERLAIN: Great. Thanks

very much, Ramzi.

Hello, Mr. President, Members of the Commission. For the record, my name is Rob Chamberlain, Senior Project Officer and the Director of the Regulatory Improvements and Major Projects Management.

So the purpose is to give you an overview of the proposed improvements to the DO Program. The goals of the DO Program are to assist the Commission regarding designation of DOs and to assist DOs in carrying out their duties on behalf of the Commission.

These improvements are essentially a formalization of what is currently happening.

This is just background information. Under subsection 37.1, the Commission designates DOs to carry out duties on their behalf. The tag line there which says:

"DOs are designated by the Commission to make licensing decisions for lower risk facilities and activities."

(As read)

So the next two slide DO regulatory duties. Here are four of the nine

regulatory duties available for DO decision. The first bullet on prescribed equipment; examples of prescribed equipment are radiation devices and particle accelerators.

The second bullet on certifying/decertifying persons; examples are nuclear power plant operators, exposure device operators and radiation safety officers.

As noted in the tag line, due to the appeal process on decertification, the decertification of nuclear power plant operators will only be exercised by the Executive VP of ROB or the Vice President of Technical Support Branch.

Issuing licences. Issuing licences are for lower risk facilities and activities. This does not include licences for nuclear power plants or other Class 1, 1A or 1B facilities, all of which require Commission approval.

Types of DO issued licences are nuclear medicine, industry radiography and these are outlined in the classes of licences, CMD 01-M17.

And the last bullet, DOs can renew, suspend, revoke or replace or authorize

transfer for the same classes of licence as they are permitted to issue.

This slide here, this is the five remaining regulatory duties for DO decision. DOs may designate inspectors and this is done following completion of the CNSC's inspector training and qualification program. This program is now almost five years old. It's a success story and has been recognized internationally as a good practice.

DOs can make orders like inspectors may make; confirm, amend or replace them as well; authorize the return to work in cases radiation doses have exceeded limits; and, issue notices of violations as administrative monetary penalties.

This is an example really of the most common DO duty that's exercised, is issuing a licence. So Staff conducts a licence assessment, puts the recommendations into a Designated Officer document, a DOD as opposed to CMD. The DO conducts the review, they may ask for more information and they make a decision, issue a licence or send a letter of refusal.

It's important to note that rigor

is applied to all requests for DO decisions and there's no compromise to safety.

Some of the history of the DO Program. Back in the year 2000, coming into force, the NSCA include a provision for designating DOs. Two changes were made to duties last year pertaining to licence transfers and the issuing of administrative monetary penalties.

Now, what we've listed here is only three of the eight CMDs taken to the Commission on the DO Program. The others were administrative in nature to align with operational changes and I refer you to Annex "B" of the CMD for the complete CMD history.

So last year we started this operational review of the DO Program. This was the first major review since its inception in the year 2000. The review was triggered as part of the commitment to ongoing improvements under the CNSC's management system.

So this is where the Staff review started. Who are our DOs, what do they do and what needs to change?

Well, currently there are 47 positions with DO duties, but some DOs rarely

exercise those duties. The distribution of DO positions didn't match the licensing decision-making roles in ROB and TSB and a need was identified for back-up DOs in high volume areas. So here's an improvement opportunity now to strengthen and structure a consistent approach to designating the DOs.

So what did Staff evaluate? Well, Staff evaluated all nine regulatory duties against the operational needs of ROB and TSB; Staff then confirmed the best fit for DO positions and duties based on number and frequency, type of duties, licensing, decision-making roles and the number of DOs to meet the operational needs.

What are the results? Well, 20 DOs rarely exercise DO duties; 31 DO positions are needed across the CNSC to address all DO duties including the volume of lower-risk licensing decisions. Staff will conduct a periodic review of DO designations and, on the subject of decertification of nuclear power plant operators an internal governance structure is in place. Looking internationally, no technical support organization renders licensing decisions.

So the proposed improvements.

Staff proposes that 20 current positions no longer require DO duties and that the proper 31 positions by title of office have DO duties assigned to them.

Now, please note that the Annex to this presentation summarizes the duties by branch and directorate, if you wish to see that.

A couple of slides here on conclusion. Staff concluded efficiencies would be gained by reducing the number of DOs from 47 to 31 and I refer you to Annex "D" of CMD 14-M24B for that Annex.

Staff believe that the impact by these improvements are low risk because DO decisions can be made by the remaining DOs and the DO structure includes back-ups in the event the primary DO is absent or not available.

The DO Program is going to be supported by a process document and work instructions, as well as tools and references to assist DOs in carrying out their duties on behalf of the Commission.

So if accepted by the Commission, the consequential actions will take place; namely, discontinuance of the current DO list and

revocation of all current certificates of Designated Officer and then the issuance of new certificates in accordance with that Annex "D".

So Staff recommends the Commission accept the DO positions and duties as illustrated in the Annex.

Staff are now available to answer your questions.

THE PRESIDENT: Thank you.

Question? Monsieur Harvey...?

MEMBER HARVEY: You have a sort of periodical or annual evaluation of DO decision and how does it work? I mean, once you are a DO you can do your job and how is it supervised and how can you say that all have been respected in all the current DO requirements in...?

MR. JAMMAL: It's Ramzi Jammal, for the record. Your question is very valid. Two things:

The DO process itself. The DO renders a decision based on recommendation from Staff, so the decision is based on recommendation from Staff and the DO has the power to request additional information, just like the Commission. As a matter of fact, the Rules of Procedure apply

to the DO with respect to the decision of the DO.

You are asking a question, do we do an audit function to make sure the DO is rendering the proper decision? We have in DNSR, in that directorate, there is a cross-verification with respect to the decision presented by Staff to the Designated Officer, more of a quality assurance, to make sure that all the requirements have been completed and then the DO decision is rendered according to the Rules of Procedure.

We should not forget the fact that if the DO renders a decision where he or she does not approve a licence, nor certifying a prescribed; so, in other words, if the applicant did not meet the requirements for the DO to issue the licence or prescribed equipment certification, the matter is referred to the Commission for information and there is always an appeal mechanism, that the DO decision can be appealed to the Commission.

But the room is full of my colleagues who are the Designated Officer, and then I will pass on the mic for any added information, specific, Mr. Fondrick, Mr. Régimbald group and the most voluminous activity with

respect to the DO decision.

THE PRESIDENT: Just to put context in there, there is a nice table on page 7 that will give you what DOs do in the CNSC and, by and large, the NSR, they are licensing 2,000 kind of a year, so that's their factory here.

MEMBER HARVEY: I don't know about that, but my point was just because we are giving our responsibility to somebody else, is there any means to control it and to be sure that what we gave to somebody is okay, and not more than that, except what has been... Mr. Régimbald?

MR. RÉGIMBALD: Yes, André Régimbald, for the record. In the Directorate of Nuclear Substance Regulation, I'm the Director General and I have my Directors who are Designated Officers. We work very well, we work close by. We don't have a specific audit function or a systematic review function because, as Mr. Fondrick will explain, there are over 2,000 licensing decisions a year. There are procedures in place, we have to abide by the Rules of Procedure.

I have a regular performance review with Peter and all my other directors and

the annual performance review. So -- and also there are processed in place that, like Mr. Jammal explained, that the licensee can -- if the licensee is not satisfied then there are mechanisms to report any deviations or unsatisfactory rendering of service.

So I'll let Mr. Fundarek elaborate on his role and perhaps explain what sort of quality control mechanisms are in place. And also Ms Murthy and the other --

MEMBER HARVEY: I don't plan ---

MR. REGIMBALD: Yeah.

MEMBER HARVEY: It's just a feeling, I wanted to have your answer, and that's okay. I mean, at the moment it's just I say, somebody is not alone in his office and doing what he wants to do. I mean there is a collegiality inside of the Commission.

THE PRESIDENT: No, but I -- they're the most scrutinized. They have annual reports, you know, they come up with annual reports. We have an ordered function, so make sure that the -- that procedures are okay, and we have an evaluation function that talks about the regulatory scheme and whether they're doing

their -- performing according to our own regulatory documents. So all of these are in play.

MEMBER HARVEY: I've got the answer I was looking for, that's okay.

MR. JAMMAL: I haven't surveyed the -- it's Ramzi Jammal for the record.

Just, with all seriousness, if the licensee is not happy at all and there is always the appealing mechanism to the Commission. In addition, you asked the question if the subject or the matter is -- I won't go to complex, but it's more of a public interest we refer such cases to the Commission. For example, steam generator, it was referred to the Commission in order to render its decision.

So the -- at the end the Commission always have the utmost power, whether it be a panel of one or the Commission as a whole, to revoke, amend, or change the DO's decision.

THE PRESIDENT: I know Peter is dying to say something about this.

MR. FUNDAREK: Peter Fundarek for the record.

I just want to add that the Act

and Regulations also limit the power of the DO to making decisions with respect to where an applicant has submitted an application. Only the Commission has the authority to act on its own motion. So that's the first level of control, that we can only act where there is an application by an applicant.

As a designated officer, if I come to the -- if I receive a recommendation from my staff that says not to issue a licence, not to authorize a transfer, or not to certify a piece of prescribed equipment, I have to at that point stop the process and provide the applicant with an opportunity to be heard. To provide any additional information pursuant to the regulations and the prescribed rules of procedure, so that the applicant has the option at that point in time, to provide additional information for my consideration before I render a designated officer decision.

Once that information is all collected, as Mr. Régimbald indicated, we have written assessment forms that the licensing specialists complete. That's documented. All that other information is documented. It goes for

a quality assurance review by senior staff, they concur with the recommendation. It comes to me for the designated officer decision, and like I said, at that point if I need to I can ask the applicant to provide additional information. I can go back to my staff and ask them for additional information and then when I'm satisfied, then I render the decision.

If the licensee is -- or sorry, if the applicant is still not satisfied with the decision, at that point they can then also appeal to the Commission.

THE PRESIDENT: Ms Velshi?

MEMBER VELSHI: I've got a few short questions. So first of all, I applaud you for this initiative.

So for those 20 who will have, if the recommendation's accepted, have the designated officer revoked, what was their reaction to that likely to be?

MR. JAMMAL: Chairman -- Ramzi Jammal for the record.

It's -- as this project started the governance and operational review was done within the CNSC and we have an operation

management committee which I chair, and this information was built over time from a multidisciplinary team. The team consisted of multiple directorates from all the branches who are impacted by this decision.

So the review had shown -- actually, it was lead by Mr. Chamberlain who would not embark on the details. So the analysis was done and the information was shared with all of the designated officers who are my colleagues around the table, the DGs.

And this presentation was shared with them in order to make sure we do not omit, to verify, to evaluate, that what we've done is adequate, and their decision was -- yes, they never rendered a decision, so there is no point being the designated officer.

MEMBER VELSHI: Okay. So it's not as though they feel there's a major part of a recognition that's suddenly been taken away from them or something?

MR. JAMMAL: Ramzi Jammal for the record.

Not at all. It was more of an operational need and the data itself, the data

spoke for itself. Where for -- since the existence of the CNSC there was no DO decision rendered.

THE PRESIDENT: Now, that's include DAA, right?

MR. JAMMAL: Correct.

THE PRESIDENT: Okay.

MEMBER VELSHI: I know the recommendation is to revoke the designation for all and then reissue it to the 31. So why not just revoke it for the 20 and then issue it for the additional whatever it is, four or so?

MR. LEBLANC: I mean, we ask ourselves that question. The reason we're not doing it is the certificate refers to a particular CMD that's been updated that provides to them those authorities. So we need to issue new certificates, and this is handled by the Secretariat.

THE PRESIDENT: Any other questions?

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

I'd just like to really clarify one thing. The designation of a DO is not a staff

cutting measure. If I -- I just want to make sure it's -- I do not want to leave the perception that if the designation is removed the person will lose his or her job.

MEMBER VELSHI: Yeah. It wasn't that. It's sometimes, you know a job evaluation is based on what kind of responsibilities you have. And if that's seen to have been a core part of their job and now it's taken off and -- yeah. But you've answered that. Thank you.

THE PRESIDENT: Anybody else? Okay. Thank you. Thank you very much.

Yeah, dinner. So I am -- no because I have to read -- this concludes the public meeting for today. The meeting will resume tomorrow -- this is the public meeting -- at 2:30. Thank you for your participation. But we are --

MR. LEBLANC: Back at 9:00 for the --

THE PRESIDENT: -- back at 9:00 for --

MR. LEBLANC: The McMaster.

THE PRESIDENT: -- for the McMaster. Okay.

So we are back here tomorrow at

9:00 for the public hearing on the McMaster application.

Thank you.

--- Whereupon the meeting adjourned at 8:20 p.m.,
to resume on Thursday, May 8, 2014
at 9:00 a.m. / La réunion est ajournée
à 20 h 20, pour reprendre le jeudi
8 mai 2014 à 9 h 00