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NUCLEAR REGULATORY COMMISSION

OFFICE OF THE SECRETARY

BRIEFING ON PROPOSED EXPORT OF HIGH ENRICHED

URANIUM TO CANADA

PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Green Plaza Area
11555 Rockville Pike
Rockville, Maryland

Monday, July 10, 2000

The Commission met in open session, pursuant to notice, at 1:30 p.m., the Honorable RICHARD A. MESERVE, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

- RICHARD A. MESERVE, CHAIRMAN
- NILS J. DIAZ, Member of the Commission
- EDWARD McGAFFIGAN, JR., Member of the Commission
- JEFFREY S. MERRIFIELD, Member of the Commission

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STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

- DR. IAIN C. TREVENA, MDS NORDION
- DR. JEAN PIERRE LABRIE, ATOMIC ENERGY OF CANADA, LTD.
- MR. GRANT R. MALKOSKE, MDS NORDION
- MR. JAMES A. GLASGOW, MORGAN, LEWIS & BOCKIUS, LLP
- MR. PAUL LEVENTHAL, NUCLEAR CONTROL INSTITUTE
- MR. ALAN KUPERMAN, NUCLEAR CONTROL INSTITUTE
- MR. RICHARD J. K. STRATFORD, DEPARTMENT OF STATE
- DR. ARMANDO TRAVELLI, ARGONNE NATIONAL LABORATORY

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P R O C E E D I N G S

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[1:30 p.m.]

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CHAIRMAN MESERVE: We're here this afternoon for a briefing on a proposed export of highly-enriched uranium to Canada. The purpose of our meeting this afternoon is to hear from the applicant, MDS Nordion of Canada, from the Nuclear Control Institute, and from representatives of the Executive Branch of the United States Government. This meeting really arises from a memorandum and order that was issued by the Commission on June 29, 1999, regarding the authorization of the proposed export.

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All such exports of highly-enriched uranium for use in reactors are subject to the Schumer amendment. That amendment allows the export to occur only if certain conditions are met that relate basically to a United States policy for proliferation reasons to encourage the use of low-enriched uranium rather than high-enriched uranium in research and related reactors abroad.

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We required in our order of June 29, 1999, that there be annual reports that would be submitted by the applicant, and the Executive Branch had also agreed to submit an annual report as to the progress that had been made in meeting the requirements of the Schumer amendment.

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We're here today to have a hearing with regard to the annual reports that were submitted by Nordion on May

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31st and by the Executive Branch just recently, in early

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July.

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The Nuclear Control Institute has corresponded with us on this subject and has raised some concerns as to compliance with the Schumer amendments, and we'll also be hearing from them.

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The first panel consists of representatives of MDS Nordion, and they include Grant Malkoske, who is a vice president; Dr. Iain Travena, who is a senior vice president; Dr. Jean Pierre Labrie, who is with AECL in Canada; and James Glasgow, who is a partner at Morgan, Lewis & Bockius.

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Why don't we proceed?

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COMMISSIONER MERRIFIELD: Mr. Chairman, before we turn over to the witnesses, I would like to make a brief opening statement along the lines of the statement that I made last year when we had our hearing in 1999, before you became Chairman.

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I'm very sensitive, coming from the State of New Hampshire, which borders Canada, and coming from a state in

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20 which over 30 percent of the population is of
21 French-Canadian descent -- I want to make an initial
22 observation.

23 What this meeting is about today, as the Chairman
24 has asserted, is the application of the Schumer amendment
25 and our efforts and the efforts on the part of the NRC to

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1 help control the proliferation of highly-enriched uranium.

2 What this meeting is not about, in my view, is any
3 kind of an accusation against our neighbor, Canada.

4 Canada is clearly one of our most trusted allies
5 of the United States.

6 I don't think anyone coming before this -- and
7 having read the briefing papers today, I don't think anyone
8 would make an accusation of any kind of untrustworthiness of
9 our Canadian allies.

10 Indeed, quite contrary, I think the Canadians are
11 some of the most trusted of our allies in terms of holding
12 this material.

13 Nonetheless, obviously we have the requirements of
14 law, and that is the reason why we are here today, but for
15 my own part, I certainly want to make it clear that I
16 believe that Canada has and will continue to be among the
17 most important trading partners and allies of our country,
18 and I certainly wouldn't want that to be left off the
19 record, for my part.

20 CHAIRMAN MESERVE: And I'm sure that's something
21 that the entirety of the Commission would support and agree
22 with.

23 Let me turn to my other colleagues and see if they
24 have an opening comment.

25 COMMISSIONER MCGAFFIGAN: I'll just make a brief

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1 comment.

2 I agree, Canada is a great ally, but we also have
3 to carry out the law, and that's where Commissioner
4 Merrifield started.

5 So, I'll be very interested in whether Nordion has
6 been doing all it can to help us carry out our
7 responsibilities under U.S. law.

8 CHAIRMAN MESERVE: Why don't we proceed?

9 DR. TRAVENA: Okay.

10 I have some slides to go through, and I have some
11 speaking notes around those slides.

12 Thank you very much, Mr. Chairman and
13 Commissioners, for the opportunity to be here today to
14 update you on the progress that we're making in our LEU
15 target development program for the MAPLE reactors and the NU

16 processing facility.

17 MDS Nordion is committed to converting the MAPLE
18 reactors and NU processing facility to the production of
19 medical isotopes using low-enriched uranium, or LEU, as the
20 target material in these reactors.

21 I believe it is important to continually keep in
22 mind what we are building.

23 These are not research reactors.

24 The facilities themselves will consist of two
25 MAPLE reactors and a NU processing facility that will be

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1 used solely for the continuous commercial production of
2 medical isotopes.

3 These medical isotopes are used in the United
4 States, Canada, and worldwide to diagnose and treat patients
5 in critical health-care applications.

6 Slide two.

7 It is important to realize the broad context of
8 what we are doing with our medical isotope supply stream.

9 The NRU reactor is aging and undergoing an
10 important upgrade program to enable its continued operation.

11 Of significant concern to our ongoing secure
12 supply of isotopes is the fact that the fissile liquid waste
13 storage tank from NRU molybdenum processing will reach its
14 design capacity in the spring of 2001.

15 Indeed, senior officials at the Canadian Nuclear
16 Safety Commission have expressed their viewpoint that, by
17 the end of this calendar year, 2000, we will or may have
18 reached the practical operational limit of this facility.

19 Undoubtedly, this adds to our sense of urgency in
20 operating the MAPLE reactors and the NU processing
21 facilities to ensure we maintain a secure, reliable supply
22 of medical isotopes.

23 Nonetheless, we remain committed to an LEU target
24 development program and are diligently identifying and
25 addressing the significant technical issues associated with

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1 introducing these targets into the facilities.

2 We believe the significant progress to date on our
3 initial feasibility study and the active U.S.-Canadian
4 cooperation on this undertaking meets the spirit and the
5 intent of the U.S. NRC memorandum and order of June 29,
6 1999, as well as the intent of the Schumer amendment.

7 All options are being considered to enable a
8 timely conversion to LEU for medical isotope production in
9 the MAPLE facilities.

10 Slide three.

11 We have planned three phases to the LEU target
12 development and conversion program.

13 These phases are, in fact, the same ones as we
14 proposed in our early contemplation of conversion from NEU
15 to LEU.

16 With regard to the completed initial feasibility
17 study, it is important to recognize that this feasibility
18 study went significantly beyond the study envisaged in the
19 U.S. NRC memorandum and order of June 29, 1999, when a
20 target completion date of three months was stated by Argonne
21 National Laboratories.

22 We were able to assess the Commission's interests
23 in making minor modifications before going active and in
24 addressing reasonable measures to preserve the ability to
25 convert at a later date.

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1 This, we believe, we done in time to consider the
2 prudence of any suggested minor modifications.

3 However, beyond that, we were also able to examine
4 critical technical issues related to extracting molybdenum
5 from LEU targets and processing the liquid waste from these
6 targets.

7 All together, this has enabled us to identify
8 challenges that must be resolved to enable conversion.

9 This progress was addressed in the report filed
10 with the U.S. State Department, USD, and U.S. NRC on April
11 17 of the year 2000.

12 The next phase which we will initiate is a
13 conversion development program which we believe will take to
14 around the year of the year 2001 to complete.

15 The final phase will be the conversion program
16 implementation, which will include the requisite
17 environmental assessments, safety analyses and licensing to
18 operate the facilities with LEU targets.

19 Slide four.

20 During the initial feasibility study, we have
21 determined that operation of the MAPLE reactors with LEU
22 targets is technically feasible, and ACEL has proceeded to
23 develop the configuration for the LEU target.

24 This configuration was appended to our annual
25 report dated May 31, 2000.

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1 We have also convened several meetings with CNSC
2 officials to discuss the licensing and regulatory conditions
3 that must be addressed in Canada.

4 Our understanding is that we must perform an
5 environmental assessment, a process during which we expect
6 to hold meetings where the public is invited to attend and
7 to comment.

8 Additional, critical heat flux and irradiation

9 tests of the LEU targets will have to be performed to
10 demonstrate the safety margins in the safety analysis
11 report, and finally, we will have to obtain CNSC approval at
12 public hearings.

13 The Canadian regulatory process is consultative,
14 with no fixed timeline.

15 We have been advised that the regulatory process
16 will take a minimum of three years from the time the
17 regulatory submissions are made.

18 Somewhat in parallel with the regulatory process,
19 we will be proceeding with the development, analysis, and
20 testing of the LEU target.

21 We must, of course, also establish a qualified
22 program to manufacture test targets before they are
23 available for the critical heat flux and irradiation test
24 program.

25 Slide five.

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1 Throughout the initial feasibility study, we have
2 kept Argonne National Labs informed to the extent possible
3 without divulging our commercial proprietary information.

4 A chapter from the NPF safety analysis report was
5 provided in May 1999.

6 In September 1999, we provided an update
7 identifying calcination as a process limitation, and most
8 recently, we hosted a visit with SGN on June 30, 2000.

9 In parallel, we have undertaken substantial
10 technical work with AECL and SGN, the technical experts of
11 the isotope extraction and calcination process. This work
12 was instrumental in being able to assess issues relating to
13 liquid waste volumes.

14 As a result, we believe that liquid waste volume
15 from processing LEU targets is not the limiting factor for
16 conversion.

17 We do not believe that completion of the initial
18 feasibility study within the three-month timeline was
19 adequate to really understand the key issues. We took the
20 initiative to consult with contractors who are intimately
21 knowledgeable about the processes, and with their qualified
22 technical assistance, the feasibility study still took until
23 April of this year to complete and report on. During this
24 period, we certainly were alert to the possibility to
25 identify and capture any opportunities which could be

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1 applied to facilitate the conversion process later.

2 During the work with AECL, we have been able to
3 study the molybdenum dissolution chemistry and recovery
4 process, comparing LEU and HEU targets. We are pleased with
5 the positive and encouraging results we have obtained in

6 this molybdenum process study.

7 While our objective is to convert the existing
8 NPF, we also have identified site space at Chalk River
9 Laboratories for a new facility should one be required.

10 Slide six.

11 Through the feasibility study assessment, we have
12 determined what we think is a key process challenge that
13 must be resolved to convert the existing NPF process.

14 The LEU targets require 4.7 times the amount of
15 uranium than an ATU target to provide equivalent molybdenum
16 production.

17 This places increased demand on the process
18 solidification and concrete canister storage systems for
19 waste generated from processing LEU targets.

20 Our work to date has identified the capability and
21 capacity of the calcination system as the main issue.

22 We will also have to address any regulatory issues
23 related to generation and processing of additional waste
24 from LEU targets.

25 For example, at their June 29th public meeting,

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1 the CNSC asked specifically about how this will be handled.
2 We understand these questions will have to be addressed
3 during an environmental assessment.

4 Slide seven.

5 In our deliberations with SGN and ACL, we
6 identified and extensively explored several options to
7 address the waste system limitations, the four which you see
8 listed on the viewgraph.

9 We believe the viable options in the existing NPF
10 are the last two.

11 The currently designed and constructed facilities
12 and systems are custom-designed to fit the existing building
13 and process equipment.

14 However, by proceeding in parallel with
15 operational process improvements and waste process
16 development, we expect to address the technical issues
17 related to solid waste processing and storage.

18 Slide eight.

19 We want to assure the Commission that we carefully
20 explored and considered whether any prudent minor
21 modifications could be made to NPF prior to its coming
22 on-line.

23 We did not identify any minor modifications to
24 facilitate later conversion.

25 It is only through operational process

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1 improvements that we can understand how to reduce the liquid

2 waste from processing LEU targets to be similar in volume to
3 HEU targets.

4 Also, as calcining is the key technical issue, no
5 additional liquid waste storage tanks are needed.

6 Unfortunately, the existing cell size cannot
7 accommodate larger calcining equipment to address the
8 throughput problem.

9 We explored and discussed this again at our
10 meeting on June 30th between Argonne National Laboratories,
11 SGN, AECL, and MDS Nordion.

12 We believe the conceptual development program must
13 thoroughly explore what process changes to the calcining
14 system can be implemented.

15 Slide nine.

16 There has been discussion about simply adding a
17 pipe from the liquid waste vault to allow future hookup to
18 processing lines before commencing active operation in NPF.
19 This does not solve our waste throughput problem. We would
20 still require waste processing cells, equipment, and nuclear
21 ventilation systems.

22 The front end of the process would still have to
23 go through the existing original cells.

24 The installation of a pipe would have created
25 regulatory concerns, delayed startup, and jeopardized

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1 medical isotope supply, all for something that does not
2 solve our problem.

3 Significant implementation costs would have been
4 involved in realizing the total modifications involved.

5 Slide 10.

6 We have commented previously on the licensing
7 concerns we had with this idea and have documented those
8 concerns in our April 17, 2000, report.

9 It is, I believe, noteworthy that, at its June
10 29th public meeting, the Canadian Nuclear Safety Commission
11 concluded that adding a pipe was not a minor modification.

12 If the only technical solution to calcining of the
13 waste from LEU targets is installation of new waste cells,
14 we will review our approach to this matter.

15 Because of the high cost that would have been
16 incurred in that case, we believe we would prefer to
17 construct a new facility to have processing redundancy and
18 further enhance our security and reliability of medical
19 isotope supply.

20 However, we are not yet at that point in our
21 evaluation.

22 Slide 11.

23 We are proceeding with phase two, the conversion
24 development program, and as next steps, we will address the

25 key technical, regulatory, and economic issues relating to

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1 converting to LEU targets.

2 We will, through our R&D; program, identify
3 technical issues for resolution.

4 We will have to develop a high-level approach to
5 this conceptual development program to assess those key
6 issues.

7 Once again, the key technical challenge will be
8 the calcining system capability and capacity.

9 During our visit to SGN on June 30th with ANL, we
10 explored several options to approve the calcination process.
11 We believe we must, in parallel, gain operational experience
12 to identify process improvements and perform a technical
13 evaluation with our contractors.

14 This will meet the starting medical isotope
15 production with HEU targets.

16 Although not expressly identified on this slide,
17 our molybdenum recovery work to date indicates increased
18 liquid waste volumes from LEU targets to optimize yields.
19 However, we believe that, through the conversion development
20 program, we can develop methods to achieve comparable
21 volumes of liquid to process LEU targets as they're obtained
22 from processing HEU targets.

23 Slide 12.

24 We must determine, in consultation with the
25 principle regulators who are interested in these health-care

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1 products, the regulatory milestones, the timeline that must
2 be achieved to implement the conversion program.

3 For example, we must consult with FDA and our
4 customers to ensure we adequately address the drug
5 regulations by converting to LEU targets.

6 Throughout this conversion process, we also want
7 to work with both nuclear regulators, the U.S. NRC and the
8 CSNC, to ensure we are meeting the requisite licensing
9 requirements. The approach chosen must be both technically
10 and economically feasible, and of course, it must ensure the
11 reliable supply of medical isotopes, particularly
12 molybdenum-99.

13 Slide 13.

14 We believe the work performed by MDS Nordion
15 complies with the spirit and intent of the Schumer amendment
16 and thus believe that export of HEU targets under license
17 number XSNM03060 should continue unimpeded and unrestricted.
18 There is no alternative target that can be currently used in
19 the reactor.

20 We are committed to using an alternative to HEU

21 once such a target has been developed and can be used for
22 the MAPLE reactors and the NU processing facility.

23 Also, the U.S.-Canada development program is being
24 undertaken to provide assurances that an alternative LEU
25 target will be used, and in cooperation with the U.S.

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1 program, we believe we have the capability to develop and
2 qualify the target for use in reactors licensed in Canada.

3 Slide 14, the last slide, please.

4 In summary, MDS Nordion is committed to convert
5 the MAPLE reactors and NU processing facility through the
6 use of LEU targets for medical isotope production in a
7 timely and expeditious manner.

8 An active LEU target development program is
9 underway.

10 Capability of the waste calcination system has
11 been identified as the key technical constraint.

12 No prudent minor modifications have been
13 identified which could be implemented now.

14 MAPLE and NPF startup with NEU targets is critical
15 to ensure the current isotope supply.

16 Also, the supply of HEU targets for the MAPLE
17 reactors are necessary to maintain security of medical
18 isotope supply until an LEU target can be implemented.

19 We also believe we are compliant with the spirit
20 and intent of our export license and the Schumer amendment.

21 We must start up the MAPLE facilities with HEU
22 targets to ensure a reliable and secure supply of medical
23 isotopes.

24 The U.S. Government should remain confident in our
25 conversion program and that a reliable and unimpeded supply

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1 of HEU targets under the export license is facilitating the
2 development of an LEU target for implementation in the MAPLE
3 reactors and NU processing facility.

4 Only by thoroughly understanding the technical
5 issues, as shown by our progress to date, can we develop an
6 LEU target and convert the MAPLE reactors and NU processing
7 facility in a timely and expeditious manner.

8 Thank you very much.

9 CHAIRMAN MESERVE: Thank you.

10 Let me turn to my colleagues for questions.

11 Commissioner Diaz?

12 COMMISSIONER DIAZ: Thank you, Mr. Chairman.

13 I would like to concur with my fellow
14 commissioners that the issue in here is not our
15 relationships with Canada or even, at the long run, the
16 reliability of the supply of medical radio-isotopes, which
17 is very important, but we are dealing with complying with

18 the law, and that's really the bottom line of what we need
19 to do, you know, when we look at your request.

20 I have, first, a comment.

21 In slide seven, you made a comment that is not
22 written, but that -- and essentially, I'm quoting you --
23 that you expected to address the technical issues, and you
24 know, have a handicap of being a technical person, and I
25 think you really meant that you expected to resolve the

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1 technical issues to the point that you will get to a
2 solution, because you're not only addressing them, you're
3 going to have to come to a solution, and that solution -- we
4 need to have a time when you're going to have to resolve
5 them.

6 DR. TRAVENA: Yes. I think it's hard for us to
7 exactly know when one part will stop and another part will
8 start.

9 We believe, through the second phase, we need to
10 find solutions to the problems, and that will then allow us
11 to proceed with the final phase of the program, which is the
12 implementation phase.

13 COMMISSIONER DIAZ: I think you stated that you
14 already know what the issues are, or all of the large
15 issues. You know what the issues are. You might not know
16 all of the minor issues, but you know what the large issues
17 are. Is that correct?

18 DR. TRAVENA: We believe calcination is the issue.
19 What we don't know is the solution to the problem. So, that
20 still has to be determined.

21 COMMISSIONER DIAZ: All right.

22 Once the solution, you know -- I mean the
23 production begins in the NPF, those shielded vaults will be
24 closed so that you will not be able to make major
25 modifications to them. Is that correct?

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1 In other words, you will not be able to change
2 equipment even if somebody comes up with a new piece of
3 equipment that actually solves the issue.

4 Is that correct?

5 DR. TRAVENA: No, that's not precisely correct.

6 The way the facilities have been designed is to be
7 able to completely maintain the process equipment. So, with
8 the manipulators, there is an ability to dismantle and
9 reassemble the equipment.

10 We also have penetrations in the vaults to be able
11 to introduce new equipment or new components through a
12 preventative maintenance program.

13 So, while the size of the openings is limited,

14 there is nonetheless the ability to enter new equipment into
15 the cells.

16 COMMISSIONER DIAZ: Okay. But it has to fit what
17 the design is, so you have a design that only fits -- it's
18 like having an access hole and everything has to fit through
19 that.

20 DR. TRAVENA: That's correct.

21 COMMISSIONER DIAZ: On your slide number 10, you
22 stated that, because of the high cost to install waste
23 cells, construction of a facility to have redundancy is
24 preferred. Again, the word is preferred, but does it mean
25 that you consider that conversion to LEU target is not

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1 feasible, technically or economically, with the facility as
2 designed and that, you know, only if you construct a new
3 facility will you be able to use LEU targets?

4 DR. TRAVENA: Yes. I think the -- if the existing
5 facility cannot be modified, the thing that we explored
6 through this area of modifications was do we just add waste
7 processing to the cells?

8 We did not think that would give us process
9 redundancy.

10 So, really, we see two streams of opportunity.
11 The one we really will focus on is to improve the process in
12 the existing NPF.

13 Should that hit a dead-end, for whatever reason,
14 then the next option would be construction of a new
15 facility, in which case we wouldn't just put in a couple of
16 waste processing cells; we would look at it and ensure we
17 had redundancy.

18 COMMISSIONER DIAZ: Okay. But the use of the word
19 today is it is preferred, meaning that you have already
20 arrived at a -- not a final but a tentative preliminary
21 conclusion or a conclusion, maybe not final, that it will
22 not be possible to modify the existing facilities.

23 DR. TRAVENA: No. Maybe that's not very clear.

24 COMMISSIONER DIAZ: Okay.

25 DR. TRAVENA: The preference is to find a

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1 modification to the existing NPF.

2 COMMISSIONER DIAZ: Okay.

3 DR. TRAVENA: Coming out of the June hearing last
4 year, you recall there was some discussions around minor
5 modifications.

6 That would have led to having new waste processing
7 cells.

8 That is not a preferred option for us.

9 If we had to go down that stream to have new hot
10 cells, then we would rather have a facility that could give

11 us process redundancy.

12 So, the preferred step is to modify the existing
13 NPF.

14 The alternate step would be to look at
15 constructing a new NPF.

16 It wouldn't have all the apparatus that the
17 current one does, but it would have more apparatus than just
18 waste processing cells.

19 COMMISSIONER DIAZ: And have you -- in this last
20 option, have you considered how long will it take if you
21 have to go that way to actually implement such a solution?

22 DR. TRAVENA: We think it could take in the
23 three-to-five-year timeframe.

24 If you look, for example, at the facility that we
25 currently have, that project has been underway since 1996,

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1 and so, we're nearing the five-year mark.

2 Now, we think, to a certain extent, some of the
3 design will be complete, the process design will be
4 complete. So, we should be able to, we think, do better
5 than that, but we believe it's a three-to-five-year
6 timeframe.

7 COMMISSIONER DIAZ: I see.

8 Notwithstanding the fact that the volume of
9 uranium is much larger -- you say 4.7 times, I think was the
10 number you used -- you don't see any significant technical
11 issues with the target itself?

12 Have you been able to resolve this with ANL to a
13 reasonably, you know, achievable conclusion?

14 DR. TRAVENA: It's a point where we haven't really
15 explored in full detail with ANL.

16 AECL has come up with a target configuration which
17 is similar to the HEU target configuration, and we believe,
18 because of the licensing program that we've gone with the
19 MAPLE reactors, that that concept will work.

20 However, we do believe we will have to manufacture
21 some.

22 In our discussions with the CNSC, we will have to
23 perform critical heat flux tests and radiation tests, but I
24 mean basically it's concentric cylinders, and they will
25 change a little bit in diameter. So, the concept is very

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1 similar to what we're currently using, and we're confident
2 that that will work.

3 COMMISSIONER DIAZ: Okay.

4 Thank you, Mr. Chairman.

5 CHAIRMAN MESERVE: Commissioner McGaffigan.

6 COMMISSIONER MCGAFFIGAN: Let me try to get to the

7 heart of this fairly quickly.

8 The timetable for developing a path forward to LEU
9 targets -- in Mr. Travelli's trip report that we just got on
10 Friday, and he only wrote on Friday, probably, he says that
11 you stated your intention to prepare a plan, a plan for
12 resolution of the obstacles by September 2000. Is that
13 correct?

14 DR. TRAVENA: Yes. I think what we need to do is
15 develop a high-level approach to those critical issues that
16 need to be examined in the conversion development program.

17 COMMISSIONER MCGAFFIGAN: In the conversion, not
18 the NU processing facility but the conversion of the
19 existing facilities.

20 DR. TRAVENA: Well, I guess conversion -- we call
21 conversion when you go from HEU to LEU. So, it's a broad
22 context of conversion.

23 So, in that regard, there's some technical issues
24 around calcining, around reduction of liquid waste volume
25 that have to be sorted out.

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1 We believe that, in order to get at those
2 technical issues, we will require operational experience and
3 we will have to do some development work, an R&D; program.

4 Then building on from that, there are regulatory
5 issues that need to be worked through.

6 COMMISSIONER MCGAFFIGAN: There are lots of
7 disagreements between your testimony and that of the Nuclear
8 Control Institute. I'm going to try to get to some of them.

9 NCI, in its prepared remarks, hangs a fair amount
10 on Mr. Travelli's memo, in trying to lay out what they
11 suggest the license condition be that you all, within
12 three-and-a-half years, have this process complete, and they
13 point to the Petten reactor, where we're requiring a
14 timeline for conversion in that case of the fuel.

15 So, the question -- you know, Mr. Travelli
16 suggests in his memo, at the very end of it, that you'd have
17 a plan by September, technical implementation of a plan
18 might require about 18 months, safety approvals and
19 environmental impact statements might require three years or
20 more.

21 In their statement, NCI suggests that these be --
22 could be done in parallel, and indeed, they've had,
23 presumably on Friday, a conversation with Mr. Aly up at
24 CNSC, who suggested that the time period for the three years
25 might already be running.

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1 It isn't three years from the date of submission
2 of your requirements.

3 I don't have the NCI testimony directly in front

4 of me, but this could be done from -- well, by NCI's clock,
5 that clock could already be running.

6 So, is it reasonable to expect of you to have this
7 completed within three-and-a-half years?

8 DR. TRAVENA: I do not think so.

9 COMMISSIONER MCGAFFIGAN: What time period can you
10 give us? I mean a century or less than a century?

11 DR. TRAVENA: I think, back to Commissioner Diaz's
12 point, you know, if you think that there's three phases,
13 we've done the first phase, and we already saw what happened
14 to a three-month timeline.

15 We were really uncomfortable with that, and in
16 fact, it was proven not to be the case, and so, you know,
17 we're very sensitive to the fact that we haven't missed what
18 we think was a non-achievable timeline.

19 We believe that, in the next phase, that's where
20 we really need to find the technical solution, as
21 Commissioner Diaz has said, and then implement those
22 solutions in the third phase.

23 So, to your point, we believe that this is a
24 five-year timeline that we're looking at. It's in the order
25 of five years.

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1 By the time you resolve the technical issues, by
2 the time you figure out the way to implement them, by the
3 time you actually do the implementation and get the
4 licensing approvals, I believe this will be more like a
5 five-year timeframe.

6 COMMISSIONER MCGAFFIGAN: How much HEU do you
7 need? I'm going to go to their second point, the second
8 condition. They suggest that we reduce the license to 70
9 kilograms, because you've already missed a year-and-a-half,
10 so we're talking about three-and-a-half years remaining, and
11 you only need, according to a document that they cite, that
12 you submitted to CNSC, 20 kilograms a year. So, 20 times
13 three-and-a-half equals 70. So, they're suggesting that we
14 reduce it.

15 But what is your requirement? Is it 20 or is it
16 26 kilograms per year?

17 DR. TRAVENA: The annual rate for utilization in
18 the reactor is in the order of 20 kilos a year.

19 However, what that does not give us is any
20 inventory of targets should there be an interruption in the
21 supply stream.

22 So, if you go back to the original license where
23 we had asked for 40 kilos in 1999, the intention of that was
24 to have an inventory of targets so that we didn't have a
25 supply stream interruption through fabrication difficulties,

1 through HEU sourcing difficulties, through transportation
2 difficulties.

3 COMMISSIONER MCGAFFIGAN: It would strike me that
4 that would be a one-time thing.

5 Once you have -- you know, you want to have --
6 it's 20 plus X, X being what you need. Beyond that -- but
7 it isn't 20 plus X every year.

8 DR. TRAVENA: No, that's right.

9 So, the first year was intended to be 20 plus 20.
10 So, that would have been a one-year operating supply and a
11 one-year inventory.

12 COMMISSIONER MCGAFFIGAN: Right.

13 DR. TRAVENA: We did not get that material.

14 So, if you say what are we operating off, yes,
15 it's about a 20-year or 20-kilo-a-year run rate, but we do
16 not have any inventory of target material.

17 COMMISSIONER MCGAFFIGAN: I see.

18 DR. TRAVENA: So, reducing it to 70 kilograms
19 seems to be a rather unreasonable step to take and not have
20 any operating inventory.

21 COMMISSIONER MCGAFFIGAN: But 90 might not be,
22 based on the arithmetic we've just gone through. If
23 three-and-a-half years plus 20 --

24 DR. TRAVENA: Or 110 might not be unreasonable,
25 you know.

30

1 So, I guess you can try and find the right number.
2 Whether 130 is exactly the right number today --

3 COMMISSIONER MCGAFFIGAN: It's robust. 130 is a
4 robust number which will give you, by your calculation,
5 five-and-a-half years' supply, with the 20-kilogram margin.

6 DR. TRAVENA: I guess, you know, five years of
7 operating targets at 20 a year is 100, plus 20 kilos for
8 inventory is 120.

9 COMMISSIONER MCGAFFIGAN: Okay.

10 The next item -- I'm a little -- I'm trying to
11 understand how you're going to -- they suggest that we ask
12 you to come up with a conversion implementation plan. I'm
13 sure you'll say that's premature, but given the option, your
14 preferred option, how do you do the conversion, assuming all
15 goes well?

16 In your preferred option, are there any physical
17 changes?

18 There's a pipe that has to go into the calciner to
19 introduce this oxalic acid and hydrogen peroxide.

20 Again, I'm trying to learn from Mr. Travelli's
21 trip report.

22 What modifications would be required under your

23 preferred option, and could they -- are they consistent with
24 providing the supply that's required to your customers, or
25 does it require a long shutdown, in which case how do you --

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1 are we ever going to do it?

2 DR. TRAVENA: Let me try and come at it a couple
3 ways.

4 Are they consistent with providing a long-term
5 supply? Yes.

6 I do not think we would enter into a program that
7 would jeopardize supply. That is not our intent, not our
8 desire.

9 COMMISSIONER MCGAFFIGAN: How do you do it?

10 DR. TRAVENA: We don't know. We don't know. And
11 I think that's, frankly, why we need to operate these
12 facilities and determine some of the process improvements.

13 COMMISSIONER MCGAFFIGAN: But can you do it
14 physically -- if this discussion that came up about how to
15 deal with the addition of a uranium precipitating agent to
16 the can -- isn't that something that would require a
17 physical modification to the facility, and if you're doing a
18 physical modification to a facility that daily tries to turn
19 out a certain amount of moly-99, how do you do it? You can
20 do it with it operating?

21 MR. MALKOSKE: Can I answer that specific point?

22 When we discussed that specific point with SGN,
23 first of all, if the pipe into the calciner was the right
24 thing to do, our consultant has advised us it can be done
25 without shutting down the facility, because they can

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1 re-enter equipment in as part of the regular routine
2 maintenance program, but I think it's also important to know
3 that, as we discussed that point around the oxalate, it's
4 not necessarily the right answer.

5 It was an idea that was discussed. We don't know
6 if it's meritorious as this point or not, and that's where we
7 have to really get into the process development program, is
8 to exactly explore ideas like that and see what makes sense
9 to implement.

10 COMMISSIONER MCGAFFIGAN: One last question, if I
11 could.

12 The FDA process -- for your current -- for the NU
13 processing facility you hope to start up shortly, NCI points
14 out that you are presuming a nine-month approval process or
15 less from the FDA and Health Canada. Is that a good number
16 for us to assume? I mean you apparently are assuming it
17 because you have to have a sample to give to them before
18 they'll approve.

19 MR. MALKOSKE: I'll specifically answer that
20 question, since I addressed it at the previous hearing.

21 The FDA will determine the timeline that's
22 appropriate.

23 With the current facility that we have got now, we
24 are using HEU and a chemical process that's very similar to
25 what we had with NRU. There are some very minor

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1 differences.

2 When the FDA is looking at something which is only
3 a minor difference, and the regulatory bodies do that, then
4 it becomes a relatively straightforward issue. However,
5 it's only the regulatory body that decides how regulatorily
6 straightforward it is.

7 With LEU, which is a different starting material,
8 then you're into something that a regulatory body would say
9 that's a significant change and they'd have to look at much
10 more evaluation.

11 So, we believe the timeframe for that will be
12 longer.

13 However, when we're at that stage in the process,
14 you know, the NRC is going to be aware of that, and it will
15 be up to us and the NRC to discuss with the FDA about timely
16 -- looking at the documentation in a timely way.

17 COMMISSIONER MCGAFFIGAN: Could you introduce an
18 LEU target and get the data you need while you hadn't made
19 the total commitment to switch to LEU?

20 MR. MALKOSKE: I'm not sure how you'd do that.
21 I'm not sure where you'd process that.

22 COMMISSIONER MCGAFFIGAN: Okay.

23 MR. MALKOSKE: What you'd need to do is process it
24 in your plant.

25 COMMISSIONER MCGAFFIGAN: Thank you.

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1 CHAIRMAN MESERVE: Commissioner Merrifield.

2 COMMISSIONER MERRIFIELD: I'd just like to focus
3 on the issue of time.

4 The tie-up, as you've explained, is the calciner,
5 and how long before you've got an understanding that that
6 modification could or could not be made to accommodate the
7 LEU?

8 DR. TRAVENA: It will be the fall of this year,
9 probably into the November timeframe, before we start
10 routine operations, and we believe that only after we've
11 started the routine operations will we get enough process
12 history to really start to do development work and
13 understand what changes we can do.

14 I don't have exactly a number that I can pull out
15 of the hat for you, and I think it would be the wrong thing

16 to do, but that's why we said, by the time we start
17 operations, working with our contractors, with ACEL and with
18 SGN, in parallel, I think that's when we can see what
19 calcining changes can be made, and it's not just necessarily
20 an equipment change; it's also a process change.

21 When we were in France on the 30th of June with
22 Dr. Travelli, we spent a fair bit of time talking about a
23 process, and a continuous commercial operation -- I think
24 this is a difference we need to think about.

25 This isn't a research facility where you run it

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1 for a half-a-day and then you're down for a period of time.
2 You're running this operation day in and day out. Yes,
3 there's time for maintenance, there's time for equipment
4 change-out, but we need to be is smart enough to modify
5 these processes as we're operating. So, that's going to be
6 the target that we need to explore through this development
7 program.

8 COMMISSIONER MERRIFIELD: All right.

9 So, you bring the facility up in November, and it
10 would take a matter of months -- without putting a specific
11 number on it -- a matter of months to make that analysis, or
12 are we talking years?

13 DR. TRAVENA: No, I don't think it's years.

14 I think it's more months, and that's why we've
15 kind of said within this next phase, the concept development
16 phase of about 18 months, going to the end of 2001 -- that's
17 when we hope to be able to identify and come up with
18 solutions to these technical issues, and then the final
19 phase would be implementation, change out of equipment,
20 change out of processes, go through all the regulatory
21 submissions to get approval to operate.

22 COMMISSIONER MERRIFIELD: Okay.

23 So, in 2001, you will have your analysis, and you
24 can say, well, we're going to get on the calciner --
25 modification of the calciner in the existing process, or you

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1 make the determination that you really need to build a whole
2 NU processing facility. That is sort of your decision tree.

3 Setting aside regulatory approvals, how long, if
4 you did go down the route of building a NU processing
5 facility, from the point of making a determination that
6 that's the route you want to go, approximately how long
7 would it take you to build that type of a facility?

8 DR. LABRIE: It should take a comparable time, at
9 least, to the facility we are just completing. We have to
10 go through an environmental approval process. We have to
11 perform the safety analyses to operate a facility with LEU

12 targets. We need construction approval to build this
13 facility, and eventually we'll need an operating license
14 once we have completed our final safety analyses, and then
15 we have to build the facility, commission it, and put it
16 into routine operation.

17 So, the current facility -- the project started in
18 September of '96.

19 We have now completed all of what we call the
20 inactive tests at that facility.

21 We are now ready to start the active commissioning
22 of the facility.

23 So, it gives you an idea of the timeline, and
24 we've gone through the same process of environmental
25 approval and so on.

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1 COMMISSIONER MCGAFFIGAN: That's if you add a new
2 facility, but if you're just making modifications to the
3 existing facility that are modest, presumably the timeline
4 is shorter, isn't it?

5 DR. LABRIE: We will have to go through a similar
6 process to make modifications to the existing facility. We
7 will be bringing in LEU targets. Our environmental
8 assessment is for highly-enriched uranium.

9 COMMISSIONER MCGAFFIGAN: I understand there's
10 analysis, but in terms of the physically -- you're talking
11 about a facility you're started constructing in '96 and are
12 ready to operate now, and I guess, in Canada, you're allowed
13 to build a facility and get your operating license, what, at
14 the end?

15 You get a construction authorization -- I'm trying
16 to get the start of this process.

17 Was it '92 that you did your environmental impact
18 statement and your safety analyses?

19 DR. LABRIE: On the current project?

20 COMMISSIONER MCGAFFIGAN: On the current project.

21 DR. LABRIE: The environmental assessment was
22 submitted to, at the time, the ACB in October of 1996, and
23 the approval of the environmental assessment was granted in
24 April of '97.

25 We submitted our safety analyses for the --

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1 leading to the construction approval -- I believe it's in
2 June of '97, and we received the construction approval in
3 December of '97. We completed our final safety analyses --
4 I believe it was in August of '98, and we received an
5 operating license for the first MAPLE reactor and for the NU
6 processing facility in August of '99, and we just received
7 our operating license, which was an amendment to the
8 operating license of the MAPLE 1 reactor, in June of 2000,

9 and that gives you an idea of the time it takes.

10 COMMISSIONER MERRIFIELD: Two final questions.

11 If I get this right, the estimate is, if you had
12 to go down the route of building a NU processing facility,
13 rather than modifying the calciner, that would be around \$30
14 million?

15 DR. TRAVENA: The \$30 million was talked about in
16 terms of just the waste processing facility.

17 COMMISSIONER MERRIFIELD: Okay.

18 DR. TRAVENA: But you know, we're not 100-percent
19 sure.

20 COMMISSIONER MERRIFIELD: Let me ask it this way.
21 Is that a -- the cost, whatever that is --

22 DR. TRAVENA: Yes.

23 COMMISSIONER MERRIFIELD: Is that a showstopper
24 for you?

25 DR. TRAVENA: At this point in time, we don't

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1 know, and I think what we really need to do is take a look
2 at all of the options and assess this in terms of the
3 business that we are operating.

4 So, we're not taking this lightly. As I've said,
5 we are committed to the conversion process. We are
6 concerned about costs, and our absolute drive is to try and
7 find a way, if possible, to convert the existing NPF,
8 because it will be the low-cost option.

9 So, that's really where we're putting our effort
10 with ACL, and so, while I don't want to miss your point and
11 feel that you haven't been -- your point addressed, I'm
12 concerned about that, but if you go back to your point about
13 the physical implementation of a change, I would hope that
14 the physical implementation of a change, if we're modifying
15 the existing NPF, is of shorter timeline than building a new
16 NPF, but then, on top of that, you must layer the regulatory
17 process, and so, that's -- we've got to work that through
18 with the Canadian Nuclear Safety Commission and see where
19 that will take us.

20 COMMISSIONER MERRIFIELD: One last -- my last
21 question is this:

22 In their testimony today, NCI offers a series of
23 recommendations to the Commission about things that we could
24 or couldn't require of you all.

25 One of those is that we require the applicant to

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1 present to the Commission -- and they say within three
2 months -- a timetable for expeditious conversion to LEU
3 targets.

4 Setting aside whether you can do -- provide a

5 timetable in three months or whether it would fall later on
6 in the year, is it possible to come up with a timetable of
7 the point at which you could convert to LEU targets?

8 DR. TRAVENA: We do not think so, and I believe
9 that because we must go into this development program first.

10 You know, if you go back to June of '99, somebody
11 thought we could complete a technical feasibility study in
12 three months, and so, I think it's dangerous to say today
13 that conversion will be completed by this date, because we
14 haven't yet identified or really assessed all the technical
15 issues. We haven't come up with a solution to those
16 technical issues, and so, I don't see how, until that is
17 done, a person can say here's the timeline that it's going
18 to take. I just don't think it's practical.

19 I think what we need to do is to be committed to a
20 process, and the process needs to be one of identifying
21 those issues that need to be resolved, the key technical and
22 regulatory and environmental issues that need to be
23 resolved, and to make sure that we are keeping you folks
24 apprised of the progress that we're making.

25 So, we already have within the license the

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1 requirement for an annual report. We have been meeting with
2 state department and NRC staff and DOE staff even more
3 frequently than that to inform them of the progress that we
4 have been making.

5 So, I feel we've got a concerted effort to inform
6 people of the progress that we're making on this issue.

7 COMMISSIONER MERRIFIELD: Thank you, Mr. Chairman.

8 CHAIRMAN MESERVE: The last question -- the
9 question was when do you think you'll be able to provide a
10 timeline, and you said you could not do it in a few months,
11 but wouldn't your report that you envision preparing by the
12 end of 2001, which would be this intermediate phase -- isn't
13 one of the outputs from that -- wouldn't that include a
14 timeline?

15 DR. TRAVENA: I think that should include a
16 timeline, because then we're far enough down the process to
17 have assessed the technical issues and an implementation
18 plan, yes.

19 So, that final phase, which is the implementation
20 program, should have with it a timeline. We should have
21 identified the technical issues, the solutions to the
22 technical issues, we should have identified the regulatory
23 timeframes, as well.

24 COMMISSIONER DIAZ: Mr. Chairman, I'm sorry, but
25 the question is will it include a timeline, not should. We

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1 know that it should. I mean that's a given, it should, but

2 will it include a timeline?

3 I mean at some time you have to have it, and it
4 will have it, not it should.

5 DR. TRAVENA: I believe coming out of phase two
6 that we can provide you a timeline, and I don't see why we
7 should not.

8 So, will we? Yes, we will.

9 Again, the part of our frustration, frankly, is we
10 had a regulatory timeframe for the current operations. It
11 didn't work out.

12 Now, that didn't mean we didn't have a timeframe.
13 We did have a timeframe.

14 We monitored progress, we monitored slippage, and
15 so, we could provide a timeframe, as well, and hopefully we
16 can achieve it, but the process is not, Mr. Chairman,
17 completely under our control.

18 CHAIRMAN MESERVE: We jumped quickly over the
19 issue of the targets, because you believe that that's a
20 technically solvable problem.

21 The NCI submission, as Commissioner McGaffigan
22 indicated, they've interpreted something that the CNSC has
23 told them, that the three-year timeline has run.

24 Your slide suggests that there is no alternate
25 target that, in fact, has been fabricated yet, and

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1 obviously, you haven't done any testing of targets.

2 So we have a common understanding of when this
3 three-year clock runs, for when the regulator thinks they
4 need to evaluate, when do you think that you would be in a
5 position to submit the necessary -- you or AECL -- to submit
6 the necessary documentation to the CNSC to get that part of
7 the project underway?

8 DR. TRAVENA: Again, I think it will be towards
9 the end of year 2001.

10 The reason for that is what we need to do -- it's
11 an integrated system.

12 We've got MAPLE reactors, we've got a NU
13 processing facility, one relies on the other, the target
14 affects the process, and so, what we really need to do is to
15 make sure we understand all the issues around process and
16 target, so we can take an integrated approach to the CNSC,
17 and of course, permanent waste disposal is an issue, as
18 well.

19 So, that's the timeline that we believe we would
20 approach the CNSC with licensing, and that's when I think
21 the three-year timeframe would start to march.

22 CHAIRMAN MESERVE: Okay.

23 Thank you very much.

24 COMMISSIONER MCGAFFIGAN: Can I ask one more
25 question?

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1 NCI, in its testimony, says that -- you've been
2 with the project -- that you committed in 1990 -- in
3 December 1990, nearly 10 years ago, AECL declared -- maybe
4 this should be directed to AECL -- declared in support of a
5 license application for export of HEU that it was committed
6 to develop an LEU target by '98 and phase out HEU by 2000.

7 Is that true?

8 DR. LABRIE: There was a project which preceded
9 this one in which we had looked at the -- using the current
10 technology to try to undertake -- it was going to go -- this
11 is a project that was discontinued because it was not
12 economically viable, and it triggered, really --

13 COMMISSIONER MCGAFFIGAN: -- this lawsuit in
14 Canada. Okay.

15 Would you agree with the next sentence, that
16 despite this early commitment, the applicant intentionally
17 designed the NPF to handle a process flow and level of waste
18 adequate for HEU targets but which it knew would be
19 inadequate for LEU targets?

20 DR. LABRIE: The facility we have is a facility we
21 have been contracted by MDS Nordion to undertake, and it's
22 been built and meets all Canadian standards, safety
23 standards and so on.

24 MR. GLASGOW: May I ask a point of clarification,
25 Mr. Chairman?

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1 CHAIRMAN MESERVE: Please.

2 MR. GLASGOW: I have heard at various times of, of
3 course, an intent or interest on the Commission's part about
4 trying to nail down some timelines and the like, and I think
5 that's understandable.

6 But in trying to shape the contours of the Schumer
7 amendment and ascertain what this amendment means in this
8 kind of a situation, the Commission spoke in its June 16
9 order about appropriate deference and consideration of the
10 Canadian regulator and to also appropriate attention to the
11 Executive Branch.

12 And while I'm sure these things are well in the
13 Commission's mind, I just would like to come back to them
14 briefly and just point them out, for their role and for the
15 effect they have on the scope, the depth, the intensity of
16 the Commission's examination of specific technical points
17 and the deference that is appropriate to the views of the
18 Executive Branch as well as the Canadian regulatory body.

19 And the point of clarification, though, is that --
20 may I understand that we are not today, during this public

21 meeting, having the process that is contemplated by section
22 110.52 in the regulations, which speaks to consideration of
23 modification, suspension of licenses, and we would trust
24 that, in view of the abundant determination here and
25 statements made of the good faith and progress of the

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1 applicant, that that is not on the Commission's mind,
2 particularly since the Executive Branch does not recommend
3 that, but for point of clarification, we understand that,
4 before there can be any modification, suspension of license,
5 it would be necessary to have procedures specified in
6 110.52, coupled with the hearing and other procedures
7 specified in subpart (i).

8 CHAIRMAN MESERVE: I'd like to thank you all for
9 your participation here this afternoon. We have some other
10 speakers this afternoon who will be addressing the same
11 matter, and our next panel is some representatives from the
12 Nuclear Control Institute. Thank you very much for
13 participating.

14 Could the next panel approach the table?

15 They consist of Paul Leventhal, who is the
16 president of the Nuclear Control Institute, and Alan
17 Kuperman, who is a senior policy analyst with NCI.

18 Please proceed.

19 MR. LEVENTHAL: Mr. Chairman, thank you very much.

20 NCI's testimony today will be presented by myself
21 -- I'm Paul Leventhal, President, and I'd like to begin with
22 some general points, and then Alan Kuperman, our senior
23 policy analyst, who has been handling this subject in some
24 considerable detail over a period of years, will provide the
25 detailed technical presentation.

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1 I'd like to thank you, Mr. Chairman, and the other
2 members of the Commission for the considerable attention
3 that you're devoting to the subject at this time and over
4 the past year, and we surely appreciate the courtesies
5 you've extended to Nuclear Control Institute in considering
6 our petition to intervene.

7 The larger point I'd like to make is that we
8 should not lose sight of the fact that this is an important
9 element of the international RARTR program, the reduced
10 enrichment for research and test reactors program, the
11 objective of which, I'm sure you know, is to eliminate
12 commerce in highly-enriched uranium.

13 And unlike the plutonium issue, which is a very
14 difficult one -- of course, it takes on almost religious and
15 ideological proportions, with a very considerable industrial
16 interest into keeping things pretty much the way they were

17 originally conceived despite the fact that realities on the
18 ground have changed with regard to fuel consumption -- in
19 the case of HEU, it isn't nearly as complicated, but it is,
20 as you just heard from the industry witness, difficult.

21 Right now, there's about 50 kilograms of
22 highly-enriched uranium a year in commerce for the purpose
23 of producing medical isotopes, and given the increasing
24 demand for these life-saving isotopes and the apparent
25 interest in new producers coming into the field, this number

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1 could double or triple over the next decade.

2 So, we are talking about a not inconsiderable
3 amount of highly-enriched uranium, which potentially could
4 be eliminated from commerce if this case is given the
5 attention that it very much deserves.

6 Considerable progress, as you know, has been made
7 on the fuel side of the ledger in the reduced enrichment
8 program. Where, at the peak, there was as much as three
9 metric tons a year being injected into commerce, most of it
10 by the United States, worldwide we're now down to a few
11 hundred kilograms a year, and the U.S. supply is zero, and
12 we would like to very much achieve the same objective with
13 regard to HEU for the purpose of medical isotope production.

14 Now, clearly, the devil is in the details, and the
15 Commission has to determine what is credible and what is
16 incredible in terms of testimony that you just heard, but
17 you should rest assured that other isotope producers are
18 watching this case very closely, and in particular, the
19 European community, where Mallinkrodt is the principle
20 producer, the Belgians also are taking an interest in this
21 case, as are the Koreans.

22 There are a number of smaller producers, including
23 South Africa, Indonesia, Argentina.

24 There's an opportunity here, in other words, to
25 establish a regime that all producers can ultimately come

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1 into step with, but since the largest producer is MDS
2 Nordion, this case takes on particular importance.

3 Now, the last line of questioning was an
4 interesting one, about what the applicant committed to in
5 1990 and why it didn't fulfill that commitment to develop
6 the LEU target and to have it in place, ready to go by the
7 year 2000, and that could be the subject of a separate
8 hearing.

9 But surely certain technical safety assumptions
10 were made which Argonne National Laboratory apparently felt
11 to be not grounded in fact, but nonetheless, the licensee
12 proceeded with a design that was not compatible with LEU,
13 and you are now faced with a situation as to how to proceed

14 from this point forward so that five years from now you
15 don't find yourself exactly at the point where you were five
16 years ago with a request by the applicant to please continue
17 producing HEU, because by golly, it turned out to be
18 infeasible and too costly to convert.

19 There is adequate indication right now that the
20 technical solution is within reach.

21 The question is, is the Commission prepared to
22 provide, along the lines that we recommend and Alan Kuperman
23 will momentarily go through, to establish conditionality, to
24 establish a timeline so that it is clear to the applicant
25 that the wiggle room that he still desires will no longer be

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1 tolerated by the Commission, the indulgence of the Executive
2 Branch will not be supported by the Commission, which is in
3 a position to take an independent regulatory position based
4 on both law and policy.

5 So, I just wanted to draw the larger context. The
6 RARTR program hangs in the balance. It is not an
7 insignificant program.

8 It is an opportunity to eliminate commerce in one
9 of the two materials used to make nuclear weapons, and
10 therefore, we consider it extremely important that you take
11 every opportunity to impose the restrictions necessary to
12 make sure that the job gets done.

13 With that, I'd like to turn to Mr. Kuperman now,
14 who will present the balance of our testimony.

15 MR. KUPERMAN: Thank you.

16 Thank you, Mr. Chairman and members of the
17 Commission.

18 I want to associate myself with Mr. Leventhal's
19 remarks about how grateful we are that you're giving this
20 case such close oversight, as was envisioned by the Schumer
21 amendment.

22 In my presentation today, I would like to make
23 four points summarizing our testimony, and from the
24 questions you asked during the first panel, it seems like
25 many of you, if not all of you, have read it extremely

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1 closely.

2 So, what I'll try and do is maybe just emphasize a
3 few of the points we find most important and maybe associate
4 them with some of the comments that the witnesses made
5 during the first panel.

6 These four points -- I'll make one just quickly to
7 summarize the key points of last year's order by the
8 Commission; second, summarize the positive aspects of the
9 applicant's response; third, look at some of the more

10 troubling aspects of the applicant's non-response to last
11 year's order; and then, finally, go over the four
12 recommendations that we've made to the Commission.

13 I would like to quote just one quote from the --
14 last year's order by the Commission, if you'll indulge me,
15 because I think it's central to the Commission's
16 consideration today.

17 Quote, "It is the Commission's understanding that
18 Argonne National Laboratory will be able to complete a
19 conversion feasibility study promptly, within approximately
20 three months of receiving the necessary technical
21 information. The Commission further understands that Atomic
22 Energy Canada Limited will cooperate fully with Argonne
23 National Laboratory to complete a feasibility study as soon
24 as possible. In light of these commitments, the Commission
25 is encouraged that AECL may have a feasibility study in hand

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1 in time to consider whether minor modifications could be
2 made prior to the MAPLE reactors and their processing
3 facility coming on line that would permit the use of LEU
4 targets or take other reasonable measures that would at
5 least preserve the opportunity to move to LEU targets in the
6 future," unquote.

7 The point of this provision, as the Commission
8 expressed it, was based on the reasonable assumption that,
9 if you made modifications prior to startup, it would be,
10 one, less expensive and, two, it would avoid the problem of
11 interrupting production of isotopes, as compared with trying
12 to make those modifications after the startup of the
13 facility, so that if you made the modifications prior to
14 startup, it would be more likely that, in the end, the
15 facility actually would be converted to LEU.

16 Point two, the positive aspects of the applicant's
17 response:

18 I think that the applicant should be commended for
19 some of the progress that it has made over the past year,
20 and in fact, it's quite remarkable that, although prior to
21 this year, all sorts of possible obstacles were raised to
22 conversion to LEU, it now turns out, after a year, that
23 almost all -- in fact, all but one of those potential
24 obstacles has disappeared.

25 And the only remaining obstacle, as the witnesses

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1 said during the first panel, has to do with the calciner,
2 and even that no longer has to do with the volume of the
3 flow in the facility, it only has to do with the mass of
4 uranium that's associated with these targets.

5 And there's no way to reduce the mass of uranium
6 in the targets, now it's just a question of can you modify

7 the calciner in a way so that the throughput capacity and
8 amount per waste can is sufficient that it can process the
9 LEU targets.

10 All of the other problems have gone away. That's
11 the good news.

12 Point three, the bad news, the troubling aspects
13 of the applicant's response over the last year:

14 First, the applicant did not share information
15 with Argonne, as the Commission expressed was its
16 expectation in last year's order, and the reason it was the
17 Commission's expectation, I believe, is that the applicant
18 said it would share information with Argonne.

19 It got Argonne to sign a confidentiality
20 agreement, it got Argonne to sign intellectual property
21 agreements, all premised on the notion that the applicant
22 would then share information with Argonne so Argonne could
23 prepare the feasibility study, but the applicant then
24 refused to do so.

25 The applicant did, on its own produce a

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1 feasibility study, but it submitted that to the Commission
2 seven months later than the Commission said it expected the
3 feasibility study and only two months prior to the planned
4 startup of the new production facility.

5 By delaying the presentation of this feasibility
6 study to the Commission, the applicant effectively made it
7 impossible to make modifications to the new production
8 facility prior to startup.

9 Had the feasibility study been prepared on time,
10 within three months, by September 1999, the applicant then
11 would have had nine full months to analyze this calciner
12 issue and try and resolve it prior to startup, possibly even
13 making modifications prior to startup, which would avoid
14 this whole question of a possible shutdown during conversion
15 or certainly reduce that problem.

16 Indeed, the first meeting to discuss this calciner
17 issue that involved Argonne was 10 days ago.

18 That's more than one year after last year's order
19 by the Commission.

20 It was 10 days prior to this meeting, and I would
21 suggest it's not a coincidence that they tried to get it in
22 under the wire, but that's the sort of meeting that should
23 have taken place nine months ago.

24 My point is that not only did the applicant
25 blatantly fail to live up to its commitments to provide the

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1 necessary information to Argonne, but by delaying the
2 feasibility study, it undermined the Commission's primary

3 intent of enabling modifications to the new production
4 facility prior to startup, and as was discussed during the
5 last panel, this is -- there is a pattern of this sort of
6 behavior by the applicant over the last full 10 years of
7 saying that it's going to do something and then actually not
8 doing so.

9 Were this the first time, I think our
10 recommendations might not be as forceful as they are, but
11 the fact that this is over 10 years, commitments that have
12 been made and then reneged upon, makes us skeptical of the
13 commitments that the applicant is making and compels us to
14 urge the Commission to impose further conditions on the
15 license to ensure that the applicant does actually live up
16 to its commitments this time for the first time.

17 Finally, fourth, the recommendations that NCI is
18 making today to the NRC, as it considers, according to its
19 order of last year, whether to, quote/unquote, "modify,
20 suspend, or revoke the license," unquote:

21 Our first recommendation and our primary
22 recommendation is that the Commission add conditions to the
23 license to impose a strict timetable on conversion, and I
24 think, going over the history as I just did, you understand
25 why we're so concerned about this.

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1 There is a need -- the applicant has shown that,
2 if it is not held to a strict timetable, it has a habit of
3 not fulfilling its commitments or not fulfilling its
4 commitments on time, and there is also a strong precedent,
5 as Commissioner McGaffigan mentioned, in the Petten case,
6 where the U.S. Government required both that a conversion be
7 done as quickly as possible but, two, secondly, that there
8 was a drop-dead date.

9 In other words, you're not getting anymore HEU
10 after this date, whether or not you've converted, and that's
11 the sort of a strict timetable that we think would be
12 prudent in this case.

13 Now, it's the question of the details of the
14 timetable.

15 I think there was some confusion in the last panel
16 about this three years that might be required for obtaining
17 regulatory approvals in Canada.

18 First of all, the discussion we had with the chief
19 scientist at the Canadian Nuclear Safety Commission on this
20 issue -- it wasn't on Friday. It was a couple of months
21 ago, and what he told me was that, when the CNSC talks about
22 three years for regulatory approval, they're talking about
23 from the time that the applicant starts working on this
24 problem, in other words from the time the applicant starts
25 designing an LEU target.

1 So, it's not three years from the time there's a
2 final target design that is then submitted to the CNSC; it's
3 from the beginning of the process, which Dr. Aly said had
4 already started.

5 In other words, the clock already started ticking,
6 and if you look at the applicant's testimony today, you'll
7 see that they consider the preliminary design work on the
8 LEU target to be one of their major accomplishments of the
9 last year.

10 So, whenever that accomplishment started is when
11 the three-year timetable -- which is an estimate, but it's
12 when that timetable started for regulatory approval.

13 CHAIRMAN MESERVE: Excuse me. I don't mean to
14 interrupt, but let me just ask a question.

15 Did Dr. Aly tell you that the clock had started on
16 the three years?

17 MR. KUPERMAN: Yes. In fact -- because I was
18 asking, well, why is it going to take three years, and he
19 said no, no, no, no, it's three years from the -- the entire
20 process from the beginning of designing.

21 CHAIRMAN MESERVE: Did he tell you that he thought
22 that the beginning had already been accomplished, that the
23 clock was running at the time you talked to him?

24 MR. KUPERMAN: Yes.

25 CHAIRMAN MESERVE: Okay.

1 MR. KUPERMAN: I don't know if he used the word
2 "the clock is running," because I don't know if I used the
3 word "the clock is running," but yes, that the three years
4 already had started.

5 The second -- continuing on this first
6 recommendation, there's the question of what really needs to
7 be done for conversion, and there are these three steps that
8 have been discussed in terms of coming up with a plan first,
9 doing the technical work second; three, getting regulatory
10 approval, and I was encouraged by the testimony of Dr.
11 Malkoske in the first panel where he said, I believe,
12 quote/unquote, that these could be conducted in parallel or
13 at least partly in parallel, and maybe you can check the
14 transcript afterwards.

15 That's exactly what we say in our testimony.

16 If that's the case, that means that the
17 time-limiting, the limiting factor here is the regulatory
18 approval, which is somewhere in the range of three years,
19 and as I say, that clock already started. So, we're talking
20 about less than three years for the Canadian side of
21 regulatory approval.

22 On top of that, you have to add the FDA approval
23 in the U.S. and the parallel approval by Health Canada, but
24 we're talking somewhere in the range of three-and-a-half
25 years maximum, and again just to sort of put this in

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1 context, the applicant said today that to build an entirely
2 new production facility would require three to five years to
3 design, build it, and get regulatory approval and then, in
4 the next breath, said that, to make a minor modification to
5 the calciner and get regulatory approval would also take in
6 the range of three to five years, which is something I think
7 the Commission may want to probe further into.

8 Our second of the four recommendations has to do
9 with the question of how much HEU the applicant actually
10 requires over the five-year course of the license.

11 I think during its testimony today, the applicant
12 conceded that it doesn't need the 130 kilograms that was
13 approved by the Commission last year, but maybe we need to
14 start thinking about exactly how much it does need over the
15 course of the license.

16 The license runs five years starting from last
17 year, and the facility still has not started up.

18 So, as Commissioner McGaffigan indicated, the
19 facility will only run for three-and-a-half years under this
20 license.

21 So, the facility can only require around 70
22 kilograms of HEU over the three-and-a-half years of this
23 license.

24 Now, it might require -- if it hadn't converted in
25 three-and-a-half years, it might require more HEU after

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1 that, but presumably that would be a new license, because
2 the existing license time would have expired.

3 So, that's why we urge that the Commission
4 immediately reduce the amount of HEU approved under the
5 existing license to no more than 100 kilograms, and perhaps
6 it should go down lower, to 70, which is what, apparently,
7 they would need, or maybe 70-plus, this little buffer of 10
8 or something, but considering that the Commission is trying
9 to hold the applicant to sort of a short tether, I don't
10 think the Commission would be well advised to give the
11 applicant a large buffer. That would sort of be at cross
12 purposes.

13 Our third of the four recommendations is -- has to
14 do with somehow providing an extra incentive for the
15 applicant to start acting in a more expeditious manner than
16 it has been doing.

17 The applicant, during the last panel, said
18 repeatedly that the feasibility study took us a year and not

19 three months, but it's not clear that it needed to take a
20 year rather than three months.

21 After all, it was based on the applicant's
22 testimony last year that the Commission thought it would
23 take three months.

24 Well, now, the applicant is saying that,
25 coincidentally, it's going to take three months again for

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1 the next feasibility study, by September 2000, but perhaps
2 one way to provide the applicant with extra incentive, to
3 actually meet this deadline, would be to say -- for the
4 Commission to say, well, we're suspending the license until
5 we get that new feasibility study.

6 Then my guess is you would get the feasibility
7 study in three months.

8 If you don't have that sort of condition, my guess
9 is you won't get the feasibility study in three months,
10 anymore than you got the earlier feasibility study in three
11 months.

12 Just to be clear, this sort of a conditional
13 suspension of the license for what should be only three
14 months would not interfere with the production of medical
15 isotopes and the safe and secure supply of those isotopes,
16 which NCI wholeheartedly supports.

17 The NRU reactor and processing plant, and
18 especially the processing plant, according to the applicant,
19 can operate at least through April of 2001.

20 Now, this is directly contradictory to the
21 testimony of the applicant just a year ago, where it swore
22 up and down that the NRU waste tank was going to run out by
23 the end of 2000.

24 Now all of a sudden we have some extra months.

25 One of the good consequences of that is the

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1 Commission now can suspend the license until the feasibility
2 study is produced to the Commission's satisfaction, and as I
3 say, there would be no interruption in the production of
4 medical isotopes.

5 Finally, fourth -- and I think this is -- aside
6 from our first recommendation, this is perhaps -- well,
7 maybe they're all equally important, but this one is, in
8 some ways, the most troubling concern, and I think
9 Commissioner McGaffigan really, really focused in like a
10 laser beam on what the problem is here, and that is how do
11 you get there from here?

12 How do you convert the existing NU processing
13 facility from HEU to LEU without interrupting the supply of
14 medical isotopes, which no one wants to do, and as we said

15 earlier, there's two reasons why the supply of medical
16 isotopes could be interrupted by such a conversion or
17 there's two potential obstacles.

18 One is that it could be quite expensive, and so,
19 the applicant might say it's not justified.

20 In fact, it cites -- in its view-graphs today, it
21 says that we have to determine whether it's, quote/unquote,
22 "economically feasible" or not before we decide whether
23 we're going to go ahead with it, but the second problem is
24 would trying to convert require a lengthy shutdown of the NU
25 processing facility and, thereby, interrupt the production

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1 and supply of medical isotopes?

2 Last year, the applicant testified that, in fact,
3 it would require a shutdown.

4 It said that, for safeguards reasons, we would
5 have to shut it down and clean out the pipes, clean out the
6 HEU before we could introduce LEU, or else we wouldn't know
7 if there was some MUF, some material unaccounted for.

8 Well, how do you do that without interrupting the
9 supply?

10 Now, Commissioner McGaffigan today focused on a
11 second problem, which is, well, where do you process these
12 LEU targets in order to get FDA approval?

13 How do you do that? Because the FDA presumably is
14 going to require that the LEU targets be processed in the
15 same facility that they would be processed in on a
16 commercial basis.

17 In other words, you have to run LEU targets
18 through the NPF before you can even go to the FDA, but once
19 you've introduced LEU targets to the NPF, it means you've
20 stopped using HEU targets in the NPF.

21 But you haven't yet gotten FDA approval for the
22 LEU targets.

23 So, now you're in this window, which the applicant
24 is saying is going to be nine months or more, where you stop
25 producing isotopes with HEU, but your LEU target isotopes

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1 aren't licensed by the FDA.

2 Well, now you're interrupting the supply of vital
3 medical isotopes.

4 Certainly no reasonable person would want to do
5 that, right?

6 So, then the applicant is going to come back and
7 say, therefore, we can't convert, or the only way we can
8 convert is to build a second NU processing facility, which
9 is well more than \$30 million, because just the waste cells
10 is \$30 million.

11 So maybe we're talking \$50 million.

12 Is the applicant then going to say that that is
13 not justified on economic grounds, that there is a economic
14 loophole in the Schumer amendment and therefore we're not
15 required to convert?

16 It's extremely troubling, and that's why, from the
17 beginning of this process, we have wanted and urged that the
18 feasibility study be done quickly and that modifications be
19 done prior to startup of the new production facility,
20 because the applicant, we warned, was going to present the
21 Commission with a fate accompli, and it looks like that's
22 exactly what the applicant is doing.

23 So, what we would recommend is that, if it turns
24 out that the only obstacle to conversion is the expense,
25 because the applicant has to build a second NU processing

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1 facility -- and the reason that it has to build a second NU
2 processing facility is because of its own dilatory behavior,
3 because it refused to act expeditiously enough to modify the
4 original NU processing facility -- well, then that is no
5 excuse under the Schumer amendment for not converting to
6 LEU, and if that is, in fact, the case, then the applicant
7 is going to have to either accept the cost of the NU
8 processing facility or cease getting any HEU in the interim
9 from the United States.

10 Now, maybe I'm wrong. Maybe there's a magical way
11 to convert from HEU to LEU without shutting down isotope
12 production for an extended period, but if there is, then
13 it's the applicant's responsibility to present that
14 blueprint to the Commission.

15 So, that's why our fourth recommendation is that
16 we urge the Commission to require the applicant to present a
17 blueprint as quickly as possible for how the heck you get
18 from here to there; how do you get from HEU targets to LEU
19 targets without interrupting the supply of vital medical
20 isotopes?

21 Thank you very much.

22 CHAIRMAN MESERVE: Commissioner McGaffigan.

23 COMMISSIONER MCGAFFIGAN: You give me too much
24 credit about focusing like a laser beam. I'm stumbling
25 through trying to understand how this works, and I almost

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1 don't want to ask you questions, because my questions really
2 are more for them.

3 But you sort of get into a Catch-22 position with
4 this FDA approval unless the LEU targets can be processed,
5 FDA would allow them to be processed, introduced in the
6 reactor, processed somewhere else, and use that.

7 But on the economics of -- if they do end up with

8 a new NU processing facility, a second processing facility
9 -- and Commissioner Merrifield tried to ask them about the
10 30 million, the 50 million, whatever the number is -- they
11 are going to get an auxiliary benefit out of that in terms
12 of assurance of supply, and since you were involved in the
13 Schumer amendment, aside from your final point about perhaps
14 disregarding all of the costs, which under the law might be
15 pretty difficult, but how do we allocate the extra assurance
16 of supply benefit that they will get, you know, against
17 whatever the cost will be?

18 I actually don't have any idea of the economics of
19 these facilities, what the amount of -- how \$50 million
20 corresponds to the monthly revenues that they generate or
21 whatever, the annual revenues they generate, but I'm trying
22 to put all this in some perspective.

23 If assurance of supply, having a second processing
24 facility, has a real benefit associated with it, aside from
25 the benefit from non-proliferation perspective, do you have

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1 any analytical way we should approach that?

2 MR. KUPERMAN: That's a good question.

3 I don't have, offhand, a calculus that should be
4 used, but I do think that there is a more fundamental answer
5 to your question, and that is whose responsibility is it
6 under the Schumer amendment if a operator or isotope
7 producer willingly builds a facility that cannot use either
8 LEU fuel or LEU targets, and there's a precedent for this,
9 and that's the FRM-2 research reactor in Germany, which was
10 constructed after the Schumer amendment was enacted into law
11 in 1992, and the Technical University of Munich, in that
12 case, willingly, knowingly designed a reactor that could not
13 use LEU, that was designed to use HEU, and that was a core
14 design that actually, in that size core, could not be
15 converted to LEU -- in fact, no matter how high a density of
16 LEU you were able to design.

17 The U.S. Government -- the Germans then said, aha,
18 under the Schumer amendment, if we can't convert to LEU, you
19 must supply us HEU, and the U.S. Government said no, sir,
20 you knew what the rules were, and they put out a statement
21 in 1994, the state department did, saying that the U.S.
22 would not supply HEU to this German reactor, and so, I think
23 that may be the most important precedent for this Nordion
24 case, where the applicant knowingly and willingly designed a
25 facility that had a waste system -- in fact, they designed

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1 the whole NPF to be able to use HEU and not to be able to
2 use LEU.

3 If, as a result of that, they have to build an
4 entirely new production facility, I think that's their

5 problem under the Schumer amendment.

6 So, that would be my first answer.

7 MR. LEVENTHAL: If I could just add to that, I
8 think what's really needed here is a clear statement from
9 the Commission that this whole process, beginning in 1990,
10 where the last major license was approved on the basis of a
11 commitment made by the licensee that conversion would take
12 place by the time the next major license was to come into
13 play a decade later, the fact that every opportunity that
14 has presented itself up to this point has not been
15 satisfied, then any additional costs that the applicant must
16 go through to be able to approve the LEU target in order to
17 have it licensed is not -- will not be taken into
18 consideration by the Commission as an extraordinary cost
19 that prejudices the conversion itself.

20 In other words, that's the cost of doing business.
21 They made a decision every step of the way that they were
22 going to begin with an HEU processing facility when the
23 Commission clearly expected that the next facility would be
24 an LEU facility, and whatever additional step they have to
25 take has to be done at their own expense and does not

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1 disqualify conversion under the Schumer amendment.

2 I think that's what the Commission has to state in
3 either modifying the license or further elaborating on the
4 current license.

5 MR. KUPERMAN: Presumably on your mind and on
6 others' minds may be, well, we can't require them to do
7 something that would be so expensive that they couldn't sell
8 their product, and I think, on that point, it's very
9 important to look back a few years.

10 When they decided they were going to build these
11 two reactors and the NU processing facility, which they said
12 cost \$130 million -- I believe that's Canadian -- there was
13 concerns that that also would be a prohibitive cost.

14 And what they did is they came to the U.S., which
15 is the major market for their product, and they got together
16 with the pharmaceutical companies that buy their moly-99,
17 and they said, look, we want to assure the supply of
18 radio-isotopes, but it's going to increase the cost, and
19 unless you guys are willing to pay that extra cost, we can't
20 do it.

21 And as I understand it, in a meeting which I think
22 was 1995, the American pharmaceutical companies said, okay,
23 we're willing to accept an increase in the cost of moly-99
24 in order to build these two new reactors and NPF and assure
25 the supply.

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1 So, perhaps if they have to build a second NPF,
2 then they're going to have to do the same sort of thing,
3 come to the U.S. and say, now, on non-proliferation grounds,
4 we need to build a second NPF, and that's going to raise the
5 price marginally again, and we need you pharmaceutical
6 companies to eat that cost for the sake of
7 non-proliferation.

8 So, it's not as if there's some sort of drop-dead
9 figure where, if the price goes up X, now it's not
10 profitable for them.

11 They were able to get a \$130 million cost
12 amortized, essentially, by the pharmaceutical companies.

13 CHAIRMAN MESERVE: Commissioner Merrifield.

14 COMMISSIONER MERRIFIELD: I'm a little troubled by
15 your last statement, Mr. Kuperman.

16 I mean what you're saying is Nordion can come down
17 to the U.S. and meet with the pharmaceutical companies again
18 and say we've got these additional proliferation concerns,
19 we need more money to build this processing facility.

20 Around a table, I mean that all sounds very good,
21 but we've got letters from members of the medical community
22 about these materials.

23 To the extent -- setting aside everything else --
24 to the extent that the medical community agrees to those
25 payments, those are costs that are passed off to someone in

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1 the United States, presumably the pharmaceutical company
2 isn't going to eat that cost, that cost is passed off to
3 either insurance companies or consumers, and within that
4 consideration is the notion that there is some percentage of
5 people there for whom that additional marginal cost,
6 whatever that is, will put the cost of those life-saving
7 medical treatments beyond their reach.

8 I just want to sort of throw that out on the
9 table, because you know, we can't consider these things in a
10 vacuum. These are people's lives.

11 We can't simply say, well, we're just going to
12 throw more money at it.

13 There will be people who will not have medical
14 treatments and their lives will not be saved.

15 MR. LEVENTHAL: I'm not sure it's that extreme a
16 situation, Commissioner Merrifield.

17 I think one thing the Commission should look into
18 is what percentage of the final delivered cost of the
19 medical isotope to the patient is represented by the
20 production itself, and our understanding is that it's a
21 very, very small percentage, and it's one that would not
22 make the delivered costs of the medical isotope, by any
23 means, prohibitive.

24 The RARTR program has always been premised on the
25 notion that there is some additional cost to conversion, and

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1 the objective of the program has been to try to establish a
2 level playing field so that no one producer gains
3 competitive advantage over the others by continuing to
4 produce targets, in this case, with highly-enriched uranium
5 while others have to undertake a higher cost and make
6 themselves non-competitive, and I think here the Commission
7 could have the objective of trying to establish what the
8 basic cost is of conversion, it will be well understood,
9 hopefully it will show that it is a very, very small
10 percentage of the final delivered cost of the medical
11 isotopes to the patients, and then you help to establish a
12 level playing field which the other producers can then fall
13 into line with.

14 COMMISSIONER MERRIFIELD: I understand that. I
15 don't want to go too far down this road, but the point I'm
16 trying to make is it may be a relatively small increment,
17 but to the extent that you're passing that on to consumers,
18 there is someone out there who that will be more than what
19 they're willing to bear.

20 I was a political science major in college, not an
21 economics major, but I do remember my Ec 1 and 2, and that
22 seems like a pretty simple economic principle, that
23 increasing marginal costs for someone does make a
24 difference.

25 Anyway, I don't want to quibble on that.

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1 You did focus in your statement, Mr. Kuperman, on
2 the SRM, staff requirements memo that the Commission put out
3 last June.

4 In our order, we also stated that, under the
5 Schumer amendment, cost is a factor to determining the
6 feasibility of LEU targets or for a reactor, and in that
7 context, we recognized that the applicant will have to
8 consider the commitments as made to the Canadian government
9 and its customers in regards to ensuring supply and keeping
10 costs to a minimum.

11 Now, you made a series of four recommendations to
12 us about things we should or shouldn't do.

13 What level of confidence do you have that, if we
14 were to take your recommendations, that they would not
15 impact supply or increase the cost?

16 MR. KUPERMAN: I think Paul addressed the cost
17 issue.

18 As he said, the numbers we've seen are somewhere
19 -- the costs of moly as a percentage of the cost of the

20 final delivered pharmaceutical is less than 5 percent, but I
21 do take your point about supply and demand, of course, one
22 way would be for the pharmaceutical company to make a
23 slightly smaller profit, then the actual price to the
24 customer wouldn't go up, and so, no single patient would
25 miss one single dose of isotope.

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1 As for the other recommendations, I think
2 recommendation two on reducing the total amount of HEU under
3 the license is not a problem, because the applicant itself
4 said it only uses 20 kilograms a year.

5 The license will only have three-and-a-half years
6 of life by the time they start up production, so they don't
7 need much more than 70 kilograms.

8 On the third recommendation, where we suggest that
9 the license be suspended for three months until they finish
10 their feasibility study, again, they would still have at
11 least six months before the NRU shuts down.

12 So, I don't think that's likely to impact -- and
13 when I say NRU, I mean the processing facility. The reactor
14 is supposed to run till 2005.

15 So, I don't think that would interrupt the supply
16 of medical isotopes.

17 Recommendation 4 is that they provide a better
18 blueprint for conversion.

19 So, that certainly wouldn't interrupt the supply
20 of medical isotopes.

21 So, the only question is really recommendation 1,
22 which is that you ask the applicant to present to you a
23 serious blueprint, a serious timetable for conversion, and
24 that it stick to it, but I think the language we used is
25 that you should -- we would recommend that the Commission

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1 state that it is going to suspend the license if the
2 applicant slips significantly behind on that timetable
3 without good cause.

4 Now, if it does have good cause for slipping
5 behind, if it turns out that something they thought was
6 technically possible is not technically possible, if it
7 turns out that they present information on a timely basis to
8 the CNSC but the CNSC withholds action for several years, it
9 would seem to me that would be a reasonable and legitimate
10 excuse for delaying the timetable.

11 So, then the only question would be what happens
12 if they present a timetable to you and then they knowingly
13 and willingly act in a dilatory manner again? Would that
14 endanger -- and then the Commission might be compelled to
15 suspend the license.

16 Would that endanger the production and supply of

17 medical isotopes?

18 Theoretically, it could. In a sense, I think the
19 applicant is playing a game of chicken with the Commission,
20 saying we dare you to say that we're being as dilatory as
21 we're being, and then you guys will be responsible for
22 cutting off the supply of medical isotopes.

23 I don't think that the Commission should in any
24 way let itself be intimidated in that manner, but then
25 there's also sort of the fall-back option: Well, what

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1 happens in the worst of all situations if a big boulder fell
2 on the NPF and stopped production?

3 Would American medical community be cut off from
4 medical isotopes?

5 Well, no, they wouldn't. There are other
6 producers around the world who have surplus capacity.

7 There's Mallinkrodt which produces at the Petten
8 reactor.

9 There's IRE in Belgium which produces at several
10 reactors.

11 There's South Africans who produce, Argentina has
12 a small production, and there's several who are getting into
13 the business, and the U.S., as you know, is considering
14 getting into the business.

15 In fact, as I understand it, no one in this
16 business makes a profit at this point. It's all sort of
17 based on the idea that, in the future, the market will grow
18 so large that it will be profitable, and they're sort of
19 fighting for market share desperately in order to ensure
20 that future of profitability.

21 But at the current time, there is a massive
22 surplus of capacity for production of medical isotopes.

23 So, I think in the worst case situation where they
24 act in bad faith and you were compelled to cut them off, no,
25 I don't think that the supply of medical isotopes to the

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1 U.S. would be endangered.

2 COMMISSIONER MERRIFIELD: Thank you.

3 MR. LEVENTHAL: If I could add just very briefly
4 to that, I think the Commission has a responsibility to
5 establish what might be described as a dynamic tension
6 between the non-proliferation interest of ending commerce in
7 HEU for the purpose of producing medical isotopes on the one
8 hand and ensuring that the production of medical isotopes is
9 not arbitrarily cut off because of something the Commission
10 does, and I think the best way to kind of referee that
11 tension is for the Commission to establish that it wants
12 timelines established and honored and will not look kindly

13 upon any further slippage.

14 I think that's what's really needed.

15 It's an expression by the Commission to the
16 applicant that we want no further dallying on this, we want
17 a firm commitment to meet the expectations, and the
18 Commission is going to follow this every step of the way,
19 and I think, with close oversight, you will not run into the
20 kind of draconian situation that you are concerned about,
21 but I think what hasn't yet occurred is for the applicant to
22 hear loud and clear from the NRC, and hopefully from the
23 Executive Branch, as well, that we really want to see this
24 accomplished, because it's one of the larger U.S.
25 non-proliferation objectives to complete the RARTR program

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1 with regard to isotope production as well as with regard to
2 fuel.

3 CHAIRMAN MESERVE: I was not a participant last
4 year in the process that led to the Commission's memorandum
5 and order of June 29th, so this is a new issue to me.

6 I have been struck and welcome the comment that
7 you made that there had been very significant progress in
8 the last year in that the issue about the target seems to be
9 one that everyone agrees is going to be resolvable -- there
10 are some time issues associated with when that can be done
11 -- and that, similarly, with regard to the NU processing
12 facility, that all of the issues associated with conversion
13 to LEU have been narrowed down to one processing step, and
14 in fact, dealing with one problem in one processing step,
15 and it seems to me that that does suggest to me that there
16 really has been rather remarkable progress that's been made
17 in a year.

18 Now, the applicant, having, I think, established
19 something of a track record for us, at least in its most
20 recent submissions that it's really addressing aggressively,
21 says, well, we think the lowest-cost option for dealing with
22 this problem is to have some experience with the calcining
23 step, see if we can make processing improvements that will
24 enable us to use this facility we've just constructed, and
25 that, on its face, seems plausible to me, too, in that if

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1 your problem is a processing stage, you want to do some
2 experiments with it and run it.

3 Do you disagree with their strategy? I realize
4 you have some problems with the timeline, but in terms of
5 the strategy that they've articulated to us as to how
6 they're going to address the problem, it sounds to me like
7 we've really made some quite remarkable progress.

8 MR. LEVENTHAL: Well, there's some history to
9 this, of course.

10 Yes, they've come to these understandings over the
11 past year, but there's been a long attempt to dialogue
12 between Argonne and the Canadians on some of these technical
13 problems which were anticipated, and I think Argonne
14 correctly foresaw that the volume of liquid waste was not
15 going to be a problem, and now the applicant has
16 acknowledged that over the past year.

17 What we're pointing to is a history of dilatory
18 activity that always seems to push the timeline further and
19 further into the future without a firm commitment to
20 actually convert, and in that regard, I would take some
21 exception to the Executive Branch testimony, which includes
22 statements that the Executive Branch believes that MDS
23 Nordion is making a credible good-faith effort to study the
24 feasibility of converting their new medical isotope
25 production process to LEU.

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1 Well, if that's the best that we believe they're
2 making a good-faith effort on, which is to further study the
3 feasibility, I'm personally not satisfied with that.

4 What we want to see is a credible good-faith
5 effort to actually convert within a timeline. That's what I
6 think is needed now, and the Executive Branch doesn't seem
7 to be demanding it, but I believe the NRC, as an independent
8 regulatory commission, with the licensing authority, can
9 demand that and make it very clear that we want to see this
10 job done, not simply studied further.

11 So, yes, they've made progress over the past year,
12 but it's taken them a decade to reach that point, and they
13 should have reached it by the time this license came up, so
14 that this license could have been LEU instead of HEU.

15 CHAIRMAN MESERVE: Commissioner Diaz.

16 MR. KUPERMAN: Could I just briefly also address
17 your specific question as whether I disagree with their
18 strategy or not?

19 CHAIRMAN MESERVE: Please be brief, because I'm
20 worried about our time for our Executive Branch.

21 MR. KUPERMAN: Okay.

22 You know, this whole question of the feasibility
23 study has been looking at can you convert from the existing
24 NPF, from NEU to LEU. It's taken a year. They now say it's
25 going to take three more months for the feasibility study

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1 and then another 18 months to solve technical problems, but
2 it would seem to me it's putting the cart before the horse
3 in terms of strategy, because the fundamental question is
4 can you get there from here?

5 I mean is it possible to convert the existing NPF

6 without interrupting the supply of medical isotopes? If
7 it's not, then that's something you should know now and they
8 should know that a year ago, whether there's any path
9 forward that would allow that.

10 If it's not, then they should have, a year ago,
11 decided to build a new production facility.

12 Otherwise, we're going to find ourselves at the
13 end of 2001 saying -- answering a question that we knew the
14 answer to three years ago, which is that there is no way to
15 convert the existing facility without interrupting the
16 supply of medical isotopes.

17 So, yeah, I guess I do question some aspects of
18 their strategy without at all taking away from what I said
19 in our prepared testimony, which is that they've made a heck
20 of a lot of progress in resolving problems that they said
21 were problems and that turned out not to be problems.

22 CHAIRMAN MESERVE: Thank you.

23 Commissioner Diaz?

24 COMMISSIONER DIAZ: Yes.

25 First I'd like to go back to the statement that

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1 you quoted the Commission. It's on page 2 of your
2 testimony, and I find it very interesting, because being
3 surrounded by lawyers, I always expect that lawyers will
4 catch these little innuendos in here, but if you read this
5 statement, it is quite interesting.

6 It is the Commission's understanding that Argonne
7 National Lab will be able to complete a feasibility study
8 promptly, within approximately three months of receiving the
9 necessary technical information. If Argonne doesn't receive
10 the necessary technical information, this is an open-ended
11 statement.

12 So, the Commission did not state it, you know,
13 precisely, what we wanted, and so, what that tells me is
14 that we need to look in this case -- and maybe you agree or
15 disagree with that -- when do we use should's and when do we
16 use will's and when do we use shall's, because obviously
17 this does not compel anybody except Argonne, if they receive
18 the technical information, to do it in three months, but
19 they didn't receive it, they didn't have to do it.

20 So, anyhow, my fellow lawyers will, I'm sure, take
21 a look at that issue.

22 Let me go back at some of your recommendations.
23 I'd like to go quickly into this.

24 Of course, you know, the first recommendation
25 about three-and-a-half years, being a technical person, it

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1 is not possible to determine at this time, with the
2 information the Commission has in front, to put a precise

3 amount of time, which goes back to the issue of timetable,
4 which every single one of the recommendations goes back to.

5 The second one is reduce the amount to 100
6 kilograms, which might appear to be reasonable.

7 However, it does kind of conflict with the
8 recommendation of suspending the license until the
9 feasibility study, and my question is, being that there has
10 to be a balance between the supply -- because even if there
11 are other suppliers, an interruption of supply, in medical
12 business, it's a traumatic issue, it's not something that
13 you change, I mean the quality control and the quality
14 assurance and the requirements.

15 From your experiences, what is a reasonable amount
16 of time that, let's say, a regulatory body can say give me a
17 timetable within one year, 18 months?

18 What is an amount of time that now that you've
19 been looking at this for so long that will appear to be
20 reasonably achievable, that will still allow, you know,
21 ensuring the supply but will provide some covenant or some
22 requirement that a timetable will be provided?

23 Certainly it's not three months and certainly it's
24 not six months.

25 Do you have some idea of what a reasonable time

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1 would be or do you have a suggestion?

2 MR. LEVENTHAL: Well, my understanding is that,
3 after the visit to SGN in France, Argonne felt that the
4 solution identification part of the feasibility study could
5 be completed within three months' time, and that's what
6 we're asking for.

7 We're asking for a suspension for that three-month
8 period to provide the applicant the opportunity and the
9 incentive to actually complete that on an expedited basis,
10 and we feel, without that extra incentive of a suspension,
11 they're not likely to meet it, and I think you heard from
12 the first panel that now they're talking about a longer
13 period of time than three months.

14 So, if you're really interested in moving the
15 process along on an expedited basis, you have to provide the
16 incentive, we feel.

17 The Commission has the discretion to indicate what
18 it wants by a date certain in order that the licensing
19 process proceed in a manner that you're comfortable with,
20 and it's this dynamic tension that I referred to before.

21 How do you assure that the non-proliferation
22 objective is met without raising the risk of interrupting
23 the supply, and that's where I think you're in a position of
24 setting deadlines, timelines, and firm statements of

1 COMMISSIONER DIAZ: I understand, but it seems to
2 me like, you know, although, you know, not questioning the
3 technical judgement of Argonne National Lab, I'm looking at
4 the realities of life and adjustment of markets and supplies
5 and potential disruptions, and I think that three months is
6 a short period of time to impose such a restriction.

7 MR. KUPERMAN: Well, I would just cite the
8 Executive Branch's prepared testimony today, where actually
9 this timeline, they say, is not just Argonne's. They say,
10 quote, "Argonne, Nordion, and AECL have agreed on the
11 following timeline," unquote. That's from their prepared
12 testimony, on page 3.

13 So that seems to be in contradiction to what Dr.
14 Malkoske said today as a witness, where he said we don't
15 want to state any timeline or be held to any timeline at
16 this time, but -- so, maybe there's a need for the
17 Commission to reconcile those two points, and again, the
18 question maybe also to look into is whether these are in
19 parallel or not, which Malkoske said they could be.

20 COMMISSIONER DIAZ: Thank you very much.

21 CHAIRMAN MESERVE: Thank you.

22 I read that paragraph to say there will be a plan
23 for resolution that is in three months, and then 18 months
24 to achieve the resolution of the technical issues, which may
25 be consistent with the 2001 date that they were talking

1 about.

2 In any event, I'd like to thank you very much for
3 your presentation. It's been helpful.

4 And now we're going to hear from the Executive
5 Branch.

6 CHAIRMAN MESERVE: Our participants from the
7 Executive Branch include Richard Stratford, who is the
8 Director of the Office of Nuclear Energy Affairs,
9 Nonproliferation Bureau of the State Department; Robin
10 DeLaBarre, who is also from the Office of Nuclear Energy
11 Affairs, and Christine Martin; Richard Goorevich, who is the
12 Director, Nuclear Transfer and Supplier Policy Division of
13 DOE; Sean Tyson, International Policy and Analysis Division
14 of DOE; and Dr. Armando Travelli, who is a gentleman who
15 we've referenced before, who is the manager of the RARTR
16 program at Argonne.

17 Welcome. I apologize that we've been late in
18 getting to you.

19 MR. STRATFORD: That's fine, Mr. Chairman. Thank
20 you very much.

21 Mr. Chairman and members of the Commission, I'll

22 be brief.

23 You have the submission of the Executive Branch in
24 the form of my letter of July 6th as well as the remarks
25 that were prepared and circulated for this meeting.

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1 To those remarks, I would only like to add the
2 following:

3 The debate over whether to continue to ship HEU to
4 Canada for use in the MAPLE reactors to produce medical
5 isotopes seems to boil down to one issue.

6 That is whether or not changes to the waste
7 calcining process can be made now that either can't be made
8 after the facility goes hot or that the changes would be so
9 significantly more expensive in the future as to preclude
10 making them for economic reasons.

11 The applicant says there aren't any such changes.
12 SGN, which designed and built the waste calcining equipment,
13 says there are no such changes. Argonne, with over 20
14 years' involvement in the RARTR program, concurs that there
15 are no such changes.

16 Dr. Alan Krass of my office, who visited the
17 facility last month, came home and reported to me that he
18 knew of no such changes.

19 The only claim that changes can and should be made
20 now comes from the intervenors, who don't identify what
21 those changes might be.

22 Yet, the argument is that those changes, whatever
23 they are, should be made before startup.

24 Then it is argued that these changes won't take
25 very long and there is no harm to delaying startup until the

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1 changes are designed and implemented.

2 Well, how long a delay are we talking about?

3 Answer: Totally unknown.

4 If we decide to go to baffles, they have not been
5 designed, they have not been tested.

6 If we go to introducing a precipitating agent,
7 ditto.

8 Moreover, there is the regulatory process to go
9 through in Canada before any changes can be made.

10 I notice that the intervenors made the same
11 arguments to the AECSB, now the Canadian Nuclear Safety
12 Commission, which ruled decisively against the assertion,
13 noting, quote, "The Commission accepts that modifications
14 now to the processing facility could negatively affect
15 safety and, therefore, does not accept the intervenor's
16 request to withhold approval," close quote.

17 If that same decision had been made by the NRC in

18 reference to a U.S. facility, I wonder how we would react to
19 a decision by another state to deny export of fuel to such a
20 U.S. facility until the as-yet-unspecified changes had
21 nevertheless been made in the face of such a decision.

22 The second point I wish to make has to do with the
23 cooperative, not antagonistic nature of the RARTR program
24 and the conversion process.

25 The effort to minimize the use of HEU in research

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1 reactors and medical isotope production has been a long,
2 difficult, and admittedly slow process, but it has also been
3 largely successful, and largely, in my judgement, because it
4 has been a cooperative effort.

5 We have made clear from day one that we are
6 not-slash-not, as we put it in cable traffic, about the
7 business of shutting down medical isotope production
8 programs, research programs, or calling into question the
9 bona fides of our cooperating partners, unless, of course,
10 there's a good reason to raise a question, but that reason
11 does not exist here, in our judgement.

12 Considering that the RARTR program has been going
13 on for over 20 years but only the last four years has been
14 focused on target development, I'm not surprised that it
15 takes time to figure out how to convert a medical isotope
16 production reactor and its isotope separation and waste
17 process.

18 Please note one aspect of what I just said because
19 of the discussion about a commitment in 1990 but a plan,
20 nevertheless, to build an HEU target-using facility.

21 Number one, HEU was still the commodity of choice.
22 There is still not anybody in the world who uses LEU for
23 targets except for the Australians on a very minor basis.

24 Remember, it was only four years ago, in 1996,
25 that we turned any serious attention in this country to

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1 target development.

2 There have been issues over confidentiality, but
3 they have been resolved.

4 There was, past tense, a question of whether an
5 LEU target could be used, also resolved.

6 There is the issue of the waste calcining process,
7 and we hear that it is on the way to being resolved.

8 We in the Executive Branch do not have a question
9 about anybody's bona fides, nor, apparently, do the Canadian
10 regulatory authorities, nor do we want to turn what should
11 be and has been a straightforward effort at cooperation into
12 a legalistic, antagonistic, or accusatory process in which
13 allegations of bad faith seem to be the order of the day.

14 We do believe that good-faith efforts are being

15 made by the parties to examine, develop, and implement a
16 path to conversion.

17 We have not found it necessary to negotiate
18 conversion schedules, hold, quote, "feet to the fire,"
19 unquote, or otherwise treat our cooperating partners as if
20 they weren't fully committed to the conversion process.

21 My third point is one I believe I made last year,
22 and it relates to NCI's statement here that ATU for fuel
23 exports are now at zero, but they're not going to be at zero
24 for very much longer, because we have been successful in
25 getting commitments to convert Grenoble, BR-2, and Petten,

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1 in return for which we committed to make good-faith efforts
2 to obtain approval to export HEU to fuel those reactors
3 pending conversion.

4 So, you're going to be seeing licenses for fuel.
5 In the case of Petten, NCI is right. We set a limit on
6 Petten, and the limit was 2006, after which you're cut off,
7 and Petten will be using fuel that is already assumed to be
8 okay and usable.

9 That six years is for nothing more than getting a
10 licensing amendment.

11 So, if I were to say, okay, let's do six years for
12 Canada, I suspect I would get violent objections from the
13 intervenors. No, no, that's too long. But are we going to
14 start second-guessing the six years that we gave The
15 Netherlands in diplomatic notes and start having yearly
16 reviews of whether or not the regulatory authority is moving
17 fast enough for our judgement?

18 I hope the fact that HEU exports will rise on a
19 temporary basis will be seen as part of a success story, not
20 a diminution of our efforts to minimize the use of HEU.

21 The fourth point -- and I think this is our real
22 one -- is that the present review process is working. We do
23 not think it is necessary to require additional reports or
24 more frequent reports.

25 Regardless of speculation about various timelines,

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1 I do not think that we will know in three months, in six
2 months, or in nine months that baffles or a precipitation
3 process can be designed, engineered, tested, and approved by
4 regulatory authorities.

5 We don't know which one is the solution, or if any
6 of them are the solution.

7 Hence, to terminate the license pending the
8 submission of a report that outlines what changes will be
9 made and how, as the intervenors argue, is a formula for
10 blocking shipments and startup on an indefinite basis. If

11 one was to do that, then are we supposed to come back in
12 three months and have another discussion of whether the
13 latest report is satisfactory to us, which it won't be,
14 because I don't think it will identify the way forward.

15 I noted Commissioner Merrifield's comment and I
16 interpreted him to be saying something like let's get
17 serious here.

18 Are we seriously thinking about cutting off the
19 principle source of medical isotopes for this country?
20 Well, by operation, we might have to do that under certain
21 circumstances. We recognize that.

22 But in my judgement, those circumstances would
23 have to border on outright fraud, not an external judgement
24 that conversion is not moving fast enough.

25 Witness what I said about Petten. We gave Petten

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1 six years just for a regulatory process.

2 Do we want to start calling up the regulatory
3 authority and saying please send someone over here for a
4 discussion of whether or not you're moving fast enough,
5 otherwise we're going to ignore the diplomatic notes and cut
6 you off at an earlier date.

7 Yet, in a situation where we don't have a clue how
8 to solve the technical problems, we're having discussions of
9 timelines that deal in three-month segments. Just don't
10 think that makes sense.

11 And if we did have to cut off supply to Canada by
12 operation of law, what do I think would happen? I think
13 we'd have a medical crisis on our hands, and what would
14 happen at that point? I think two things would happen.

15 First, there would be efforts by some to change
16 the law, and there would very quickly be serious scrutiny of
17 how we got into a medical crisis in the U.S., and second, I
18 have to say that my judgement is that there would be a
19 realization in the Executive Branch that an external source
20 of supply would have to be found immediately, and recall
21 that when the Nuclear Nonproliferation Act of 1978 forced us
22 to terminate supply of nuclear fuel to India, the French has
23 to step in and satisfy our obligations for us under the
24 U.S.-India agreement.

25 So, would we complain if the Canadians, at that

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1 point, during a medical crisis, turned to an external
2 source? Frankly, I don't think so.

3 So, in a nutshell, we think the process has been
4 going very well. A lot of the technical problems have been
5 cleared away. We now know exactly where we have to focus.
6 There will be a plan on how to get there, and we think that
7 the existing review process of reports on an annual basis,

8 followed by a public meeting such as this one, if the
9 Commission desires, is a sensible way to proceed.

10 We're not going to have something in three months.
11 We might have something in 12 months, and terminating the
12 license at this point I think would be a serious mistake.

13 With respect to the amount, I leave it to the
14 applicant to argue for what they need. I would simply note
15 that what the Commission approved last year -- last year,
16 when the reactor wasn't even ready to start up, what you
17 approved was 40 kg's in calendar year '99 followed by 22
18 kg's in each of the four out-years.

19 We are now almost exactly one year later in time,
20 and we are facing startup fairly soon.

21 So, what's the most sensible number? Probably 40
22 in calendar-year 2000 followed by 22 in the three out-years.
23 That's the most sensible way to look at the numbers.

24 So, thank you, Mr. Chairman. I will stop here.
25 We're happy to answer any questions.

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1 CHAIRMAN MESERVE: Thank you very much.

2 Commissioner Merrifield.

3 COMMISSIONER MERRIFIELD: Just to clarify the last
4 statement that you made, you seem to indicate that it does
5 make sense for us to come back a year hence to review the
6 continuing process?

7 MR. STRATFORD: Absolutely. You made exactly the
8 right judgement a year ago. I think it's still the right
9 judgement.

10 COMMISSIONER MERRIFIELD: I also wanted to make
11 one other question.

12 You mentioned the ongoing discussions,
13 negotiations we've been having with other foreign partners.
14 You mentioned The Netherlands and agreements that have been
15 made between State Department and between representatives of
16 The Netherlands relative to those reactors, and we'll be
17 seeing those agreements coming before the Commission at some
18 point in the future.

19 It wasn't your intention to leave any doubt that
20 the Commission does have an independent role in reviewing
21 those agreements.

22 MR. STRATFORD: No, absolutely, and that's the
23 reason the notes are phrased the way they are, because the
24 people at Grenoble and the people at Petten came back and
25 say, okay, we agree to convert, you agree to supply us

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1 stuff, which my immediate answer, having been in this
2 business a long time, is no, sorry, independent regulatory
3 agency in the U.S.

4 What I can do is I can give you a statement to the
5 effect that the Executive Branch will make its best efforts
6 to obtain an export license from the appropriate authorities
7 for the export of that material, but then, in at least one
8 set of those notes, there is another line which says, in
9 essence, oh, by the way, if we fail and you don't get the
10 HEU for any reason whatsoever, all bets are off, including
11 your commitment to convert.

12 So, it's a quid pro quo, but it explicitly
13 acknowledges the independence of your role.

14 COMMISSIONER MERRIFIELD: Thank you.

15 CHAIRMAN MESERVE: NCI, as you heard, has raised a
16 large number of concerns about perceived delaying tactics by
17 MDS Nordion.

18 Do you share those concerns?

19 MR. STRATFORD: No.

20 I recognize that there was a serious to and fro on
21 confidentiality, and I don't blame Nordion for that, but we
22 resolved that issue.

23 I realize that there are concerns that there has
24 been foot-dragging, but I'm not sure I'd characterize it as
25 foot-dragging.

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1 The biggest focus seems to be that the feasibility
2 study didn't come in on time. That's the big one, as I see
3 it.

4 Well, I'm not sure that it might not have been
5 able to come in a little earlier, but I'm not sure that
6 that's a distinction without a difference.

7 I see a process that is working. It is not to
8 everyone's satisfaction.

9 There are, I suspect, suspicions on both sides,
10 between our two sides, but it's working, and if you look at
11 where the amount of progress has been made over the last 12
12 months, it is really substantial.

13 We took Argonne -- not we -- they took Argonne off
14 to see SGN. That was a very productive discussion. People
15 know where they have to focus.

16 But I cannot guarantee that I'm going to be able
17 to come back in a year and say baffles are the answer or
18 precipitating agent is the answer or even, gee, we're just
19 going to have to move to an all-new facility. I don't know
20 that we're going to be there.

21 But I'm not going to start throwing around
22 allegations of bad faith because we're not there. What I am
23 going to try to do is what I did in April, which is get
24 everybody into a room and knock heads so we start making
25 progress a little faster than we did before.

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1 CHAIRMAN MESERVE: Thank you.

2 Commissioner Diaz.

3 COMMISSIONER DIAZ: Yes.

4 Mr. Stratford, I guess a lot of the thing goes
5 back to this issue of providing a reasonable timetable, and
6 I think, you know, I stated before that I think that, you
7 know, three months might not be a reasonable timetable
8 considering the implications of the medical supplies.

9 However, you know, in your testimony, I seem to
10 imply that you are concerned about establishing a timetable
11 that will be required, and I don't think that's, you know --
12 or is that what you said?

13 MR. STRATFORD: That's very close to what I said,
14 Commissioner, and there's a couple of aspects to that.

15 Number one, I haven't a clue what the timetable
16 is. I know it's not three months. I don't know whether
17 it's six, nine, a year, or something else, and it's a
18 timetable for what?

19 Because what I heard in arguments from NCI was,
20 well, it's a timetable in which you shouldn't allow startup
21 or a license until what you have in front of you is a clear
22 path towards conversion: This is what we're going to do and
23 this is when we're going to do it. And I don't know when
24 we're going to know that, and I don't think, if we don't
25 know it three months from now -- let's say we set a

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1 nine-month timetable.

2 Do we want to come back here again in nine months
3 and have a debate about why this plan is so bad because it
4 doesn't tell us exactly what we need to do or how much it's
5 going to cost?

6 I don't think we need to do that. What I do think
7 we need to do is come back a year from now and see where we
8 are and what has been achieved.

9 I think if you hold people's feet to the fire by
10 setting timetables, number one, you're going to find the
11 timetable is not met, and number two, I think it's genuinely
12 going to leave a bad taste in a lot of mouths, and if you're
13 going to have timetables for these guys, then where are we
14 going to go on Petten, Grenoble, and BR-2?

15 Timetables for regulatory proceedings? Timetables
16 for Grenoble development of fuel, which is going to be a
17 bear, by the way.

18 COMMISSIONER DIAZ: Is it reasonable to establish
19 a timetable not to study, necessarily, but to determine the
20 feasibility of what needs to be done, not to do it? What's
21 wrong with that?

22 There's an issue of words in here, to study. You

23 never finish.

24 I think the issue is we need to have a
25 determination of the feasibility of conversion, and I think

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1 that, you know -- and I think I heard NCI -- I think they
2 were very reasonable -- saying that, you know, if there are,
3 you know, circumstances of regulatory authorities -- but
4 from the technical viewpoint of the applicant, the
5 determination of the feasibility of conversion is key to
6 this issue, and I don't know either what is the real
7 timetable.

8 Maybe we should request or require that the
9 applicant tell us what is the time in which they could
10 establish or determine what the feasibility is, and that's a
11 real important step, and it seems to me like it would be a
12 reasonable, you know, step forward to clarify where do we
13 stand on the issue of conversion, and unless we have that,
14 we're not going anywhere fast.

15 MR. STRATFORD: What, in my judgement, is
16 reasonable is to ask everybody to come back at some date
17 certain, whether that be six months or a year, and say where
18 we are in determining feasibility.

19 What is not reasonable is to say come back in six
20 months and tell me it is feasible and this is how you're
21 going to do it.

22 If I turn to the -- you know, the anti-missile
23 guys and say, okay, I've had enough, I want a timetable in
24 which you're going to come back and tell me it can be done,
25 can't do that.

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1 All they can do is keep running tests until they
2 know a lot more than they do.

3 COMMISSIONER DIAZ: A determination of feasibility
4 is a very clear specific term. It requires that options be
5 analyzed and solutions be, you know, established and that,
6 you know, a preferred approach be set, and that's a
7 determination, and I think, you know, that -- and I know
8 what the timetable is, but whether it's a year from now or
9 15 months from now, I think we need to have such, you know,
10 conclusion of the feasibility of doing it, not to study it
11 but to determine whether it is feasible, and maybe the
12 conclusion is it's not feasible, you know, but we need to
13 know that, and I think we need to go through the process of
14 establishing what is, you know, the critical pathway for the
15 technical issues and put them down.

16 MR. STRATFORD: In my judgement, what would be
17 reasonable would be requesting that, in the next annual
18 report, that all of the parties -- the applicant, the
19 Executive Branch, Argonne working for DOE -- make their best

20 efforts to focus the report on the options and which of
21 those options might or might not be feasible and, to the
22 extent possible, provide their view on whether any of them
23 are feasible and, if so, how it might be done. That, I
24 think, is a reasonable request.

25 COMMISSIONER DIAZ: It is good to see you again,

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1 sir. I haven't seen you for too long. I think I was a
2 child when I first met you.

3 Has the issue of proprietary information been
4 resolved to the satisfaction that you have the technical
5 information required to do your job, sir?

6 MR. TRAVELLI: I think it is today. Essentially
7 what it boils down to is that MDS Nordion decided that all
8 those issues which created problems with confidentiality
9 were such that they were resolved.

10 Essentially, MDS Nordion either had resolved or
11 felt confident that they could resolve those issues in such
12 a way that the information that otherwise would have needed
13 to be transmitted to Argonne no longer needs to be
14 transmitted, and instead, the remaining issue, which is
15 about calcining, is less sensitive for Nordion because it is
16 a process developed by another company, and so, we received,
17 10 days ago, a good amount of information about this
18 residual problem, and we think that, from this point in, we
19 can work with MDS Nordion to make suggestions or to provide
20 whatever assistance we can in this area, and since this is
21 the only area which now is important and the confidentiality
22 issues are not as important as for the others, I would say
23 that, yes, they have been resolved.

24 COMMISSIONER DIAZ: Okay.

25 From your expert viewpoint and since timetables

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1 are obviously a key issue, what do you think would be a
2 reasonable timetable for the determination of the
3 feasibility of the conversion?

4 MR. TRAVELLI: As he said today, Mr. Malkoske
5 thought that, in about 18 months, there will be a completed
6 technical study of what would need to be done.

7 I picture that probably the feasibility could be
8 established sometime before that, because to solve entirely
9 the issue would imply first to have the feasibility and then
10 stepping up to the details.

11 So, I would say it's between now and 18 months
12 from now, maybe one year.

13 COMMISSIONER DIAZ: A year from now you think will
14 be a reasonably achievable time?

15 MR. TRAVELLI: For the feasibility. I think that

16 probably Mr. Malkoske would agree with me, but that's my gut
17 feeling, that it's not a certainty, but I would guess that
18 probably a year from now, someone would be able to step up
19 here and say yes.

20 CHAIRMAN MESERVE: Commissioner McGaffigan.

21 COMMISSIONER MCGAFFIGAN: Mr. Stratford, you
22 started off by saying there was serious -- at some point you
23 said there was serious to and fro on confidentiality, you
24 understood why, but we've resolved that issue.

25 I honestly thought -- and the reason we had what

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1 we had in the order last year was that we had similar
2 testimony last year that all the necessary confidentiality
3 agreements had been entered into and it looked like
4 everything was a go and therefore the information was going
5 to get shared with Argonne, and I think Dr. Travelli
6 testified he could do something in three months, or his
7 colleague who was with him last year testified that he could
8 do something in three months.

9 Last year's order, in hindsight, looks like it's
10 Alice In Wonderland-like, but based on the testimony we had
11 last year, it's what the lawyers in this room thought would
12 -- you know, based on what various folks had said -- was a
13 reasonable thing, but the heart of it was that the
14 confidentiality was resolved.

15 Dr. Travelli now tells us that the way
16 confidentiality has been resolved is that basically Nordion
17 has solved all the issues on its own except for this one
18 issue where they feel comfortable bringing Argonne in, and
19 that's a very interesting different approach to how to
20 resolve confidentiality from what I was under the impression
21 of last year.

22 So, why was I wrong last year in thinking the
23 confidentiality issue was resolved? I don't have the
24 transcript. I didn't pull it out, but I could have sworn
25 that the overall testimony last year was that that issue was

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1 behind us as of June of '99.

2 MR. STRATFORD: That was my recollection, too, and
3 I may have overstated the phrase to-ing and fro-ing, but I
4 think there were certainly some indications of concerns
5 about transfer of information.

6 But I think, you know, as to the details of that,
7 I think I just have to leave that to Argonne to address that
8 again.

9 COMMISSIONER MCGAFFIGAN: Well, we may not need to
10 go further.

11 Dr. Travelli, do you have the resources at Argonne
12 -- assuming over the next 18 months you're going to interact

13 seriously with MDS Nordion and ACEL, do you have the
14 resources to do that, to help them resolve this calciner
15 issue?

16 MR. TRAVELLI: I believe we do, but that will be
17 done during the next fiscal year.

18 COMMISSIONER MCGAFFIGAN: Well, some of it might
19 be the next three months.

20 MR. TRAVELLI: We do have the resources to address
21 that probably during the next three months, and we have been
22 told by the Department of Energy that we can count on
23 similar support for the next year.

24 COMMISSIONER MCGAFFIGAN: So, you have the
25 resources.

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1 The issue, then, of what to expect -- I mean,
2 essentially, Mr. Stratford has taken your memo of your trip
3 report and made it part of his testimony, so either of you
4 can answer this, but the plans to resolve obstacles is just
5 a plan to resolve obstacles.

6 Then, in an 18-month period -- they should have
7 that within a couple months, is what both of you have said.
8 Then, over the next 18 months, they figure out whether the
9 obstacles can be overcome doing experiments.

10 I mean, to some extent, Commissioner Diaz has
11 already been through this.

12 At some point during that period, they get a sense
13 as to whether the low-cost solution, namely modifying the
14 current facility, is going to work or not, and you've
15 guesstimated that that might be a year into that 18-month
16 period, Dr. Travelli.

17 MR. TRAVELLI: Yes.

18 COMMISSIONER MCGAFFIGAN: At the end of the
19 process -- you know, I was struggling earlier with -- based
20 on your experience with reactors, Dr. Travelli, and these
21 sorts of processing facilities, how do they make the
22 conversion without disrupting supply?

23 If it's as simple as what you all were suggesting
24 last week -- and they are not buying onto, but adding a
25 uranium precipitating agent, which apparently requires some

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1 modification -- how do they do that, and also, you're not
2 familiar with the FDA process, but this issue of getting the
3 LEU targets, you know, processed so that they can produce
4 the moly-99, so they can go to FDA and say, look, this is
5 what the product that we're going to be selling is -- how
6 does all that work? Do you have a clue?

7 MR. TRAVELLI: I can tell you what my impression
8 is, but probably our colleagues from Canada would be in

9 better condition to answer your question.

10 From a technical point of view, to make sure, for
11 instance, that the calcining process works, you can do tests
12 in a laboratory, and then we found out at SGN that they
13 still have their pilot plant which they had working there to
14 test the system which is now being implemented in Canada.

15 That pilot plant is still available at SGN, so
16 that after one has a design about how the system should be
17 modified, they could modify in that way the pilot plant and
18 do the actual tests at SGN to confirm the validity of the
19 design. That is from a technical point of view.

20 To have the FDA approval, I don't know exactly
21 what the requirements are, but the point is that the new
22 facility is going to enter into operation soon, and the FDA
23 has not yet seen what the results of that facility is.

24 So, obviously, the FDA allows for some
25 extrapolation.

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1 COMMISSIONER MCGAFFIGAN: I am not a technical --
2 is it conceivable, if it were not for the FDA approval
3 process, that you could satisfy the Canadian regulator with
4 these tests at SGN or whatever in terms of the safety
5 analysis that you would need to do, and then could you then
6 carry out the conversion without disrupting supply, and then
7 one day switch over from HEU to LEU targets?

8 MR. TRAVELLI: Not entirely, because SGN is
9 involved only in the calcination process, and the FDA will
10 be more interested --

11 COMMISSIONER MCGAFFIGAN: -- in waste processing.

12 MR. TRAVELLI: Not in the waste. The FDA will be
13 involved in --

14 COMMISSIONER MCGAFFIGAN: I'm leaving FDA out.
15 I'm trying to figure out how the Canadian regulator gets
16 satisfied on a safety case and an environmental case.

17 MR. TRAVELLI: At least for the calcining process,
18 they could do that that way.

19 The main issue will be the other parts of the
20 process, and that, I don't know really how MDS Nordion plans
21 to address that problem.

22 COMMISSIONER MCGAFFIGAN: I'm just troubled, Mr.
23 Chairman, as to how, even if everything turns out swimmingly
24 and the technical types resolve all the technical issues and
25 it's technically feasible and they even can do the low-cost

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1 option, what today's testimony, more than anything, has made
2 me worry about is how do they actually do it without
3 disrupting supply, and there's various regulatory Catch-22's
4 that seem to lie over this process, even if it's wildly
5 successful technically, but I may be confused.

6 CHAIRMAN MESERVE: Is there anyone from MDS
7 Nordion who can address that quickly?

8 DR. TRAVENA: I got your question before, and I
9 didn't understand it, that's why I didn't answer it in full,
10 so I'll explain what needs to happen, and the issue really
11 is -- there's two issues.

12 One is IAEA and HEU control. So, as you're
13 looking at can you convert, the issue is can you move LEU
14 through the system at the same time as you've got HEU in the
15 tanks, and that's going to be a complex issue, because
16 things are going to be mixed.

17 Now, I believe that, with the right kind of
18 controls and with the willingness of the IAEA to recognize
19 that we have an awkward situation, that we could, with
20 special monitoring, work through that issue, but we haven't
21 talked to IAEA yet.

22 But you know, talking to the State Department
23 experts, they seem to think that this is a reasonable thing,
24 given the end result that we want to achieve.

25 The second issue is with respect to the FDA, and
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1 the FDA's issue is associated with what's called good
2 manufacturing processes, which means you don't want to carry
3 out a process that's different from your existing process in
4 the same equipment unless you've somehow cleaned and
5 prepared that equipment before you run the good stuff again.

6 So, for example, if we have a process that today
7 is using an HEU target and you have equipment that's for
8 that and it's perhaps dedicated equipment so it's in line,
9 you can, from a drug manufacturing perspective, if you clean
10 the lines after you've used the LEU, then you can go back to
11 HEU again.

12 So, for example, you could carry out the tests --
13 we haven't figured out the details yet -- that says we'll
14 run HEU, we'll flush the system, we'll run LEU through the
15 system, and then we'll flush the system again from the
16 processing product perspective before we go back to HEU.

17 So, it is possible.

18 For example, when we're currently looking at how
19 we look at the product from our MAPLE reactors going through
20 our existing processing facilities at Nordion and we have
21 only one set of cells where we do our moly processing,
22 we're, in fact, doing just that, but in fact, because things
23 are a little bit easier there, we, in fact, will have
24 duplicate process equipment in the cell, and we'll put the
25 other glassware in the cell to do the stuff from MAPLE,

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1 because we don't want to miss the MAPLE stuff with the stuff

2 from the NRU reactor.

3 COMMISSIONER MCGAFFIGAN: Just to follow up very
4 briefly, the flushing process you talk about -- does that
5 disrupt supply?

6 DR. TRAVENA: No, we're talking about a washing
7 process.

8 COMMISSIONER MCGAFFIGAN: Does it takes hours
9 rather than --

10 DR. TRAVENA: We don't know yet, we haven't done
11 it, but it's common --

12 COMMISSIONER MCGAFFIGAN: You can do it without
13 disrupting supply.

14 DR. TRAVENA: Yeah, we believe we can. It's a
15 little bit awkward, and we haven't figured out exactly how
16 to do it yet.

17 COMMISSIONER MCGAFFIGAN: Thank you, Mr. Chairman.

18 CHAIRMAN MESERVE: I'd like to thank all of the
19 participants for their presence today.

20 We've run quite a bit longer than we had
21 anticipated, and I apologize to those who had made other
22 plans for the late afternoon, but I think it does reflect
23 the seriousness with which the Commission approaches its
24 obligations in this matter.

25 I'd like to thank you all again, and with that,

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1 we're adjourned.

2 [Whereupon, at 4:07 p.m., the briefing was
3 concluded.]