1 --- Upon resuming in public at 10:36 a.m. 2 THE CHAIRPERSON: Good morning, ladies and 3 gentleman, and welcome to this public hearing of the 4 Canadian Nuclear Safety Commission. 5 I would like to begin by introducing the 6 Members of the Commission who are with us today for the 7 hearing. 8 On my right is Dr. Moyra McDill and Dr. 9 Christopher Barnes. On my left is Mr. Alan Graham. 10 Monsieur André Harvey who was with us for 11 Day One can't be with us today unfortunately. And 12 therefore, he will not, Mr. Harvey will not participate in the decision process. 13 14 In addition to Mr. Marc Leblanc, the 15 Secretary of the Commission, we also have Miss Samantha 16 Maislin-Dickson, who is the Acting General Counsel to the 17 Commission, with us on the podium today. 18 I would like to emphasise that the 19 Commission is a quasi-judicial administrative tribunal. It's independent of all influence, be that political 20 21 government, private sector or non-governmental 22 organizations. 23 The Commission Members are appointed by the 24 Governor in Council to serve during good behaviour, not at 25 pleasure, on the basis of their exceptional achievements

1 and their excellent reputation.

2 Our responsibility is to ensure that the 3 use of nuclear materials and the operation of nuclear 4 facilities is done in a manner that protects the environment, health, safety, security of Canadians. 5 The 6 Commission does not have an economic mandate and its 7 decisions are not based on the economic impact of the 8 facility nor on the impact of our decision on the 9 facility. It is the safety and security of people and the 10 protection of the environment that are paramount. 11 I would also like to note that the 12 Commission is still on enhanced security status as are 13 many of the facilities that we regulate, including the 14 Chalk River laboratories today. 15 I will, if necessary, take measures to 16 ensure that security matters of a sensitive nature are not 17 discussed in public and we will, if necessary, move in 18 camera at any time for discussions on security matters. 19 The item on the agenda today is Hearing Day 20 Two on the matter of the application by Atomic Energy of 21 Canada Limited for an operating licence for its Dedicated 22 Isotope Facilities located at the AECL's Chalk River 23 Laboratories in Chalk River. MR. LEBLANC: As the President has 24 25 indicated, this is Public Hearing Day Two. Day One of the

public hearing on this application was held on June 22nd,
2007. The Notice of Public Hearing 2007-H10 was published
on April 19th, 2007. The public was invited to
participate either by oral presentation or written
submission. August 13, 2007 was the deadline set for
filing by intervenors.

7 The Commission received 13 requests for 8 intervention. One submission was received shortly after 9 the deadline. Based on a consideration of the matter, a 10 panel of the Commission accepted the intervention.

11 The Commission strongly urges all parties 12 to file their submissions within the deadlines that are 13 set in the public Notice of hearings, in compliance with 14 the CNSC Rules of Procedure.

Presentations were made on Day One by the applicant, Atomic Energy of Canada Limited, under Commission Member Documents, or CMD 07-H16.1 and 07-H16.1A, and by Commission staff under CMD 07-H16 and 07-H16.A.

20 September 5th was the deadline for filing 21 of supplementary information. We know that supplementary 22 information has been filed by CNSC staff, AECL, as well as 23 intervenors.

24 THE CHAIRPERSON: With that preamble, I
 25 would like to start the hearing today by calling on the

presentation from AECL outlined in Commission Member Document 07-H16.1B. I note that Mr. Brian McGee is with us today, but I understand that Dr. Torgerson, who is the Senior Vice-President and Chief Technology Officer will be involved in the presentation today.

6 Welcome, gentlemen, to the Commission and 7 the floor is yours, gentlemen. Thank you.

- 9 Atomic Energy of Canada Limited:
- 10 Application for an operating
- licence for its Dedicated 11
- 12 Isotope Facilities Located at AECL's
- Chalk River Laboratories in 13
- 14 Chalk River, Ontario
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- 07-H16.1B 16
- Oral presentation by 17
- 18 Atomic Energy of Canada Limited

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MR. TORGERSON: Well, good morning, and 21 thank you very much, Madam Chair and members of the 22 Commission.

23 My name is Dave Torgerson. I am Senior 24 Vice-President and Chief Technology Officer of Atomic 25 Energy of Canada Limited.

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1 With me today are Mr. Brian McGee who is 2 Vice-President and Chief Nuclear Officer, and Mr. Ron 3 Cullen, Vice-President Projects, as well as some of the 4 members of AECL's team who have been working on this very 5 important project. 6 We are here today in support of our 7 application for the renewal of the MAPLE reactors and New 8 Processing Facilities licences for a period of 47 months to October 31st, 2011. 9 10 We have also requested the Commission 11 combine these licences into one licence for the Dedicated 12 Isotope Facilities, or DIF, which consist of MAPLE 1 and 13 2, the Iodine Production Facility and the New Processing 14 Facility. 15 Combining the licences and the 47-month 16 renewal period will align the DIF licence with the CRL 17 site licence and will facilitate the eventual inclusion of the DIF licence into the CRL site licence. 18 19 We recognize and fully accept our 20 obligation to demonstrate to the Commission that we have 21 operated the Dedicated Isotope Facility safely and that we 22 will continue to do so with due regard to the environment, 23 security and Canada's international obligations. I want 24 to assure the Commission that I take this obligation very 25 seriously, as does our board of directors.

1 I would like to thank all of the 2 stakeholders who have either travelled here today to 3 participate in the licence renewal process or have 4 submitted written interventions. We are very appreciative 5 of the support and interest from our community 6 stakeholders. 7 In closing, Madam Chair, I want to 8 reiterate to the Commission that AECL is deeply committed 9 to the safe and responsible operation of our facilities. 10 We recognize our obligations to uphold the trust and 11 confidence of both the Commission as well as the public 12 and we will not compromise this trust. 13 I will now turn it over to Brian McGee and 14 Ron Cullen to provide a further update. Thank you for 15 your attention. 16 MR. McGEE: Good morning, Madam Chair and 17 Members of the Commission. For the record, I am Brian

19At the Public Hearing Day One on June 22nd,202007 we committed to provide certain information for Day21Two. Our Day Two CMD includes this information, as well22as an update on progress between Day One and Day Two.23Our presentation today covers key issues24from Day One, specifically the organizational structure

McGee, Vice-President and Chief Nuclear Officer of AECL.

25 associated with the Dedicated Isotope Facilities,

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1 elaboration of how the operations organization exercises 2 oversight of the project, an update on our plan and 3 schedule and an update on the positive coefficient of 4 reactivity issue. 5 We will also provide an update on progress 6 we have made at DIF since the Hearing Day One. 7 This slide shows how the Dedicated Isotope 8 Facilities and the MMIR project organizations are linked 9 and where the quality assurance functions sits. The President and Chief Executive Officer 10 11 has overall responsibility for all of AECL's activities 12 and operations. The authority for operation of AECL licence 13 14 facilities, including DIF, is delegated to the Chief 15 Technology Officer, Dr. Torgerson, as shown on the left-16 hand side of this slide. This authority is further 17 delegated to me as the Chief Nuclear Officer. 18 The Dedicated Isotope Facilities Operations 19 Director, who is also the Facility Authority, reports to 20 me, to the General Manager of Reactor Operations. The 21 Facility Authority has the responsibility for the safe 22 operation of the Dedicated Isotope Facilities, including 23 approval of modifications to the facilities. 24 The Authority for the management of the 25 Dedicated Isotope Facilities project is delegated from the

President and Chief Executive Officer to the Chief
 Operating Officer shown on the right-hand side of this
 slide. This authority is further delegated to Ron Cullen,
 Vice-President of Projects.

5 The MMIR Project Director reports to the 6 Vice-President of Projects. The Project Director is 7 responsible for the work undertaken by the MMIR project 8 personnel. He also has the overall line management 9 responsibility and accountability for the effective 10 implementation of the MMIR Project Quality Assurance 11 Program.

12 The Manager for Dedicated Isotope Facility 13 Quality Assurance works in the MMIR project organization 14 and reports administratively to the MMIR Project Director 15 and functionally to the Director of Corporate Standards 16 and CANDU products and services quality assurance. This 17 ensures a functional link to the corporate quality 18 assurance organization.

19The Dedicated Isotope Facility Quality20Representative, or FQR, Facility Quality Representative,21works in the Dedicated Isotope Facility Operations22organization.

The FQR reports administratively to the
 Director, DIF Operations, and functionally to the Manager,
 DIF Quality Assurance.

Both the manager for DIF quality assurance and the DIF Facility Quality Representative, or FQR, work closely together to ensure integration of the quality assurance function in both organizations.

5 This slide illustrates how the operations 6 organization exercises authority for overseeing all 7 activities in DIF, including project activities that 8 affect the facility.

9 The Facility Authority, or the Facility 10 Manager, approves all changes or modifications to the DIF 11 including their installation, ensuring that both 12 operations and maintenance considerations are taken into 13 account. All fieldwork is controlled by procedures 14 developed to meet the Operations Quality Assurance manual. 15 There is no distinction between execution of project work 16 or operations work from a quality assurance perspective. 17 In addition, the Facility Manager or Facility Authority 18 has to accept a system or a facility before it can be put 19 into service.

At the Hearing Day One there were questions around our plan and schedule for the Dedicated Isotope Facilities. I would like to clarify our intentions. During the proposed 47-month licence period, we intend to finish the PCR tests and resolve the

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PCR issue.

1 This will likely require design changes. 2 The nature of these changes will be determined by the 3 results of the tests remaining to be done over the next 4 few months. 5 Following implementation of the design 6 changes we'll commission them and bring MAPLE 1 into 7 service. We note the proposed licence condition requiring 8 Commission approval prior to MAPLE 1 being turned over to 9 Operations. This would involve a public hearing at which 10 we would seek Commission approval. 11 We also intend to bring the New Processing Facility into service and produce medical isotopes from 12 13 targets irradiated in MAPLE 1. 14 Finally, we will bring MAPLE 2 into 15 service. We in the Operations organization are relying on 16 our colleagues in the MMIR project to complete the project 17 and to deliver the facilities to us. 18 I will now turn the presentation over to 19 Ron Cullen, Vice-President of Projects, to update you on 20 our progress on the project. 21 MR. CULLEN: For the record my name is Ron 22 Cullen; Vice-President of Projects. Thank you, Brian. 23 Madam Chair, Commissioners, before I get 24 into the schedule itself I think it is important to point 25 out that the overall DIF schedule; that is, the schedule

1 for MAPLE 1, MAPLE 2, and NPF, depends very much on the 2 schedule and success of the PCR tests that are presently 3 underway on MAPLE 1. We need to complete the test to determine 4 5 the solution to the PCR issue so that we can resolve the 6 issue and get MAPLE 1 up and running. 7 This needs to be completed prior to 8 resuming the commissioning of MAPLE 2, as shown on the top 9 path of this slide. 10 We will also need to irradiate targets in 11 MAPLE 1 so that we can complete active commissioning in 12 NPF, as shown on the bottom path. So the overall schedule 13 is highly dependant on the schedule and results for PCR 14 testing in MAPLE 1. 15 This slide and the next one focus on the 16 MAPLE 1 schedule. At the Day One Hearing we were asked to 17 return on Day Two with an updated schedule and to compare 18 our current schedule to the one we presented at the 19 hearing for the previous licence renewal in 2005. 20 We have provided this information in the 21 CMD and the next few slides are a summary. 22 This slide shows the key MAPLE 1 milestones 23 from the 2005 schedule, on the top line, and the same 24 milestones from the schedule we presented on Day One on 25 the bottom line. As indicated by the middle line, in

February 2006 the entire project was redefined as AECL
 became owner of DIF.

The schedule was reviewed and revised and 3 4 the target in-service date moved to October 2008. This meant that after February 2006 the schedule presented in 5 6 2005 was no longer applicable. As reflected by the dotted 7 line and the shaded milestones on the top line of this 8 slide, CNSC staff was kept fully appraised of this change 9 and we informed the Commission of this change in our mid-10 term report in December 2006.

11 The key milestones, as presented at the Day 12 One Hearing in June of this year are shown on the bottom 13 line. The blue colour denotes the progress up to Day One 14 Hearing and the green represents the plan after Day One.

For example, we exited the guaranteed shutdown state, or GSS, in April 2006 and operated MAPLE 1 at two kilowatts, as stated in the June 2006 and up to Day One we were preparing for the PCR test at five megawatts.

Progress since Day One, and our plan going forward; that is, the green part of the bottom slide -- on this slide is expanded upon the next slide. This slide expands the timeline from the Hearing Day One to mid-2008. As a reminder, at the time of the hearing

on Day One we were preparing the MAPLE 1 core to measurethe PCR in the Series-300 tests which involves the use of

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LEU driver fuel instead of HEU targets.

Between Day One and now we tested the reactivity devices in MAPLE 1 and confirmed that the safety systems have sufficient re-activity depth for the modified core.
We measured the flow with a modified core geometry and assessed the impact on the safety analysis to confirm the adequacy of the safety case for this core

9 configuration.

10 We received approval from CNSC staff to 11 complete the Series-300 tests, allowing us to start the 12 power manoeuvre from low power to five megawatt to measure 13 the PCR. We completed the tests on August 24th.

14I am pleased to report that all of these15activities were carried out diligently and safely. There16were no significant events associated with this work.

17I will come back to the results of the most18recent tests after the next few slides on the schedule.

Our plan going forward over the next several months, as shown in the bottom right of this slide, is to complete the Series 400-A and 400 A-1 tests. We expect these tests to be completed in early of the New Year and we would expect our analysis of the results of these tests will help determine the optimum design solution to lower the PCR.

1 Our overall strategy, following these 2 tests, remains the same as we presented on the Day One 3 Hearing.

Our path forward, after the upcoming PCR tests depends on the outcome of those tests. And as I mentioned earlier, this means that subsequent schedule contains large uncertainties so that we cannot present a firm schedule for the steps after completion of these tests at this time.

10 Nevertheless, we understand the 11 Commission's interest in the schedule and therefore we 12 propose to come back to the Commission following the PCR 13 testing to provide an update on both the progress and 14 schedule; that is, rather than speculate on exactly what 15 will take place and when it will take place after we 16 complete the PCR testing, we would prefer to update the 17 Commission when we are more confident in the longer term schedule. 18

In the interim we will continue to have regular communications with CNSC staff and keep them informed of our progress. We will continue to provide CNSC staff with updated working schedules to facilitate CNSC staff resource planning.

24 We have found that this dialogue with CNSC 25 staff is an effective way to communicate an advance notice

1 of when requests for approval will be submitted. 2 Our working schedules for the PCR tests 3 typically assume that we will receive a response from CNSC 4 staff within one month of submitting our request for 5 approval. This allows time for CNSC staff review, receipt 6 of questions and comments and provision of supplementary 7 information. 8 This slide shows the key NPF milestones 9 from the 2005 schedule, on the top line, and the schedule 10 we presented on Day One on the bottom line. 11 Similar to MAPLE 1 schedule, the NPF 12 schedule was revised in February of 2006 when the project was redefined. 13 14 The bottom line also shows progress in the 15 blue colour, up to the Hearing Day One in June of this 16 year. 17 This slide expands the timeline from the 18 Hearing Day One to mid-2008. Similarly, to the earlier 19 slide on the MAPLE 1 schedule, between Hearing Day One and 20 now we successfully completed design qualification tests 21 for the cementation system and we have started the tests for the calcination system. This is significant progress 22 23 as these systems are critical to the success of the NPF. 24 We implemented all recommendations from the 25 HAZOP studies into the design changes required for the

1 active commissioning of NPF.

2 We continued inactive commissioning of NPF 3 systems, such as the MAPLE NPF airlocks and waste disposal 4 canisters as part of the commissioning work. 5 We prepared commissioning procedures for 6 other systems, such as the active ventilation system, the 7 liquid waste system and the vacuum transfer system. 8 Going forward over the next several months, 9 we will complete the design qualification test for the 10 calcinations system; continue implementation of the HAZOP 11 recommendations required for the in-service and the 12 implementation of additional design changes. Beyond that, the schedule for NPF is 13 14 dependent on the MAPLE 1 schedule, because active 15 commissioning in NPF; that is, commissioning with 16 irradiated targets relies on our ability to irradiate the 17 targets in MAPLE 1. We propose to update the Commission 18 on NPF progress at the same time as the MAPLE 1 update. 19 As I mentioned earlier, we completed the 20 300-Series test a few weeks ago providing information on 21 the effects of the HEU targets on the PCR. One proposed 22 mechanism that bowing of the targets; that is, small 23 deformation of the targets due to temperature 24 differentials, has contributed to the PCR. 25 The most recent test was designed to

1 investigate the effects of the HEU targets by replacing 2 them with LEU driver fuel. The results showed about a 30 3 percent reduction in the PCR, which is within the expected 4 range. This reduction confirms that the HEU targets are a 5 significant contributor to the PCR.

6 The next test will investigate the 7 contributions from other phenomena believed to contribute 8 to the positive PCR.

9 After all of these tests are completed and 10 evaluated we will be in a better position to identify the 11 specific design changes required to finally resolve the 12 PCR issue, and at the same time to provide an update 13 schedule for the next steps.

14 This slide summarizes the independent 15 support of other organizations provided on the PCR. The 16 PCR measurements, how they are measured, processing and 17 analysis were reviewed by two independent and third-party 18 organizations, Brookhaven National Laboratory in the 19 United States and INVAP in Argentina. These reviews 20 concluded that all measurements and data analysis were 21 done correctly. Both organizations made recommendations 22 which have been included in the PCR test plan.

23 The Idaho National Laboratory has been 24 contracted to provide an independent calculation to 25 support AECL's work to investigate the positive power

1 coefficient of reactivity issue. 2 The scope of these independent calculations 3 were described in our CMD for the Day One Public Hearing. 4 I will now turn the presentation back to Mr. Brian McGee. 5 6 Thank you. 7 MR. McGEE: Thank you, Ron. 8 Brian McGee for the record. 9 Over the last couple of months we have also completed other tests. The MAPLE 2 Reactor has been 10 11 defueled and now resides in the guaranteed shutdown state. 12 After receiving the CNSC staff report from 13 the April 2007 commissioning audit we prepared an action 14 plan to resolve the items detailed in the report. The 15 actions are now being implemented and we are actively 16 resolving the outstanding issues. 17 We have continued to operate MAPLE 1 safely 18 and to commission the New Processing Facility safely and 19 we will continue to do so. 20 Since Hearing Day One we have had no free 21 day resets and no lost time accidents in the Dedicated 22 Isotope Facilities. We continue to raise impact reports 23 as a vehicle to prevent significant events. 24 In conclusion, we believe that our 25 performance and progress since Public Hearing Day One

supports our application for a 47-month renewal of DIF
 licence. Our Commission Member Document and presentation
 today have responded to the questions raised during the
 Public Hearing Day One.

5 We have also updated the Members of the 6 Commission on activities at DIF since Day One. In 7 particular, we are pleased to report the progress of the 8 series 300 test which have confirmed one significant 9 contributor to the positive PCR.

We have been in discussions with the CNSC 10 11 staff on the proposed modifications to the DIF licence 12 included in their CMD. We agree with these proposed 13 changes. Specifically with respect to the clauses on 14 criticality safety, these clauses are consistent with 15 those added to the Chalk River Laboratory site licence 16 last year. While we are still gaining experience with 17 those clauses we have no concerns with adding them to the 18 Dedicated Isotope Facilities licence at this time.

In conclusion, I would like to reiterate that AECL staff has operated the Dedicated Isotope Facilities in a safe and competent manner, and I give you my commitment that we will continue to do so through the proposed licence period.

24 We are committed to the safe operation of 25 our site and I am accountable to ensure that our

1 operations meet regulatory requirements and are carried 2 out safely and with due regard to the environment, security and Canada's international obligations. 3 4 Thank you. And we would be pleased to 5 answer any questions. 6 THE CHAIRPERSON: Thank you very much, 7 gentlemen. 8 We will now turn to the CNSC staff for 9 their presentation outlined in CMD 07-H16.B, and I will turn to Mr. Barclay Howden, the Director General 10 11 responsible for this facility. 12 Mr. Howden. 13 14 07-H16.B 15 Oral presentation by 16 CNSC staff 17 18 MR. HOWDEN: Thank you. 19 Madam Chair, Members of the Commission, for 20 the record, my name is Barclay Howden. I am the Director 21 General of the Directorate of Nuclear Cycle and Facilities 22 Regulation. 23 With me today are Mr. Miguel Santini, 24 Director of the Chalk River Laboratories Compliance and 25 Licensing Division; Mr. Bruce Pearson, Project Officer for

1 the MAPLE reactors; Mr. Étienne Langlois, Project Officer 2 for the New Processing Facility, and the rest of our 3 facility assessment and compliance team. 4 CNSC staff has reviewed the application from AECL to renew the operating licenses for the MAPLE 5 6 Reactors and New Processing Facility at Chalk River 7 Laboratories and to replace these individual licenses with 8 one consolidated licence for the Dedicated Isotope 9 Facilities and has formed a position on the application and put forward recommendations for your consideration. 10 11 Before we proceed with the detailed presentation I wish to note a typographical error made in 12 13 part three of the proposed licence. The expiry date for 14 the proposed licence is stated as October 30th, 2011. However, it should state October 31st, 2011. 15 16 I will now turn the presentation over to 17 Mr. Pearson. 18 MR. PEARSON: Good morning, Madam Chair and 19 Members of the Commission. For the record, my name is 20 Bruce Pearson, Project Officer for the MAPLE Reactors. 21 Atomic Energy of Canada Limited has applied 22 for renewal and replacement of licenses to operate the 23 MAPLE Reactors and New Processing Facility at the Chalk 24 River Laboratories.

CNSC staff prepared CMD 07-H16 and 07-H16.B

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which contained recommendations for the Commission on this
 application. This presentation provides an update on
 progress made since Hearing Day One.

Our presentation has four sections: 4 5 First, to update the Commission on 6 additional information made available since Day One that 7 is relevant to our assessment of the safety areas, 8 outstanding licensing actions and project schedule; 9 second, to identify changes to the proposed operating 10 licence; third, to state our overall conclusions, and 11 finally, to make recommendations to the Commission.

12 Updated information on safety areas will 13 cover operating performance, performance assurance; in 14 particular commissioning and quality assurance, and 15 environmental protection.

In the area of operating performance we can state that there have been no events of major significance that have been reported in the past three months. This is a very limited period of operation. However, the result may be viewed as ongoing support for the improving trend and performance that was identified in CMD 07-H16.

In the area of performance assurance, and in particular commissioning and quality assurance, we can inform the Commission that the report for the Dedicated Isotope Facilities commissioning and quality assurance

program audit, which was referenced in CMD 07-H16, has now been issued. As a result of the audit CNSC staff issued five action notices and one recommendation.

4 In addition, since Hearing Day One several 5 directives from the 2003 commissioning QA audit have been 6 closed. However, two directives still remain open. One 7 is a repeat finding in the 2007 audit and therefore cannot 8 be closed, and the second requires further improvements to 9 be made to AECL's QA program review process before closure 10 can be achieved.

In the area of environmental protection we can report that the inspection referenced in CMD 07-H16 of the implementation of the environmental protection program at the Dedicated Isotope Facilities was completed during July 23rd to 25th of this year.

As a result of the inspection no As a result of the inspection no significant non-compliances were identified. However, the need for some improvements to document control and program management were noted.

20 CNSC staff concluded from the inspection 21 that the program meets regulatory requirements and the 22 inspection confirmed a "B" rating for implementation. 23 This table is reproduced from the Hearing Day One CMD. 24 To summarize, and remind the Commission 25 members of the ratings given to the safety areas for the

MAPLE reactions and New Processing Facility, as indicated,
 there has been no change in the CNSC staff assessment of
 these areas since Day One.

Since Hearing Day One some progress has
been made towards resolution of the positive power
coefficient of reactivity. Despite some schedule delays
experienced since Day One the 300-Series of PCR tests are
now complete.

9 The preliminary results from these tests 10 show that the presence of moly targets in the MAPLE 11 reactor core accounts for 36 percent of the magnitude of 12 the measured positive PCR.

This result would indicate that other major contributors to the positive PCR may exist. Such other potential contributors are intended to be assessed during the next phase of PCR tests and that is the 400-Series of tests.

18 Since Hearing Day One the MAPLE 2 Reactor 19 has been placed into the alternate guaranteed shutdown 20 state as per the approved operational limits and 21 conditions document.

The MAPLE 2 Reactor will remain in the GSS unless removal is granted under licence condition 11.2 of the proposed Dedicated Isotope Facilities operating licence.

1 In section 3 of CMD 07-H16.B CNSC staff 2 provided tentative dates for in-service operation of the 3 MAPLE 1 and MAPLE 2 Reactors. However, as stated in CMD 4 07-H16, these dates are uncertain and highly dependant 5 upon the outcome of the PCR test program. Because of this 6 uncertainty AECL has proposed to present an updated plan 7 and schedule at a public meeting of the Commission after 8 the PCR tests are completed.

9 Since Hearing Day One there have been some 10 additional changes to the proposed operating licence for 11 the Dedicated Isotope Facilities. In particular, the 12 pressure boundary licence condition has been changed to 13 require the use of updated CSA standards. A licence 14 condition has been added to specify requirement for 15 criticality safety and Appendix A has been updated to 16 reference the latest version of the Chalk River laboratory site security report. 17

18 Since Hearing Day One CNSC staff's 19 conclusions have remained unchanged. These conclusions 20 are that an environmental assessment under the Canadian 21 Environmental Assessment Act is not required for the 22 proposed licence renewal; that AECL is qualified to carry 23 on the licensed activities; and that AECL has made, and in 24 the opinion of staff, will continue to make adequate 25 provision for the protection of the environment, the

1 health and safety of persons, and the maintenance of 2 national security and measures required to implement 3 international obligations to which Canada has agreed. 4 As stated in CMD 07-H16 and CMD 07-H16.B, 5 CNSC staff recommends that the Commission accept its 6 assessment that the conduct of an environmental assessment 7 of this project under the Canadian Environmental 8 Assessment Act is not required; delegate the authority to 9 staff to make approvals pursuant to licence conditions as 10 detailed in CMD 07-H16 and summarized in section 8.2 of 11 that CMD and renew/replace the proposed operating licence to operate the Dedicated Isotope Facilities for a 47-month 12 period to October 31st, 2011. 13 14 That concludes my presentation. I will now 15 return the floor to Mr. Howden. 16 MR. HOWDEN: Thank you, Barclay Howden speaking. 17 18 I just wanted to be clear on what the

19 recommendation on the licence is. Currently there are two 20 licences; one for the MAPLE Reactors and one for the New 21 Processing Facility. So if the Commission accepts the 22 recommendation from staff the result will be a single 23 licence for the Dedicated Isotope Facilities. 24 And that concludes our presentation and

25 staff is ready to respond to questions.

1 Thank you. 2 THE CHAIRPERSON: Thank you very much. 3 We will open the floor for round one of We will start with Dr. McDill. 4 questions. 5 MEMBER McDILL: Thank you. 6 At the end of the last meeting I asked for 7 the PCR resolution document and I was pleased to see it in 8 today's information. 9 But I have to tell you that it troubles me 10 and I think I'd like to start with -- I don't think it 11 appeared on the screen unless looking down that positive 12 PCR resolution program on Figure 9, on page 24, of the -of AECL's document. 13 14 Does AECL have that as an overhead, as a 15 slide? MR. MCGEE: We don't have it as a slide. 16 17 MEMBER McDILL: That's fine, then I'll discuss it. 18 THE CHAIRPERSON: I think -- I believe we 19 20 can put it on as an overhead, can we not? Could we get 21 the document -- the Secretary is bringing it down and we 22 can put it up. 23 MEMBER McDILL: Thank you, Madam Chair; 24 I'll wait then for a minute. 25 THE CHAIRPERSON: Unless we can enlarge it.

1 That's all we've got, but at least leave it there. 2 MEMBER McDILL: Thank you for that. I wonder if I could ask -- although it's 3 4 very small -- AECL to point out roughly where as of today we are positioned on that chart, on that diagram. 5 6 MR. McGEE: Brian McGee for the record. 7 I'll ask Jean-Pierre Labrie to answer that 8 question please. 9 MR. LABRIE: For the record my name is 10 Jean-Pierre Labrie. I'm the Director of Special Projects, 11 Commercial and Client Interface. 12 If you start from the bottom of the 13 diagram, above the first diamond, from the bottom of the 14 diagram, you see "test plan" and "in reactor tests". This 15 is where we are currently on our program. 16 MEMBER McDILL: Thank you. 17 My focus will be on the diamond below that. 18 I'd like to ask Mr. Howden staff -- pardon me -- on the 19 last day, and I think I'll read it back; Mr. Howden was 20 addressing a question and he said the first part goes back 21 to the original safety analysis report that was performed, 22 setup probably about 10 years ago or so and that report 23 was accepted based on the design that was proposed. And 24 so as we go forward, you know, some of the principles 25 within the safety report, such as the negative PCR has

1 been carried forward. 2 So the original safety analysis is based on 3 a certain design and the triangle or diamond below, test 4 plan and in reactor test says "acceptably low or negative 5 PCR." 6 And I would like to ask staff, if the 7 original safety analysis report was based on a negative 8 PCR what are the implications of that diamond? 9 THE CHAIRPERSON: I'd just like to elaborate that Dr. McDill was noting from the transcripts 10 11 from Day One pages -- I believe it's 91 and 92 -- 91 and 12 So that's the material that we're looking at. 92. And turn it over to Mr. Howden. 13 14 MR. HOWDEN: Barclay Howden speaking. 15 The position that I stated there remains 16 what I had stated during the mid-term where what we were 17 looking at is the reactor design was such that the PCR was 18 supposed to be negative and then the entire safety 19 analysis was based on that, plus all sorts of other 20 considerations. Our position remains the same today, that 21 the safety analysis that was used for the original 22 issuance of the licence is that there would be a negative

24 We also stated that if it wasn't negative 25 we would have a difficult time accepting that, and we have

Our position is that the PCR should be negative.

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PCR.

1 not gone through, in detail, to develop what our 2 acceptance criteria would be for "acceptably low". In our 3 view the -- but we are working our way through that 4 process. 5 However, in our view it's up to AECL to 6 propose their design changes, redo their safety analysis 7 based on that design and then propose it that it's an 8 acceptably safe operation. 9 So at this point we remain of the position 10 that AECL should be working towards returning the PCR to 11 negative for this reactor to support the safety case which 12 supports the original design. 13 **MEMBER McDILL:** Thank you. In the original 14 Safety Analysis Report -- can you elaborate on the 15 requirements for containment versus confinement with 16 respect to negative PCR? 17 **THE CHAIRPERSON:** Perhaps we'll start with the licensee and then move to the staff afterwards. 18 19 20 MEMBER McDILL: Thank you, Madam Chair. 21 THE CHAIRPERSON: So we are looking at the 22 complete envelope. 23 Brian McGee for the record. MR. McGEE: 24 I'll ask Albert Lee to answer that 25 question.

1 Albert Lee for the record; the MR. LEE: 2 Safety and Licensing Manager for the MMIR Project. 3 In the original Safety Analysis Report that 4 was produced in 1998, we analyzed all of the design basis 5 accidents based upon a vented confinement concept for the building. The use of -- the crediting of negative 6 7 reactivity feedback, as power increased, was primarily 8 used in the accident analyses for loss of regulation 9 accidents. These are accidents where one postulates an 10 uncontrolled increase in reactor power as a result of a 11 reactivity addition. 12 For those events we demonstrated that the 13 two safety systems that are provided could both 14 effectively shutdown the reactor prior to any fuel failure 15 occurring and therefore, the dose to the public from those 16 events was always analyzed to be zero. 17 Even today, for the safety analyses that we 18 have done, support the PCR tests. For the 100-Series, 19 200-Series and 300-Series tests we've analyzed it with the 20 assumption of a positive power coefficient reactivity. We 21 have demonstrated in the safety cases that all of the loss 22 of regulation accidents are safely terminated by action of 23 the first and second shutdown systems. 24 Both are demonstrated to be effective and

no fuel failure occurs and therefore, the dose to the

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1 public is always zero. As a result, there is no 2 requirement for us to credit the use of a containment. MEMBER McDILL: Does staff concur that 3 there is no requirement to credit the use of the negative 4 5 PCR for containment? 6 MR. HOWDEN: Barclay Howden speaking. 7 I'm going to ask Bruce Pearson to speak to 8 the Safety Analysis Report that was done in 1998 and sort 9 of the process that we have reached today. MR. PEARSON: For the record, Bruce 10 11 Pearson; Project Officer for the MAPLE Reactors. 12 When we looked at the original safety case we looked at the overall defence and depth included, and 13 14 that included crediting inherent safety features, such as 15 the negative feedback that the PCR would provide, and also 16 engineered design features like SS1 and SS2 which met 17 requirements for independence, diversity, et cetera. 18 Based on the combination of inherently safe 19 features and engineered design features, we concluded that 20 the need for containment was obviated by the fact that the 21 probability of any accidents that would challenge 22 containment would have been extremely low. 23 So basically, the combination of the design 24 features provided in the original design allowed us to 25 come to the conclusion that confinement would be an

1 appropriate measure to have in place.

2 MEMBER McDILL: Thank you. 3 On page 23 of the same report there is a 4 reference to the higher margin than that assumed in the 5 safety case, a PCR value of 0.402. Is that AECL's 6 position that that's as high as it's going to go or might 7 it go higher or lower? 8 MR. McGEE: Brian McGee for the record. 9 I'll ask Albert Lee to answer that 10 question. 11 MR. LEE: We've developed the value of 0.402 milli-k per megawatt as a bonding limit to be used 12 13 in the safety analysis by analyzing all of the data that 14 we collected on the power coefficient for reactivity, both 15 in tests done in -- primary tests done in 2003 and further 16 supported by the data collected in tests done in 2007. 17 We took the best estimate value of the 18 measured power coefficient reactivity from those tests. 19 We increased the value by approximately two standard 20 deviations. In other words, what we did was we increased 21 it by the uncertainties allocated at the 95 percent 22 confidence level one-sided limit to arrive at a constant 23 value of 0.402 milli-k per megawatt. We assume that it 24 would be a constant value in the safety analysis for all 25 power transients, for all power.

1 MEMBER McDILL: Is staff comfortable with 2 that number? 3 Maybe I should rephrase that: Does staff 4 agree with that number as opposed to ---5 MR. PEARSON: For the record, Bruce 6 Pearson; Project Officer for the MAPLE Reactors. 7 When we -- the basis for acceptance to 8 proceed with the tests is based on AECL demonstrating that 9 it's adequately safe to proceed with the tests. Included 10 in the assessment that we do, is we recognize that in 11 performing these tests it's for a very short period of 12 time, so that we do give a good deal of consideration to the fact that the time at risk has been minimized and it's 13 14 just a short term test that's being done. 15 Other factors that we consider in looking 16 at the safety of the test is the measures in place to 17 confirm that the design itself is safe and catering for 18 the test. 19 The value of the PCR, we reviewed a considerable amount of data and also the information that 20 21 AECL produced and for the tests that were being done and 22 that have been approved to date, we were in agreement with 23 the acceptability of the 0.402 that was used in developing 24 the safety case. 25 DR. McDILL: Thank you.

1 My last question then for this round is, is 2 that 0.402 the number that is going to be used in Figure 3 10, where you -- it's not up there -- it's on Figure 10 of 4 the AECL document, there is a diamond near the bottom right-hand corner, which is PCR greater than zero, less 5 6 than in the safety case. There is also a diamond at the 7 safety case for 8 megawatts in that same part of the 8 block.

9 Is that the number that is going to be used 10 there or is there a different number that is going to be 11 used there when we get to the safety case for 8 megawatts? 12 MR. McGEE: Brian McGee, for the record.

I will ask Albert Lee to respond.

14 **MR. LEE:** Albert Lee, for the record.

The value of the positive power coefficient reactivity that we would use in a safety case to support our application to operate up to 8 megawatts will be dependent upon the final results of the PCR tests and the measures that we implement to mitigate the positive PCR.

20 We will not necessarily use a value of 21 0.402 milli-k per megawatt for the PCR value and the 22 safety analysis if we're able to demonstrate that we have 23 effective measures to mitigate it and significantly reduce 24 the value.

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DR. McDILL: Thank you, Madam Chair.

1 THE CHAIRPERSON: I would just like to 2 return a bit for just a follow-up question to the AECL. 3 Dr. McDill started by the Figure 9, in terms of the 4 program and asked staff about their view as to what was acceptably low or negative PCR. I would like to have 5 AECL's view as to how that diamond would be defined? 6 7 MR. McGEE: Brian McGee, for the record. 8 I will ask Albert Lee to answer the 9 question, but I want to emphasise that we are focusing on 10 reducing the PCR and eliminating it at this point in time. 11 I will ask Albert to -- if we came to the 12 point where that was part of our decision-making process, 13 explain how we would go about that. 14 MR. LEE: Thank you. Albert Lee for the 15 record. 16 If you turn to Figure 10 on page 25 of the 17 AECL Commission Member Document, you will see a figure 18 that shows the PCR testing logic chart. 19 The diamond that was on Figure 9 is further 20 elaborated in terms of the bottom part of that figure 21 where we looked to -- we asked questions about whether we have successfully made the PCR negative, as shown in a 22 23 number of diamonds leading to defining a safety case to 24 operate at 8 megawatts.

If we are successful and to find it to be

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negative and measure it to be negative and confirm it to
 be negative, we will use those results to define a
 bounding value to use in the safety case that would be
 acceptably low.

5 If you go on, there is a diamond in the 6 lower right-hand corner that shows a decision box for 7 where the value of the PCR is greater than zero but less 8 than the value that we would use in the safety case.

9 The value we would choose would be a value 10 that would effectively demonstrate that for all of the 11 design basis events -- those consequence to members of the 12 public and to the workers, and to onsite staff, meet the 13 same criteria that we used in the original safety analysis 14 in the FSAR.

15 If we could demonstrate that we have 16 effective trip coverage and meet all the safety analysis 17 acceptance criteria for a value of the PCR that is 18 acceptably low but greater than zero, we would then make 19 an application to operate the reactor, at up to 8 20 megawatts while we develop a longer term solution to make 21 it negative.

22 THE CHAIRPERSON: Sorry, I don't quite 23 understand this because it is new information in terms of 24 the process here.

25 So correct me if I'm wrong in my

1 understanding of this. My understanding then is if going 2 down Figure 10, the PCR testing logic chart, going down 3 the right-hand side and again the Secretary has sought to 4 put it up, but it's pretty difficult to read on there, but 5 that is the chart you are referring to.

6 If we go down the side and we get to the 7 block which is PCR that is greater than zero and less than 8 some -- yet unspecified number, if I understand that, and 9 that would have a specific safety case attached to it 10 which would be evaluated within the design specifications 11 and there would be modifications as necessary.

12 Then, if I understood you, there would be an approval that -- I presume and I'll ask staff to help 13 14 me understand that -- that would be submitted to the 15 staff. I suppose that would have implications on what 16 staff have suggested in terms of returning to the Commission. So what would the staff do? What would the 17 18 staff be recommending based on this licence to come to the 19 Commission?

20 And then AECL would apply for approval to 21 operate that but it would be a two-pronged approach. This 22 is where I get very unclear. It would be approval based 23 on that safety case to operate the MAPLE at 8 megawatts, 24 while at the same time seeking further investigations in 25 terms of moving towards the negative PCR or -- that part

1 it went too quickly for me to understand, Mr. McGee. 2 Brian McGee, for the record. MR. McGee: 3 First, I'd like to emphasise that we would 4 not ask staff or present to staff a request to operate or a safety analysis that we weren't first satisfied was an 5 6 acceptable safety case. The 4.02 (sic) milli-k number 7 that was discussed earlier is a bounding scenario that is 8 being used for the PCR testing at this time and is a 9 bounding scenario under the current safety analysis. 10 If we were unsuccessful in completely 11 resolving the PCR issue through design changes, the safety case would be revised to a new bounding number. 12 So at this point, it is somewhat 13 14 speculative but I will ask Albert Lee to elaborate, if you 15 would like to, on that response and to help clarify where 16 our thinking is. 17 But at this point, it is somewhat 18 speculative to go to any decision-making type of criteria 19 at this point because our focus is still to go through the 20 PCR testing, to undertake to resolve the PCR issue, and 21 our belief is that we can reduce it to zero or negative. 22 But I will ask Albert Lee to respond. 23 MR. LEE: Thank you. Albert Lee, for the 24 record. 25 I agree with everything that Mr. McGee has

said. The current value of 0.402 milli-k per megawatt is
 the bounding value that we are using for the current
 series of PCR tests.

Our intent is to define possible remedies to reduce the value of the PCR. Based upon how far we are able to reduce the value of the PCR, we will revise and update the safety analysis to support a mode of operation with whatever the remedies are installed in the core.

9 At this time we are not able to define how 10 low that value of the PCR would be and what we would use 11 in the safety analysis. So we would have to come back 12 with that after we've got the design changes.

13**THE CHAIRPERSON:** But was my interpretation14of Figure 10 correct?

MR. LEE: Yes. Your interpretation of Figure 10 is correct. Coming down the right-hand side, we are looking at trying to make it as low as possible, preferably negative and depending on the result and depending on whether we believe we have an acceptable safety case to try and proceed to operate.

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 THE CHAIRPERSON: Could I have staff's

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 comment please?

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 MR. HOWDEN: Thank you. Barclay Howden

24 speaking.

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The tests that are ongoing now are

1 important to measure the PCR under different conditions 2 with certain changes to the core and we've reviewed the safety cases with the time at risk and other 3 4 considerations, we're satisfied they're being done safely. 5 But the tests are also being done to 6 understand the phenomena and this is -- this is an issue. 7 It's one thing to have the value of what it is, but to --8 you need to understand it as well, because if you 9 understand it then it gives you a degree of predictability 10 because then you can model it then you can validate it and 11 then when you go through your safety and accident 12 assessments and you're using your models, you have a high level of confidence. 13 14 So I just wanted to emphasize that the 15 measurement is important, but understanding it is equally 16 important. 17 And so if someone couldn't model it but 18 they were confident of a bound, they'd have to be very 19 convincing that the safety case is then bounded. 20 And -- and I think that's the issue that 21 staff is struggling with, is that you can measure it but 22 can you understand it well enough to either model it or 23 bound it and -- and such that when a safety case is 24

24 presented, you say, yes, have a high level of confidence 25 that you are in that safety envelope.

So what we're seeing for the tests are not only measurements but also understanding and you can see each test has a different sort of thing to try to get an idea of what the contribution is.

5 So I think we agree with AECL that there's 6 a lot of -- a lot of things that still have to be done to 7 reduce the uncertainties.

8 From our perspective, from a regulatory 9 perspective, the licence that we have and the conditions 10 that we have, we feel is sufficient to provide us with 11 regulatory control to make sure that nothing goes forward 12 unless it's safe and if, in our opinion, it isn't, it just 13 is shut down, you go into the GSS until you ponder your 14 next move.

And so when we look at their plans, we look at it from -- we have two considerations. I think last time I said that activities are very important because they have to be sequenced to make sure that you benefit from the last test before you go to the next one and that's very much focused on being effective, from a regulatory standpoint.

The timing, even though we've downplayed it, it does have importance in terms of managing your resources and trying to be efficient. Like we like to -we -- we block out our staff's time to do work and so if

1 we have a good idea of the timing we can be more efficient 2 because if you miss a time slot, that staff member may be unavailable for another month or so. 3 4 So, I think at this point we're confident 5 with the regulatory regime. 6 Where we're uncertain is -- is the 7 understanding of the phenomena and if that could be done 8 that will improve things greatly because you will have a 9 measure and you'll understand why it's there; then you can 10 actually take it and start to engineer solutions to your 11 problem. 12 Does that respond to your question, Madame? 13 **THE CHAIRPERSON:** Well you've actually 14 raised another -- another question. 15 But just so that I follow my train of 16 thought here, so when the staff looks at Figure 10, which 17 AECL referred to and I looked at the questioning on the 18 right-hand side of Figure 10 at the end. 19 So the staff are saying that they 20 understand Figure 10 and they understand the -- the 21 options that have been put forward, understanding, you 22 know, what Mr. McGee said in terms of the direction AECL 23 wishes to go. And -- and understanding that in your 24 recommendations to the Commission in terms of when we

would -- some of the hold points and when we would come

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back, could you just delineate your understanding of that lower, right-hand side of the document and what exactly would the Commission and therefore in a -- I think you've recommended a one-day public hearing -- what would be evident in that -- in that lower, right-hand corner, to the Commission?

7 MR. SANTINI: Miguel Santini for the 8 record.

9 The lower box in -- in Figure No.10 in the 10 AECL submission coincides with one of the conditions in 11 the proposed licence which basically the reactor will 12 switch to the in-service status, at which time we'll come 13 to the Commission.

14 Now, what we have to understand at that 15 moment -- at that moment we will have to see how -- what 16 AECL has put in place in order to resolve the PCR issue 17 and the differences for now in interpretations is what 18 resolution of the PCR is.

19 In AECL's mind, resolution of the PCR is as
20 low as achievable, considering that the safety case
21 supports operations.

And in our mind, and for now is the PCR ought to be negative in order to -- to come back to original safety basis and licensing basis in -- in the original operating licence.

1 In AECL's submission, we would expect that 2 AECL would submit a new safety case, a safety case that 3 will go back to the origins justifying what additional 4 measures that had to be put in place in order to be able to operate at one with a positive PCR. 5 6 Now I would like to emphasize what -- what 7 Mr. Howden said with respect to the phenomena in the core. 8 The problem is not only the value of the 9 PCR but the understanding of what causes it. When you 10 don't understand what causes it you try to assign in such 11 a way that you always are on the safe side. 12 When you don't understand then the safety side -- the safe side is negative because when it is 13 14 positive you basically you don't -- you can't capture 15 everything with the models and you have an undesirable 16 effect to safety. 17 So basically we will expect AECL to come 18 back to us with a -- with a very robust new safety case where they have demonstrated all of the engineering 19 solutions to address this -- this value but, at the same 20 21 time, we would expect them to -- to have a very good 22 understanding of what is causing the positive PCR. 23 THE CHAIRPERSON: That opens a set of 24 questions, but I'll let my colleagues go and then I'll

come back if it's necessary to come back to that.

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1 I think, if you agree, Dr. McDill, we'll 2 move to Dr. Barnes. 3 Dr. Barnes. MEMBER BARNES: If I can continue the 4 5 questions on the PCR, if I may. 6 This has been going on for many years now 7 and I guess I'm surprised at some of the diagrams provided 8 by AECL that suggest -- for example, on your -- your 9 schedule, page 10, where you have an in-service in about 10 one year from now. 11 And given the fact that we're still --12 clearly don't understand the issue in the way that AECL 13 has just said, I'm surprised that you would be bold enough 14 to suggest that you would be in-service, what appears to 15 be the fall of 2008. 16 Is this realistic or just based on a whole 17 set of assumptions that if they all work that might be conceivable? Given the time it would take to demonstrate 18 19 the case that's just been stated by -- by staff, I just 20 personally can't see how you could possibly be in-service 21 one year from now. 22 Brian McGee, for the record. MR. McGEE: 23 Our focus, right at this point in time, is 24 to execute the PCR test plan. It's a well thought out, 25 well-detailed integrated plan with a series of activities

1 that were carefully networked as we go through it.
2 At the outcome of that, we'll have a better
3 understanding of the time that it will take to complete
4 whatever design changes and activities are required to
5 achieve that.

6 The schedule, beyond the current PCR 7 testing regime, is primarily established for business 8 planning and financial planning and financial decision-9 making purposes. So at this point in time, from a 10 technical perspective, the schedule that we're focusing on 11 is the schedule to go through the PCR test plan in a 12 rigorous and prudent manner and at the end of that plan we 13 expect to be in a position where we have a greater 14 understanding of the design changes that will be required 15 to achieve the in-service of the facility.

MEMBER BARNES: I come back to the test plan and through this process we certainly encouraged and pleased to see that AECL, for some time now, has been receiving external advice. You had that on the coloured boxes of the previous overhead, which is Figure 9, from INL, BNL and INVAP.

Could you -- just a couple of questions on that, could you give us some kind of verbal assessment of -- of the value you found in those external reviews, relative to your own thinking. Were they substantial, the

1 contributions, were they sort of simply incremental? 2 MR. McGEE: Brian McGee for the record. I'll ask Jean-Pierre Labrie to answer. 3 4 MR. LABRIE: For the record, my name is 5 Jean-Pierre Labrie. 6 We have been working with Brookhaven 7 National Laboratory, Idaho National Laboratory and INVAP 8 for a long time now. We've had very regular dialogue and 9 we still have dialogues and meetings with these 10 organizations. 11 Basically the outcome of the work that 12 Brookhaven has done was to reconfirm that the analysis methods that AECL is using to calculate the PCR from the 13 14 data is correct. 15 From INL, what we have as an output is that 16 the models that we've been using are modeling that they've 17 reproduced independently from us, is correct and from 18 INVAP it was mainly their insight into their design of 19 reactors and obviously they have provided very valuable 20 recommendations that we have incorporated in our PCR logic 21 diagram to identify the causes for the positive PCR and 22 the design changes that will be implemented to resolve 23 these. 24 MEMBER BARNES: And on Figure 9, would we

24 **MEMBER BARNES:** And on Figure 9, would we
25 expect those external interactions to continue, in the

1 lowest part of the diagram? 2 MR. McGEE: Brian McGee for the record. I'll ask Jean-Pierre Labrie to answer. 3 4 MR. LABRIE: For the record, my name is 5 Jean-Pierre Labrie. 6 We are still in interactions with these 7 organizations. We still have INL doing some scoping 8 calculations for us, for example, so the activity is still 9 ongoing with these organizations. 10 MEMBER BARNES: And what proportion of that 11 information that's provided externally is accessible to 12 CNSC staff? MR. McGEE: Brian McGee for the record. 13 14 I'll ask Jean-Pierre Labrie to answer. 15 MR. LABRIE: For the record, my name is Jean-Pierre Labrie. 16 17 We have provided to the CNSC staff all the 18 documents that we have received from these organizations 19 and the recommendations and our proposed disposition of 20 these recommendations in the test plan. 21 MEMBER BARNES: And to CNSC staff, an 22 encouragement that certainly commission, didn't AECL took 23 on its own direction to seek external advice in what 24 obviously is a very complex issue and -- and sort of 25 difficult issue to resolve.

To what extent has CNSC staff taken 1 2 external advice? 3 MR. PEARSON: Bruce Pearson for the record. 4 The only external advice that we've sought on this issue of the positive PCR was quite some time ago; 5 6 back when the positive PCR issue was first raised. And we 7 did hire a consultant to do an independent look at -- at 8 the data in parallel with our -- our look at the data. 9 With regards to our -- our follow-up 10 actions and monitoring the progress that AECL is making 11 with their consultants, we do get the final reports. We 12 do attend progress meetings and there's been two separate 13 occasions that staff has actually traveled to Idaho 14 National Labs and to Brookhaven National Labs to 15 participate in meetings and discussions with consultants. 16 MEMBER BARNES: Given that we're now -- it 17 seems to me -- over the next several months, going to come 18 into a rather crucial time as the tests go into the 400-19 Series, 500-Series and the licensee will be coming forward 20 for some final -- I think so-called final recommendations 21 for licensing approvals, do you have any comment whether, 22 in terms of the expertise you have currently in -- CNSC 23 staff it would be wise, beneficial or whatever, to secure 24 external advice to make sure that staff is fully able to 25 cover all aspects given the kind of uncertainties that

1 staff has just -- just indicated understanding the system, 2 not just having some -- some milestones met? 3 MR. SANTINI: Miguel Santini for the 4 record. 5 We haven't considered seeking external 6 advice on the review of the hypothetical case that the 7 AECL comes back to us requesting approval with a positive 8 PCR because this is still hypothetical, but we will 9 certainly consider, if that happens to have -- to seek external advice on that. 10 11 We have done extensive research in terms of 12 how the PCR is considered by -- by other regulators in the 13 world. And in general, as in our case, the PCR is not 14 prescribed as to be negative for the sign and -- and be 15 acceptable. There are only two regulators in the world 16 that prescribe the PCR to be negative. 17 Now the -- the approach that we use is --18 is risk informed, so we will not say that a positive PCR 19 is not acceptable at all until we finally see the safety 20 case and see how that supports operation with a positive 21 PCR. 22 Having said that, I would like to go back 23 to a previous answer regarding the -- the information 24 obtained from different sources of expertise around the 25 world by AECL.

1 We have reviewed their reports and in our 2 views, yes, in general AECL's methodology and approaches 3 have been confirmed by these experts. The problem is that 4 they all coincided and the models used are okay and everything seems -- they -- they think they did everything 5 6 right but the issue is the models do not represent what is 7 happening in the core and that's the issue. 8 **MEMBER BARNES:** Just a couple of diagrams 9 -- questions to AECL on your organizational chart which we 10 asked you to provide, and I appreciate that. 11 This is on page 4 of your CMD. 12 The first is the location of the Manager, 13 the quality assurance which is towards the bottom right, 14 and Senior Quality Representative. And I wonder if it's 15 appropriate to ask whether in reporting to both the 16 Director, DIF, sort of some degree and also the Director 17 of MMIR, whether that -- given the situation that we're 18 in, whether that should report at a higher level? 19 MR. McGEE: Brian McGee for the record. 20 Commissioner Barnes, are you referring to 21 the facility quality representative in your question? 22 **MEMBER BARNES:** No, the Manager of Quality 23 Assurance; the one to the right, Senior Quality

24 Representative.

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MR. MCGEE: Brian McGee for the record,

1 then. 2 So your question is, should he report to 3 the Director of DIF operations? 4 MEMBER BARNES: Yes, or even -- or even 5 higher in the organization? 6 MR. McGEE: Brian McGee for the record. 7 The -- we believe that the Manager of 8 Quality Assurance and the Senior Quality Representative is 9 -- is properly placed in the organization given the roles 10 and responsibilities and the accountabilities associated 11 with that role. 12 The individual has a relationship -- a functional relationship with the corporate quality 13 14 assurance office, which gives it a strength and 15 relationship to -- for anything that they see that the 16 individual in the role sees that they believe should be changed. 17 18 So the nature of the -- the role 19 relationship is the individual identifies something that 20 they believe needs to be changed, they work with the --21 with the Director of the MMIR project with it. If they don't get the adequate satisfaction, the nature of the 22 23 authorities with the role, give them the ability to go to 24 the Corporate Compliance Organization. So they do have an 25 outlet for -- for identifying give them the ability to go

1 to the corporate compliance organization so they do have 2 an outlet for identifying concerns, and it's to a senior 3 level person in the corporate compliance organization. 4 **MEMBER BARNES:** Does that happen? 5 MR. McGEE: Brian McGee for the record. 6 I don't -- I can -- Brian McGee for the 7 record. 8 I don't have a specific example but I've 9 been told it does, on occasion. 10 MEMBER BARNES: Staff, are you happy with 11 that positioning of essentially the QA? 12 MR. HOWDEN: Barclay Howden speaking. 13 I'm going to ask our Quality Management 14 Specialist, Paul Wong, to respond. 15 MR. WONG: For the record, my name is Paul 16 Wong; Quality Management Specialist. 17 We have asked AECL the same question as you 18 raised, many years ago, and we have engaged corporate QA 19 up to the chief quality officer on this question and we 20 have struggled with this arrangement ourselves. 21 But the resolution -- there were some 22 issues that they managed to -- they took some changes --23 made some changes -- and the result is the arrangement 24 that Mr. McGee has just described and also presented in 25 the CMD.

1 Obviously, we do prefer, as you pointed 2 out, that a senior quality manager reports to a higher 3 level of management and it is indirectly in a way doing 4 so.

5 CNSC doesn't prescribe an explicit 6 acceptable organization structure. We focus on the 7 effectiveness of this organization and the primary focus 8 we concern ourselves on is whether these individuals, with 9 their assigned responsibilities, are able to discharge 10 these responsibilities and provide the necessary oversight 11 and also have the necessary authority and freedom from any 12 undue pressure.

As a result, what we have been doing, we have monitored the setup and the way it has worked and we have not been -- we haven't found any deficiency as a result of this arrangement and we continue to monitor it and we accept, currently, the situation, unless we find some deficiencies.

19MEMBER BARNES: Okay, thank you.20Just while we are on that diagram, it may21just be a graphical issue but I notice in the boxes at the22bottom that the ones on the left, the five on the left are23all managers and the five on the right are all directors.24Is a particular reason for that titling?

25 MR. MCGEE: Brian McGee for the record.

1 I'll talk about the operation side of the 2 organization and then I'll turn it to Ron Cullen to talk 3 about the project side of the organization. 4 The organizational structure and the level 5 of the managers in the operation side of the Dedicated 6 Isotope Facilities is consistent with the organizational 7 pattern and level that we use across the Chalk River 8 laboratory site for positions of that nature. 9 I'll turn to Ron Cullen to answer on the 10 project side. Ron Cullen for the record. 11 MR. CULLEN: 12 The position of directors as shown under 13 the Projects Group are primarily titles that have derived 14 from when other projects that have been overseas where 15 titles were significant in executing in the projects. So 16 these have carried forward into the current organization 17 and we find them, in a sense, quite effective in executing 18 the physical work in the field. 19 MEMBER BARNES: That will be it for this 20 round, Madam Chair. 21 THE CHAIRPERSON: Mr. Graham. 22 MEMBER GRAHAM: Thank you. 23 I've just got a couple of questions, first

24 with regard to what my colleagues have been asking. Just 25 to get this clear in my mind, CNSC are still working

1 towards the fact that we would licence under a negative 2 PCR, I guess that's -- or a negative coefficient. 3 Positive is still hypothetical. I think those words were 4 used. But at the end of the day, AECL will probably be 5 back to operate MAPLE 1 at a positive PCR. 6 My first question would be is because of 7 that and because it requires design change and because it 8 requires a safety case would that trigger an EA under 9 CEAA? 10 THE CHAIRPERSON: Mr. Graham will have to 11 ask AECL for comment on your ---12 MEMBER GRAHAM: Okay. Would you like to 13 comment -- at the end of the day, if you can -- I mean, I 14 have read here as a layperson, you know, 2.8 and then 15 you're down to different values. And looking at the 16 charts I know the best scenario is to develop what you've

budgets and so on, which we've all heard about these today 19 -- at the end of the day may you be back? Do you think 20 that it's possible that you may be back to operate the 21 MAPLE 1 with a positive PCR? 22 MR. McGEE: Brian McGee for the record. 23 Our total focus, organizational focus at

always gone after but if you do have to, in timeframes and

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24 this moment in time is to take the PCR negative. The test 25 regime and all the work that we're putting into the PCR

test plan, in executing those activities, and taking a prudent and rigorous approach as we go through it, is all focused around taking that PCR negative.

In the event that we were unsuccessful and, as Mr. Santini described, we understand the phenomena well enough to be able to construct a safety case; then I cannot preclude the possibility that we would come back with a safety case but it would have to be a sound safety case that we are convinced of and that we're able to convince others of, including the CNSC staff.

I can't preclude that that is a possibility but it's not a part of our focus right at this time. Our focus is to eliminate the PCR, to drive it negative, and to, you know, revise the safety analysis, the safety case associated with a negative PCR and come back for approval at that time.

17 Does that answer the question? 18 MEMBER GRAHAM: Yes. 19 And my next question to you then is the 20 timeframe -- you're looking at that will probably take up 21 to a year to be able to work towards reaching the negative 22 PCR? 23 Brian McGee for the record. MR. McGEE:

24 Our PCR test plan shows us coming back to 25 the Commission for a public meeting, not a hearing or an

1 approval to operate but for a public meeting to describe 2 to you at that time at the completion of PCR testing what 3 we have found. We expect that to happen in O-1 of 2008. So it's much closer than a one-year time period. 4 5 We're now approaching Series 400 testing. 6 This is not -- I want to be clear about this. This is not 7 to come and seek approval to operate. It's to come to a 8 meeting and present to you what we have found as we have 9 completed the PCR test plan. 10 THE CHAIRPERSON: If I may, Mr. Graham, I 11 realize that this is a hypothetical and, you know, we are discussing these issues. 12 The reason I think -- if I could just 13 14 comment on why the Commission wants to talk about this is 15 this is a licensing hearing and so it's meant to be more 16 exhaustive than any updates or one-day hearings or 17 meetings or whatever the Commission decides to do. 18 So it's extremely important, I think, for 19 us to have an adequate framework so that we can look at 20 these -- perhaps more delineate in specific decisions 21 under a framework of broad understanding about the 22 direction. 23 So it should not be looked at as the 24 Commission making any comments about what would be 25 acceptable or unacceptable or what the options are; it's

1 just merely understanding the diagrams that were put on 2 the table. It is not to be seen as anything other than 3 what we understand is the direction of this. It's just to 4 adequately frame it so that later on when we come back 5 with specific ideas, we understand which part of the tree 6 we are hanging this off. So I just am concerned we are 7 going over here a bit.

8 Mr. Graham?

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MEMBER GRAHAM: 9 Thank you. On that, does CNSC staff care to respond? 10

MR. HOWDEN: Barclay Howden speaking. 12 Mr. Graham, from the process standpoint is an application would come in, and we would look at it 13 14 whether it is a project under CEAA, and it would be yes; 15 then it would be what is the licensee requesting, it would 16 be likely an amendment of the license, which is a trigger 17 under CEAA. And then an EA has to be done.

18 Then you would look and say has an EA 19 previously been done that covers this thing? So we would 20 have to look at the existing EA that exists for this 21 facility to determine whether an EA would be required. 22 And it is either "yes" or "no" and then after that steps 23 are done, you would go back to licensing which would be in 24 front of the Commission.

25 MEMBER GRAHAM: Thank you.

1 On the licensing part and with regard to 2 your CMD in number 3, proposed licence length and you are 3 proposing the 47 months but you are also talking about two 4 hold points for Commission consideration and approval. 5 I believe those are in August of 2008 and 6 August of 2009; is that correct? 7 MR. HOWDEN: Barclay Howden speaking. 8 In the original CMD, that was what was 9 proposed based on the schedule known at that time. 10 Based on all the discussions today and the 11 supplemental information that those dates have been pushed 12 out and they are quite uncertain because they are 13 dependent on the resolution of the PCR issue. 14 What we have asked from the Commission is 15 that if the Commission issues the licence for 47 months, 16 delegation of authority for certain authorizations but 17 indicating that we recommend that if there is a request to 18 go into service, which was that lower right-hand box on 19 Figure 10, ---20 MRMBER GRAHAM: Right. 21 MR. HOWDEN: --- for MAPLE 1, that that 22 would be -- our proposal was that the Commission would 23 take that particular decision. 24 When that may occur, we are hearing it

might be a year out from now, but really it depends on the

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PCR resolution in terms of the path forward before that could come back. So based on our knowledge at the time, that was the intention, is that we would come back to the Commission for MAPLE 1 and MAPLE 2 with those two dates.

5 Let's not worry about the dates. Let's say 6 there could be two hold points and, in the interim, staff 7 requested delegated authority and also staff proposed a 8 mid-term report, just to update you. I believe AECL has 9 proposed to come back, post-PCR to bring you up to date.

10 **MEMBER GRAHAM:** So as it stands right now, 11 there would be a meeting, AECL would come to a meeting on 12 status -- on where status is and we would also do a mid-13 term. Is that more or less what the process would be 14 right now?

MR. HOWDEN: From information updates, that
is correct. From hearing standpoint, that is still
speculative as to how the PCR resolution goes.

18 MEMBER GRAHAM: So really, I guess, just to 19 get it clear in my mind and trying to follow the charts, 20 over a 47-month period, if schedules go as planned, how 21 many times would AECL be back before the Commission, 22 either in meeting or in reviews and hearings? 23 MR. HOWDEN: Barclay Howden speaking. 24 There would be two information sessions; 25 post-PCR, mid-term, and then potentially two hearings for

1 MAPLE 1 and MAPLE 2. So that could be four visits back to 2 the Commission within that 47-month term.

3 THE CHAIRPERSON: First of all, I would 4 like to point out that this is what is proposed not what 5 the Commission has decided and, if you agree Mr. Graham, I 6 think we should ask -- I was going to do it later anyway, 7 but ask AECL their view on this. This is what is proposed 8 by the staff, but we haven't heard anything from AECL yet 9 on this.

10MEMBER GRAHAM:I agree with that. Go11ahead.

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MR. McGEE: Brian McGee for the record.

We agree with the proposal. We believe it is important to come back and inform the Commission of the results of the PCR testing in an information session. The information session at mid-licence term is fairly typical and we would expect to see that and we support coming to the Commission in a hearing format for declaration of MAPLE 1 in-service, as well as MAPLE 2.

20THE CHAIRPERSON: Back to you, Mr. Graham.21MEMBER GRAHAM: That's all.

22 THE CHAIRPERSON: I just have a couple of
23 areas that I would like to look at.

24 First of all, I realize looking back at the 25 transcripts in Day One, we had the application to put the

1 licences together and I think everyone sort of went off 2 assuming that this was -- there was reasons for this. 3 Just for the record, I think it is 4 important for us to understand from AECL and from staff 5 why there is an advantage to putting the two licences 6 together. It doesn't have to be a long discussion, but I 7 think that we need this for the record. Why do you think 8 this should be done? 9 MR. McGEE: Brian McGee for the record. Just for my clarity, are we talking about 10 11 within the DIF Facility? 12 THE CHAIRPERSON: Yes. 13 MR. McGEE: Brian McGee for the record. 14 We believe that having the DIF Facility 15 managed within -- the operating licence is a significant 16 part of our operating documentation and a significant part 17 of the operation of the facility. So for purposes of 18 clarity and consistency across the organization it is 19 being managed under the leadership of a Director of 20 Operations. 21 We believe that it's a sound approach to 22 take to have all the facilities, within the facility, if 23 you want, governed under one operating licence. And that 24 way it gives a consolidated and an integrated view of

performance as well, so that as we go through the

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1 operational period, both ourselves, staff and the 2 Commission ultimately have an integrated and a consolidated view of how the facilities are being 3 operated. 4 5 THE CHAIRPERSON: Staff? 6 MR. SANTINI: Miguel Santini, for the 7 record. 8 Yes, we share this view with AECL. We have 9 to consider that all of the facilities at the sites are 10 managed or are kind of conducted using the same site-wide 11 programs, and these site-wide programs should be complied 12 with by all of the activities at the site. 13 From the administration perspective of the 14 licence it is tremendously simpler to have everything 15 consolidated under a single document. And when amendments 16 are required, when the reviews of these program documents 17 are required and approved by the Commission, it is simpler 18 to go that way. 19 THE CHAIRPERSON: I would just like to 20 qualify though, Mr. Santini, we're -- in agreeing to the 21 length of a licence, the Commission is not binding the 22 Commission at that point in terms of that discussion. 23 What we are talking about just 24 understanding that this is in a more efficient way of 25 operating, without losing the effectiveness of the

1 regulatory oversight. Is that what I can write down? 2 MR. SANTINI: Absolutely and that's why we 3 recommended to the Commission to two separate hearings 4 additional, given the licence period for approval to switch to in-service status. 5 6 THE CHAIRPERSON: I also think it is 7 interesting that we are seeing in other areas where we 8 have a hearing around a result rather than a time period. 9 I think that's one of the things we have looked at as 10 well. 11 I would just like to come back, if I may, 12 to a comment that was made by staff in terms of understanding, back to the PCR, in terms of the phenomena. 13 14 We heard from the staff, Mr. Howden particularly, about 15 the issues of understanding -- and modelling and 16 understanding, how the phenomena are bound and the 17 contribution -- those kinds of issues -- the understanding 18 rather than necessarily the number. 19 Mr. McGee, I would like to hear from AECL, 20 your thoughts on the importance of that understanding to 21 your confidence in operating this facility safely under 22 whatever is the bottom-line number. 23 MR. MCGEE: Brian McGee for the record. 24 I will make a couple of comments and I will 25 turn it over to Albert Bell (sic) to expand on as he sees

1 fit.

2 The safety analysis is really part of the 3 design basis of the facility and managing that design 4 basis effectively and having a sound understanding of the 5 design basis is really a cornerstone of sound operations, 6 safe and reliable operations. 7 So, understanding the phenomena that make 8 up the safety analysis, that piece of your design basis, 9 are really critical from an operating perspective in terms 10 of defining the safe operating envelope and those 11 operational aspects that are critical -- understanding the 12 phenomena is a central part of having a sound safety 13 analysis. 14 I'll turn it over to Albert Bell (sic), if 15 he'd like to expand on that. MR. LEE: Albert Lee for the record. 16

I agree with Mr. McGee's comments. Having a sound understanding of the phenomena and the behaviour is very important to supporting a robust and well developed safety case. It also provides support to how operations can proceed in day-to-day operation.

22 So among the efforts that we're undertaking 23 to resolve the PCR issue, we are investigating all the 24 phenomena and investigating the best means to understand 25 the cause of the phenomena and how to mathematically

1 represent the phenomena in the models. 2 THE CHAIRPERSON: Thank you very much. 3 I propose that we take a break. We will take a one-hour break for lunch and we will be back then 4 5 at 12:18. 6 The Commission will decide if it wants 7 further questions on round two and then we will do the 8 intervenors after that. So we will move back here in one 9 hour. 10 Thank you. 11 --- Upon recessing at 12:19 p.m. 12 --- Upon resuming at 1:18 p.m. 13 THE CHAIRPERSON: If I could ask you to 14 take your seats, please? 15 I understand from my colleagues that we may 16 have a couple of more questions on round two and then 17 we'll be moving quite soon into the intervenors for today. So we will start then with Dr. McDill. 18 19 MEMBER McDILL: Thank you. 20 My question is general in nature and it's 21 directed at staff. If basically we have information one 22 year out and the licence is for 47 months, because AECL 23 has said decisions have to be based on results that will 24 come in. 25 Is a 47-month licence appropriate?

1 MR. HOWDEN: Barclay Howden for the record. 2 In terms of regulating this particular 3 facility, Dr. McDill, what we've done is, like we've done 4 with other facilities, we've done an assessment of all the programs that are needed to operate it safely, as well as 5 6 an assessment of their implementation and we've provided 7 that information to you in the form of "meets 8 requirements" or "doesn't meet requirements". 9 We followed up on an ongoing basis, so in 10 terms of -- from an ongoing regulatory oversight and safe 11 operation, we're satisfied that over a 47-month period 12 that there's not an issue. 13 I guess from the perspective of issues that 14 are unresolved, hence should we be licensing more on a 15 phased basis which is what we used -- which what we do 16 often is that we go through construction, commissioning, 17 operations, et cetera. 18 And normally what we tried to do was tie 19 the licence in to those particular phases. And we did do 20 that with this reactor, but then we got to the point where 21 we ran into significant issues. The first issues were the 22 shutoff rods didn't drop and then once they got past that 23 issue then we got to the point of getting actually into 24 commissioning and this PCR issue raising its head. 25 So from our perspective we would normally,

1 I think, go along in a phased approach. But I think just 2 because this is on an established site and it is drawing 3 off the site-wide programs, we have a high level of 4 confidence that those programs can be maintained over the 5 period of 47 months.

6 Because of the uncertainties we've tried to 7 introduce the regulatory hold points to basically say, 8 okay, over the course of this licence period there's going 9 to be a number of regulatory decision points, some for 10 staff under delegated authority and some for the 11 Commission.

12 What we wanted to do with those is have 13 focussed hearings, very much on the particular issue at 14 hand as opposed to having a broad re-licensing hearing 15 where we revisit all the programs in a systematic way. 16 What we would do is report our compliance 17 results to assure you that those programs that are 18 underpinning operations are still in good shape but we 19 wanted to focus on the regulatory issue at hand.

20 So that's a long answer to say that we can 21 go both ways. We could propose, "Let's just have a one-22 year licence and come back in a year", or we can go for 23 four years.

24 Because of the schedule issues it's 25 difficult to start putting temporal times on the licence.

1 So that's why we tried to bound it with the 47 months and 2 then put forward the activities that had to be 3 accomplished during the course of the licence period 4 without knowing the timing. 5 So from our perspective we also saw it as a 6 way that we could from a regulatory standpoint, manage the 7 licence in an efficient manner while maintaining our 8 effectiveness. Certainly, the 47 months allows us to roll 9 it into our baseline compliance activities with our site 10 office. 11 So the -- even though we've got these 12 project-related issues, the site office is still working 13 in the background on all the programs that support the 14 facility; doing rounds, looking at environmental 15 protection. 16 So from a planning perspective it does 17 promote some efficiency for us, to be able to just come 18 back to you on topic-specific issues.

19MEMBER McDILL:Thank you.Maybe AECL20would like to comment as well.

21 MR. McGEE: Brian McGee for the record. 22 A 47-month licence is appropriate in this 23 case. The controls available to CNSC staff and to the 24 Commission, ranging from routine monitoring discussions 25 that we have on a regular basis with staff, to more

1 elaborate oversight mechanisms to inspection and audit 2 tools available, as well as enforcement tools, provide a robust framework for the licensing of the facility. 3 4 In addition to that, the -- our proposal to 5 come back at the end of the PCR testing gives the 6 Commission itself another opportunity to monitor 7 performance at that level through an information session. 8 The mid-term licence review is another opportunity that 9 provides the Commission with a firsthand look at how 10 performance is trending. 11 And then of course the actual approval 12 points, the hold points that has been described by CNSC 13 staff, where we will come back to the Commission in a full 14 hearing session; all provide robust mechanisms to support 15 a 47-month licence. 16 MEMBER McDILL: Thank you, Madam Chair. 17 THE CHAIRPERSON: Other questions; Mr. 18 Graham? 19 MEMBER GRAHAM: Yes, I just have two The first one is to CNSC staff. In 2.3 of 20 questions. 21 your CMD H-16.B, under the heading of "Environmental 22 Protection" regarding the DIF review that was done on July 23 23rd to the 25th, you go on to say that:

24 "The implementation process still25 needs improvements, mainly in document

1 control and program management." 2 Is there anything that should be reported to the Commission with regard to deficiencies in this 3 4 program or anything that was not of a routine --5 improvements that were needed but of major improvements 6 over? 7 MR. HOWDEN: Barclay Howden speaking. 8 I think overall our view is that we didn't 9 have anything to report to you that would be significant. 10 But I'm going to ask Christian Carrier who 11 is the project officer who was involved in the inspection 12 to provide you, just a very brief overview of some of the 13 things that were found and whether -- and why we saw them 14 as just things that just needed improvement, just part of 15 normal program improvement. 16 Thank you. 17 MR. CARRIER: Christian Carrier for the 18 record, from the Chalk River Laboratories Compliance and 19 Licensing Division. 20 So we carried out an inspection in July. 21 It was a two day and a half inspection and we covered a 22 number of aspects in the environmental monitoring program 23 and the facilities. 24 So we reviewed document control, 25 calibration, maintenance of records, verification of the

airborne monitoring systems and effluent system in
 general, including liquid.

Configuration management of the facility; project management; monitoring laboratory -- it was analysing the samples -- and the training program for the people at the facilities on the environmental monitoring program.

8 So generally speaking we had made a number 9 of observations that translated into a number of action 10 notices and recommendations.

We have four action notices and two recommendations and we have one positive observation regarding the training of staff at the facility, regarding implementation of the program which we thought was important to note.

So regarding the action notices, we have observed that some of the documentation was out dated. According to AECL's own procedure the documentation should be updated and reviewed every year on a yearly basis and some of the documentation dated as late as the year 2000. I understand from the discussion with AECL

22 staff that the overall program at the Chalk River site is 23 under review and consideration was being made as to 24 incorporate some of this information within the site. 25 So part of that situation of outdated

1 information may relate to the fact that the facilities
2 have not really been -- have been operating but not very
3 heavily during those years. In addition, there are
4 considerations into changing the structure of that
5 documentation.

6 Another observation that was made was that 7 some of the equipment in the field that we are seeing was 8 -- had a calibration sticker suggesting that the 9 calibration was outdated. Again, some of this equipment 10 was not that critical for the effluent monitoring but they 11 were part of the configuration so AECL normally should 12 ensure that these pieces of equipment should be 13 calibrated.

Another observation that has been made is some components in the field were found to have been replaced with other components that didn't meet the prescribed quality for the monitoring equipment. That is expected from time to time.

However, we have seen that at least one piece of equipment had been replaced and had been staying in position for about six months. It doesn't mean the facility was not being monitored at that stage. However, the facility -- well, there is redundant capability to monitor the facility in this case. However, it is an observation we have to note in the inspection report. So

1 that was not a situation by which a facility would not
2 have been monitored properly.

And one last observation that was made is in some cases we have observed that the documentation that was describing the facility in the final Safety Analysis Report and in other documents were not consistent in what was observed in the field. So observations were made to AECL to ensure that consistency between documentation and what existed in the field would be consistent.

10So I don't know if that answers your11question.

12 In terms of significance, if I were to summarize, I do believe that the facilities were properly 13 14 monitored for the status of operation in those days. In 15 some cases some of the pieces of equipment were not 16 functional but in areas where actually no radioactive 17 material was present. So the observation was made to AECL 18 that our expectation was that -- well, our position was 19 that the facility was in operation and normally the 20 equipment should have been able to do the monitoring even 21 though there was no radioactive material present.

It is an observation. We don't feel that it has a significant impact on the program. However, we clarified our expectations to AECL on that.

We do believe also that the systems in

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1 place currently gives us confidence at a time of more 2 operation of the facility, the equipment will be in place 3 to do proper monitoring of the facilities for effluent 4 monitoring. 5 So I hope that answers your question. 6 MEMBER GRAHAM: Yes, it does, and thank 7 you. 8 I guess my question would be to AECL. Ι 9 mean, even though it may not be of significance it still 10 indicates lack of control in some of these things. Would 11 you like to care to comment as to when you'll have those -12 - at least those four action notices, action items 13 resolved and brought up to the expectation of CNSC? 14 MR. MCGEE: Brian McGee for the record. 15 I'll ask Don Taylor to describe the 16 timeline associated with the specifics of those action 17 notices. 18 The Environmental Management System at 19 Chalk River Laboratories is a site-wide program and an 20 area of demonstrated performance. It is ISO-14001 21 certified and has just now gone through this fiscal year a 22 subsequent recertification. So we now have two 14001 23 certifications under our belts from an experiential 24 perspective. 25

The other aspect of the environmental

1 program is that under the site licence that was obtained 2 mid -- last calendar year -- were required to migrate to 3 S-296 and we are well on the way to doing that. On a 4 site-wide basis we are driving the environmental program to meet the S-296 requirements for the CNSC. So the 5 6 program is a demonstrated area of performance. 7 Central in both of those aspects is 8 continuous improvement. And so the continuous improvement 9 aspects that are identified as part of the CNSC inspection 10 are important as well as the ongoing improvements and on 11 an annual basis we have an improvement plan for each of 12 the facilities onsite to address improved performance in 13 the environmental management system. 14 I'll turn it over to Don to talk 15 specifically about the timeline. 16 MR. TAYLOR: For the record Don Taylor, Director of DIF Operations. 17 I'm afraid I don't know the detailed 18 19 timelines for these four actions at this point in time but we do have knowledge of the observations and we are 20 21 setting action plans to take care of them through our 22 processes. We will treat them very seriously as we do 23 with all of these. 24 MEMBER GRAHAM: Thank you. 25 I just have one other question and this is

1 for clarification, I guess; 2.4.3 regarding the MIPF 2 production. 3 MIPF is continuing. However, there is no

4 substantive progress to report from Hearing Day One. Does 5 that production -- is that subject to MAPLE 1 in full 6 production or can it be -- is the MIPF producing when you 7 are at stage 300 Series or 400 Series and so on, just for 8 clarification?

9 MR. MCGEE: Brian McGee for the record. 10 The MIPF is reliant on MAPLE 1 full 11 commercial operation, that's correct.

12**THE CHAIRPERSON:** Any further questions?13Dr. Barnes.

14 **MEMBER BARNES:** This might be a

duplication, for which I apologize. I'll just go back tostaff because I'm struggling a little bit myself.

17 I can understand the logic for the various 18 licenses and to some extent the logic for a 47-month term, 19 but given the issues that we've been addressing here now 20 for quite some time and the difficulty of AECL being able 21 to achieve the appropriate resolution to the PCR problem 22 which affects MAPLE 1, MAPLE 2, it seems to me that on the 23 one hand there is a need to have some extended licence 24 length, but there certainly needs to be some review 25 points. On the one hand you're talking about certain hold points from a milestone perspective. Second, in your document, although it's sort of -- a little bit buried in there -- it's not in the initial sort of final recommendations -- you're talking about having a sort of a mid-term review in, I think, about October or thereabouts in 2009.

7 It would seem to me that it would be good 8 to have a review towards sort of active commissioning of 9 MAPLE 1 and, presumably, MAPLE 2 that might be twinned 10 depending on progress and then the NPF commissioning and 11 of course with the NIPF too.

12 So on the one hand we have a longer licence 13 term. We have the specific problem with PCR which makes 14 it difficult today to predict when there would be active 15 commissioning of MAPLE 1, 2 and the NPF but four years is 16 a long time for a licence when there has been this 17 important issue before us. So the nature of these 18 meetings, I think, is important to me and the timing of 19 them.

20 So could I just ask you -- sorry for the 21 repetition but from a staff viewpoint, how do you think it 22 is best to have the Commission look at these and 23 particularly in a public forum?

24MR. HOWDEN: Thank you. Barclay Howden25speaking.

I think the way we structured things with the mid-term and then the two hold points, we thought that they would be staggered such that you would be getting that information. With AECL proposing a post-PCR testing update I think that's a good thing.

6 We would definitely take direction from the 7 Commission whether you wanted another update at the active 8 commissioning phase. I would suggest that if the timing -9 - it all depends on how things pan out but the timing 10 might actually align with the mid-term so we could kill 11 those two at the same time. But if they were stretched 12 out, certainly if the Commission desired we would be more than happy to provide an update to make sure that you're 13 14 well-apprised and that the public is well-apprised.

We're not against making those updates and I think something around active commissioning could -could be taken care of for sure, because 47 months, as you say, is a long period for a facility that is undergoing change, as opposed to one that's just steady with not very many changes, so we certainly take that direction from the Commission.

22 **MEMBER BARNES:** I particularly consider it 23 still to, I think, significant C-ratings in operating 24 performance and performance assurance, which seem to be 25 tied to some of the difficulties that AECL is having.

1 MR. HOWDEN: Barclay Howden speaking. 2 Yes, we acknowledge that and we also 3 acknowledge that AECL makes strong commitments to bring 4 those up to meet expectations and I think if they reach 5 those that would -- that would also -- rather than 6 reporting updates, which tend to be negative, to provide 7 some positive updates as well. 8 Thank you. 9 THE CHAIRPERSON: I will recall, for the 10 staff, that I had -- and I'm trying to recall which 11 licence it was, a recent licence at CRL -- mentioned that 12 what would be helpful because of the complexity of the 13 site, for a background document to be developed that would 14 offer this continuity as well, no matter what the 15 licence's like because it's a complex site, you know, 16 looking at pulling out the various aspects without having 17 to go back to a total relooking at things because one 18 should not assume that the Commission looks at this every 19 day. 20 I mean, it looks at it a very -- period of

time and in pulling that out in a way that would cite this appropriately, I think, no matter what is the decision of the Commission would be helpful and I think you'll recall that I asked for that to be done.

25 Further questions at this time?

1 Okay, well thank you very much, we've 2 finished round one and now we're going to move to the 3 intervenor's part of the hearing today, Hearing Day Two. 4 Before I start, I would like to mention to 5 all the intervenors that we do appreciate you taking the 6 time to interest yourself in this particular licence and 7 we will be -- we will be -- we can assure you that we've 8 read your written submissions in -- in great detail and 9 that your written submissions will also be considered, as 10 well as your orals today and that we've allotted 11 approximately 10 minutes to each of the presentations and 12 look forward to your oral and written comments. First I'd like to move to the first written 13 14 presentation by the Canadian Nuclear Workers' Council. 15 Mr. David Shier has been with us before. We do have CMD 07-H16.2, 07 H16.2A. 16 17 And the floor is yours, sir. 18 07-H16.2 / 07-H16.2A 19 20 Oral presentation by the 21 Canadian Nuclear 22 Workers' Council 23 24 MR. SHIER: Thank you and good afternoon, 25 Madam Chairperson and Members of the Commission.

1 For the record, my name is David Shier; I'm 2 the President of the Canadian Nuclear Workers' Council. With me today I have several leaders of the 3 unions that are members of our council from Chalk River 4 and I would like to take the time to introduce them. 5 6 To my right is Gord Tapp. Gord is one of 7 the leaders of the Chalk River Technicians and 8 Technologists Union. 9 Beside Gord is Tom Brunette. Tom is the 10 Union Leader for the Operators at the MAPLE site, as well as the other facilities at the Chalk River site. 11 12 Behind me is Pam Pickering. Pam is the Leader of the Allied Trades Council, which represents 13 14 eight unions on the site. 15 And beside Pam is Ken Philipose. Ken is 16 the representative of the union for the professional 17 engineers at -- and scientists at Chalk River. 18 We are here today in support of the AECL's 19 application for the renewal of the licence and you do have 20 our written submissions so we're going to be fairly brief 21 and just highlight a few points we'd like to expand on. 22 So our presentation will consist of a quick 23 overview of the labour relations, conventional health and 24 safety, radiological health and safety, community 25 perspective and our conclusions and recommendations. And

again, this is all from the view of the people in the
 workplace, through the leaders of their union.

As we indicated, there is 11 bargaining units onsite and there is approximately eight collective agreements and it's fortunate at this time that all the bargaining is being completed and most of the unions are into collective agreements up until 2011, except for the Power Worker Unit, which theirs is up to 2009.

9 The health and safety structure, as we're 10 very -- health and safety is a very paramount point of the 11 Nuclear Worker Council and we're encouraged to see the 12 improvements in the health and safety performance and we 13 assure you that the workers onsite are very well aware of 14 their safety rights.

In putting together this presentation, the authors, we toured the actual facility and talked to the workers and we can assure you that they are well aware of their rights and feel safe in working in the facility.

The Joint Health and Safety Committee has been very active and they are, as you'll see from our written submission, they are undergoing a quantification, which basically reducing their numbers to make the committee more effective and we're optimistic that is going to happen.

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The dose reduction; we looked right across

1 the site and it has been reduced and again we believe that 2 is from the involvement of the -- of the workers and some 3 of the new processes that are in place.

The community perspective; as we always indicate, it's the workers that reside in the communities and they are involved with a lot of community functions so they're continually in contact with members of the public and they're naturally questioned about the site and they're able to give their views, naturally.

10As we say, if it wasn't safe there they11wouldn't be there or they would be making sure that the12issues were dealt with.

The Nuclear Worker Council; we coordinate 13 14 some efforts in the area at different times and I guess 15 one area is the Renfrew and District Labour Council, which 16 has a large number of unions in the area and there's 17 several of the unions at Chalk River which are members of 18 that council, which again provides the opportunity for the 19 workers to tell -- answer any questions and tell people 20 exactly what it's like at that particular location.

21 So in conclusion, we indicate that the 22 public can be assured any issue involving public safety 23 will be addressed by the onsite unions and we encourage 24 the Commission to renew the operating licence for the 25 site.

1 And in conclusion, I would like to -- and 2 naturally we are prepared to take any questions that you 3 may have at this time. 4 Thank you. 5 THE CHAIRPERSON: Thank you very much. 6 And although we've had individual members 7 before, we haven't had the organization together so that 8 was an interesting development for us as well. 9 Any questions from my colleagues? 10 Yes, Dr. Barnes. 11 **MEMBER BARNES:** There has been a 12 significant reshaping of AECL's management, individuals and organizational charts; that's why we asked probably 13 14 for it for this Day Two meeting, but it's now been in 15 place for a little while so I would appreciate any 16 comments that the unions might want to make on whether 17 you've seen any significant -- I'll say -- improvement, from the viewpoint of workers on -- onsite? 18 19 MR. SHIER: I'll give you a response from 20 my perspective and then I'll ask if any of the other 21 members would like to add anything. 22 But from what I get from being external to 23 the site and hearing from the -- the different unions that 24 they indicate to me there has been a big positive affect; 25 that a lot of the things are being brought forward now

1 that weren't before; health and safety is improving; 2 there's more of an open atmosphere. 3 And now, with that, I'll ask if anybody 4 else wants to make any comments to that effect. 5 MR. PHILIPOSE: For the record, my name is 6 Ken Philipose. I represent the Chalk River Professional 7 Employees Union. 8 Yes, there was -- there have been a lot of 9 changes in management and our site is growing; we have new 10 people and there are new challenges. 11 Like Dave said, just to the -- I mention 12 that many of these organizational changes are brought in -13 - improvements in the way reporting structure and the way 14 things are being heard, so it's -- it's positive. 15 THE CHAIRPERSON: Any questions? 16 Mr. Graham? 17 One of the changes that has also happened on the same time is that there is a CNSC site presence. 18 19 Mr. Shier is used to this because of his 20 involvement in the NPP site, so I just wondered if there 21 was any comments with regards to -- you don't get to 22 choose whether we have site staff, let me make that clear, 23 but any comments about having a site -- CNSC staff -- site 24 staff on the -- in Chalk River?

MR. SHIER: David Shier, for the record.

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1 Yes, we just found out about that and --2 well, we'll probably be having some discussions with the 3 unions there to have some dialogue with the -- the site representative. We found that fairly positive, especially 4 5 around the generating stations. So we think also publicly 6 that it is a good move as well because it shows a regular 7 -- being onsite -- and I think that will help solve some 8 problems with the public.

9 But definitely from a worker perspective, 10 we will be pursuing that avenue of having some meetings 11 with them.

12 **THE CHAIRPERSON:** For those that aren't 13 aware, on the NPP sites what we have said to the 14 representatives is it's important for them to know that 15 that is another safety valve, I guess, if I can put it 16 that way that if there are issues that come up onsite that 17 the CNSC site staff are requested to interact with 18 employees if they feel that there is some safety issue 19 that you need to talk about.

20 Clearly, we don't want to get into the 21 union management issues. We very clearly do not get into 22 that, but we do want to know that that's an added safety 23 issue for the employees and also for the management under 24 Mr. Santini as well.

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But that is what we do at the NPP sites, is

1 one of the beauties of having onsite staff. 2 Further questions? Well, thank you very much. 3 We do 4 appreciate it. We realize we are a little bit delayed, 5 but thank you very much for coming. 6 We are now going to move to the next 7 intervention, which is an oral presentation by the 8 Corporation of the Town of Deep River outlined in MCD 07-9 H16.3. We are pleased to welcome Her Worship, the Mayor 10 of Deep River, to us today. Thank you very much, ma'am, 11 for coming. We will let you get seated here. 12 Thank you very much for coming. The floor is yours. 13 14 15 07-H16.3 16 Oral presentation by the 17 Corporation of the 18 Town of Deep River 19 20 MS. AIKENS: Thank you very much. For the 21 record, my name is Ann Aikens, the Mayor of Deep River. 22 I would like to thank you for the 23 opportunity to appear before the Commission to express my 24 support for the 47-month renewal for the operating licence 25 for MAPLE and NPF.

As head of council, it is important for me to make the time to personally hear the submissions by AECL, by CNSC staff and to listen to the thoughtful and probing questions asked by Commission Members because it continues to assure me and my community that safety continues to be the primary consideration for everyone involved.

8 Deep River and Renfrew County are very 9 proud to be home to AECL and to Chalk River Laboratories. 10 The economic impact of AECL is very important to our 11 community.

12 AECL is the second largest employer in the County of Renfrew. It employs more than 2,100 employees 13 14 who live in 25 small communities in the Ottawa Valley. I 15 think sometimes people believe it's just Deep River that 16 is impacted by the employment, but that's not the case. 17 More than half of the employees are spread between other 18 small municipalities in Renfrew County. As such, they 19 constitute four percent of our total labour force. Their salaries contribute to the prosperity of the region and 20 the success of our businesses, large and small. 21 22 Therefore, they contribute to the health and safety and 23 well being of these communities. So it is a very 24 important contribution.

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All that being said, it is important for us

to realize and important for us to make sure that that's being done in a safe environment. We feel fortunate to be living and being involved with a workforce and an employer that has such a rigorous safety oversight. It makes it very beneficial to our communities.

6 Besides the impact, I want to talk also 7 about some of the major accomplishments that I have seen 8 in the short time that I have been the head of council. 9 AECL's management continues to keep us very well informed.

10 I am particularly impressed with the 11 efforts that AECL has undertaken to create the 12 Environmental Stewardship Committee. I benefit greatly as 13 head of council from the opportunity to share the opinions 14 of the other stakeholders around the table, and this is a new initiative for us. At some of those meetings, the 15 16 CNSC representative that you talked about previously with 17 labour unions is available, and I have shared discussions 18 with that person over lunch. It also gives me an 19 opportunity to hear from other stakeholders and to see 20 their perspective and to understand their concerns as we 21 move forward collectively to come up with positive 22 solutions.

None of this would have been possible
without the initiative of the new management at AECL, and
I would very much like to highlight how important that is

1 as we go forward, not just on this licence renewal but on 2 the other ones as well.

3 From a community point of view, there has been a lot of discussion about the whole issue about the 4 5 47 months and whether or not that's too long or not too 6 long. But from a community point of view, it's very 7 important and very helpful to us, not just for me as the 8 head of Deep River's council and community but also for my 9 colleagues at Renfrew County Council to be able to see 10 these individual licences in context to the overall site 11 licence and to know that it is not just specifically one 12 item that is being dealt with. It is being dealt with in 13 the context of the health and safety and wellbeing of our 14 communities for all activities that go on in the 15 operations on the site.

16 Further to what has been said, both by 17 Commission staff and by AECL, I would support the fact 18 that we would encourage a 47-month licence renewal. The 19 intervening points that they have for public information, 20 I think, are also very important and we would be very 21 interested to see those results as they come forward in 22 their testing.

But again, consolidating all of those
licence initiatives is very important to the communities.
It helps us to understand it in context. It helps us to

see it in context going forward, rather than isolating one
 particular operation on the site.

In closing, because most of this stuff is 3 4 in our brief as well and I know you have other things to 5 talk about today as well, we are very proud to be part and 6 to be the host of AECL's community. As a community 7 member, we chose to come to Deep River from Mississauga. 8 We chose to raise our families there over 25 years ago. I 9 have never once worried about the safety of my children as 10 a mother and as head of council, I don't ever worry about 11 the safety of my community because we are located close to 12 AECL. I think I have stated that in previous submissions 13 to this to the Commission -- but I wanted to make that 14 crystal clear.

15 There are many places and many industries 16 that you could live beside that have not anywhere close to 17 the oversight or the kinds of rigorous demands that AECL 18 has for providing a safe community. As such, I applaud 19 the efforts of the Commission. I applaud AECL and I 20 applaud Commission staff for making sure that we move 21 forward collectively to make sure that this is done in the 22 best interests of my community, of Renfrew County and of 23 Canada. And as we move forward, the things that we are 24 going to learn in the ways that we are going to process 25 isotopes in the future will probably benefit all of the

1 world in isotope production.

2 So I look forward to moving forward 3 collectively on this, and I thank you for the opportunity 4 to identify my community's support. 5 I would also, before I conclude, like to 6 bring greetings from the warden from the County of 7 Renfrew, Warden Janice Visneskie. They had hoped that 8 they would be able to participate by telephone conference 9 -- both her and Bob Sweet, who is the Mayor of Petawawa. 10 They are previously engaged in a conference that they were 11 registered for, and they asked me today if I would bring 12 their greetings and their support to the Commission's 13 attention in a personal way. Although you do have their 14 written submission, they were wishing that they could have 15 done this by telephone because they had a previous 16 commitment. 17 So again, thank you for your time and I 18 would be happy to answer any questions that you may have. 19 THE CHAIRPERSON: Thank you very much and 20 thank you for coming. Questions from my colleagues? 21 I would like to thank you very much and I 22 just want to say that spending time with you and listening 23 to your submission is very important to us. I mean, 24 obviously, the communities have played a major role for us 25 in looking at the programs of the industries that we

1 regulate.

2	And the acceptance, what I tend to call the
3	social licence, is incredibly important to the companies
4	and to us as well. So we would like to thank you very
5	much for taking this time to be with us and we certainly
6	have read the written submissions from your colleagues as
7	well.
8	Thank you very much.
9	I would like to now move to the next
10	submission, which is an oral submission by MDS Nordion,
11	CMD 07-H16.4. Mr. Graham Malkoske, Vice-President of
12	Strategic Technology at MDS Nordion, is with us again.
13	Oh, and the President of MDS Nordion, Mr. West.
14	We would like to thank you for being here
15	today, gentlemen, and the floor is yours, sir, when you
16	are ready.
17	
18	07-H16.4
19	Oral presentation by
20	MDS Nordion
21	
22	MR. WEST: Good afternoon, Madam Chair, and
23	the Commission.
24	I am, for the record, Steve West, President
25	of MDS Nordion.

1 We are pleased to be here today to appear 2 before the Commission to fully support the application by 3 AECL for the renewal of the operating licence for the 4 Dedicated Isotopes Facilities. 5 I am going to handover now to Mr. Grant 6 Malkoske who will be giving our presentation. 7 MR. MALKOSKE: For the record, my name is 8 Grant Malkoske, Vice-President, Strategic Technologies 9 with MDS Nordion. 10 So our intervention is clearly in support 11 of AECL's application for an operating licence for the 12 Dedicated Isotope Facilities, for the period of 47 months. We think that the importance of these 13 14 dedicated, Isotope Facilities to the reliable supply of 15 nuclear medicine isotopes for the global healthcare 16 industry is really paramount and we feel a strong 17 obligation to be able to continue to supply these isotopes 18 for patient needs. 19 It's also -- our intervention is also a 20 recognition of the licensing activities of the Commission, 21 as well as AECL, to ensure both the safe commissioning and 22 the safe in-service operation of these Dedicated Isotope 23 Facilities. They will be the workhorses for the future 24 production of medical isotopes.

And so, as we take a look at the supply

25

chain today for medical isotopes coming from Canada - certainly NRU and the Moly Processing Facility continue to
 be the paramount producers of these medical isotopes
 internationally.

5 Some 60 percent of the world's medical 6 isotopes come from Canada. Some 50 percent of the supply 7 into the United States comes from Canada. So on the one 8 hand it truly is a privilege, on the other hand it's a 9 serious obligation to be able to continue supplying these 10 needs for patients.

And as this slide shows, the expectation is that MAPLE and the Dedicated Isotope Facilities will pick up this obligation, hopefully in the near future.

14 The diagnosis of disease is something that 15 is being used around the world; today, the diagnosis of 16 disease using Moly 99 and Tech 99 is some 80 percent of 17 the medical isotope procedures. And so, monitoring 18 health, expediting treatment, as this slide shows, is 19 something that only comes from these medical isotopes and 20 there are relatively few of these suppliers around the 21 world.

This slide shows some of the applications; you've seen this slide before. I think the point that I'd emphasize here is that the secure, reliable supply of medical isotopes is what we think, an imperative

obligation upon each and every one of us, as we make sure
 that these patient needs are being met.

3 Some of the new, exciting opportunities as 4 we go forward in the future is, as we see science 5 advancing health care applications, the whole field of 6 molecular imaging where, based on nuclear technologies, we 7 can look at these imaging technologies to better able us 8 to diagnose the need for different drug tools for patient 9 care.

And molecular imaging is going to speed up this drug discovery, bring on new applications that truly are exciting. And one of the examples we have here, on the bottom of the slide, is a radio labelling of monoclonal antibodies with Iodine-131 which is produced here for treatment of non-Hodgkin's Lymphoma that product being called Bexar.

17 Also, there are new, targeted diagnostics 18 and therapies; some for brain cancer, treating 19 neuroblastoma as an example. And so, the bottom left 20 picture shows a pictograph here of a brain tumour being 21 treated. So often the tumour is resected and any residual 22 cancer cells are treated with Iodine-131 or Iodine-125, 23 which could be introduced into the cavity and make sure 24 all the cancer cells are destroyed.

25 And so these targeted radionucleic

therapies are really exciting opportunities for the
 future.

This slide is one that has become a 3 4 hallmark of many of the things that we do. 5 To make sure that these essential criteria 6 for medical isotope supply continue to be adhered to, as 7 we deliver a product around the world. And so, the 8 continuous product supply, the regulatory requirements, 9 the product quality, the consistency of delivery, all 10 become very important for patients to be able to depend 11 upon this product for meeting their needs. 12 And of course, it is truly a just in time 13 application from the time of reactor extraction, by the 14 time that is delivered to Ottawa, processed, put on a

15 plane, delivered to Logan Airport in Boston, taken to a 16 radio-pharmaceutical facility, made into a technetium 17 generator, delivered to a clinic, provided to a patient --18 as little as 41 hours.

Self-supply logistics certainly are
critical; cross-border commerce becomes a fundamental
point of importance for us.

You've see this slide -- the dependency on Canada for medical isotopes and I alluded to some of the numbers prior. There are about 60 countries that rely on Canada for its supply of reactor isotopes.

1 NRU, today, continues to be the workhorse. 2 And it's been very dependable; we certainly have seen a 3 lot of investment by Atomic Energy of Canada to ensure 4 that NRU and the Moly processing facility continue to operate consistently, reliably, within the safety envelope 5 6 that is prescribed and these isotopes are produced and 7 distributed coming out of the NRU system. 8 It's interesting to note the strategic 9 value that Canada, Nordion and AECL play to the industry. 10 It's important to have security of supply. Backup 11 arrangements are in place with other producers but 12 nonetheless, there are no other producers around the world 13 that collectively can fill the gap if Canada's supply 14 chain were to go down.

And interestingly, we had a situation just in the last couple of years -- twice -- in the United States where one of the generator manufacturers had to shut down their production line, leaving only one other manufacturer.

20 And all of the isotopes for the United 21 States, in that case, were supplied from Canada. So, 22 supply -- production and supply was ramped up at NRU, 23 production and supply ramped up at Nordion. 24 Other worldwide backup arrangements were

25 put in place and distribution was made to other countries

1 from those other suppliers and we think it's really a
2 testimony to a lot of dedicated effort by many people to
3 ensure that this was done consistently, reliably and
4 safely.

5 So, certainly we see here how NRU is 6 essential today and the expectation is that the Dedicated 7 Isotope Facilities will assume NRU's supply, performance 8 obligations.

9 These isotopes, the "big four" as we call 10 them -- Moly-99, Iodine-131, Xenon-133, Iodine-125, these 11 will be the essential products that will come out of this 12 Dedicated Isotope Facility and be distributed around the 13 world.

We are concerned, of course, about progress in bringing the Dedicated Isotope Facility's project to completion. We've listened very intently today to some of the discussions that have gone on around the MAPLE Reactors, the positive power coefficient of reactivity.

We're also interested in seeing the Iodine Facility brought to in-service operation, as well as the NPF and so there is a lot of work to be done. We know that time is important but nonetheless, we expect that the completion of these facilities will be done safely, will be done effectively so that their ongoing in-service operation is not compromised.

1 So then, in summary, we think that this 2 reliable isotope supply is an essential obligation that we 3 must continue to uphold, both at AECL and at Nordion. 4 The entire supply chain has to continue to meet patient needs and the focus on this obligation, we 5 6 think being given in Canada by AECL and by Nordion 7 certainly is important and our customers and patients 8 around the world would agree with that. 9 So then in summary, we support AECL's 10 application. We're confident of their ability to ensure 11 the safety of the workers and the public, to implement an 12 effective quality management program for commissioning and 13 for operations; to ensure the ongoing safety and 14 reliability of their operations and also to ensure that 15 they continue to meet the regulatory and environmental 16 protection requirements. 17 We support the application they have made 18 to renew these licenses for the Dedicated Isotope Facilities to October 31st, 2011. 19 20 Thank you, Madam Chair and Members of the

21 Commission.

22THE CHAIRPERSON: Well, thank you both to23Mr. West and Mr. Malkoske for being with us today.

24 Are there any questions from Commission 25 Members?

1 Yes, Dr. Barnes. 2 MEMBER BARNES: Just in your last slide, you mentioned the issue of quality management which I 3 4 raised. Your words are that you are confident in the 5 AECL's ability to implement an effective quality 6 management program for commissioning and operations. 7 Do you think that the existing Quality 8 Management Program is satisfactory or needs significant 9 improvement? 10 MR. MALKOSKE: I don't know if I can 11 comment that it needs significant improvement -- is it on? 12 Yeah. 13 I don't know if I could comment that it 14 needs significant improvement. 15 We've listened to some of the results from 16 the 2003 audit, some of the results that were discussed 17 today from the 2007 audit and without having the detailed information available to us, it would seem that there is 18 19 some work to do, to make sure that the program -- the site 20 program, the AECL corporate programs continue to be 21 robust. Maybe even some adjustments to make sure that 22 they're effective but we're certainly not experts in that 23 We would leave that to both AECL and the auditors area. 24 to determine that.

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THE CHAIRPERSON: But I think you would

1 admit that that is key to your certainty of supply and the 2 quality of supply is going to be the quality management 3 program that they have in place.

4 MR. MALKOSKE: Yes, I think as we have 5 listened to discussions that have gone on over the last 6 number of years, if we're going to have continuity of 7 supply, dependability of supply, that that is an important 8 factor to demonstrate to our customers that that can be 9 achieved and adhered to.

 10
 THE CHAIRPERSON: Further questions from my

 11
 colleagues?

12 Yes, all I can say is you probably very succinctly put in your slides the real issue that is 13 14 before us, period, is the Commission has as you well know because you're a licensee too; this safety -- the 15 16 overwhelming safety mandate. But the Commission doesn't 17 live in a bubble. It knows that there is clearly some key 18 issues that you have outlined very succinctly in your 19 slides to do with reliance on the NRU and it did go 20 through a very vigorous re-licensing and improvement 21 program. But inevitably, this gap analysis is of great 22 importance to you which you've outlined succinctly.

But from the Commission's point of view it is very much an issue that we are aware of but won't, as you again clearly pointed out, be the issue that drives

1 the Commission. So I think it's very important to have 2 this succinctly put on paper. So thank you very much. 3 So thank you very much for coming, 4 gentlemen. 5 We will now move to the written submissions. We have a written submission from the Town 6 7 of Petawawa as outlined in CMD 07-H16 -- my apologies. 8 It's the afternoon, I guess. 9 We are moving now to the next submission 10 which is a written submission from the Fire Department of the Corporation of the Town of Laurentian Hills, CMD 07-11 12 H16.5. 13 14 07-H16.5 15 Written submission from the 16 Fire Department of the 17 Corporation of the Town of Laurentian Hills 18 19 20 THE CHAIRPERSON: Are there any questions 21 or comments from Commission Members with regards to this 22 submission? 23 Thank you very much. 24 We will now move to the next submission 25 which is a written submission from the Renfrew County

1 Catholic District School Board, CMD 07-H16.6. 2 3 07-H16.6 Written submission from the 4 5 Renfrew County Catholic 6 District School Board 7 8 THE CHAIRPERSON: Are there any questions 9 or comments with regards to this submission? 10 Now, we'll move to the one that I discussed which is CMD 07-H16.7. 11 12 13 07-H16.7 14 Written submission from the 15 Town of Petawawa 16 17 THE CHAIRPERSON: Are there any questions or comments with regards to this submission? 18 19 You see, I could have kept going. 20 The next submission is a written submission 21 from the City of Pembroke, CMD 07-H16.8. 22 23 07-H16.8 24 Written submission from the 25 City of Pembroke

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2	THE CHAIRPERSON: Are there any questions
3	or comments with regards to this? No? Thank you very
4	much.
5	Then we move to the next submission which
6	is a written submission from Mr. J.A.G. Severin, CMD 07-
7	н16.9.
8	
9	07-н16.9
10	Written submission from
11	J.A.G. Severin
12	
13	THE CHAIRPERSON: Are there any questions
14	or comments with regards to this written submission?
15	Seeing none, I'll move to the next one
16	which is a written submission from the Pembroke Regional
17	Hospital, CMD 07-H16.10.
18	
19	07-н16.10
20	Written submission from the
21	Pembroke Regional Hospital
22	
23	THE CHAIRPERSON: Are there any questions
24	or comments with regards to this written submission?
25	We will now move to the next submission

1	which is the written submission from Renfrew County
2	District School Board, CMD 07-H16.11.
3	
4	07-H16.11
5	Written submission from the
6	Renfrew County District
7	School Board
8	
9	THE CHAIRPERSON: Are there any questions
10	or comments?
11	The next submission is a written submission
12	from Deep River District United Way, CMD 07-H16.12.
13	
14	07-H16.12
15	Written submission from the
16	Deep River District United Way
17	
18	THE CHAIRPERSON: Are there any questions
19	or comments with regard to this written submission?
20	Moving to the next written submission, a
21	written submission from the County of Renfrew, CMD 07-
22	H16.13.
23	
24	07-H16.13
25	Written submission from the

1 County of Renfrew 2 THE CHAIRPERSON: Are there any questions or comments with regards to this submission? 3 The next one is the written submission from 4 5 the United Way/ Centraide of the Upper Ottawa Valley, CMD 6 07-H16.14. 7 8 07-H16.14 9 Written submission from the United Way / Centraide of the 10 Upper Ottawa Valley Inc. 11 12 THE CHAIRPERSON: Any questions or comments with regards to this submission? 13 14 That brings to the end the matters before 15 the Commission on this area. I suggest -- with respect to 16 this matter I propose that the Commission confer with 17 regards to the information that was considered today and then determine if further information is needed or if the 18 19 Commission is ready to proceed with a decision, and we 20 will advise accordingly. 21 Thank you very much, ladies and gentlemen, for joining us today. 22 23 The hearing on the application by SRB 24 Technologies will be starting at three o'clock. 25 Thank you very much.

1 --- Upon recessing at 2:12 p.m.