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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON PROPOSED EXPORT OF HIGH ENRICHED URANIUM TO CANADA PUBLIC MEETING

Location: Rockville, Maryland

Date: Wednesday, June 16, 1999

Pages: 1 - 136

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OFFICE OF THE SECRETARY

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BRIEFING ON PROPOSED EXPORT OF

HIGH ENRICHED URANIUM TO CANADA

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PUBLIC MEETING

Nuclear Regulatory Commission

Room 16-1F

One White Flint North

11555 Rockville Pike

Rockville, Maryland

Wednesday, June 16, 1999

The Commission met in open session, pursuant to notice, at 9:07 a.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission

EDWARD McGAFFIGAN, JR., Member of the Commission

GRETA J. DICUS, Member of the Commission

JEFFREY S. MERRIFIELD, Member of the Commission

NILS J. DIAZ, Member of the Commission

STAFF AND PRESENTERS SEATED AND THE COMMISSION TABLE:

KAREN D. CYR, General Counsel

ANNETTE VIETTI-COOK, Secretary

DR. IAIN C. TREVENA, Senior Vice President, Nuclear Medicine, MDS Nordion

GRANT R. MALKOSKE, Vice President, Engineering & Technology, MDS Nordion

DAVID L. NICHOLDS, General Counsel & Corporate Secretary, MDS Nordion

DR. JEAN PIERRE LABRIE, General Manager, Research and Isotope Reactor Business, Atomic Energy of Canada, Ltd. (AECL)

GREG SAYER, Legal Counsel, AECL

JAMES A. GLASGOW, Legal Counsel, AECL

JOHN E. MATTHEWS, Legal Counsel, AECL

PAUL LEVENTHAL, President, Nuclear Control Institute (NCI)

ALAN KUPERMAN, Senior Policy Analyst, NCI

RICHARD J. K. STRATFORD, Director, Office of Nuclear Energy

TRICIA DEDIK, Director, Nuclear Transfer and Supplier Policy Division, Office of Arms Control and Nonproliferation, Dept. of Energy (DOE)

EDWARD T. FEI, Director, International Policy Analysis

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

[Continued]

RICHARD GOOREVICH, Nuclear Transfer and Supplier Policy Division, Office of Arms Control and Nonproliferation, DOE

SAMIT K. BHATTACHARYYA, Technology Development Director, Argonne National Laboratory (ANL); or

ARMANDO TRAVELLI, RERTR Program Manager, Argonne National Laboratory (ANL)

JIM SNELGROVE, Coordinator for Engineering Applications, Argonne National Laboratory (ANL)

GRANT BILL ZAGOTA, RERTR Program, Argonne National Laboratory

P R O C E E D I N G S

[9:07 a.m.]

CHAIRMAN JACKSON: Ladies and gentlemen, good morning.

The purpose of our meeting this morning is for the Commission to hear the views of three separate panels on a very specific matter, namely whether the Commission should approve the application for exporting a five-year supply of highly enriched uranium to Canada as targets for medical isotope production in the MAPLE 1 and 2 reactors. Those reactors currently are under construction by Atomic Energy of Canada, Limited, or AECL, in connection with their Chalk River Nuclear Laboratories.

Several factors make this decision particular complex, more so than perhaps some other import/export decisions over which the Commission routinely has jurisdiction. In this case MDS Nordion, Inc. currently operates the NRU reactor to supply a major percentage of the world market requirements for several radioisotopes that are vital to nuclear medicine. The NRU reactor has been operating for 43 years and questions exist about how long it can continue as a reliable supply source, a point that should be clarified by our discussion today.

For export decisions of this sort, the Commission considers of primary importance whether such an export would

be inimical to the U.S. common defense and security. However, a remaining key focus involves Section 134 of the Atomic Energy Act, commonly known as the Schumer Amendment, which requires that three conditions be fulfilled before the Commission can improve an ETU license application for isotope production targets.

The first is that there is no LEU target that can be used in the reactor; the second, that the proposed recipient has provided assurances that it will not switch -- that it will switch, rather, to an LEU target as soon as one is qualified that will not impose a large increase in total operating cost for the reactor; and third, the U.S. is actively developing an LEU target that can be used in the reactors.

By convening this meeting today, the Commission hopes to become more informed on whether this application in fact meets the conditions of the Schumer Amendment, whether any possible alternative courses of action including merits and weaknesses if those alternatives exist, and of course it wants to be informed of the views of all parties.

In our series of three panels, we will be hearing the views of the Applicant, the views of the Nuclear Control Institute, and the views of the U.S. Executive Branch.

The members of our first panel, already seated across from us, are Dr. Iain C. Trevena, Senior Vice

President for Nuclear Medicine at MDS Nordion, and Dr. Jean Pierre Labrie, General Manager for Research and Isotope Reactor Business at Atomic Energy of Canada.

I welcome you and the others seated at the table this morning, and I neglected to mention that on the inimicality question the Commission feels that the criterion has been satisfied so our focus this morning does relate to the Schumer Amendment.

Unless my Commission colleagues have any opening comments they wish to make, I would invite you to begin your presentation. Thank you.

DR. LABRIE: Good morning, Madam Chair and members of the Commission. Thank you for the invitation to make a presentation on our export license application.

My name is Jean Pierre Labrie. I am the General Manager of AECL's research and isotope reactor business. I am here today with Mr. Grant Malkoske, at my extreme right, who is the Vice President of Engineering and Technology at MDS Nordion; Dr. Iain Trevena, who is the Senior Vice President of Nuclear Medicine at MDS Nordion; and to my left is Mr. Jim Glasgow, who is an attorney for Transnuclear, AECL Transnuclear being the applicant for AECL for this export license application; and Mr. John Matthews, also an attorney for Transnuclear and AECL.

Also in the audience we have Mr. Carl Hartill, who

is the First Secretary for the Energy Sector at the Canadian Embassy.

My responsibilities at AECL are to supply isotopes from our NRU reactor and to build and operate for MDS Nordion the two new MAPLE reactors and a new processing facility. MDS Nordion have contracted AECL to supply these isotopes from the NRU reactor and also to build and operate these facilities. I would like to see the first slide, please.

CHAIRMAN JACKSON: May we have the first slide, please?

DR. LABRIE: I'd like to have the second slide, please.

Thank you.

I also have some pictures which could help the Commissioners see more easily.

Thanks.

This picture shows a section of the Chalk River laboratories. In the background on the right is the NRX reactor, the red brick building, and this reactor is in a state of permanent shutdown. In the back, the other red brick building is the NRU reactor, which is currently operated to provide isotopes, and also to support our research program.

In the foreground is the MAPLE1 reactor. On the

left is the MAPLE2 reactor. And in the back is the new processing facility. These facilities, all the civil work is very advanced, we're past the 90 percent mark in terms of the civil construction of these facilities.

The next slide shows the inside -- a section of the inside of the new processing facility, and what this shows is one of the hot cells, which is all made of high-density concrete for shielding purposes.

So in terms of giving you an update on the project for the construction of these facilities, this project started in September of 1996. We had the approval of the environmental screening completed in April of 1997. We received the construction approval from the Atomic Energy Control Board in December of 1997. And we received the initial consideration of our operating license from the Atomic Energy Control Board in May of 1999. And we are preparing for receiving our operating license to start the commissioning of these facilities in August of 1999, after which we will be starting the commissioning of these facilities. So basically the buildings are built. We are now preparing ourselves to start the commissioning phase of this project.

I will now turn over to Dr. Trevena, who will give you an overview of the MDS Nordion program in terms of isotope business.

DR. TREVENA: Thank you very much. Madam Chairman, Commissioners, it's a great pleasure for me to be here today to talk to you about our isotope business. What I'd like to do first is maybe look at slide number 3, please.

What I plan to do today is give you a brief overview of our isotope business. I'll talk a little bit about the MAPLE projects. MMIR is MDS Nordion Medical Isotope Reactor Project, and I will refer to it as a MAPLE project, because that's the one that's most commonly used.

I'll talk about our plans for the conversion to LEU targets, and at the end I'll briefly summarize elements of our cooperation with Argonne National Laboratories.

I'd like to move to the next slide, please.

What I'd like to do very briefly is to talk about our nuclear medicine. I won't dwell on this too much, but just to remind you that in the U.S. there's about 36,000 daily diagnostic procedures used with technetium-99m. Technetium-99m is derived from molybdenum-99m.

The key areas of nuclear medicine, as we see them today, are in cardiology and oncology. Cardiology, especially with respect to the emergency room, allows physicians to ensure the appropriate treatment for patients by giving a respective view of the disease state. Cardiology in terms of imaging during treatment of cancer,

so that the progression of the disease can be assessed and treatment can be assessed. So when a patient has metastases, by using a technetium product, you can actually see these metastases disappearing as the treatment -- either radiation treatment or chemotherapy -- progresses. So this is a key requirement for nuclear medicine in the United States and worldwide.

Next slide, please.

I'd like to touch on Nordion's role with respect to key medical isotopes. Nordion has found itself as the significant supplier in the world. We supply about 65 percent of the world's requirements for molybdenum-99, and that's used in diagnostic procedures that I talked about earlier. With iodine-131 we supply more than 90 percent. I don't have a good number, but essentially we supply most of the world's I-131. That's used in the treatment of thyroid cancer, and also more recently in the developing areas for products such as treatment of diseases such as non-Hodgkins lymphoma, which are labeled monoclonal antibody. Xenon-133 is mainly used for lung ventilation studies. Those three products are all derived from a molybdenum process, so the iodine-131 and xenon-133 in our MAPLE reactors will in fact be products that are produced along with the molybdenum.

Iodine-125 is a separate product that's key in our nuclear medicine business, and that has more recently been

finding development with the treatment of prostate cancer. For men it's much more preferable to have prostate cancer treated if it's caught early with radiation such as iodine-125, which is much preferable to surgery because the side effects are a lot less with respect to, for example, incontinence.

I'd like to move to the next slide, please.

I wanted to talk a little bit about the NRU reactor. As Chairman Jackson mentioned earlier, this reactor has been operating since 1957. It is an old reactor. We've been very fortunate that since we had the last major shutdown, there have been no major interruptions of supply with respect to the reactor going down. That is we have to say an unusual event for an old reactor.

As the reactor ages, there will be unplanned events with respect to shutdowns. There are also normally, when a reactor is operating, there are requirements for planned shutdowns, and if you look at other research reactors around the world, they will typically go down for periods of six weeks or more periods during the year in order to manage planned maintenance and also perhaps even unplanned events. AECL has managed through a very comprehensive maintenance program to manage all its maintenance in routine five-day shutdowns once a month, and what's that allowed us to do is ensure a continuous supply

of molybdenum without any interruptions.

I should just mention what continuous supply means to the customers in the United States, and I'll pick one of our customers who requires product to be delivered to them by ten o'clock every morning.

We finish our processes first thing in the morning. We then do our quality-control checks. The product goes on a charter aircraft and is delivered straight to the customer, where we've arranged emergency customs clearance; customs clearance is there just for this one plane. And then they take it on the truck, it goes to their quality control and it's in the process, and they have product going out to hospitals that night.

Why is that important? It's a major cost issue for these customers. The product decays at 1 percent per hour. So they want to get the product first thing in the morning for them, and we can't get it any earlier than that practically, so that they can get product moving out by the carriers to their customers so it's arriving in hospitals and pharmacies that night or the following morning for use. The way we manage our regular shutdowns -- in our reactor so that there's no possibility of reduction in supply.

I should also mention that our customers, especially the ones in the United States, expect that if we have a problem -- if they have a problem with respect to

something happening in their operation, they expect to be able to call us and get immediate response capability with respect to supply. So this is a business that just in time was invented for. This is the life we live on. We have to be responsive. We cannot allow for problems that are unexpected.

So again last major shutdown, the last major shutdown was in '91. Unfortunately this lasted 11 months. It was a simple what seemed to be from a chemist's perspective a pipe break in a water cooling system, but before the regulatory authorities were satisfied that all the work had been done to ensure that the reactor was safe to operate, this took 11 months.

CHAIRMAN JACKSON: So let me just ask this question. So the bottom line at a certain level is not that you have a predicted end point of the lifetime of this reactor, but rather that it's aging and you know or you have the concern that more and more problems may creep up as a consequence of the aging.

DR. TREVENA: That's right.

CHAIRMAN JACKSON: Is that a fair statement?

DR. TREVENA: That's our concern.

CHAIRMAN JACKSON: Okay.

DR. TREVENA: Something unexpected.

Just to touch on one final point, I should just

mention that with respect to NRU we have a storage tank that's used to contain our high-level fission waste. That storage tank will be filled by the end of the year 2000. And this is a highly regulated storage tank. It's not something that you can just build another one. And the Atomic Energy Control Board has indicated that they would not accept another tank. This was set up to be a temporary tank that's lasted a lot longer than the regulatory body has been comfortable with. So it will be filled by the end of the year 2000. So that's an issue for us. I think that will be mentioned in some of the documents.

COMMISSIONER McGAFFIGAN: Madam Chairman?

CHAIRMAN JACKSON: Please.

COMMISSIONER McGAFFIGAN: In 1991 how was moly-99 supplied to your customers when you were out for 11 months?

DR. TREVENA: Sorry. Thank you.

Fortunately at that time we had a backup reactor on the site, NRX reactor, so because AECL always had two reactors for us, when the NRU reactor went down, the NRX reactor went immediately into operation. And you'll see in a later slide we are now in an unfortunate position where we don't have a backup reactor to NRU. So that makes the industry especially nervous.

The next slide, please.

Slide number 7, please.

I want to tell you a little bit about the history of how we came to our MAPLE reactor project. The industry was exceptionally worried about security of supply when the NRX reactor went down in '93. The DOE you are aware were involved in starting a program. But the industry didn't necessarily believe that that would be a final solution. We were actively talking getting assistance from the medical users -- not just our customers, but the physicians themselves. And that culminated in a meeting that we had in Chicago in 1995 in August where we met with the leaders of the nuclear medicine community. Again, the users, not the producers of product. And at that meeting there was an endorsement of the MAPLE project as defined today, which is for two new reactors and a processing facility. Why two new reactors? They wanted to have two reactors because that allowed for the possibility of one reactor was down there would be this backup reactor on site to be able to go into production.

In order to make this deal happen, we then entered into agreements, into contract with our customers for -- and this was a partnership type of a deal -- and what we asked our partners in the nuclear medicine industry to do is to help fund this project, for which we asked them to pay an extraordinary price increase. So we entered into contracts with them. The customers from their part wanted to make

sure that we delivered on our project. So all our contracts with our major customers in North America have requirements that if we don't deliver our project on the time lines that we said we would, they have the right to terminate the contract with us, which puts us at a little bit of a -- very much a disadvantage. But they felt very strongly that this would ensure that we delivered on time, because security of supply was an issue.

One other point is that I think it may be well known that as a result of a settlement of a legal action we had with the Canadian Government around the MAPLE project, we received an interest-free loan in order to go forward with this project. The terms of this loan are such that if we fail to meet the delivery deadlines with respect to the time when these reactors are operating, then that loan is immediately payable as a result of a default condition, and that would allow us to pay the $100 million immediately rather than over a period of time, as in the loan condition. So again there was a requirement that we would work with AECL to ensure that this problem was solved.

I'd like to look at the next slide, please.

As part of the requirement for the new project, what we needed to do --

CHAIRMAN JACKSON: Excuse me.

COMMISSIONER McGAFFIGAN: I'm sorry, but I saw

Senator Bingaman at our high-level waste hearing make a comment about a contract condition like this in a separate context. But would the -- if for some reason you weren't able to start up as a result of an NRC decision or whatever, would the Canadian Government bankrupt you guys to the tune of $100 million. I mean, Senator Bingaman asked would the State of Minnesota legislature shut down reactors prematurely and drive up the cost of electricity and didn't get much of an answer from a group, but, you know, sometimes these contract clauses are there, but they aren't really -- it's in no one's interest to execute them.

DR. TREVENA: Maybe I could ask my lawyer to talk to that, David Nicholds. I can't comment on what the Government might do. It certainly would -- we don't have $100 million to be able to pay that money.

MR. NICHOLDS: Perhaps I could respond then. These agreements, to say that there was extensive negotiations is a huge understatement. And one of the things obviously that we were concerned about was the potential for force majeure in preventing us from going ahead, which for instance an NRC decision would qualify for. In the circumstances with the Government, they didn't really see the value in that argument and determined that whatever happened, because of the special situation, they expected to get all of their money back immediately and with interest.

We had to put in place in fact a mechanism to make sure that that would happen if we were unable to deliver. So that if we don't irradiate targets by December of '99, that's what happens.

COMMISSIONER McGAFFIGAN: There is no force majeure clause.

MR. NICHOLDS: There is a force majeure, but it doesn't cover this.

CHAIRMAN JACKSON: Thank you.

DR. TREVENA: Thank you, David.

So just to recap, MAPLE1 we expect to start up, that reactor would become active in the fall of '99, and MAPLE2 about May of the year 2000.

I'd like to talk about slide number 8, the processing facility. In order to carry out processing for our product from the new MAPLE reactor, we couldn't do it in the existing processing facility because it's not designed for that. The new targets that the AECL designed we're going to require some specific mechanisms to be able to declad and handle the targets, make the iodine and make the iodine-131 and the xenon-133 into the bank of hot cells for that purpose. What AECL has right now for doing moly out of NRU is a single hot cell and ancillary equipment for doing other work, and iodine-131 happens to be made in a different way, which we will not be able to do in MAPLE because the

flux won't be high enough. It's made by an in gamma radiation.

The key thing from AECL's perspective, from Nordion's perspective, and from the perspective of the Atomic Energy Control Board, is that the new processing facility will be able to handle the waste in line. So rather than having the high-level liquid waste going into a storage tank for future disposal and dealing with, the high-level liquid waste will be put into a tank underneath the hot cell bank and then after a period of decay time it comes up into a hot cell where this particular waste is evaporated to dryness and then can be put into a capsule for final disposal. And AECL has on their site licensed concrete containers that have been licensed for this waste disposal so all the waste is handled in a nice, orderly way.

The capital cost for this project was estimated to be about $140 million, mainly because of regulatory issues. This is now rising to about $160 million of capital for us, and that since 1996 there was money spent before '96 on this project, but that hasn't been accounted for. We were just counting the money from our new contract going forward.

COMMISSIONER MERRIFIELD: Just by way of clarification, is that -- are those Canadian or American dollars?

DR. TREVENA: They are Canadian dollars. The

small dollars.

COMMISSIONER MERRIFIELD: That's what, 70 cents to the dollar?

DR. TREVENA: They're still big for us.

COMMISSIONER McGAFFIGAN: Well, I understand.

MR. MALKOSKE: Thereabouts.

COMMISSIONER MERRIFIELD: Thereabouts?

DR. TREVENA: I'd like now to move to slide number 9 and talk about HEU as target material. So why did we move to a HEU target? We were faced in '95-'96, and we talked to our customers with a time issue, they were looking for security of supply to be addressed in the fastest way possible. We looked at an HEU target as being something that we knew how to handle. We knew what the results were likely going to be. We knew that when we went to the FDA to explain what our new process would be, we would certainly be using a new reactor, which would be an issue for them. We also knew that the process chemistry would be almost the same -- not exactly the same, but almost the same. And, most importantly, the starting material would be the same, so the impurity level, the impurity profile would be similar. And that's important to the FDA. The concern for us of course was transuranics which you'd get with a lower enriched uranium.

The key thing from our perspective is that we felt

that if we moved to the use of some other target material it's going to put our project in jeopardy. Just to give you an idea, we of course have had to staff up in anticipation of starting this MAPLE project, so we have people that are on board. The run rate for us for every month that we're late in this project is $600,000 a month. That's money that's out of our pockets. So, you know, time is important to us, and together with AECL we're watching the time line very carefully.

Move to the next slide, please.

COMMISSIONER MERRIFIELD: I --

DR. TREVENA: Yes, sorry.

COMMISSIONER MERRIFIELD: By way of clarification, the hearing, the meeting that we are having today is focusing on the issue of HEU and LEU as it relates to the American-Canadian exchange. Has there been any investigation on your part of attempting to obtain HEU from sources other than the United States?

DR. TREVENA: No, we haven't. We have assumed -- oh, well, I shouldn't say -- Nordion has assumed the U.S. would have an interest in HEU shipments even outside the U.S. so we have chosen to deal in a straightforward manner with the U.S. rather than, for example, going to some other source to get HEU.

COMMISSIONER MERRIFIELD: So, to put it bluntly,

all your eggs are in this basket?

DR. TREVENA: That's correct, yes.

COMMISSIONER MERRIFIELD: Thank you.

DR. TREVENA: At present, there is not an LEU target that is currently available. I just should mention that mention has been made of the Indonesians. Their work is certainly very encouraging, but you should remember that the Indonesians measure their moly production in terms of tens of curies per week. The Australians also use an LEU target. Their production capacity is about 200 curies per week. Nordion's current production is about 4,500 curies per week, so the scale is different.

There are two other companies that currently operate moly on our scale and they are in Holland -- Petten in Holland, and -- sorry, three -- Petten in Holland, IRE in Belgium, and AEC in South Africa, and they all use HEU targets.

So as we look at the issues regarding an LEU target, the one that we are faced with is a target mass that is five times the size and so as a first approximation we were looking at liquid waste that would be five times the volume, which was a significant issue for us, and that was the one we were looking to find how to solve.

The other issue of course is because it is a different starting material, the drug or regulatory approval

could be more complex. The FDA would likely ask for more testing in order to satisfy themselves that the product was suitable. Next slide, please.

I think to understand why the nuclear medicine community was so concerned in the '95-'96 time period, I think it is worthwhile looking at some history here. The reactors that are currently used in high level production are all 1965 vintage or earlier. They are research reactors, so they are subject to the vagaries of government funding and programs because they are run as well as other programs, and then there were the things that happened in North America that made people nervous -- the G.E. reactor, which is a good reactor for moly production, was shut down because it was found to be on a seismic fault. The Cintichem reactor was shut down 10 years later when they had a leak in their waste systems and it never started up again. The NRX reactor was shut down in 1993 essentially because of old age. AECL made an assessment that it was no longer safe to operate that reactor and closed it down. Next slide, please.

If we then look at how we address a conversion from an HEU to an LEU target, I'll deal with it from a reactor perspective and then I will deal with it from a processing perspective.

From a reactor perspective, one needs to find a

way to deal with five times the target mass, and AECL believe that their current design of target can be modified to do that. It is a cylindrical target where you would just do your magic geometry and end up with a target that is slightly thicker and it meets the objectives. You have to model that design and make sure it is safe with respect to doing your computer code calculations to make sure the cooling is adequate, and then we need to test that.

Testing that new target design could happen for example in the NRU reactor or it could happen in a reactor in the United States. It could also happen in our MAPLE reactor. We could also do the testing there.

Once the testing is completed, you have to go through a program of ramping up to full power with a full complement of targets, so it is the same kind of process that AECL is currently involved in now, and the Atomic Energy Control Board needs to be satisfied through the piece that things are appropriate.

From the perspective of the reactor itself, it doesn't matter to the reactor whether it sees an LEU target configuration or an HEU target configuration. There is nothing bad that can happen to the reactor by putting an HEU target in first and then an LEU target second. That's just straightforward.

What is important for Nordion to remember is that

in order to get licensing it was our plan throughout this process to have MAPLE 1 an MAPLE 2 go through a joint licensing process. That allows us economies with respect to regulatory cost. If we were to sort of put one reactor on hold, for a few years for example, and only use or put in MAPLE 1, then we would be going through a separate regulatory process which might in fact change, because regulatory processes do change and they don't necessarily make the hurdles any easier.

We also, of course, as I mentioned earlier, have contract obligations with respect to the Canadian government and our customers that are driving us to make sure that the commissioning of these reactors happens on a timely schedule.

COMMISSIONER McGAFFIGAN: Madam Chairman, could I clarify?

CHAIRMAN JACKSON: Please.

COMMISSIONER McGAFFIGAN: When your lawyer came to the microphone earlier, this lack of a force majeure clause applies not only to the December '99 date for MAPLE 1 but whatever it was, April 2000, date for MAPLE 2, so you have to hit both dates in order for this clause not to --

DR. TREVENA: That's correct with the customers, but I don't recall from the government. David?

MR. MATTHEWS: My understanding is that it is with

both. There is a requirement that once notified that the reactors are ready for acceptance testing. That testing has to be completed within nine months for both units and Unit 2 would be ready in the year 2000.

COMMISSIONER McGAFFIGAN: And so the $100 million immediate payment affects the second reactor as well as the first?

CHAIRMAN JACKSON: You can actually use the podium over there, so you don't have to jump up and down.

MR. NICHOLDS: I'm sorry, I missed a bit of that dialogue but perhaps on this issue -- I actually went out. I wanted to verify something in connection with the agreements and I have got to correct a statement that I made earlier, for which I apologize.

I thought I had all of the provisions with respect to these agreements, but when I checked back there was one other provision and basically with respect to the loan agreement with the government there is the possibility of avoiding the accelerated payment in the event of force majeure, so we are obligated to pay sort of in any event if we don't build, but we can pay it over a longer period of time, so I wanted to correct the previous statement that I made in that regard.

COMMISSIONER McGAFFIGAN: So a force majeure -- if, and I am not prejudging anything here, I am just trying

to get facts -- if there were an NRC problem, you would not be on -- the force majeure clause protects you against that?

MR. NICHOLDS: It protects us against that accelerated payment, as I read it, yes.

COMMISSIONER McGAFFIGAN: Okay. Thank you.

DR. TREVENA: It doesn't affect the customer contracts?

MR. NICHOLDS: No.

COMMISSIONER McGAFFIGAN: I understand.

DR. TREVENA: Thank you. I would like to look now at the other half of the conversion issue, which is the NPF, the processing issue.

CHAIRMAN JACKSON: Excuse me --

DR. TREVENA: Sorry.

COMMISSIONER MERRIFIELD: On the Slide Number 12, the last statement on there is there are no issues with having HEU targets in the reactor prior to the conversion.

In the testimony that we will be receiving from the Nuclear Control Institute, they raised the issue of cost. If you go ahead and use the HEU in the MAPLE reactors and subsequently convert to LEU that there is an increased cost associated with that interim use of HEU, so to speak.

I am wondering if you might address that issue.

DR. TREVENA: Why don't I address it from the reactor perspective, because that is a statement that they

made in one of their documents.

COMMISSIONER MERRIFIELD: Right.

DR. TREVENA: So if -- perhaps Jean Pierre Labrie could best answer that since I am not a reactor expert and I am liable to get my tongue twisted up.

COMMISSIONER MERRIFIELD: Okay.

DR. LABRIE: From the reactor perspective, conversion after we have started up with highly enriched uranium is not a problem. It is not a big cost increment other than having to relicense the reactor and having to do a lot of safety analyses to demonstrate that the reactor operates within the same safety envelope as with HEU targets.

The issue is really with the new processing facility and I am sort of getting ahead of Dr. Trevena's presentation. Where we solidify the processing waste, where we basically dissolve highly enriched uranium and move highly enriched uranium in solutions in various tanks -- this is where there is a problem because this new processing facility has been sized for highly enriched uranium. It is licensed for highly enriched uranium and as you know, you cannot mix a highly enriched uranium stream with a low enriched uranium stream in a very short timeframe without having first cleaned the system from highly enriched uranium to do your accountancy properly and then move into low

enriched uranium assuming there would be no design changes, which we believe there are significant design changes that are required for the new processing facility, but for the MAPLE reactor, there's no significant design change other than analyses.

COMMISSIONER DIAZ: I understand that. So from the reactor perspective, there is really very little that has to do with whether it's HEU or LEU and I think that's correct. It's afterwards. What prevents you from licensing the reactor for both HEU and LEU at the same time?

DR. LABRIE: There is nothing that would prevent us from doing that apart -- AECL is essentially under contract with MDS Nordion and if MDS Nordion would like us to undertake at this time the licensing of the MAPLE reactor for an LEU target, we will be very pleased to undertake that.

COMMISSIONER DIAZ: But does that seem to be an economical manner in which to proceed since you already have the reactor portion. I understand about the processing facilities being different. It doesn't seem like having dealt with both HEU and LEU that it would be a significant safety issue to license a reactor --

DR. LABRIE: We would have to undertake several critical, you know, CHF tests and various tests to demonstrate that the performance of the HEU target is within

the safety envelope of the LEU -- of an HEU target.

COMMISSIONER DIAZ: Correct.

CHAIRMAN JACKSON: Let me go back for a moment on the issue of drug regulatory approval.

The main issue there, the transuranic content, or other issues?

DR. TREVENA: Just to be clear, it is, and I do believe that the chemical processing will be able to get rid of the transuranics. But the fact that they're in a higher concentration than -- at the starting material than with HEU will give the FDA concern, and they will just -- they will -- and when you start off with a different starting material with the FDA, you go through a different approval process than if you don't change the starting material.

The FDA just looks at something from a very procedural perspective rather than necessarily always a science perspective.

I hope I didn't say anything negative there.

CHAIRMAN JACKSON: Well, you did, but it's okay. I mean, you have a right to make your statement.

But you do point out that in the processing that issue --

DR. TREVENA: Yes, it is an issue that we have to address. I think that's an issue that we can resolve. But it is an issue -- we have hurdles, but I see that hurdle as

being one that's resolvable.

COMMISSIONER McGAFFIGAN: Madam Chairman.

CHAIRMAN JACKSON: Please.

COMMISSIONER McGAFFIGAN: Has the FDA already approved the HEU material? I mean, do you already have -- for starting up in December of '99, do you already have FDA approval?

DR. TREVENA: No, we would need to do some processing first so that we need to --

COMMISSIONER McGAFFIGAN: So there's a period where you produce some material and prove that you're meeting specs --

DR. TREVENA: Yes, we need to -- the process requires us to modify our drug master file, provide product to customers, and the customers would then interact with the FDA, given the differences in our DMF, and they would, together with the FDA, decide what appropriate testing was required.

COMMISSIONER McGAFFIGAN: And how long does that process take typically?

DR. TREVENA: I am not sure there's a typical process. It could be six months. It could be a year. I would imagine that because this is an important product and this is -- we would get the FDA to look kindly on something to move forward in a relatively quick way. But we haven't

had that discussion with the FDA yet.

COMMISSIONER DICUS: Could I have a clarification now on this time line that you're on with your agreement with the Canadian Government. That is for the reactors to be operational. That's not to have the FDA approval.

DR. TREVENA: That's correct. That of course is our --

COMMISSIONER DICUS: That's going to be after the fact.

DR. TREVENA: Yes. The government just wanted to be sure that because they'd been labeled with somehow not doing their best for security of supply when we had the legal problem with the MAPLE project, that they had a way forward, would they be able to say that we've met our obligations to the world's nuclear medicine community.

So I'd like now to talk about conversion with respect to the slide number 13, the NPF. The new processing facility, when we first went into our project it was always on the critical path. That particular -- that building was being -- it was on a design and build process, because we didn't have time to design it before we started to build it. And that's added to our costs. But we knew that we had to drive for this time line.

I mentioned before the current -- the waste tanks that we currently have that we use for product. NRU will be

full at end of the year 2000. And I also mentioned that you can't process MAPLE targets in that single hot cell that we use. It's not set up to do that.

The civil construction you saw from the slide that Dr. Labrie showed earlier is virtually complete. The NPF construction itself is 60 percent. There's still some internal work going on.

Within the facility -- the facility was designed to optimize the use of space, and we have storage tanks in there that are used for the high-level liquid waste. I should just mention that the storage tanks are twice what they were in our original plan. In terms of how we --

COMMISSIONER McGAFFIGAN: Sorry. Is that as a result of interaction with the regulator, or this is just prudent planning, or what drove you to double the size?

DR. TREVENA: We looked at the heat content of the solutions, and as a result of that the AECL decided together with us that it was prudent to double the size of the tanks. And fortunately we had enough room in the building within the concrete to be able to do that.

So as we look at how to solve the chemistry problem, what we need to do is we need to find a way to process five times the amount of uranium while maintaining the same volume of solution. We also need to be able to process that more concentrated uranium solution in a way

that gives us the same purity profile, and the issue is that perhaps the separations may be slightly different as you change the uranium content, and you have higher-density solutions. And transuranics are an issue, and as I mentioned earlier, I think we can solve those.

Move to the next slide.

What I want to do very briefly here is take you through where we've been working with Argonne Labs.

We met with Argonne Labs for a first I would say good technical meeting on November 5. At that time we very quickly agreed that the way forward was to use a modified AECL target design, because that would lead to the fastest regulatory approval.

At that time also we said it looks like if we can solve the problem of the liquid volume, then we've got a way forward that looks like it's got no major hurdles to it. We were very pleased to hear from Argonne Labs at a high level, at a very high level, as they understood our process they believed that such a solution seemed feasible. So we were very encouraged. We met them again in January, and at that time we talked about an agreement, the way forward, what we would do with our -- with the scope of work.

And then move to the next slide.

Argonne came back very quickly with the scope of work, and we then needed to deal with the issue of a

confidentiality agreement. So we prepared a package of information for them, prepared a confidentiality agreement, one on one. By April Argonne felt that they wanted more of a three-way agreement, and there was more discussion.

And just go to slide 16.

And May 6 we had agreed to the right confidentiality agreement between ourselves and Argonne Labs that allowed us to move forward. We executed the agreement. We authorized AECL to submit the technical information, and Argonne had this technical information on May 20. They've had a chance to review that information. They have some questions for more information that they would like to get in order to satisfy their needs.

And that's where we are at this moment in time.

CHAIRMAN JACKSON: Okay. Thank you.

Commissioner Dicus.

COMMISSIONER DICUS: Yes. The NCI -- Nuclear Control Institute -- has a proposal suggesting that the NRC approve a one-year supply subject to annual renewals. Do you care to comment on that?

DR. TREVENA: This process is a very costly one for Nordion in terms of this kind of process to get approval every year. It also makes our customers very nervous, and they look at security of supply, and molybdenum is key for customers, HEU is currently key, so they're every year

wondering whether we're going to get cut off by supply. It makes people very nervous.

COMMISSIONER DICUS: Okay. Thank you.

CHAIRMAN JACKSON: Any other questions?

Commissioner Diaz.

COMMISSIONER DIAZ: On this issue of increasing costs from all the possible difficulties, I assume your costs are passed on to the patient.

DR. TREVENA: That would be nice. The way --

COMMISSIONER DIAZ: Not true?

DR. TREVENA: I should explain what happens. With our MAPLE project we estimated some costs. We sat down with our customers, shared with them at a high level why we wanted to do what we wanted to do and why we thought a certain price increase was appropriate. Some of our customers did their own modeling to make sure that we weren't cheating them and were only charging them the appropriate increase. We had contracts with the customers. The customers didn't want to be blind-sided with us coming up with future cost increases. And so we entered into long-term agreements with a pricing formula that was set over a ten-year period. So we have no obligation to -- we have no opportunity to increase prices to our customers through the year 2006.

CHAIRMAN JACKSON: Okay. Thank you.

Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: I have the Schumer amendment in front of me, and I'm going to read a definition that's I think crucial to this discussion that's in the Schumer amendment. A fuel or target can be used, in quotation marks, in a nuclear research or test reactor if (a) the fuel or target has been qualified by the reduced enrichment research and test reactor program of the Department of Energy and (b) use of the fuel or target will permit the large majority of ongoing and planned experiments and isotope production to be conducted in the reactor without a large increase in the total cost of operating the reactor.

Obviously (a) isn't true yet because you're working, you've just signed this confidentiality agreement with Argonne. But I want to explore (b) and try to understand your perspective about whether -- what the prospects are for this program now that it may be started. It meeting the definition of a fuel or target that can be used under subsection (b) of this definition.

Is there a prospect, given the difficulties you see on the processing side, that the result of this will be a process that could be conducted, quote, without a large increase in the total cost of operating the reactor? Is that a feasible outcome of the undertaking with Argonne?

DR. TREVENA: Well, first of all, maybe I should indicate that AECL and ourselves technically don't quite agree on this, so AECL believes, based on the work that they've done, that it's likely that an LEU target would increase the volumes of liquid waste that would be generated such that we would need to find another solution for liquid waste.

In our conversations with Argonne, they gave us reason to feel optimistic that we could conceive of a process whereby we would manage to maintain the volume of liquid. And we haven't really pursued in detail what the implications would be if that wasn't the case. But if in fact we can do it with the same volume, then I think we're in a process implementation phase.

We have to address the issues that Dr. Labrie mentioned about how do we move through a process that was HEU into LEU. There's an accountability issue there, but I would hope that if the right people sat down in a room from the IAEA and whatever and said how do we deal with this complex accountability issue, because we want to start moving HEU through tanks that have got HEU already in them. Will you let us do that? This is the process. Maybe the right minds can come up with a way that makes sense. It will be less tidy than accountability has been before.

If we have to go to additional storage tanks, that

might have to be done in a mechanism that we haven't defined yet. But I'm not looking to that for the solution. I would want to drive for a solution that maintained volumes. And I think it's possible. I think we just have to drive hard for that.

COMMISSIONER McGAFFIGAN: I might ask the AECL, you know, would this, if the AECL view proves right about the prospects for this research program, would AECL be of the view that they would not qualify for the subsection (b) definition of without a large increase in the total cost of operating the reactor?

DR. LABRIE: We, the program, we haven't seen any work coming out of the Argonne studies yet, and it is very difficult for me to comment on the outcome of work that is just starting. Probably what I'm trying to get to is that I don't think this could be done very quickly, over a very short time frame. It will take some time to resolve. And in the end I think once we have taken the time required to analyze the situation in more detail, look at the Argonne work, I think we can make an assessment then, that Nordion will be in a position to better assess the economic impact of a conversion.

COMMISSIONER McGAFFIGAN: The reason I'm exploring this is just that in some of the briefs that I've read leading up to this meeting there is a sort of a sense in

some of the briefs that the prospects are not particularly high for this to prove economical, and then there's some hints that it might, and I'm just -- what you're saying is this research program that has to be pursued and then we'll be able to determine whether the increase in operating cost is large or not.

DR. TREVENA: It's really a timing issue. When you think of some of the early correspondence that came out, we were believing that we'll have five times the amount of liquid waste. We can't get out of that issue.

Based on a very good November 5 conversation that we had with Argonne, Argonne led us to believe that, you know, you may be able to do this process with the same amount of liquid waste. Or maybe more -- this is me speaking -- but still able to handle it within the processing facility, recognize that we did double the tanks, so we have something there, but we haven't -- you need to do the work first to find out how you can do it, and, you know, yes, you know, it's possible that you might say well, you need to spend a large amount of money.

But, you know, from our perspective we're going to be looking for a commercially feasible way to do this. We're not going to say the highest-cost way is the best way. We're going to say well, let's try hard to find a solution that makes sense. We're in this business to make money. We

believe that moving to an LEU target is the right thing for us to do.

The thought of me and my colleagues coming here on a regular basis in order to continue our business is not something we frankly relish. We need to find a solution, but as Dr. Labrie said, we don't think that that can happen in a fast way. We need to get our reactors up and running with HEU, and then we need to plan an orderly move to LEU with Argonne's help.

COMMISSIONER McGAFFIGAN: What is the scale of the research effort, I mean, that you -- I see from the executive branch's brief that we're planning to spend something like $75,000 this year and something similar next year on this effort, which sounds like it barely pays travel costs, although Canada is very close. But what would really be required to -- is this a paperwork exercise where stuff is going to be --

DR. TREVENA: No, this is real work.

COMMISSIONER McGAFFIGAN: This is real work.

DR. TREVENA: This is real work -- the chemistry work -- I'm a chemist -- the chemistry work initially I think should be relatively straightforward to sort of say yes, it looks feasible, it looks like you can do the job, and this is the kind of volume increase you're looking at. But that's only to start. You're then dealing with the

whole regulatory issue, you're dealing with AECL finalizing a design for a new target, getting all the proper licensing and testing done, and then looking at the details of the chemistry to make sure that it works. And the thing that's going to hold you up the most is the whole licensing interaction with the Atomic Energy Control Board throughout the whole piece.

CHAIRMAN JACKSON: Does the issue not come down in the end to time and not money per se, because it's pay me now or pay me later?

I mean, if your intent actually is to do the conversion and you know that in fact by converting later you have introduced complexities into the process, technical complexities, which themselves have a cost attached, that the up-front cost of perhaps doing the dual licensing must not be the issue, it must really relate to the time line?

DR. TREVENA: It's the time line. We need to have product available from our new processes in the year 2000, and --

CHAIRMAN JACKSON: But in principle, unless there is a specific problem with the existing NRU reactor, which you presumably would keep operating until you had proven in the new reactor, and barring an unforeseen circumstance, you would still have your supply capability.

DR. TREVENA: Well, there's two things. First of

all, I think AECL has been very good at keeping NRU going, but that's -- for that reactor like that to be operating for eight years without a shutdown of more than five days is rather unusual.

And that is a continuing concern, frankly, for us as a --

CHAIRMAN JACKSON: No, I understand the point you are making, but that is kind of like the question of, if my birthday is today, am I 49, or am I 50 or 51? I mean, do I suddenly fall off the cliff because I have a birthday? Maybe I do, but I guess I am just trying to, you know, have some real understanding of crossover points here. Okay.

MR. MATTHEWS: Madame Chairman, there is a technical barrier and that is the waste tanks will be full at the end of the year 2000.

CHAIRMAN JACKSON: Okay. So that is the --

MR. MATTHEWS: The ACB will not license an increase in that capacity or an additional tank.

CHAIRMAN JACKSON: Okay.

DR. TREVENA: Thank you. I had forgotten.

CHAIRMAN JACKSON: Thank you.

Commissioner Merrifield.

COMMISSIONER MERRIFIELD: Two questions. The first one is I was wondering if you could walk through for me and clarify the issue of who picks up the relative costs

from switching from HEU to LEU. Obviously, some of this is going to be borne by Argonne in the United States in terms of developing the targets. But in terms of the equipment or process modifications that would have to be made to the reactor, are those costs that would be borne by yourselves, or is that a cost that you would get something back from the United States?

DR. TREVENA: To be clear, any work that has to be done with respect to capital costs, new modification of facilities, would be MDS Nordion's cost expense. And that, as we looked at that issue, we would be looking at the commercial viability issue.

With respect to all the development costs, that is an issue that we would like Argonne to be able to address. And we have had discussions with Argonne about how this would work and we haven't come to a resolution on that yet.

COMMISSIONER MERRIFIELD: So that remains to be resolved. But you have committed as a company to paying the capital costs of modifications to the plant to switch from LEU -- from HEU to LEU.

DR. TREVENA: Yes. Should we be able to do it, and should it be the right thing for us to do? If the cost is too great for us to be able to manage, then we will be addressing the commercial viability issue. But it is not our intent to ask the U.S. government to pay for this cost,

that would be completing inappropriate, nor will the Canadian government pay for that.

COMMISSIONER MERRIFIELD: Right. Right. But that is a commitment that you are willing to make, --

DR. TREVENA: Yes.

COMMISSIONER MERRIFIELD: -- notwithstanding the fact that on the international market there are other sources of HEU that will be available.

I think -- I mean I am not trying to pin your down.

DR. TREVENA: Oh, no.

COMMISSIONER MERRIFIELD: What I am trying to demonstrate here is that there is an international market for HEU.

DR. TREVENA: Yes.

COMMISSIONER MERRIFIELD: And despite that, since that would likely be a less expensive method of dealing with this issue, you as a company have committed to the capital cost necessary to switch to LEU if that is feasible?

DR. TREVENA: We hadn't frankly considered the thought of going round somewhere else to get HEU. It was something that we thought was appropriate. As I mentioned before, we think that the U.S. is involved in HEU transactions throughout the world, and we want to look to HEU for as long as we need it from the U.S., because we

think that supply will be most reliable. And we believe that recognizing the benefit that we give to U.S. citizens with respect to the supply of nuclear medicine, we thought the U.S. would be motivated to make sure there was no interruption in supply.

COMMISSIONER DIAZ: Excuse me, if I can look back on Commissioner Merrifield. I thought you said that you have already increased the price --

DR. TREVENA: Yes.

COMMISSIONER DIAZ: -- of, you know, technetium or the moly, or, you know, whatever all the isotopes you sell, to take into account the cost of all these facilities. Do I understand that that includes the potential cost of changing to LEU that you already raised the price?

DR. TREVENA: No, we didn't anticipate that back in '96.

COMMISSIONER DIAZ: So that will be an added cost?

DR. TREVENA: That will be an added cost for us to bear.

COMMISSIONER DIAZ: For you to bear, not for the patient to bear?

DR. TREVENA: That's correct.

COMMISSIONER DIAZ: Okay. Thank you.

COMMISSIONER MERRIFIELD: The second question I want to ask, and just to point out, we have been looking at

the language today of the Schumer amendment or the heart of that language. The reason -- when that legislation was passed back in 1991, there was a series of findings that went along with that as well. I would read those of those.

"Congress finds the following: (1) Highly enriched uranium exported for civilian research purposes readily can be utilized to make nuclear weapons if diverted for such purposes or intercepted by terrorists. (2) It has been the stated policy of the United States since 1978 to reduce exports of highly enriched uranium to the maximum extent possible in order to reduce this risk." Referring back to Number 1.

Now, my understanding is that Canada is a signatory to the Non-proliferation Treaty. Are you aware of any indications on the part of the Canada to attempt to divert HEU for the purposes of developing weaponry?

DR. TREVENA: I believe that Canada's position on that is very clear, but I can't talk for the Canadian government, but that is just as a Canadian citizen.

COMMISSIONER MERRIFIELD: Right. My understanding is that Canada has no interest in --

DR. TREVENA: That's correct. Yeah.

COMMISSIONER MERRIFIELD: And do you have any understanding that Canada is any more dangerous as it relates to international terrorism than the United States?

DR. TREVENA: I don't believe it is, no.

COMMISSIONER MERRIFIELD: Okay. That was my understanding as well. Thank you.

MR. GLASGOW: May I just make a short interjection? Is that those do not seem to be difficult propositions to agree with. But the State Department for the Executive Branch has addressed this rather thoroughly in its submissions to the Commission and has noted the sterling character and nonproliferation credentials of the Canadian government. The United States has had cooperation in this area for more than 40 years and is on the verge of renewing that agreement for another 30 years.

CHAIRMAN JACKSON: Right. And I am sure that we are going to have an opportunity to hear from Mr. Stratford in this regard.

COMMISSIONER McGAFFIGAN: Madame Chairman, there is just one question that I meant to ask and didn't. On these contract clauses you have with the people you supply, that it would be subject to termination, I think was what the idea, -- given that you are the only supplier at the moment, that isn't a big deal, but is the fear that this private entity who is going to have to take over the Sandia reactor and start marketing, according to the Executive Branch, at some point when they are brought on, and it has the capability of meeting 100 percent of the U.S. market,

that there would then -- you would lose people?

DR. TREVENA: Yes.

COMMISSIONER McGAFFIGAN: I am trying to understand again whether the sanction is real, that you would lose people to that supplier at that point, this privatized entity that is using the Sandia reactors?

DR. TREVENA: The issue for us in Sandia. There is also an issue for -- there are other suppliers in the world.

COMMISSIONER McGAFFIGAN: Right.

DR. TREVENA: Our customers would look to us for a reliable supply. We think we do a good job. We do know that other people using facilities that are more government owned could in fact offer pricing that is maybe much more attractive than we do, because we made a commitment into the long-term for security of supply. So there might be periods were someone might, on an opportunistic basis, buy product from a lower cost supplier and then move back to us as the lower cost supplier, and it was no longer able to supply, for whatever reasons. The Sandia reactor starts up and then a government program changes for defense reasons and it has to close down.

COMMISSIONER McGAFFIGAN: But it is feasible to get -- I mean the other two major suppliers are in Holland and Belgium and it is feasible for moly-99 to be --

DR. TREVENA: Yes, in fact --

COMMISSIONER McGAFFIGAN: Despite the short half-life and everything?

DR. TREVENA: In fact, yes. In fact, one of the major producers of generators, Malinckrodt in the United States, gets its supply of -- all its supply of moly from Europe.

COMMISSIONER McGAFFIGAN: It does?

DR. TREVENA: Yes.

CHAIRMAN JACKSON: Okay. Are there further questions?

[No response.]

CHAIRMAN JACKSON: Thank you very much. We will now hear from the second panel comprising Mr. Paul Leventhal from the Nuclear Control Institute and Mr. Alan Kuperman, also from the Nuclear Control Institute.

MR. LEVENTHAL: Madam Chairman and members of the Commission, we appreciate very much that the Commission --

CHAIRMAN JACKSON: Could you move the microphone closer? Thank you.

MR. LEVENTHAL: I'm sorry. We appreciate very much that the Commission has chosen to hold the public meeting on this matter. I would like to introduce myself. I am Paul Leventhal, President of the Nuclear Control Institute. With me is Alan Kuperman, who is a Senior Policy

Analyst for NCI, has had the day-to-day responsibility for matters relating to RERTR with NCI for a number of years. During a Congressional interlude, Mr. Kuperman did assist then-Representative Schumer in developing the Schumer Amendment, so we would be pleased to discuss the intent of that during the course of our testimony.

I would like to begin by emphasizing the nonproliferation value and importance of this matter and in our view the question of commerce in HEU and now with particular respect to the use of HEU in targets it is a non proliferation issue that transcends Canada and goes to the question of whether the Commission through its action in this case may be setting the stage for continued and increasing use of highly enriched uranium worldwide for production of medical radioisotopes.

Commerce today is somewhere between, say, around 50 kilograms a year projected to probably increase to 100 kilograms a year if HEU targets continue to be used. This is in our view a test case, a precedent-setting case, because as you know HEU is one of the two principal nuclear weapon materials of proliferation concern. The Schumer Amendment and U.S. policy are intended to seek, if possible to eliminate, the commerce in this material, surely to reduce it to the fullest extent possible.

The RERTR program has been making great strides

with regard to influencing and helping foreign reactor operators as well as domestic research reactor operators in the United States to convert to high density LEU fuel when available. We believe it is important to maintain the same type of pressure, the same type of influence with regard to target material, particularly as medical radioisotopes come into increasing usage in the world.

In some respects, the RERTU program represents the best opportunity today for a nonproliferation success, if not nonproliferation success for the moment is defined as focusing on elimination of commerce in weapons-usable nuclear materials.

As you know, the plutonium question is laden with overbearing commercial interests. That makes it very difficult for the United States as a matter of policy to intervene effectively with some of our European and Japanese interlocutors for the purpose of abandoning the use of this material as a fuel -- it's something that NCI has been actively engaged in.

HEU is a better opportunity because there is less of it around, yet its significance cannot be underestimated. One has to only look at the situation in Iraq where two bombs' worth of HEU actually was in the process of being diverted for weapons purposes as the Gulf WAr was breaking out, and there were recent concerns about an equivalent

amount of material in Yugoslavia at a reactor outside of Belgrade during the recent Kosovo crisis, So we believe that HEU is important to the RERTR program, it's vital, and that this case is essential and precedent setting.

As we heard this morning from the first panel, the key issue in this case is no longer whether LEU targets can be used in the MAPLE reactors but only how this will be accomplished and when. The feasibility of conversion is now no longer in dispute, only the question of whether it could be done at an acceptable cost within the definition of the Schumer Amendment.

If the LEU targets cannot be achieved at an acceptable cost, then presumably the use of HEU is permissible under the Schumer Amendment, so we believe that the Commission has to look carefully at the facts as they are being presented to determine whether there is a viable alternative to the approach now being laid out by the Applicant.

Our concern is that the Applicant's commitment to convert at this stage is largely an exercise in rhetoric. We are concerned that the Applicant's actions seem intended to stretch out the conversion process and to make it as difficult and as closely as possible.

One example of difficulties that seem to be being imposed on the process is the insistence at this point in

time at least that the Canadian produced test targets be surely processed in the United States and possibly irradiated as well. Based on past submissions, the question of where the targets would be irradiated is still apparently an open question, and the Canadians appear to prefer that this be done in the United States. This will increase the cost of what otherwise might be routinely handled entirely in Canada.

There was also a question of whether the cost of upgrading the processing facility or developing an entirely new one for purposes of handling the LEU targets should be a cost that should be borne by the United States rather than by Canada. We did hear this morning from the representative of Nordion that they now regard this capital cost to be something that they should bear, but there were earlier submissions, both in the form of the Bengelsdorf affidavit to the last submission by Applicant, as well as minutes of a trip report between Argonne and Nordion that suggested that the question of the source of funds for the purpose of converting or modifying the new production facility to handle LEU targets was not yet clear, so we are very much focused on the question of the costs and who will assume them.

In our view, the costs of developing the targets should be a shared cost between the United States and

Canada. The cost of modifying the new production facility should be something that the Canadian side covers in its entirety. Our view is that if modifications are made to the new production facility prior to the facility becoming hot, that these costs probably can be held to no more than about one percent additional cost to the production of the final medical isotopes.

COMMISSIONER McGAFFIGAN: Can I clarify? Is that a capital cost? Are you saying it is going to cost a million dollars or whatever it is they had -- $140 or $160 was their number and it's $1.6 million extra?

MR. LEVENTHAL: Well, we have to look at the entire cost of producing the delivered medical isotopes and then estimate what the additional cost of modifying the new processing facility to handle LEU targets will be. Our estimate on that, Alan, is --

MR. KUPERMAN: The Administration's last submission to the Commission said that producing the moly is 5 percent of the total cost of delivering the medical isotope, so right there just producing the moly is only going to be five percent of the final cost, and then the question is what is the marginal increase on that five percent in order to convert to LEU and --

COMMISSIONER McGAFFIGAN: So you are saying that is 20 percent?

MR. KUPERMAN: Probably less than -- so it is less than 20 percent of $140 million. That would be $28 million. It's certainly less than that.

COMMISSIONER McGAFFIGAN: Madam Chairman --

CHAIRMAN JACKSON: Please.

COMMISSIONER McGAFFIGAN: -- could I suggest that in order to have some interaction, if on factual matters there is a disagreement from the first panel that they be free to go to the microphone. Would that be okay?

CHAIRMAN JACKSON: As long as our lawyer doesn't have a problem with that.

MS. CYR: No.

CHAIRMAN JACKSON: Okay.

MR. LEVENTHAL: We hope that this hearing will serve the purpose of resolving differences in fact between the contending parties. We think it is important that the Commission get the facts as well established as possible in order to make its decision.

CHAIRMAN JACKSON: Is there a disagreement factually on this particular point?

MR. MATTHEWS: Madam Chairman, just two points.

I believe the Schumer Amendment is clear. It talks about a large percentage increase in the cost of operating the facility, so I think you are really looking at the MAPLE project itself, not the total cost of the medical

end product.

COMMISSIONER McGAFFIGAN: Right.

MR. MATTHEWS: I think that is like suggesting that when you look at the impact on the price of an operating reactor you look at the retail price of electricity when you are doing a percentage and I don't think that is reasonable and I don't think that is a correct legal interpretation of the Schumer Amendment. Obviously that is something for the Commission to decide.

With respect to the costs of modifications, I don't believe that our client is certain what the costs would be to modify. We don't yet have an LEU target. We don't yet have a process that has been developed so we fail to understand the basis for making any estimate of the cost at this time. If NCI could explain the basis of their numbers we would be happy to listen to them.

COMMISSIONER McGAFFIGAN: Madam Chairman, back to this panel. It is, the text of the Schumer Amendment, is without a large increase in the total cost of operating the reactor, so I think that is -- the focus has to be on that. I think the Executive Branch answer to Question 2 that we have in front of us does say that it is only 5 percent of the total cost of the pharmaceutical product, but that is -- you know, these guys don't get 5 percent of the total cost. You know, it's sort of like saying the farmer gets milk to

Safeway. The farmer is getting very little of the $2.50 a gallon that I pay for skim milk.

MR. KUPERMAN: If I could address the legislative history of the Schumer Amendment, maybe we could examine what was meant by a large increase in cost. As you can imagine, following the legislation this was haggled out and there was a strong push to say, well, let's actually set a figure of 15 percent, because that had been the experience in consultations with Argonne National Laboratory that in previous conversions of reactors that significant was usually considered 15 percent, so we were going to say 15 percent, but then when someone said, well, what happens if someone comes along and says, well, it is going to be 16 percent? It's sort of the 49 or 50 question, and so we said let's try and be more flexible than that and use an adjective as opposed to a specific numeral.

COMMISSIONER McGAFFIGAN: But there is some evidence in the legislative history that large is something greater than approximately 15 percent?

MR. KUPERMAN: You could also look at the experience that Argonne has had with other -- in the next panel you could ask Argonne what they have used generally because this has been their standard even before the Schumer Amendment.

MR. GLASGOW: Madam Chairman, may I respond very

briefly to this, since we are speaking of legislative history? I have to point out that the legislative history that Mr. Kuperman mentions is not in fact in any published proceedings of the Congress. I have here the Congressional Daily Report. If the Congress had wanted to establish a percentage limit, it could have done so. It obviously did not do so. It is important to keep in mind also the diplomatic notes which constitute law of the United States and which establish no quantitative limitation and which clearly contemplate flexibility in this regard.

CHAIRMAN JACKSON: Thank you. Commissioner Merrifield?

COMMISSIONER MERRIFIELD: Yes, if I can -- I would be interested in seeing if you have some submissions that you would call the record of this. I mean I have a copy of the House report which merely refers to Section 203 as placing restrictions on the export of highly enriched uranium and the remaining basis for the most part is a statement by Congressman Schumer articulating his pleasure with the fact that his provisions were adopted and saying some things, some issues about terrorism, but I didn't -- I fail to read in any of the -- and I may not have it all, but anything that I have in front of me that mentions any of the statistics you spoke of today.

MR. LEVENTHAL: If I could simply respond

generally to this recent discussion by noting that this helps to support our case that the cost issue is central here and that the feasibility, the ultimate feasibility in terms of commercial viability of conversion, very much depends upon the way conversion is carried out.

Our basic --

COMMISSIONER MERRIFIELD: I'm sorry, but I don't mean to interject, but there's a point here. There is an assertion made that in the legislative history there is references related to what that percentage -- you know, whether there is a percentage or not --

MR. KUPERMAN: No, no. We explicitly did not use a number percentage because we were afraid of this threshold issue, this 15-16 percent issue, but if you ask Argonne in the next panel what standard they have used, they will say also roughly about 15 percent. Anything more than that was considered to be an excessive burden.

COMMISSIONER MERRIFIELD: Just to be clear, there is nothing in the legislative history that you could point to that fleshes out Commissioner McGaffigan's question?

MR. KUPERMAN: I don't believe there is any number in the legislative history because we tried to avoid it.

COMMISSIONER MERRIFIELD: Okay. "We" -- were you one of the, did you assist in drafting that?

MR. KUPERMAN: Yes, I assisted in drafting the

legislation and the floor statement -- the only one, I think, that was --

COMMISSIONER MERRIFIELD: All right. Thank you.

MR. LEVENTHAL: If I could resume by making note of the fact that --

MR. KUPERMAN: Just to make it clear, I was Congressman Schumer's legislative director at the time.

COMMISSIONER MERRIFIELD: Okay, thank you.

MR. LEVENTHAL: -- that the cost of conversion is the central question, and our feeling is that the Commission should defer action until the U.S. and Canadian governments work out a mutually-agreeable cost-sharing plan, one that analyzes the relative -- the comparative cost of proceeding with HEU targets use in the NRU reactor and operating the new production facility with HEU on the one hand, compare that cost with a conversion process that would undertake the conversion of the new production facility before it goes hot.

I think that is the key consideration. Surely the testimony you heard earlier indicates that at that point in time Nordion will make a judgment as to whether the process they are being handed is commercially viable and our concern is that to proceed the way Applicant now wants to proceed will elevate costs to the extent that it could jeopardize the ultimate conversion to LEU targets, and that would not

be in keeping with the -- surely with the objective of the Schumer Amendment.

COMMISSIONER McGAFFIGAN: Madam Chairman, there is an issue that came up with the first panel that I hadn't fully grasped --

CHAIRMAN JACKSON: Can you speak more into the micro phone?

COMMISSIONER McGAFFIGAN: -- going over the materials, and I just want to see whether you question it.

There is this physical limit that they talk about at the NRU and our Canadian regulator will not give them further permission on the waste tanks, and so that reactor it sounds like runs out of its life at the end of 2000, and, you know, in their testimony today and the Bengelsdorf memo that you referred to earlier, affidavit, that there's lots of questions as to whether you could possibly pull off the conversion to LEU before the end of 2000. Do you dispute this?

MR. LEVENTHAL: Yes -- well, we surely ask the Commission to inquire independently of its regulatory interlocutor in Canada as to what the actual situation with NRU is, how desperate is the waste tank situation. Bear in mind that the NRU, according to Applicant's plan, is a standby reactor. Clearly they intend to operate it.

If something goes wrong with either or both of the

MAPLE reactors, they by their own plan they are not prepared to shut it down on an irrevocable basis. Is there a backup waste tank arrangement available if necessary? How full is full of the existing waste tank? Is there any wiggle room at all that would permit continued use of HEU targets in the NRU while the LEU targets are developed and tested and the new production facility modified to accommodate LEU as well as HEU targets?

In our view that is the gut issue before the Commission in order to determine whether you are really impelled to act as applicant asks. We think there needs to be some additional fact-gathering by the Commission.

I just wanted to --

MR. KUPERMAN: Could I just -- on that point, just two brief points. First of all, I just would remind the Commission that they approved last year an export of HEU for target material for the NRU, specifically so that the NRU could continue to produce isotopes in case there were any delay in the MAPLE reactor. So, presumably, there is some plan for accommodating extra waste at NRU if it is necessary for Nordion's commercial purposes.

And we would just argue that the same fallback solution be used if the MAPLE reactors are to be --

COMMISSIONER McGAFFIGAN: I was wondering when you would --

MR. KUPERMAN: For the reasons that we are pushing. And the second point I would put forward is simply that in the modified plan we presented in our prepared testimony today, we argue that the MAPLE reactors might even be able to start up with HEU targets, if the processing facility has undergone a feasibility study to see what modifications are necessary for LEU, and if those modifications, if any, are made prior to the start up of that facility. And in that case, a delay in the startup of MAPLE might be less than a year and might actually go in operation before this supposed drop-dead date of December 2000.

COMMISSIONER McGAFFIGAN: So, Madame Chairman, just to clarify, --

CHAIRMAN JACKSON: Yes.

COMMISSIONER McGAFFIGAN: You do that before getting all the regulatory approvals and from FDA and all that, you just get it in there, operate -- so you wouldn't have to -- you would still have to clean it out, but you wouldn't have to make physical modifications?

MR. KUPERMAN: That is the key. The key is --

COMMISSIONER McGAFFIGAN: That is your thought?

MR. KUPERMAN: The key, absolutely, is you do the feasibility study, you do the process chemistry questions, and the real key one, it seems to me, as in the last panel,

is -- what is the volume going to be of the solution?

We know that there is going to be a 500 percent of the mass, but is it possible that the volume will not be affected because you will be able to do it at a higher concentration? If you work that out, you make any modifications necessary before the new processing facility goes hot, then the transfer from HEU to LEU should be fairly smooth.

MR. LEVENTHAL: And it is our understanding that there is a difference of viewpoint between Argonne and AECL as to the feasibility of not having to increase the waste tank capacity of the new production facility to accommodate LEU. And I think that is a technical issue that the Commission would want to inquire into to get a better understanding of how likely it would be that the NPF, the new production facility, can be modified with minimal changes and minimal costs. In any event, the costs of modifying the NPF will be much less if these are done prior to the facility going hot than after the facility going hot. And this is a matter -- a special concern to us.

CHAIRMAN JACKSON: I thought I heard the two of you say two slightly different things. You seem to be speaking of actual modification to the facility beforehand. You seem to be speaking of a feasibility study.

MR. KUPERMAN: Well, no, a feasibility study to

determine if any modifications are necessary. It is possible that no modifications are necessary for LEU.

CHAIRMAN JACKSON: So your real position is that the feasibility study should be done and if modifications are necessary, they should be done before the facility --

MR. LEVENTHAL: Right.

MR. KUPERMAN: If I didn't say that, I misspoke.

MR. LEVENTHAL: And this should be nailed down before the Commission renders its final decision. What is lacking, frankly, members of the Commission, is the formal agreement that you anticipated and expected to have in hand by the time the next application for HEU came around. That was included in your decision in approving the last application for the additional HEU for NRU and the smaller amount of HEU the test targets.

This has not been fulfilled by the Executive Branch and I think you might wish to ask Executive Branch witnesses as to whether a formal agreement that lays out the cost-sharing arrangements so we know clearly who is going to pay for what, estimates the comparative costs of doing it one way versus another and who pays. I think this is all essential to meeting the Schumer standard, because if Canada is going to proceed in a way that makes the cost of ultimate conversion prohibitive, then you may indeed not have an active fuel development program that meets the Schumer

standard, and that itself could be a basis for denying the license.

Having said that, I wish to emphasize that we, the Nuclear Control Institute, are very sensitive to the need to ensure an uninterrupted supply of medical radioisotopes. But we do believe, if you consider the two options that we lay out in our testimony, that this will provide a much more likely path to success than the plan --

COMMISSIONER McGAFFIGAN: Madame Chairman --

CHAIRMAN JACKSON: Let him finish. Let him finish.

COMMISSIONER McGAFFIGAN: The reason, we are getting far from the --

CHAIRMAN JACKSON: No, no. Right. I understand. Let him finish his sentence.

MR. LEVENTHAL: It would help if I just try to get through the --

CHAIRMAN JACKSON: I mean he is the panel at the moment.

MR. LEVENTHAL: So we believe the -- we have two versions of our plan, and we think it is preferable in terms of reaching the desired outcome than either the Canadian plan or the alternative that the Commission asked us to comment on.

The Canadian plan is to shut down the NRU

promptly, to start up both MAPLE reactors and the NPF with HEU and then consider the cost of converting the NPF after the U.S. develops the LEU targets. And our view is that this invites long delays and prohibitive costs.

The alternative that you asked us to comment on was to start up one of the MAPLE reactors with HEU targets but hold the other in reserve until the LEU target development and the NPF modification are complete. We feel that this approach would still leave the situation with an unmodified NPF to operate with HEU and, thus, invite the potential prohibitive costs that we have discussed.

Our original plan was to continue isotope reduction with HEU targets in the NRU reactor and defer startup of the MAPLE reactors until LEU targets were developed and the NPF modified on a cold basis for LEU.

Our view is that should require two to five years and would have the effect of terminating HEU exports to Canada as soon as possible without interrupting the supply of medical isotopes. But the gut question is, is the NRU available for that length of time?

Now, assuming you find that it cannot be operated based on what the regulatory authorities in Canada tell you, for five years, then startup of the MAPLE reactors could be deferred with HEU targets until, and this is what we just previously discussed, the cold NPF if modified on the basis

of a feasibility study to handle LEU in addition to HEU targets. And feel this should require two years if there is full cooperation between Canadian and U.S. authorities, and this would keep costs down and expedite conversion of the MAPLEs to LEU.

MR. KUPERMAN: I would just say two years is probably an outside estimate. If, as I said earlier, it turns out that no modifications are necessary, then you could start up at the end of the feasibility study, and that should take less than a year.

MR. LEVENTHAL: So we would hope that you would at least explore vigorously the viability of these two alternatives in relation to the ultimate objective of the Schumer amendment which is to promote conversion at reasonable costs.

CHAIRMAN JACKSON: Let me let the gentleman here speak.

MR. MATTHEWS: I guess the point that I rose to was with respect to the NRU reactor and the export license granted to provide a backup supply of HEU for that reactor. As it turned out, that HEU was necessary, has been depleted and the expectation is that the HEU available under that export will have been exported to Canada and exhausted probably by the end of the year 2000, pretty much coinciding with about the time that the tank waste -- or the waste tank

will be full.

Secondly, with respect to --

CHAIRMAN JACKSON: But I think the point he was making with respect to the previous export license had to do with a condition that the Commission attached to its approval of that export.

MR. LEVENTHAL: Right.

CHAIRMAN JACKSON: Not the issue of when the HEU would be exhausted.

MR. MATTHEWS: Well, the issue is the availability of the NRU to continue to produce medical isotopes under the current licenses. Under the current licenses it will not be available beyond the year 2000.

CHAIRMAN JACKSON: I agree, but I am speaking to a different point here. But your second point.

MR. MATTHEWS: Secondly, with respect to the possibility of making modifications to the NPF, I believe the NCI concedes that that it is likely to take at least two, and I think it could take longer than that, because in order to do the feasibility study and assess what modifications will be necessary to the NPF, you will need to develop LEU targets and do testing in order to figure out how they are then going to be processed. And to think that that is going to occur, all of that, by the end of the year 2000, I think is somewhat unrealistic.

CHAIRMAN JACKSON: Yes.

MR. LEVENTHAL: Well, again, it is a question of the viability of the NRU and coming to some independent assessment of that. We don't want in any way to suggest that there should be a question as to HEU supply for the NRU reactor if it can be operated longer. Surely, the Commission could approve additional HEU exports for that purpose.

There was also a subsequent arrangement for transfer of recovered HEU from the U.K. to Canada that was also intended for the NRU reactors, so we don't think there is really any shortage of HEU for that purpose, nor would we support any kind of a holding back of HEU for the NRU if the NRU can be operated as the test bed, both the reactor and its processing facility. And the answer to that question depends upon the waste tank situation and how critical that really is, whether there is any wiggle room to extend the use of NRU and permit the conversion to HEU to proceed for the two MAPLE reactors and its associated processing facility.

I would like to close my prepared testimony by just reviewing the possible courses of action that the Commission should take and the additional information that it perhaps needs in order to come to a decision.

In terms of establishing facts I think it's

important to determine whether there is now an active LEU target development program for the MAPLE reactors at Argonne, and if not, why not. We heard earlier that AECL is still negotiating its confidentiality agreement with Argonne, and therefore presumably until that is completed, that first threshold for an active development program has not yet been met.

The second area, a fact that needs to be explored, is the status of the NRU as we discussed, how much longer can it actually operate.

The third area of fact that needs to be fleshed out is the comparative costs of irradiating and testing the LEU targets in Canada versus the United States, and is it possible to facilitate that being done in Canada, and a cost-sharing on that. Bear in mind that the hourly cost of scientists' time at AECL is $200 we understand, and at this point in time Canada is expecting that the full cost of developing the targets will be borne by the United States, and frankly that is unrealistic in terms of the costs that have to be covered, and it's also unprecedented in terms of the type of cooperation, the U.S. RERTR cooperation the U.S. has engaged in with other industrial states.

So we are concerned that Canada is piling on the costs on the U.S. side as well as escalating costs on its side to make ultimate conversion unfeasible pursuant to

Schumer. That may be the argument you will next hear. And also the comparative costs of converting the cold NPF with the hot NPF, which I think is the critical number.

In terms of course of action, if the NRU is operable for five more years, then we would recommend that you deny the license for export of the HEU targets to the MAPLE reactors but approve exports if needed for the NRU and try to get the job done at the NRU which is capable of getting the job done, testing the -- I'm sorry, irradiating the test targets, the post-irradiation analysis. This could be done on the Canadian side through the use of the NRU and its associated processing facility if it is available. Otherwise approve the export of HEU targets for the MAPLEs on a one-year-at-a-time basis, but not until the conversion of the cold NPF to handle LEU is completed so that it can handle both LEU and HEU targets.

Under this scenario, the NRU reactor and processing facility would continue to operate for we still hold the view no more than two years.

We do feel that you should deny the request for advanced approval of five years of HEU exports. Such an approval in our view would eliminate the incentive for full Canadian cooperation. It would undermine the incentive structure of the Schumer amendment and pave the way for perpetual exports of HEU to Canada and the attendant likely

failure to convince other reactor operators and isotope producers to switch to LEU.

This case does have important precedential value. If any HEU is to be exported, we feel annual approval should be made after verifying that Canadian cooperation continues sufficient to meet the Schumer requirement for an active target development program for the MAPLE reactors.

Now before I turn to Alan for any final remarks, I would just like to make one additional point, and I was interested and pleased to see that it was raised by the first panel of witnesses. Part and parcel of this case before you and the executive branch's handling of it should be the objective of establishing a level playing field for medical radioisotope production. In other words, it should be U.S. policy in carrying out the objectives of RERTR and the Schumer amendment to encourage other governments who have producers of radioisotopes to convert to LEU.

And there should be cooperation between the United States and those other governments so that Nordion is not confronted with a Mallinckrodt, which interestingly enough is a U.S. corporation that has gone offshore to produce radioisotopes, the Petten reactor in the Netherlands, with supply of HEU from the U.K. They do not have a Schumer hurdle to encounter, unless the U.S. Government encourages the British Government to try to pursue the same policies

that encourage the conversion to LEU. We understand there have been some productive talks between Mallinckrodt and Argonne, and perhaps Argonne is in a position to comment on this.

There are other governments that are watching this case closely. Indonesia, Argentina, Belgium, South Korea, and Australia are all now committed to one degree or another to begin the conversion process. The holdouts appear to be the European Union, which operates the Petten reactor in the Netherlands, and South Africa. So this is not an isolated case with trivial nonproliferation implications. We consider this to be a precedent-setting case with very important nonproliferation policy implications, and we hope very much that the Commission will consider this matter in that context.

I would just ask Alan if he wants to conclude.

MR. KUPERMAN: I'd like to make just a few points.

First, Commissioner Merrifield raised the question of is Canada a proliferation risk, and I'd like to state for the record that the Nuclear Control Institute does not find Canada to be a proliferation risk. In the same regard, we don't believe that the United States is a proliferation risk, and yet the Commission in 1986 ordered the conversion of all licensed U.S. research reactors from HEU fuel to LEU fuel. So that there is another concern here which is

subnational threat, and even though the U.S. has perhaps the best physical security in the world, the Commission still saw it in its wisdom to convert U.S. reactors to reduce and eventually eliminate domestic civilian commerce in HEU. So there is an analogous reason to try and reduce and eliminate HEU commerce to Canada.

The second point I'd like to make goes to Paul's final point, which is the real precedent-setting nature of this license application. And I brought a -- I had actually with me a viewgraph which was prepared for another presentation, but it's applicable to this, so if we could put that viewgraph up, Tom, the chart? Yes.

This is a chart of annual U.S. HEU exports over the years, and you'll see they peaked at almost three tons in the late sixties, declined to about 1-1/2 tons in 1977, the year before the RERTR program, declined steadily after that, and came to zero the year after passage of the Schumer amendment. The point of putting this viewgraph up is not that they need to --

COMMISSIONER DIAZ: Zero?

MR. KUPERMAN: Zero. Well, zero except for this small export to Canada and one export to Europe of fuel that was supposed to be defabricated and blended down to LEU.

So it's not zero. Nor do we think they have to stay at zero in the near term. There's nothing wrong with

exporting HEU in the near term so long as it's to be phased -- in order to facilitate the phasing out, to eventually going to zero. But the point is this is the largest export license application for HEU to be used as HEU since '92, that's seven years ago, and that is really why it's such a precedent and so important that the Commission handle this first test case of the Schumer amendment with the seriousness that it deserves and which the Commission has shown so far. And I think the concern that the Commission has raised and by holding this hearing has helped to push along the applicant, who six months ago and a year ago was saying, you know, we can't do LEU targets, and now is saying we can do LEU targets, it's just a matter of when, not if.

The third point I'd like to raise is that there's a model for how to do the sort of conditionality with an applicant. For example, right now the Petten reactor is requesting HEU exports from the United States, and the U.S. Government did not accept just an oral commitment that we will convert or even a paper commitment. The Petten reactor operator commissioned a feasibility study that was performed for it by AEA in the United Kingdom, and that feasibility study just came out and says yes, we can do this, it shows a path forward for conversion of the Petten reactor fuel, not the targets. And now Petten is coming to the U.S. and

saying you see, this can be done, this is how we're going to do it, and now we need HEU exports for the interim until we convert to LEU. That's what we're asking for essentially, that there be a feasibility study and any resulting modifications done on the front side, not the back side.

COMMISSIONER McGAFFIGAN: Can I clarify, does Petten intend to go to targets or just the fuel?

MR. KUPERMAN: At this point they've only done the feasibility study on the fuel, not the targets. But they don't get the target material from the U.S., although they may have to come to the U.S. if Dounreay stays shut down, in which case this issue will come before the Commission in the future.

I'd like to raise an additional point, which shows why we're so concerned about the new processing facility going hot before the feasibility study and any necessary modifications are made. It's not just the cost issue. The cost issue is significant, and I think it would be hard to argue that the costs wouldn't go up several fold if you have to modify a hot facility as opposed to a cold facility. But it's more than that.

In the affidavit that was submitted by the applicant, prepared by Forrest Remick and Hal Bengelsdorf, they say that if you have to convert the new processing facility after it's gone hot, that facility will be shut

down, quote unquote, for an extended time. That means that the supply of medical isotopes would be interrupted, because the applicant has said you can only build up a small surplus of medical isotope in order for a short shutdown, but you cannot build up a big enough surplus of medical isotope for, quote, shutting down for quote unquote for an extended time. That's why it's imperative if you actually are serious about converting to LEU targets that you do those modifications when the facility is cold, and not after it's hot.

MR. LEVENTHAL: But then you're utilizing the NRU facility in the interim.

MR. KUPERMAN: A few final points. We're gratified that the applicant has now said that they intend to fund the modifications in the new processing facility. There was a joint trip -- a trip report, a meeting report filed by both Argonne and Nordion as recently as January in which Nordion said that no funding sources have been identified. So that's a good change.

MR. LEVENTHAL: But again, just to interject, but that is conditional upon their finding that conversion is commercially viable, that it can be done on a commercially viable basis.

MR. KUPERMAN: Three final points. One is as to the applicant's contractual obligations to its customers to provide medical isotopes, presumably if it provides those

isotopes, the customer doesn't care whether they come from the NRU reactor or from the new MAPLE reactors. If that's not correct, we probably should hear from the applicant. But since the NRU is operating and in a recent publication, Canadian publication, was said to be ready to operate through the year 2005, that doesn't seem to be a problem.

Second, and finally the question has arisen what happens if the NRU conks out. And I think that's a very legitimate concern, because we support the use of medical isotopes, we support the import of medical isotopes from Canada. And what happens if the NRU conks out under the NCI plan or the NCI modified plan? Perhaps one option which should be considered is to keep the MAPLE reactors on standby, and if need be, and if the NRU for unforeseeable circumstances conks out, then start up the MAPLE reactors, if need be with HEU targets. Because we're not looking to interrupt the supply of medical isotopes to the medical community.

MR. LEVENTHAL: And of course the question there would be could the NRU processing facility be used to process those targets that would be irradiated on a contingency basis in the MAPLE reactors so that you wouldn't have to proceed to make the new production -- excuse me, the new processing facility associated with the MAPLE reactors radioactive before completing the conversion.

MR. KUPERMAN: But even if not, then just start up the new processing facility with HEU. As I say, if that's necessary to ensure the supply of medical isotopes, so be it. The fact of the matter, that's not the case today.

CHAIRMAN JACKSON: Let me make sure I understand the points you've made. You said that if one really is serious about the conversion, it would make sense, but yet not interrupt supply. That's what would drive decision making to do it before startup, because by having things irradiated, you claim that it de facto means for a longer shutdown, because it's hard to build up --

MR. KUPERMAN: I don't claim it; the applicant claims it in an affidavit it submitted.

CHAIRMAN JACKSON: All right.

Commissioner Dicus.

COMMISSIONER DICUS: Yes. I want to go back to the supply of medical isotopes to the U.S. To what extent or how important do you think the NRC should be concerned about that and consider that in our deliberations on this issue?

MR. LEVENTHAL: Well, we think it is a matter of concern, since the United States itself is at this point dependent upon Canadian supply, although alternative supply could be worked up presumably in contingency situations because of the existence of other suppliers.

On the other hand, we don't think Nordion should be put at a competitive disadvantage relative to the other suppliers because it is being asked to conform to a nonproliferation objective and policy while the other suppliers are not.

Which brings me back to the idea of working with the Executive Branch to try and establish a level playing field, but we do believe that the approach that we lay out can be done, can be accomplished in a way that will not interfere or arbitrarily cut off the supply of medical isotopes. In fact, we have concerns that the approach that applicant is presenting does, as Alan Kuperman pointed out, does invite the possibility that while the hot plant is in the process of being converted to LEU targets, that the supply of radioisotopes may well be interrupted. And I think that is something that the Commission would wish to further vet with both the applicant and with Argonne National Laboratory.

COMMISSIONER DICUS: Okay. One other question, please. We asked a series of questions, the NRC asked a series of questions, and in its responses to these questions, the Executive Branch provided figures for the money that has been budgeted for the development of the LEU targets.

Now, in your response to that same question, I

think you state that, and I am quoting here, "There is essentially no DOE funding for this purpose." Could you explain that?

MR. LEVENTHAL: No DOE funding that is being spent, because at that point in time the necessary confidentiality arrangements between the Canadian side and the U.S. side had not been worked out, and the necessary information that Argonne would need to proceed with an active development program was not yet in hand. So it is a difference between monies that are budgeted and monies that are spent, and our response went to the question of what was actually being spent to pursue an active development program for the conversion of the reactors in question, which is the test of the Schumer amendment.

COMMISSIONER DICUS: Okay. But you do agree the money is budgeted?

MR. LEVENTHAL: Some money is budgeted. Whether it is sufficient given the kinds of costs that the Canadian side is urging the U.S. side to take on, that is something that I think you have to further develop in fact-finding.

CHAIRMAN JACKSON: Commissioner Diaz.

MR. LEVENTHAL: Let me also point out that the Executive Branch views presented to the Commission last March, there was very curious wording, which we highlighted in our response, that they spoke generally of an active

target development program at Argonne. They did not suggest that there was an active target development program specifically for the reactors in question and we would point out that it is that test that is contained in the Schumer amendment and one that should be applied by the Commission. Is there an active target development program for the MAPLE reactors presently underway at Argonne? Our understanding is that there is not.

CHAIRMAN JACKSON: Thank you.

Commissioner Diaz.

COMMISSIONER DIAZ: Yes. Of course, I do appreciate the expertise that you bring to the table on these issues of proliferation or nonproliferation, whichever way you want to look at it. I am trying to focus on what we are trying to achieve rather than the means in which we achieved it. And I think that you are pretty right, that this is a precedent-setting case in the sense that this can be used as a way of achieving what the United States has as its policy for a long time, which is going to LEU at reasonable costs.

The question that comes to my mind is, it seems we are really probably better at achieving this with our Canadian neighbors if we get set on the right path than with anybody else, because of the relationships and all of the things that you seem to agree with when you nodded.

We are then laying out a success path, even if it, you know, means some compromise technically what it starts with, and if the program that DOE has, we will be able to lay out such a program that will lead to a success that can be used globally. Wouldn't that be probably a better solution than just haggling over whether we use this reactor or that reactor?

MR. LEVENTHAL: Well, I think what you need but do not yet have from the Executive Branch, as I indicated in my initial presentation, is the formal plan that you expected to have by the time the next application for HEU export came before you. You do not have that in hand. You have views from the Executive Branch, but what is lacking is a clear understanding reached between friendly governments as to how the costs will be shared, what the potential costs are doing it one way or the other, and how those costs are going to be met in a way that will allow LEU conversion to proceed in a way that does not require prohibitive costs that could undo the whole thing.

And I think it is possible for governments of Canada and the United States to work that out. They haven't worked it out, and I think the Commission would be acting prematurely on an application until such time as it has such a plan in hand and is in a position to evaluate it.

COMMISSIONER DIAZ: But you do agree that it

doesn't matter what the reactor's sequence is as long as there is plan, a success path to achieve what the United States government has been trying to achieve?

MR. LEVENTHAL: Yes.

MR. KUPERMAN: In principle, I agree with you. Unfortunately, there is a thing -- I am getting my Ph.D. in political science up at MIT, we call it path dependency, which is that once you go down a certain path, there are certain turns you can't make to get back onto the other path. And in this case, if you start up the new processing facility with HEU, make it hot and then the producer says, well, we can't shut it down to convert it to LEU because that will interrupt the supply of medical isotopes, then you have gone down the HEU path and you are on that path in perpetuity.

So I wish we didn't have to get into the nitty-gritty of which reactor should produce isotopes over the next two years. Should this facility start up before it is modified? Et cetera. But, in fact, because of path dependency, I think we do.

COMMISSIONER DIAZ: But as a technical, a pure technical issue.

MR. KUPERMAN: A pure technical issue.

MR. LEVENTHAL: And I would remind the Commission that the government of Canada committed back in 1990 when I

think the last major export of HEU to Canada prior to the one you passed on last year, they had committed to convert to LEU targets for the MAPLE reactor. And then we heard that by 1994 they felt that this would be technically infeasible because of an apparent misunderstanding of the waste management problem, that the five times additional amount of uranium would cause processing problems that were too risky and, therefore, they decided to continue down the HEU path rather than switch, as promised, to the LEU path.

Our belief is that all of this could have gotten started a lot earlier if there were a real commitment on the part -- on the Canadian side to find a solution.

We think it important, by the way, that AECL be compensated for the work that it does, but we believe that the Canadian government has to take some responsibility for compensating AECL. If AECL were assured that there would be due compensation forthcoming, the whole process might proceed forward on a much more cooperative basis. Perhaps you would want to explore a little bit into some of the internal considerations that appear thus far to have inhibited progress in completing the desired conversion program.

CHAIRMAN JACKSON: Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: First, just a couple of factual things. One of the suggestions made late in the

presentation was that perhaps the MAPLE reactors would be the standby should NRU fail. But how do you -- in order for them to really be standby, they would have to have FDA approval, they would have to have run some stuff through. They said earlier they would have to have -- send some product to American consumers who would interact with the FDA, et cetera. So there is -- the thing is hot, if it is really in --

MR. KUPERMAN: If the test -- the question is whether these test elements, these test targets would have to be processed in a new processing facility or not, or whether they could be processed in some sort of globe box.

MR. LEVENTHAL: In the NRU.

MR. KUPERMAN: Or in the NRU's facilities. I mean that is a technical question. In some facility other than the bulk processing new production facility.

MR. LEVENTHAL: In other words, it is conceivable that the new MAPLE reactors could be the contingency fallback in case the NRU reactor goes down, but we would assume that the processing facilities associated with the NRU were still available to process those targets in order to expedite FDA approval. So, in other words, it is sort of a hybrid approach.

COMMISSIONER McGAFFIGAN: I am just trying to understand --

MR. LEVENTHAL: Depend upon the NRU reactor as long as you can.

COMMISSIONER McGAFFIGAN: Right.

MR. LEVENTHAL: Have access to the NRU processing facility and maintain the MAPLE reactors as the contingency standby.

MR. KUPERMAN: Just to conclude, this is just one potential fallback. Another is to look to either IRE in Belgium or Malinckrodt in the Netherlands, or the South African.

COMMISSIONER McGAFFIGAN: I just want to explore this fallback.

MR. KUPERMAN: Just, there is a surge capacity in the case of a problem.

COMMISSIONER McGAFFIGAN: I just want to explore this fallback, though. I mean there's lots of fallbacks, there is Sandia, et cetera, I am going to get to that. But the particular fallback you were suggesting, I am just trying to figure -- it strikes me, as I explore it with you, that you do get -- you might, let's posit and they are going to say something in a second, that you could get the FDA approvals by doing in a glove box, doing at the existing facility and not get NPF hot. But you are allowing that we would have an HEU supply there, and we would allow them to go to volume which presumably would require the NPF at that

point. I mean I can't imagine if they are meeting the entire U.S. supply that it wouldn't be hot at that point.

Then if your theory is right about the path dependency, then we are on the HEU path forever -- I'm sorry, as a contingency.

MR. KUPERMAN: Yes.

COMMISSIONER McGAFFIGAN: So you are saying in order -- you would not mind -- I am just trying to -- you would not mind, in order to ensure the medical supply that Commissioner Dicus talked about, that we get ourselves in that position where, if NRU failed, there would be instantaneous -- the FDA approvals would be there. NPF at that point would go hot, even if it hadn't gotten whatever design modifications.

MR. KUPERMAN: No.

MR. LEVENTHAL: No, that is where we would draw the line.

MR. KUPERMAN: No, no, no. If, in fact, this is the only way to ensure the supply of medical isotopes, if you can't turn to an alternate producer, Malinckrodt or the Belgians and IRE, or someone who is new on the block at that point, and this is the only way to preserve the supply of medical isotopes, then so be it. Go ahead. Use HEU targets and process them in the new processing facility if that is the only place they can be processed, and get on this HEU

path. If that is the price of continuing the supply of medical isotopes, it is the lesser evil.

MR. LEVENTHAL: But I would again raise the distinction between the use of the MAPLE reactors and the use of the MAPLE new processing facility. The NRU processing facility today is meeting the demand, the North American demand for moly-99 and its decay product, technetium. I could envision a situation where you have the MAPLE reactors on a contingency standby basis but that the targets that would be irradiated in them would be processed in the NRU plant if that were feasible.

There is a question of fact here as to how long the NRU processing facility is available because of a supposedly filled waste tank or a waste tank that is going to be filled by the end of the year 2000, and, again, we think you should independently establish that situation.

But we just want to emphasize that the key here in terms of holding down costs is converting the new processing facility before it goes hot, and if that can be achieved, it should be because it will make ultimate conversion all the more feasible.

COMMISSIONER McGAFFIGAN: Do you want to --

DR. TREVENA: Just to correct a point of fact with respect to FDA approval, FDA approval is facility-dependent. If we have our product processed in some other way as yet

undefined, then it is not approvable for processing in the NPF, you have to do it all over again. So that what you need to do is you need to define a facility, that is the facility plan that I talked about, and then you need to carry out the work in that facility plan as defined, exactly. If a producer wants to use a different facility, the approval has to be redone.

MR. LEVENTHAL: But the different facility is the one that you are now using, the NRU processing facility. So would you encounter FDA problems with that if you were using targets irradiated in the MAPLE reactors, but targets that continue to be processed in the NRU facility?

DR. TREVENA: I don't want to engage in debate, but just so we understand two things, first of all, if you get FDA approval, it is facility-dependent. If you were to get FDA approval in the NRU reactor, for example, using an NRU process, that is a fine. If you use a MAPLE reactor, and you could use an NRU process facility, then that could be approved, that you didn't have to use that all the time. The issue is the first tank that you require clarification on.

MR. LEVENTHAL: Okay.

CHAIRMAN JACKSON: We will ask the questions. Okay.

MR. LEVENTHAL: I'm sorry.

COMMISSIONER McGAFFIGAN: Let me just ask a couple of more questions. The confidentiality arrangement, implied in your statement, Mr. Leventhal, was that you don't think everything is there yet. I mean they mention the MDS Nordion, there is a previous AECL, Argonne. What in the way of confidentiality, as of May 18th, what further do you see necessary?

MR. LEVENTHAL: I thought the viewgraph indicated that while Nordion had concluded its confidentiality agreement, AECL had not -- both? It could be a point of clarification on that. Are all confidentiality agreements concluded so that the active development program can begin?

COMMISSIONER McGAFFIGAN: My impression was that they all were completed at this point, and that is just a factual matter. Maybe the Executive Branch can clarify so as not to delay thins.

Argonne funding, Commissioner Dicus referred to it. There is a figure of $75,000 or whatever. In the best of circumstances, $75,000 does buy you very much. Should we be -- not we -- should the U.S. government be putting more resources if this such a critical case on which so much hangs? Should the U.S. government be allocating a larger portion of the $5.8 million or whatever is the number in the RERTR program for this purpose?

MR. LEVENTHAL: Well, I think the fair answer to

that question is that a formal plan should be worked out, costs should be assigned and then the ability of either side to meet those costs should be determined. If additional monies have to be appropriated for this, they should be. We would truly support it. But I think the Commission has the lever hand here in establishing what it wants to be worked out prior to approval of any transfer of HEU to Canada for this purpose. And I think consultations with the Executive Branch, consultations with the members of the appropriate Appropriations Committees would be necessary. 75K will not cover it.

MR. KUPERMAN: Just to put some meat on the bones and it is very hard to project in advance what the total cost would be. But you can look at what Argonne has gone with its previous target development work --

MR. LEVENTHAL: Indonesia.

MR. KUPERMAN: -- that has already been tested in the Indonesian reactor, exactly, program. And just ballparking it, order of magnitude, it has been approximately a million a year for approximately five years. All right. So the Canadian thing could be cheaper because you are working from an existing HEU target that you are modifying. It could be more expensive because it is an industrialized country and labor costs are more expensive. But ballparking it, you are talking about maybe 5 million,

and if you are going to do it over three to five years, you are talking somewhere in the range of a million a year. So 75,000 a year is not the right order of magnitude.

The second question is, who pays? And with industrialized countries, in the past, the country itself has paid. For example, the NRU core was converted in the early '80s. That fuel was developed in conjunction with Argonne, but Canada paid for the development of the fuel, first of all and, second of all, for the conversion of the NRU core.

So when I say it is maybe going to cost around 5 million, it is not as if the U.S. government should be appropriating 5 million.

And so far there has been no indication of any funds coming forth from the Canadian side, and if that be the case -- to help develop these targets -- if that's the case, if there is going to be no Canadian contribution, I dare say there's not going to be any active development program, in which case the Schumer amendment would require that you not permit this export.

COMMISSIONER McGAFFIGAN: Okay. The Sandia reactor just -- how troubling is it to you -- it falls outside the Schumer amendment, it's not licensed by us, it's an American reactor -- but how troubling is it to you that they -- you read the executive branch answers, they chose to

use the Cintichem process, the same expediency arguments for the 1995 record of decision that we're hearing today, and so when it starts up, if it starts up, this private-sector entity operates, it is not using LEU.

MR. LEVENTHAL: Well, that is an asymmetry that needs to be corrected, but my understanding is there have already been discussions between Argonne and Sandia for the purpose of working out arrangements for converting to LEU once Sandia masters the technology that they have acquired. So I think the ultimate objective is to, if the Sandia process works out, and I think that's still problematical, but if it does, I think the objective is to work out an LEU conversion program as well.

COMMISSIONER McGAFFIGAN: Why in that case do you not run into the same problems of once things are hot, they get to be expensive to convert?

MR. LEVENTHAL: Well, that's a good question, and I think perhaps you need to inquire of the executive branch witnesses how they are going to deal with that issue, because if the U.S. violates its own policy, so to speak, it makes it harder to pursue it on a credible basis globally.

COMMISSIONER McGAFFIGAN: And that gets to my final question. You both have been intimately involved in the congressional activity on this subject, obviously. Your bottom line in one of your statements today was the

executive branch should be seeking through multilateral negotiations or bilateral negotiations with multiple parties a level playing field.

MR. LEVENTHAL: Right.

COMMISSIONER McGAFFIGAN: Why has that not -- I mean, that's sort of implied in Schumer, but it isn't in Schumer. You know, you have a unilateral U.S. lever with this operating-cost loophole that we've spent so much time today talking about. But why has, to your knowledge, Congress not mandated the executive branch seek this multilateral arrangement, and I used to be up there, Commissioner Merrifield used to be up there, you know, notwithstanding any other provision of law, the funds for, you know, some program near and dear to the heart of the Secretary of Energy shall not be available after date x unless, you know, an effort has been made -- you know, you get some constitutional issues there. I can imagine the veto message. But if it's buried in a big bill, I've seen provisions like that become enacted.

MR. KUPERMAN: I'd just like to give three very quick points on that.

One --

CHAIRMAN JACKSON: And then we're going to move on.

MR. KUPERMAN: There has been a tradition on the

RERTR initiative that the U.S. has tried to push other countries first, and then done the same thing later. I don't think that's helpful, but that has been the pattern. The RERTR program was created in '78. The Commission only required the conversion of licensed reactors in '86. And the executive branch only started exploring the conversion of unlicensed reactors in the mid-nineties. So that's a pattern. That's not an explanation.

Secondly, the Mallinckrodt facility, as I explained, so far has had a closed loop of HEU in processing with the U.K. And so it's been harder for us to exert our leverage in that situation.

MR. LEVENTHAL: But I would add to that that the Schumer amendment does facilitate such an approach if the executive branch is willing to take it. And I hope you would speak to Mr. Stratford about this in the next panel. Why isn't this being done?

There are political costs whenever the U.S. pursues a nonproliferation initiative, and invariably there's a weighing by the State Department and other executive branch agencies as to whether the cost justifies the objective. And on that we -- the NCI and the executive branch often differ.

But if this policy is ultimately to succeed, it's going to require that kind of initiative, and we feel that

the Commission is in a position because of its licensing authority to help bring about such an outcome. In other words, expectations expressed to the executive branch that if we hold Nordion's feet to the fire, if we go by the Schumer standard as it applies to Canada, then we ought to make sure that the applicant is not being put at a competitive disadvantage because we are not diplomatically pursuing comparable policies with countries that have radioisotope producers within their authority. And in our view it's absolutely essential to pursue that level playing field to make this policy credible.

CHAIRMAN JACKSON: Thank you. I'm going to go to Commissioner Merrifield, and then we'll hear from this gentleman. And then we're going to pass on to the next panel.

COMMISSIONER MERRIFIELD: Two quick questions. Reviewing section 134(a)(2), again just to repeat, it says the proposed recipient of the uranium has provided assurances that whenever an alternative nuclear reactor fuel or target can be used in that reactor, it will use that alternative in lieu of the highly enriched uranium.

From a strict interpretation that reading is anticipatory, which I think we all understand. But in your testimony today you've asked for the applicant to do a lot of things, and it's sort of a higher standard to demonstrate

presumably, you know, what the word "assurances" means. I guess that's one of the things I'm trying to grapple with now. There is really no legislative history that goes to the issue of what the Congressman meant by "assurances." And assurances can mean an awful lot of things. You've pointed out some, and you have to demonstrate a certain financial capability, and so forth. Assurances can, you know, mean less. So I'm just wondering what you can point to to give us some direction relative to that issue.

MR. LEVENTHAL: Well, the assurances at this point in time, as we state in our testimony, are rhetorical. It is an expression of willingness on the part of the Canadians to convert once the targets are developed and proved feasible.

The trap in that is the cost factor, and if they proceed in a way that unnecessarily escalates costs, then they might seek protection under that provision of the Schumer amendment that says this has to be done effectively at a reasonable cost, not a large percentage of the total cost of operating the reactor. And we think it's incumbent upon the Commission to try to make sure that a path is being pursued that will have the desired ultimate outcome to fulfill the commitment.

But there are commitments now made, and they've been transmitted by the executive branch, and the executive

branch is satisfied that that aspect of the Schumer amendment is fulfilled. Our question is whether it's all going to be able to be accomplished at an acceptable cost, and if not, do you then face the likelihood of having to approve exports of HEU to Canada indefinitely.

COMMISSIONER MERRIFIELD: But doesn't in fact that provision require basically a good-faith demonstration? Isn't that really what that's --

MR. LEVENTHAL: That's what we feel, and the good-faith demonstration would be that it's going to be pursued in a way to ensure the successful outcome of the program.

COMMISSIONER MERRIFIELD: So your point is that the demonstration being made by the applicant was not in good faith?

MR. LEVENTHAL: We think that there are problems built in that may permit Nordion in the final analysis to say it's too expensive, we can't do it on a commercially viable basis, please send us more HEU. And I think it's incumbent upon the Commission to try to avoid that outcome by helping to guide the executive branch into a formulation and a planned course of action that will help to ensure a successful outcome. I don't want to in any way deprecate the motives of the applicant. I simply want to say that the actions that they propose raise the risk of the adverse

outcome, that it's too expensive to do.

MR. KUPERMAN: I would also just direct the Commissioner to review the statements in the position of the applicant on this question of conversion over the years. For several years the position was no, it's not really going to be possible to convert to LEU. At the same time, they were signing diplomatic notes saying that we are providing assurances that we will convert at the earliest possible time. There was certainly a disjoint there.

Now their rhetoric has changed to sort of match the commitment in the diplomatic notes, but our concern is exactly, you know, that the commitment be one that can be implemented. A commitment that cannot be implemented is hardly an assurance. And that is something for the Commission to determine.

COMMISSIONER MERRIFIELD: In the interest of time I'll withhold my final question.

CHAIRMAN JACKSON: Thank you.

Yes.

MR. MALKOSKE: Just a point of clarification on two items. The first is with regards to the confidentiality agreements with AECL. Those agreements are in fact in place, and it was pursuant to those agreements that they passed on the information to Argonne in May.

Secondly, with regards to the isotope supply

systems, I think it's important to look at them as systems. There is what I would call an NRU system, which is the NRU reactor, and the hot cell for processing molybdenum from the NRU reactor and the targets and all the chemistry involved around that. The second is the MAPLE supply system. And there in fact you have the two MAPLE reactors and the new processing facility which work in concert to have the equipment to declad the new targets and process them.

So the ability to take targets from NRU, transfer it to MAPLE to the new processing facility, or vice versa from the MAPLE to the NRU processing hot cell, is in fact not in place. They are completely two different methods of operation. So, you know, it's important as we evaluate all of these eventualities and possibilities to regard them as an operating system to supply medical isotopes to the nuclear medicine community.

Thank you.

CHAIRMAN JACKSON: Let me excuse this panel and have the executive branch representatives come forward.

Mr. Stratford and I understand there's someone here from the Argonne National Laboratory.

MR. LEVENTHAL: Thank you.

CHAIRMAN JACKSON: Thank you.

Okay. Commissioner Diaz has a comment to make.

COMMISSIONER DIAZ: Thank you, Madam Chairman.

In the interest of time I just wanted to say what a unique pleasure it is for me to see Dr. Travelli sitting in here. Dr. Travelli and I go back so many years that I don't care to recall, but it is a real pleasure to see such a distinguished scientist, a person that is so well known in the community for his reputation to come and testify.

Thank you.

CHAIRMAN JACKSON: Thank you.

Mr. Stratford.

MR. STRATFORD: Thank you, Madame Chairman and Commissioners. With me today on my far right is Ed Fei from the National Security NN side of DOE, who has responsibility for the RERTR program; on my far left is Tricia Dedik, who looks after the export control process for DOE; and also with me today, both from Argonne, is Dr. Travelli, as noted, and Jim Snelgrove.

I'm going to essentially rely on our ARGONNE folks to address many of the technical questions: the question of processing, the question of what it might cost, etc. And I'll try --

CHAIRMAN JACKSON: Let me interrupt you for a minute. I will, in fact, have to leave before I'm sure you're done, so I'm apologizing ahead of time. But for the record, I will make my decision on what is in the record. But because we took the time we did on the earlier part, I'm

not going to be able to, I'm sure, stay through the balance of your presentation. So, I apologize.

MR. STRATFORD: That's fine. And in the interest of time, I will not even begin to try to read the presentation that we sent to you. You all have copies of that. But, I do want to make a few key points.

Number one, the Executive Branch looked at this particular export very carefully and, in fact, there was an ongoing dialogue with the Government of Canada and Nordion, with respect to what made sense in this particular case. It was not a question of signing the two-page note in 1997 and then saying, well, that's sufficient; I guess it doesn't matter what happens now in the process. Because, it does. And I personally sat down with representatives from the Canadian government and from the applicant and Nordion and made clear that what we were looking forward to was a truly cooperative process, in terms of trying to get the MAPLE reactors converted to the use of LEU targets.

I'm going to skip over a lot of the business on physical security and the basic reasons why we think the Schumer Amendment has been met. And I think that the section in our testimony on pages three and four about some of the arguments of the intervenors, I think, in many respects, have already been covered.

One of the points that I really want to make

really begins on page five of the testimony, and we acknowledge that there is a common goal between the Executive Branch, NRC, Congress, and intervenors, which is to reduce and ultimately eliminate the use of HEU in civil nuclear commerce. But to make that happen, we need the voluntary cooperation of operators and isotope producers. And to a large extent, we think that that cooperation has been forthcoming.

But, if an isotope producer is going to be prepared to undertake the cost to move to LEU fuel in some cases, targets in others, then they're going to want to know that there's another side of the bargain and that is that HEU is going to be forthcoming while it's necessary. And I make the point personally that if I were operating a reactor, I'd want to know that that fuel was going to be coming forward on a reliable basis.

Now, one of the points I want to stress is when I say reliable and predictable basis in the testimony, that doesn't mean that the Commission should stand aside and not investigate what has happened, what they think is going to happen, and what are the facts in the situation. I think that's necessary. I, also, take the point that simply issuing a license for 130 kilograms that is good for five years may not be the best way to have a review process. But, I certainly wouldn't want to see a situation, in which

the license is broken down into five separate licenses, which requires five separate license applications and potentially a hearing or written submissions every time.

Maybe the thing to do, noting that this material goes in annual traunches anyway of 25 to 26 kilograms, is for the Executive Branch and the Commission to get together with Argonne in tow and perhaps once a year, before the next traunch goes, sit down and say, do we think that cooperation is ongoing the way it ought to be ongoing. That, to me, seems like a sensible process and we would be happy to come over and do that, perhaps even in a public forum like this one, where the public can hear why it is we think that things have only changed for the better and, therefore, why it ought to be okay for the next traunch to go.

We expect operators or producers to cooperate in good faith with the RERTR program. By the same token, when they are prepared to make that commitment, we, at the policy level, do not try to second guess every aspect of their program. We, also, take an independent look of where things stand and we discuss it with DOE, and DOE discusses it with Argonne.

But that having been said, there are certain business judgments at stake that we think need to be honored. Here, we're facing a situation where Canada believes that 43 years of reactor operation is getting to

the point where it's no longer predictable and it is time to move to a better system, and that is a new reactor plus a new reactor backup. And in our judgment, that makes sense.

What happens if there isn't a new reactor and something does go wrong with the NRU? If you look carefully at the Executive Branch submission, you will see the word "emergency" is used, if for some reason, any reason, Canadian supply is cut off. And what happens if an emergency happens? Well, obviously, number one, we try to find other suppliers around the world. And incongruously, we're going to be acquiring isotopes from other people, who use high enriched uranium, because, for some reason, the MAPLE reactors weren't available, perhaps because we weren't prepared to fuel them.

The other aspect of an emergency is we may have to move to the isotope production reactor that we are constructing at this time. And as was noted, is it going to use HEU targets? Yes, it is. Is that, to some extent, inconsistent with our policy? Yes, it is, because sometimes policies conflict and you sometimes have to take a common sense judgment about what it takes to get where you want to go. In this case, the process that we have is Cintichem. That requires HEU. And right now, if we have to fire up that reactor, it's going to be HEU, with a commitment that it will be converted to LEU when possible, and there are

discussions to that end. So, where would that leave us? In exactly the same situation we're facing today, which is a reactor that has to use HEU now and is prepared to make a commitment to go to LEU.

I point out on page seven of the testimony, and I think this is important, that there are three or four big LEU fuel reactors that for a long time were not prepared to convert. I have to say that in the last year or so, we are making significant process, in terms of getting commitments. Grenoble has given us a written commitment to move to LEU. In return, we gave a commitment to make our best efforts to support the licensing of HEU. And they said, well, the USG will promise us HEU. I said, no, independent licensing authority, sorry, we're just Executive Branch. But, we will promise to make best efforts to get the licenses out.

Now, however, in return for that, you have to understand that we're going to take a look at whether cooperation is ongoing and best efforts are being made on your part. And if you look carefully at the Grenoble notes, you'll see at the very end of it a section which says, oh, by the way, we retain a unilateral right to decide whether the cooperation is going well and if not, then we retain the right to pull the plug on exports.

What am I saying? I'm saying that we don't take a minimalist approach to meeting the Schumer Amendment. We

respect it. It is the law of the land. And whenever we talk to foreign governments, we make it clear that there has to be an ongoing cooperation program and that has to be cooperation in good faith.

I do point out at one point that if we're not going to supply or if we are going to try to direct someone else's program to a very large extent, like, gee, I know what you've been doing for umpteen years trying to get these MAPLE reactors on line, but why don't you just not bring them on line? Why don't you just go back and use the little reactor you've been using for 43 years? Well, eventually, someone is going to say, you know, maybe it really is time to turn to an alternate source of supply.

And I heard what the applicant and I understand why. Because, they're hopeful that the fact that we now have a cooperative program will lay the basis for an interim source of supply, until they can convert. But if supply is not going to be there or the price is too high, namely, why don't you just do a fundamental revision to your entire program, if I were the operator, I would look elsewhere.

Now, does that mean Russia? Not necessarily. That's not the only source of HEU in the world. It was noted here, for example, that the UK is a supplier for Malinckrodt. I have to tell you, in response to the question about trying to get others to convert, the essence

of the RERTR program has always been a voluntary effort; look, we want to try to convince you of the worth of this and since the Schumer Amendment, oh, by the way, you're not going to get anything from us, unless you're prepared to cooperate.

Not everybody is in that situation. We just came back from South Africa, for example, where one of the purposes of the South Africa trip was exactly what was raised, which is South Africa, you're operating on HEU -- your own HEU. Don't you think it would be a good idea to move to LEU in the Safari reactor and, frankly, we'd be prepared to help you technically to let you do that. Now, I have to say the response, unfortunately, was interestingly, but we'll take it on board. Because, if you have a reactor that operates and you have a very large supply of HEU for it, you're not likely to want to move on it. And that has been the situation for a long time in Europe, with respect to many of those large research reactors.

But now, we've got Grenoble on board. We're very close to getting Belgium on board. And we're very close to solving the Petten problem. But, getting those commitments will again be a two-sided bargain, and that means not fewer kgs over the next few years or so; it's going to mean more licenses, more kgs in the near term. Now, I thought I heard earlier that a spike in the graph would not be a bad thing

on a short-term basis, if the purpose of the spike is going to get you to zero. But the point I want to make is, is that because this is such a politically sensitive subject, one has to be prepared to grapple with the fact that there's very like to be more in the next two or three years, and that's because we've finally gotten to the point where we can get at the so-called "big ones," as I call it in my testimony.

Another point on the question of conflicting policy goals, which, of course, our own potential isotope producer raises. But, you know, we face conflicting policy goals all the time. For example, we don't particularly gotten to the use of mixed oxide fuel in this country. But, we've got to get rid of excess weapons, plutonium. And, therefore, we are prepared to pursue the two-track approach, using vitrification and geologic disposal and mixed oxide use. We have never been crazy about any mixture of the civilian and the military nuclear fuel cycle. But, if we have to have tritium, then we may have to bite the bullet and make the decision to utilize civilian reactors for part of the tritium supply process.

So, there's always conflicts. And sometimes the bottom line decision just has to be a common sense decision. What is it that is going to get us to move forward? And in our judgment here, it is allowing the Canadians to go

forward with the program that they have proposed, which gives them a new reactor, a new backup to a new reactor, which will produce at the same time, and allow them to use target material, which right now is what has to be used. It's what we would have to do, if we started up at the moment.

Bottom line, I think that's a common sense decision. Let me stop here.

COMMISSIONER DICUS: Okay, thank you, very much. Are the representatives from Argonne and from DOE going to make presentations?

MR. STRATFORD: Well, let me ask them if they'd like to throw something in, at this point. Armando?

MR. TRAVELLI: I have just a couple of comments about some of the presentations that already took place. Number one, there was several times the mention of Malinckrodt and Petten and whether there was any intention of converting their Malinckrodt production reactor, in addition to the fuel, for the reactor to go to this fuel. And just at this meeting, I met Mr. Roy Brown from Malinckrodt, who called me about two weeks ago, to indicate that indeed there was an intention of Malinckrodt to enter into a cooperation agreement and they told me this morning that we would be receiving soon a confidentiality agreement, after which some cooperation with Malinckrodt could begin.

Another point was about the confidentiality agreement with MDS Nordion and ACL. And here, Mr. Malkoske did mention that indeed a confidentiality agreement is now in place. But, that is not going to be the end. This was the second confidentiality agreement and this confidentiality agreement, when signed, will enable ACL and Nordion to transmit information to Argonne, to perform a feasibility study. But when the work will begin, it was pointed out to us that a new confidentiality agreement will need to be established, to cover the intellectual property rights that might be developed during the work that will be going in process.

And third, it was indicated that the information for the feasibility study was transmitted to Argonne. And, indeed, a transfer took place and there is useful information. But, not all the information that will be needed for the feasibility study is included in those documents. And Argonne has transmitted to MDS Nordion a series of questions that we hope will be answered soon, after which the feasibility study will be able to begin. And to -- also to point out what type of worker we visualize that lies ahead.

As MDS Nordion indicated, there was a meeting in January at Argonne between ACL, MDS Nordion, and Argonne. And at that meeting, it was agreed on a succession of faces

or steps. The first step would be a feasibility study that would probably essentially be a paper study, but to look into what were the meaningful issues and what could be done and what the probability of success were for different routes that could be taken. And this would be followed by a conceptual design phase and then by a refined define phase and then, finally, by an implementation phase. And each of these three successive phases will be preceded by a review, to see whether one had to go ahead or step back. And what we have budgeted for and what we had prepared to do, as soon as the information is received, is to enter into the feasibility study, after which a meaningful schedule and cost estimates can be made.

COMMISSIONER DICUS: Okay, thank you. I think that was very helpful. Did you want to add anything to --

MR. SNELGROVE: Yes, I'd like to speak to one issue, maybe just a little more generality. But, the Schumer Amendment talks about targets, specifically. That's the only word in there. But, in reality, it's the target and the process that goes together and one cannot do work on one without the other for any specific case. And as has been said earlier today, the FDA approval requires both the target, the reactor, the process -- all the pieces that are involved in producing the end product.

So that brings me to the point that I really want

to make, at this time, and that is where could the word be done; you know, what can we, at Argonne, and the U.S. do. One of our problems here in the U.S. is that we have no research reactors that are amenable, suitable to doing this type of work. We have a very high-powered research reactor with a very long duty cycle, but a 42-day radiation of a target just won't do it for targets that need to be radiated from one -- to at most, two weeks. So, we're very limited here in the U.S., in what we can do in the actual radiation of targets. That's why we have done really all of our radiation testing outside of the U.S., so far in Indonesia. But, we, also, now have agreements with the Australians, with Anstho, with the Argentines, the Commission -- Nuclear Engineering Commission there, to do similar work.

So what it really comes down to is we really have to have a close cooperation with our Canadian friends to make this thing work. We can't do it on our own, no matter how much money might be poured into it. Certainly the money that's available today is -- Armando said is sufficient to do the feasibility study. We don't know yet how much money we have next year, but we certainly will have money to carry on with some of the work. But, it will take a substantial amount of money, in the end, that's going to need to be spent, not just in the U.S., but somehow with Canada, and from that point of view goes to this issue of where does the

money come from. It's a very important one.

I just wanted you to understand that it's not just the target issue and it's not an issue that we can solve by ourselves.

COMMISSIONER DIAZ: I'm sorry, but I have an 11:30. I have like 20 people waiting. Sorry, I apologize. I have a couple of questions for you and I want to thank you.

COMMISSIONER DICUS: Okay, thank you. Did DOE want to provide any comments?

MR. FEI: Yes, I just have a very brief statement. I'm Ed Fei and our office supervises and supports the RERTR program. And my comment would just be that what we've been talking about today are basically the problems of success; that is when this administration came in, we increased the funding for RERTR R&D, to develop high density fuels. That research has succeeded and that has led to this wave of international cooperation. So what we're seeing with Canada is working out of a -- of the next step. So, we welcome this whole process and we think this is -- this is not a problem; this is -- because we've succeeded and because we're moving forward, we have a process, and that's what we see this as.

COMMISSIONER DICUS: Okay, thank you. Did you have anything to add?

MR. GOOREVICH: [Nods no.]

COMMISSIONER DICUS: Okay. I've got a couple of questions here for Dr. Travelli from Commissioner Diaz, if I can read his writing. About how long will it take to develop the LEU targets suitable for the MAPLE reactors, including the process for separation?

MR. TRAVELLI: That's a difficult question, because, as I was mentioning, the first step of the first phase would be a feasibility study, and we estimate that the feasibility study will take about three months. It's a rough estimate, because we don't know yet how difficult the problems will be; the main problem being how much solvent does one really need to dissolve five times more uranium, and this was mentioned several times during the presentations. And we will need the data that we still don't have. And then to do the work, to see really what the best solutions will be.

After that work is done, after the feasibility study it completed, it will be possible to make an estimate about how long the next phases will take. It may be very little; it may be as much as two, three years. We don't know really. And the same is true for the cost, unfortunately.

COMMISSIONER DICUS: Okay. And his second question is: would a conversion to LEU after startup shut

down the MAPLE reactors, if they started up with HEU?

MR. TRAVELLI: Could you repeat that?

COMMISSIONER DICUS: Okay. Would a conversion to an LEU target after startup of the -- after startup of the MAPLE reactors, would they have to shutdown if they started up with HEU to convert to LEU?

MR. TRAVELLI: Let me try to clarify one important point. The reactors are not affected significantly by what target you put in them. You could use the new MAPLE targets in the NRU or the old NRU targets in the MAPLE X, or HEU target. You know, they are naturally affected very little by what targets you put in it. As it was pointed out earlier, you do need to go through an approval process. You must make sure through the licenses requirements that the reactor would be able to stand it. But, one does not have change the reactors.

What is affected very strongly is the processing facility. And so converting to LEU later would not have any affect on the reactors. But, certainly, it would have a significant affect on the processing facility.

COMMISSIONER DICUS: Okay, thank you. Commissioner McGaffigan?

COMMISSIONER MCGAFFIGAN: Let me just ask Mr. Stratford and the others, the fundamental issue that I think NCI is bringing up has to do with what was called path

dependency earlier, the notion that once they go down this path, for better or for worse, that there may be no going back; that the Schumer Amendment language that defines "can be used" with this definition that includes a large increase in operating cost will fail, if we don't take advantage of the opportunity to make the changes in the new processing facility before it starts up. That's the heart of the argument.

So, maybe it's more for your Argonne colleagues, is there truth to that argument? Will it -- I mean, you've got some experiences with -- Mr. Leventhal said, with some of the other folks and you have this 15 percent number, which may or may not -- has no statutory basis, but may have some practical basis. What are the prospects of -- if this starts up, if we grant the license, that they'll be able to make the conversion -- as you said just a moment ago, the processing facility is the heart of it -- and be able to produce without a large increase in cost?

MR. TRAVELLI: I would be much more confident in answering the question if we had a feasibility study completed already. What I can say is certainly making modification in a plant, which has began operation already is much, much more expensive and difficult than doing it in a facility where no nuclear activity has been present before. If I were to estimate, maybe a factor of 10 times

greater; maybe more.

At the same time, maybe no modifications might be needed, if there is also the feasibility study are positive. And in that case, it wouldn't matter whether it is hot or whether it is cold. And at the same time, to decide on modifications before doing the feasibility study would be very difficult. One would have to assume, for instance, the worse in every avenue that one were to study in the feasibility study. Let's assume that one says, well, let's assume that we need five time solvent, and so by hook or by crook, modify the existing facility to accommodate five times the amount of liquid solvent. That might be much more expensive than what is needed.

COMMISSIONER MCGAFFIGAN: That's with a limited facility.

MR. TRAVELLI: So, it's a difficult question and I don't know really how to address it. There is a possibility that what Mr. Leventhal was saying might come true, that the changes in the processing facility are so serious that doing them after the facility is hot might make the cost prohibitive. I hope that that is not true.

COMMISSIONER MCGAFFIGAN: This is for Ambassador Stratford, the notion you tossed out earlier was having a -- you know, granting the license for the 130 kilograms and then for each 26 kilogram traunch, having discussion in

public about how things are going. And we'd have the feasibility study. We might even have the conceptual design phase. But -- but, you -- I think the NCI folks are fearful that you'll have -- depending on the results, you'll have a catch 22, at that point. And after the first year, after it's hot, if the feasibility study turns out the wrong way, it will -- the discussion will just be this path dependency has, in fact, arisen and we're likely to have to do HEU forever. I mean, so it doesn't -- do you have any opinion as to whether that notion you threw out actually works in the technical circumstances that we are confronted with here?

MR. STRATFORD: I think it's possible that if you start up the processing line, that you can have a situation, in which it is more expensive to handle the targets in the processing line. But, I, also, think that what we're trying to do is substitute our judgment for somebody else's judgment on what they need to do to make the production of isotopes secure for years to come. And I, also, think that those are good faith business and policy judgments. And if you second guess it, in a way that turns out to create a big problem, if NRU goes down, who's at fault that we lost 60 percent of our isotopes supplied to the U.S., them or us? That's not a risk I'd want to take.

So, yes, the answer is it could get complicated

and the argument could come back to haunt you. Well, the overall cost of production now is going to be very high. But, as someone pointed out earlier, and I think it was Mr. Kuperman, the statute says the overall cost of operating the reactor. I think what we've heard so far is that the overall cost of operating a reactor is not going to be much of an increase.

Now, that having been said, can Canada come back and say, yes, I know, but the overall cost of conversion is just so significant that I don't think I can do it? Now, at that point, do we think we have reached that stage through good faith judgments? Well, if the answer is we do, well, then, maybe HEU for some period will have to be supplied. If on the other hand we think we've been tied around a lamp post in ways that we shouldn't have been and bad faith was exercised, then under those circumstances, I can almost assuredly see us saying, well, you know, we've reached the judgment that maybe things didn't go the way they should have and, therefore, we're not going to send forward an Executive Branch letter on the next traunch. But, yes, there's two sides to that.

COMMISSIONER MCGAFFIGAN: But, then you get into the exact situation you just talked about, where we're putting at risk 60 percent of the supply and having these medical consequences then, as well as now, and I'm not sure

the same policy judgment wouldn't be made. You raise a very interesting question here I haven't even thought about, until you did, without a large percentage increase in the total cost of operating the reactor might not include the reactor plus its processing facility. I --

MR. STRATFORD: We haven't really had conversations about parsing the statute so carefully. And I think probably, at some point, we may have to have those conversations. But, right now, I'm not going to ask my lawyers to sit down and start engaging in speculation about 15 percent, 5 percent, 35 percent, and what exactly goes into the 15 percent calculation.

COMMISSIONER MCGAFFIGAN: It's the last part that matters, because, you know, I think everybody agrees the reactor is not the problem, it's the processing facility. And if there's any -- I mean, I'll get off of that, because I was construing it naively to include the total cost of operating facility, not simply the reactor. But, the feasibility study -- well, Madam Chairman?

COMMISSIONER DICUS: Okay, you want to go ahead and address the point he was making?

MR. MATTHEWS: Yes, just very quickly. If I could direct your attention to the diplomatic notes between Canada and the United States, in which the processing facilities are explicitly included in the commitment made by the

Government of Canada. The language is a large percentage increase in the reactor and processing facilities.

COMMISSIONER MCGAFFIGAN: So, that's already been interpreted by Executive Branch lawyers, in preparing these notes, that that was -- that that definition included that.

MR. MATTHEWS: Yes.

COMMISSIONER MCGAFFIGAN: Okay, thank you. Because -- so my naive -- my naive reaction was the right one. With --

COMMISSIONER MERRIFIELD: That's State Department experience you had, as well.

COMMISSIONER MCGAFFIGAN: They've got good lawyers over there, I guess.

The judgment as to how active the -- item three is: United States Government is actively developing an alternative nuclear fuel or target that can be used in that reactor. You're certifying that we will. I see, as I listened to Dr. Travelli and listened to the various phases and knowing that the Senate probably today -- or yesterday voted the Energy and Water Appropriation Bill for 2000, if there's a significant change that -- in funding for the U.S., and Dr. Snelgrove -- Mr. Snelgrove mentioned the fact that even money doesn't solve everything, because we need reactors in which to radiate things, this sounds like it's going to take several years to me.

MR. STRATFORD: Even the applicant says three to five.

COMMISSIONER MCGAFFIGAN: So, it's -- and is that Argonne's judgment, that given the appropriations process, given best faith by everyone, that it will take some significant period of time? Because, earlier today, it was suggested, and maybe this is the ultimate outcome of the feasibility study, that this can go so fast that you could within a year make whatever modifications were needed to accommodate LEU in the processing facility before it started up with HEU, thereby minimizing the cost down the road. Is that a feasible outcome?

MR. TRAVELLI: There is a difference between making modifications to a facility so that in the future, you could accommodate a change --

COMMISSIONER MCGAFFIGAN: Right.

MR. TRAVELLI: -- and starting a new process. For the new process, you would have to have everything optimized, having all the permissions, all the approvals needed to implement the actual change. It's a much more time consuming effort, than just saying, oh, I need to make a bigger door in this old cell, so that the bigger dissolver can be put in.

COMMISSIONER MCGAFFIGAN: Okay.

MR. TRAVELLI: But, this said, for the

implementation of a new process, I would tend to agree with the estimates that you mentioned. Maybe -- we tried to just guess about what timetable could come up from the feasibility study, and to do the various steps that I described earlier probably we would estimate that the minimum time would be around two years.

MR. SNELGROVE: Excuse me, may I?

COMMISSIONER DICUS: No, go ahead.

MR. SNELGROVE: May I add something to that?

COMMISSIONER DICUS: Yes.

MR. SNELGROVE: Again, we have to talk about the targets, because there -- one is going -- there are still significant questions about a modified target. Tests will actually have to be run, I think, before one can say if a modified target, as AECL suggested, will work. And when you get into radiation testing and so forth, it does take time. It will be hard to envision in less than a year-and-a-half having that kind of answer, if all the money and all the facilities and the will were there today. So, it will take a minimum of two years, but I think closer to the three to five years.

COMMISSIONER MCGAFFIGAN: So, you're testifying -- I just want to tie this down and then I'll quit -- that it really isn't feasible to know how to modify the process facility by, say, this time next year, before it goes hot;

that it's too much research -- feasibility study research that needs to be done, to know whether the door needs to be bigger or whatever? So, I'm trying to tie down whether that option is a feasible option or not.

MR. SNELGROVE: I would have to agree that it will be very difficult within a year from now to say that we know this will work. We can say we have high probability this will work. But, as I said, the target is an important part of it. And, again, I don't know how quickly one could get a new target radiated and tested, until we've had more conversations with the applicants.

COMMISSIONER MCGAFFIGAN: Just one last thing. The applicant presumably, and they're sitting here, is highly motivated not to go through this process too many times, as they said earlier. If the feasibility study -- if you get this confidentiality agreement, there's apparently another one that Dr. Travelli mentioned, if everything went swell the next few months and they could -- and you guys decided that, hey, it would be prudent now before it goes hot to make this modification, we're not there, it's going to take a couple more years, but why don't you make this modification now, because we think it will solve most of the problem and certainly decrease your cost down the road, that -- is that feasible in the next six months, and a motivated licensee or applicant would say, well, gosh, it's now

prudent financially for me to make this -- make a change without all the Is dotted, Ts crossed. I'm just trying to -- what information -- I'm trying to figure out what's possible.

MR. SNELGROVE: Well, it's exactly that point, I think, that I raised in the first meeting I had with our Canadian partners, saying that it would really be nice to do a feasibility study before the thing actually had to go hot, so that one could look at if anything needs to be done. It's hard to give a yes or not answer to your question, but I would say that within -- within six months, again assuming that we get the information that we need, the agreement to cooperate -- and I'm not talking about legal agreements, but agreements between parties fully --and we said we felt we could do the feasibility study, this initial one, within about three months, it would be possible within about a six-month period to at least have an initial idea, from the processing facility point of view, what might need to be done and what might -- you know, might be done before it went hot, to enable future modifications to be made.

If the facility is modular enough, it may be that one could just go in and take out one piece of equipment and put in another. But, one has to know certain things, before we know whether even that's feasible. We don't know that, at this stage.

COMMISSIONER MCGAFFIGAN: Thank you.

COMMISSIONER DICUS: Okay, thank you. Commissioner Merrifield?

COMMISSIONER MERRIFIELD: I've got a question and a couple of comments. The question is directed to Mr. Stratford. You mentioned in your statement, you postulated perhaps that one of the things that we could potentially do is have a five-year agreement, but have meetings once a year, public meetings, and you would voluntarily come on over and meet with the Commission to underscore whether the applicant was appropriately meeting the requirements of moving forward in a good faith manner. What is your postulation of what the outcome would be at those meetings, if we determined that, now, indeed, the applicant is not making a good faith effort?

MR. STRATFORD: Well, what I was basically doing was signaling our understanding that you may not want to issue a piece of paper that says this is good for five years, 130 kgs, make your own arrangements that take away amounts whenever you feel like it, without having the opportunity to review whether or not the Schumer Amendment continues to be met every year. And it seems to me there are lots of ways of doing that. You can send us a letter each year asking and we'd send you something back. You could ask us to drop by in a closed session, except I can't

see why it would be closed, because it wouldn't be classified. And if you're all going to sit together and hear me tell you what's going on, it's going to have to be an open meeting anyway, under Sunshine, as I understand it.

So -- and then there's also the public interest aspect of all of this. If there's going to be a Commission review at your level, of whether or not Schumer continues to be met, then I don't have a problem coming over here with Argonne and DOE in tow, to engage in that discussion with you. As I said, I think the thing that ought to be avoided is new licenses that call for new license fees. And I don't necessarily see the need to bring the applicant or its representatives down on an annual basis, if we're capable of handling that.

COMMISSIONER DICUS: Yes?

DR. LABRIE: I would just like to bring a clarification to the time line that Dr. Travelli has mentioned. I would agree with him that work could be done to develop a feasibility study within the next six months. But what I want to clarify is that this, in no way, would be representative of the time it would take to implement such a change.

These facilities are class one facilities in the Canadian standard of classifying facilities, which means that you don't go ahead and change a pipe, change a tank,

and change anything, without going through a very extensive regulatory process, where basically components have to be -- first of all, you have to do consequence of failure of analysis for these components, to justify each component classification. These components need to be registered.

So, an implementation -- and we've always -- ACEL's position has always been that an implementation of a change will take at least five years to come to conclusion. It is very unrealistic to expect that this could be done in a year's time frame. We have bene working on this project since 1996 -- September, '96. We are just completing the construction of the new processing facility. We still have regulatory issues on some components to get them registered, a lot of discussions with the -- our regulator, in terms of consequences of failures and so on. So, it is a very extensive process to put together these facilities in the current regulatory climate in Canada.

COMMISSIONER DICUS: Okay. Thank you, very much. Commissioner Merrifield?

COMMISSIONER MCGAFFIGAN: Yes. In terms of comments, I'd make these: we did talk a very short bit today about the issues of these materials produced by these reactors, Technetium-99, Molybdenum-99, and the importance that they have. There is a letter, which was received by the Chairman, on June 8, 1999, from the American College of

Nuclear Physicians and the Society of Nuclear Medicine that goes into these issues. We talked today and it was mentioned that there are 36,000 patients on a daily basis, who use Moly-99 in their treatment. And this letter -- and I'd like to ask that it be included in its entirety in the record.

[Letter insert]

COMMISSIONER MCGAFFIGAN: But, it basically says that because of an inability to stockpile, any kind of supply disruptions would quickly threaten the proper treatment of patients in the United States. And I think that's a serious issue for us to consider, particularly in the balance, as I had pointed out, of the fact that the interest of the Schumer Amendment was going to issues on proliferation and terrorism, which in the case of Canada, clearly, and I think everyone agrees, is not the case.

Final comments I would make are these: what this meeting, I think, personally was about today was the Schumer Amendment and what it means relative to this applicant. There's no doubt in my mind that the Schumer Amendment is something, I think, we should be very proud of. I mean, we've had great success. I think the State Department has done a tremendous job in attempting to take it out and really sell it to a number of other countries. What our role here, I believe, is looking at the words of that

amendment, not what we may wish they might be, but the actual words of that amendment and how they relate to the actions undertaken between our government and the applicant. And that certainly will be what I'll be looking at.

What this meeting is not about, and I'm not suggesting anyone said it was, is our relationship with Canada and casting any doubt on that relationship. I come from a state, which is a border of Canada, New Hampshire. Thirty percent of the people from my home state are of French-Canadian descent. So, these issues relative to Canada are, for me, relatively important. And I certainly would want to make my personal opinion, that Canada is our closest ally, it is our most important trading partner, it is a trusted friend of this country, and certainly the decision we have to make is relative to the Schumer Amendment and the words contained in that and the obligations we have under the law; but, in no way, cast any doubt, in my mind, about our close and long relationship with our trusted neighbor. Thank you.

COMMISSIONER DICUS: Okay, thank you. Anything else that you wanted to add?

[No response.]

COMMISSIONER DICUS: Well, I think this now brings -- these presentations brings our meeting to a close. I certainly would like to thank each of the participants today

for providing their rather candid and thoughtful input. Apparently, it's not -- did you --

SPEAKER: May I make --

COMMISSIONER DICUS: Something very quickly.

COMMISSIONER MERRIFIELD: I have to say at this point, we've given these folks plenty of time to rebut all kinds of things. I've made a final closing statement and I do think that --

COMMISSIONER DICUS: I think we are going to bring the meeting to a close, at this point. I agree with you. Our discussions have been candid. I think they have been very thoughtful and we've had a great deal of input. Clearly, we have a decision to make on a very complex issue and complex consideration.

The onus on the Commission will be to consider all aspects of how public health and safety, as well as the common defense and security, which might be impacted by the various possible courses of action, and to make a reasonable, responsible, and fair decision on these issues. All of your presentations today, as well as the written submission we have already received and considered, have been extremely helpful, as we move forward to make a decision on this issue. So, once again, I thank you very much and the hearing is closed.

[Whereupon, at 12:21 p.m., the briefing was

concluded.]

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON PROPOSED EXPORT OF HIGH ENRICHED URANIUM TO CANADA PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Wednesday, June 16, 1999

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Rose Gershon

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Title: Briefing on Proposed Export of High Enriched Uranium to Canada

Scheduled: 9:00 a.m., Wednesday, June 16, 1999 (PUBLIC)

Duration: Approx 1 1/2 hrs

Participants:

Panel 1

Applicant — 30 mins**

- Dr. Iain C. Trevena, Senior Vice-President — T
  Nuclear Medicine, MDS Nordion
- Dr. Jean Pierre Labrie, General Manager — L
  Research and Isotope Reactor Business
  Atomic Energy of Canada, Ltd. (AECL)

Panel 2

Nuclear Control Institute — 30 mins**

- Paul Leventhal, President — V
  Nuclear Control Institute (NCI)

Panel 3

Executive Branch — 30 mins**

- Richard J. K. Stratford, Director — S
  Office Nuclear Energy Affairs
  Nonproliferation Bureau, State Department (DOS)
- Tricia Dedik — C
  Director, Nuclear Transfer and Supplier Policy Division
  Office of Arms Control and Nonproliferation
  Department of Energy (DOE)
- ~~Leonard S. (Sandy) Spector, Director~~ Edward T. Fei, Division Director, International Policy & Analysis Division — R
  Office of Arms Control and Nonproliferation, DOE
- Samit K. Bhattacharyya — B
  Technology Development Director
  Argonne National Laboratory (ANL)

  or
- Armando ~~Travelli~~ Travelli — J
  RERTR Program Manager
  Argonne National Laboratory (ANL)
- Jim Snelgrove — O
  Coordinator for Engineering Applications
  Argonne National Laboratory (ANL)

(Cont. next page)

** Includes time for questions and answers.

Other People Attending:

MDS Nordion:

- Grant R. Malkoske, Vice President, Engineering & Technology – P
- David L. Nicholds, General Counsel & Corporate Secretary – N

AECL:

- Greg Sayer, Legal Counsel – F
- James A. Glasgow, Legal Counsel – G
  Morgan, Lewis & Bockius, LLP
- John E. Mathews, Legal Counsel – E
  Morgan, Lewis & Bockius, LLP

DOE/ANL

- Richard Goorevich, – H
  Nuclear Transfer and Supplier Policy Division
  Office of Arms Control and Nonproliferation, DOE
- Armando Travelli, Manager – J
  Reduced Enrichment in Research and Test Reactors (RERTR)
  Program, Argonne National Laboratory
- Jim Snelgrove, Senior Physicist – O
  Argonne National Laboratory
- Grant Bill Zagota – W
  RERTR Program
  Argonne National Laboratory

M X

Matthews Glasgow Labrie Trevena Melkoske

Views of the Executive Branch

On Application XSNM03060 for Export of HEU to Canada for Medical Isotope Production

Presentation Before the Nuclear Regulatory Commission

June 16, 1999

Views of the Executive Branch

On Application XSNM03060
for Export of HEU to Canada
for Medical Isotope Production

Presentation Before the
Nuclear Regulatory Commission

June 16, 1999

Madame Chairman, Commissioners, Ladies and Gentlemen:

My name is Richard Stratford and I am the Director of the Office of Nuclear Energy Affairs in the Department of State's new Bureau of Nonproliferation. I have been asked to present the Executive Branch's views on the issuance of an export license for authorization to export to Canada 130.65 kilograms of highly enriched uranium (HEU) in the form of UO2 targets for the production of medical isotopes in the Maple 1 and 2 reactors currently under construction by Atomic Energy of Canada Limited's (AECL) Chalk River Nuclear Laboratories.

As I noted in my letter of March 5, 1999 to NRC's Acting Director of International Programs, the Executive Branch reviewed the application carefully and concluded, as we have many times in the past, that the export of HEU targets to one of our closest friends for medical isotope

production would not be inimical to the common defense and security of the United States. In making this determination, we reviewed the license application carefully in light of applicable statutes, regulations and policy and we have considered (both before and after I forwarded the Executive Branch views to the Commission) the points raised by the intervenors and by the applicant in this case.

As a result of our review, the Executive Branch concluded that the conditions of the Atomic Energy Act, as amended, are fully met for this export. These conclusions included a determination that physical protection measures are adequate against possible diversion of the HEU by terrorists or proliferant countries. In making that particular determination, we consulted with the Department of Defense to confirm that physical protection measures will be adequate to deter theft, sabotage and other acts of international terrorism which would result in diversion of the material during the export. Moreover, the Government of Canada has provided written physical protection assurances, which have been verified by visits of U.S. experts to Canadian facilities.

The preeminent issue for this hearing would seem to be whether or not the conditions set forth in Section 134 of

the Atomic Energy Act are met (i.e. the Schumer Amendment). In our judgment, the three conditions of the Schumer amendment are met. First, with respect to the availability of a low-enriched uranium (LEU) target, the Department of Energy has confirmed that no LEU target is currently available that can be used as an alternative to HEU for Canadian isotope production. Second, with respect to a commitment to convert to the use of LEU, the U.S. and Canada have exchanged diplomatic notes confirming agreement that whenever an LEU target has been qualified by the relevant authorities and does not result in a large percentage increase in the total cost of operating a reactor, including necessary associated equipment, for the production and processing of medical isotopes, such an alternative LEU target will be used in that reactor after required equipment has been installed and the necessary licenses have been obtained. Third, with respect to a U.S. development effort on LEU targets, the Argonne National Laboratory has an active DOE-funded program underway for the development of LEU targets.

The intervenors had expressed the view that the requirements of Schumer are not met because Argonne lacks the information it needs to determine if the LEU targets it

is currently developing are compatible with the Canadian isotope production process. In this connection, the intervenors have stated that the Canadian producers, MDS Nordion and Atomic Energy of Canada, Limited, have refused to permit visits by Argonne to the isotope production facility or to furnish information about the Canadian process. However, our information is that visits, meetings and exchanges of information are taking place. Moreover, representatives of MDS Nordion told us in a meeting earlier this year, and later reiterated in writing, the company's commitment to convert to LEU production targets. In light of these developments, we believe that current Canadian cooperation with Argonne clearly meets Schumer amendment requirements.

The intervenors also suggest that there is no reason why Canada cannot continue to meet medical isotope production requirements by use of the NRU reactor while reconfiguring the Maple reactors for use of LEU targets. We find Canadian concerns to be reasonable regarding the risks of having to depend on the 43 year-old NRU reactor as the sole source of medical isotopes for an indefinite period, particularly given our inability to predict how long it will take to develop an LEU target for the Maple reactors that meets both nuclear and medical safety and regulatory

standards. Moreover, we have concluded that the proposed export is clearly in the interest of the United States since Canada, through its HEU target process, currently supplies more than 60 percent of U.S. medical requirements for molybdenum-99.

Madame Chairman, Commissioners, now I come to the point that I really want to make. It is clear that the Executive Branch, the NRC, the Congress and the intervenors all desire as great a reduction as possible and, eventually, the elimination of the use of HEU in civil nuclear commerce. But to make that happen, we need the voluntary cooperation of foreign research reactor operators and medical isotope producers in ongoing efforts to convert from use of HEU to low enriched uranium (LEU) fuel and targets. That voluntary cooperation is key to the success of our effort and, to a large extent, that cooperation has been forthcoming. However, we need to bear in mind that even when reactor operators and isotope producers are prepared to convert to LEU, they will need HEU to carry them through the interim period until the necessary steps for successful conversion to LEU can be completed. And if I were a reactor operator or an official in the nuclear establishment of another government, I would want to know that fuel and target material for my reactor were going to be supplied on a

reliable and predictable basis. If we expect reactor operators and isotope producers to make serious efforts to convert to LEU, we need to make equally serious efforts to ensure a predictable and reliable supply of HEU until conversion can be accomplished.

We expect operators or producers seeking interim supplies of HEU to cooperate in good faith with the DOE RERTR Program in efforts to develop an alternative LEU fuel or target that can be used in a particular reactor. By the same token, when it is clear that there is no currently available LEU fuel or targets that can be used in a particular reactor or isotope production process, and that operators or producers are cooperating with DOE in good faith, we do not seek to second-guess how such producers run their operation. We expect that they will exercise good business judgement in seeking a timely supply of usable nuclear fuel or targets and that it is normal to assure redundant capability. That does not mean, however, that we do not exercise an independent look at whether the requirements of our law are being met. We have looked at, and we will continue to look at, whether a government's or an operator's cooperation with the RERTR development program is going forward in a productive manner.

I think it is important to note that as we negotiate the conversion of the last remaining HEU-fueled reactors and isotope production to LEU, we can expect that there will be more applications for supply of HEU, not less. The remaining reactors to be converted are the "big ones," and the ones posing the most technically difficult challenges. We are now making substantial progress in gaining the commitment of these operators and governments to conversion. But I have to tell you that the diplomatic notes that pertain to these conversions are a bit more complex and more reciprocal than in the Canadian case. In the case of Grenoble, for example, in return for a commitment to convert (and assuming an active U.S. LEU development program), we committed to make best efforts to sell HEU to the operator and to support issuance of the corresponding export licenses. If during the conversion period, each HEU application became the subject of intense debate and second guessing of operator/producer motives, we would not be perceived as a reliable supplier, and our ability to satisfy the obligations we undertook would be called into question. In which case, the operator or government would certainly seek alternative sources of HEU supply. If that happens, there will be no incentive to convert to LEU and the fundamental goal of the RERTR Program and U.S. efforts to limit uses of HEU globally will be undercut.

In short, ladies and gentlemen, we are moving ever more in the direction of a two-sided bargain -- a governmental commitment to LEU conversion, when and if possible, in return for a reliable and predictable basis on which to continue operation of existing facilities pending conversion. We think that is a fair bargain. And we firmly believe that the Government of Canada and the Canadian isotope producers are prepared to carry out their side of the bargain. For that reason, we believe that the issuance of the subject export license supports, not undercuts, our nonproliferation and nuclear supply policies.

Thank you for giving me the opportunity to make this presentation.

Tape 15A
Insert

ACNP/SNM

American College of Nuclear Physicians/Society of Nuclear Medicine

GOVERNMENT RELATIONS OFFICE

June 8, 1999

Chairman Shirley A. Jackson
US Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland

Dear Chairman Jackson:

The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) submit this letter to the Nuclear Regulatory Commission to express their continued strong support for the NRC's timely issuance of licenses authorizing the export of highly enriched uranium (HEU) contained in, or for use in, targets to be irradiated in test or research reactors to produce molybdenm-99 (Mo-99). In turn, the Mo-99 is used to obtain the decay product, technitium-99m (Tc-99m), a radioisotope used to diagnose and treat seriously ill patients in the United States and many other countries.

Last year an affidavit was filed with the Commission by William Strauss, MD and Martin Nusynowitz, MD, then Presidents of SNM and ACNP respectively. It stated SNM and ACNP's support for an export license that was sought by Transnuclear Inc. on behalf of AECL, authorizing shipment of HEU targets to Canada for irradiation in AECL's reactors. The NRC subsequently issued the license. SNM and ACNP reaffirm the position set forth in the affidavit of Drs. Strauss and Nusynowitz and urge the Commission to issue export license application XSNM-03060, which is the subject of a public meeting scheduled by the Commission for June 16, 1999.

For reasons more fully stated in the Strauss/Nusynowitz affidavit, the Society and College urges the Commission, when it considers the Schumer Amendment requirements and evaluates the Atomic Energy Act "inimicality" standard for exports, to take fully into account the vital role that such HEU exports presently play in assuring an uninterrupted supply of Mo-99 and Tc-99m. These isotopes continue to be the most effective radioisotopes for diagnosis and treatment of patients with life-threatening illness, including AIDS, cancer, lung disease, heart disease and kidney disease.

More than 80% of the approximately 12 million radiopharmaceutical medical procedures performed each year in the United States use Tc-99m. SNM and ACNP submit that any delay in issuing the pending export license application on behalf of AECL and similar, future applications would be "inimical" to the interest of the United States because it could deprive thousands of

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patients in the United States of the radioisotope that is needed for the effective diagnosis and treatment of their life threatening illness. Since Mo-99 has a half-life of only sixty-six (66) hours, it cannot be stockpiled and supply disruptions will quickly threaten the proper treatment of patients in the United States.

As is clear from the response of the U.S. Executive Branch to the Commission's Order dated April 27, 1999, the Department of Energy's Annular Core Research Reactor (ACRR) at Sandia National Laboratory will not be available on a timely basis to provide a back-up supply of Mo-99 in the event of a disruption of the supply of Mo-99 from Canadian or other sources. DOE advised the Commission as follows:

> Without the involvement of a private company and under current funding scenarios, nine to fourteen months will be needed to mobilize the Sandia facilities in response to an emergency (e.g., non-availability of medical radioisotopes from Canada.

The ACRR's availability to serve as a back-up source of Mo-99 is thus highly doubtful since private companies did not express an interest in DOE's "privatization" proposal for the ACRR and there is no assurance that Congress will appropriate the funds needed to convert the ACRR for this purpose. Consequently, if the supply of Mo-99 is disrupted in the absence of reliable and timely back-up sources of supply, thousands of patients in North America will be deprived of diagnosis and treatment with the proper radioisotope. The unavailability of Mo-99 would not only deprive some patients of treatment, but also would result in an increased need for invasive diagnostic surgery. The impacts would be felt in terms of both increased risk of loss of life and increased health costs.

While SNM and ACNP support the objectives of the U.S. Reduced Enrichment in Research and Test Reactors (RERTR) Program, they fear that many medical patients will suffer from any refusal of the NRC to accept the good faith views of the reactor operators and target processors concerning the time required to convert to LEU targets. In this regard, SNM and ACNP are aware of the publicly announced commitment of MDS-Nordion (which processes the targets irradiated by AECL to extract Mo-99 for medical use) that "it will be moving to an LEU target for molybdenum-99 production...to ensure security of supply...." However, despite the extensive ongoing collaboration with the RERTR Program's ongoing effort to develop and LEU target for the Canadian reactors, MDS-Nordion believes that such a target cannot be "...put in place in less than two years and... more realistically three to five years."

Notably, the Executive Branch's April 27, 1999 letter to the Commission does not address the time required to develop, license and use LEU targets in the Canadian reactors. SNM and ACNP respectfully suggest that such deference to the well-informed views of those who produce such radiopharmaceuticals is essential to the ability of that industry to adequately serve the needs of patients who urgently require such treatment.

In closing, SNM and ACNP urge that the Commission issue the export licenses for HEU on a timely basis when the applicants, as in this case, meet the statutory and regulatory requirements. If you have any questions regarding this matter, please contact William Uffelman, Esq., Director of Public Affairs for ACNP/SNM at 703-708-9773.

Sincerely,

Robert F. Carretta, MD
President
Society of Nuclear Medicine

James M. Woolfenden, MD
President
American College of Nuclear Physicians

Cc: Commissioner Greta J. Dicus
Commissioner Nils J. Diaz
Commissioner Edward McGaffigan, Jr
Commissioner Jeffrey S. Merrifield

Meeting with the Nuclear Regulatory Commission

June 16, 1999

Transnuclear, Inc.

Atomic Energy of Canada Limited

MDS Nordion Inc.

(Export of 93.3% Enriched Uranium)

Dkt. No. 11005070, Lic. No. XSNM 03060

Introduction and Overview

- **Introduction--AECL**
  - **Dr. Jean-Pierre Labrie, General Manager, Research and Isotope Reactor Business**
- **Presentation--MDS Nordion**
  - **Dr. Iain C. Trevena, Senior Vice President, Nuclear Medicine**

Agenda

- **Overview of MDS Nordion Medical Isotope Business**
- **MMIR Project**
- **Conversion to LEU Targets**
- **Cooperation with Argonne National Laboratory**

Applications

- **Non invasive diagnosis of disease**
- **In the U.S. 36,000 diagnostic procedures use Technetium-99m daily**
- **New radiopharmaceuticals pinpoint malignant tumours and provide dynamic information on the function of the brain and heart**

MDS Nordion's Supply Obligations

Isotope	Percent*	Application
Molybdenum-99	**65%**	**Diagnosis**
Iodine-131	**>90%**	**Therapy**
Xenon-133	**>95%**	**Diagnosis**
Iodine-125	**70%**	**Therapy**

*Data expressed as % of world market requirements

Reactor Isotope Production

- **NRU operating since 1957**
- **NRU Mo-99 production will cease in 2000**
- **Last major shutdown 1991 (11 months)**
- **Monthly 5 day shutdown for maintenance**
- **Routine supply managed through inventory build-up**
- **Reliable supply of custom product**
- **Superior service to Nuclear Medicine**
- **Short lived isotopes require uninterrupted supply**

MMIR Project

- **Two 10 MW reactors**
- **Dedicated to isotope production**
- **Secure supply assured through back-up**
- **MAPLE 1 Start-up 1999**
- **MAPLE 2 Start-up 2000**

MMIR Project

Processing Facility:

- **Hot cells for processing product and solidifying waste**
- **New Mo-99 process reduces waste, eliminates long term storage of liquid waste**

Cost:

- **$140 million since 1996 for capital**

HEU As Target Material

- **Proven technology**
- **Fastest way to security of supply**
- **Drug regulatory approval straightforward**
- **Production using HEU targets is essential to assure uninterrupted supply**
- **Failure to start production with HEU targets will put MMIR project in jeopardy**

LEU As Target Material

- **No economically feasible LEU targets are currently available**
- **Increased target mass (factor of 5)**
- **Increased volume of high level liquid waste (factor of 5)**
- **Different raw material requires higher level of testing to obtain Drug Regulatory Approval**

Other Reactors Used For High-Level Molybdenum-99 Production

- **Commissioned in 1965 or earlier**
- **Multi-purpose Research Reactors**
- **Government Funding Required for Continued Operation**
- **GE Reactor Shut Down 1980**
- **Cintichem Reactor Shut Down 1990**
- **NRX Reactor Shut Down 1993**

HEU/LEU Conversion

Reactor Considerations:

- **Modify current design to achieve 5X target mass**
- **Model safety of new design**
- **Test new design in a test reactor, e.g. NRU**
- **Obtain AECB approval for testing in MAPLE**
- **Test new targets up to full power in MAPLE**
- **Submit test results to AECB and obtain approval**

No issues with having HEU targets in the reactor prior to the conversion

HEU/LEU Conversion

NPF/Process Considerations:

- **NPF on critical path when project initiated**
- **Current high level waste tanks full end 2000**
- **Current facility unable to process targets from MAPLE**
- **NPF construction 60% complete**
- **NPF tank storage capacity already maximized**
  - **More than double original plan**

New process chemistry required

- ***To reduce volume of liquid waste during processing***
- ***Achieve product purity with 5X uranium concentration***
- ***Eliminate high levels of transuranics***

Cooperation with Argonne National Laboratory

November 5, 1998

- Agreement on LEU target based on Atomic Energy Canada Limited (AECL) target concept

January 12, 1999

- MDS Nordion (MDSN) proposal presented to demonstrate technical and commercial viability of LEU target/process in MMIR facilities:
  - Prepare confidentiality agreement
  - Prepare scope of work
  - Determine commercial terms

Cooperation with Argonne National Laboratory

January 19, 1999

- Argonne National Laboratory (ANL) submitted draft generic plan to develop LEU conversion needs for target/process

March 2, 1999

- MDSN informed ANL that technical information prepared
- Confidentiality agreement submitted to ANL

April 17, 1999

- ANL counsel forwarded to MDSN a proposed addendum to the existing ANL-AECL Non-Disclosure Agreement, which includes MDSN as a party to the Agreement in a single, tripartite arrangement

Cooperation with Argonne National Laboratory

May 6, 1999

- **MDSN re-submits amended confidentiality agreement to ANL**

May 13, 1999

- **MDSN/ANL confidentially agreement duly executed**

May 14, 1999

- **MDSN authorizes AECL to submit technical information to ANL**

May 20, 1999

- **AECL forwards technical information to ANL**

NUCLEAR CONTROL
INSTITUTE

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STATEMENT OF PAUL L. LEVENTHAL AND ALAN J. KUPERMAN
on behalf of the
NUCLEAR CONTROL INSTITUTE
on the
PROPOSED EXPORT OF HIGHLY ENRICHED URANIUM TO CANADA
presented to the
U.S. NUCLEAR REGULATORY COMMISSION
June 16, 1999

Madam Chairman, and members of the Commission, we appreciate your convening this public meeting and inviting the Nuclear Control Institute to make a presentation. We are Paul L. Leventhal, president, and Alan J. Kuperman, senior policy analyst, at NCI. Our original petition to the Commission requested an adjudicatory hearing for the purpose of deposing witnesses and establishing facts. While we believe such a formal proceeding would have been optimal, we appreciate the fact that this meeting is bringing together all relevant parties, and will afford the opportunity to hear directly from officials of Argonne National Laboratory and its Canadian interlocutors.

The matter before the Commission today is whether a key U.S. nuclear export control law -- the so-called Schumer Amendment to the Energy Policy Act of 1992 -- will be enforced to achieve its goal of phasing out remaining U.S. exports of bomb-grade, highly enriched uranium.

We are gratified that the close attention the Commission has focused on this matter, and on NCI's petition to intervene before it, already have paid dividends in terms of compelling a significant shift in the position of the applicant. For a number of years, up until a few months ago, the applicant contended it would be virtually impossible to use LEU targets in the proposed Maple reactors. Now, remarkably, the applicant not only concedes that use of LEU targets is feasible, but insists it will happen. According to the applicant, the only remaining question is when, not if.

While NCI appreciates this new rhetoric, we contend that the Commission is obligated to look beyond rhetorical commitments to make sure the applicant takes concrete steps to comply with the Schumer Amendment.

The Schumer Amendment

The Schumer Amendment was intended to permit HEU exports only on an interim basis and only to reactors that eventually would be converting to LEU. Accordingly, it requires that three conditions be fulfilled before the Commission can approve an HEU export license application for targets:

successfully developed, the applicant would consider the cost of converting the new processing facility to handle LEU targets -- a cost considerably elevated by the fact that the facility now would be radioactive. If the cost were sufficiently high, the applicant could argue that it was not required to convert to LEU despite its Schumer Amendment pledge.

2. Original NCI Plan -- In its submissions before the Commission, NCI suggested that commencement of isotope production in the Maple reactors could be deferred until LEU targets were qualified and the NPF modified to handle them, requiring two to five years. In the interim, the NRU could continue to produce such isotopes. (It already is envisioned as a back-up facility in case of problems at the Maple facilities, meaning that extra waste can be dealt with.) Once LEU targets were qualified and the NPF modified, the Maple reactors and NPF could commence operation using LEU targets, and the NRU would be shut down. This approach would have the effect of terminating HEU exports to Canada as quickly as possible, without interrupting the supply of medical isotopes, fulfilling the Schumer Amendment's intent.

3. Modified NCI Plan – The applicant expresses concern that a potential five-year delay in commencing operations at the Maple reactors could endanger the supply of isotopes because the NRU is aging. The legitimacy of this concern is called into question by recent publications indicating that the NRU can operate for at least five more years. Nevertheless, there is a way to accommodate this concern while meeting the requirements of the Schumer Amendment. Start-up of the Maple reactors and NPF could be deferred just until completion of the modification of the NPF to handle LEU targets (in addition to planned HEU targets). This option would entail conducting an assessment of the modifications necessary at the NPF to accommodate LEU targets, which among other differences have a five-fold larger amount of uranium than HEU targets. It might turn out that no modifications would be necessary, based on preliminary assessments that the concentration of uranium in solution can be increased, so that the volume is unchanged. Any modifications found necessary would be relatively inexpensive to implement because the facility would not yet be radioactive, and they could be completed in less than two years, prior to final qualification of the LEU targets. Then, the Maple reactors and NPF could commence operation with HEU targets, converting to LEU targets as soon as they were successfully qualified.

4. NRC Proposal -- In its invitation to this hearing, the Commission asked witnesses to evaluate an alternate proposal. Under this option, the applicant would commence isotope production using HEU targets at one new Maple reactor and the NPF, but the other Maple reactor would be kept on stand-by until LEU targets were developed. The benefit of this option is that it would provide the applicant an incentive to develop the LEU target to earn a return on its investment in the second Maple reactor. The drawback is that it would permit operation of the NPF with HEU targets prior to its modification to accommodate LEU targets. As noted, the NPF would become radioactive, thereby significantly increasing the cost of future conversion to accommodate LEU targets, and potentially providing the applicant an excuse not to convert and to use HEU targets in the second Maple reactor, as well.

Maple reactors and funds entirely the necessary modifications to the applicant's processing facilities, there cannot be an active LEU target development program. Under such circumstances, it would be reasonable for the Commission to conclude that there is no real commitment by the applicant to convert. In this case, the Schumer Amendment requirements are not fulfilled and the pending application should be rejected.

Trust, but Verify

The applicant has requested a five-year supply of HEU fuel, based on its promise to continue cooperating towards expeditious development of and conversion to LEU targets. The problem is that if such an export is granted, the applicant will have little incentive to continue such cooperation over the next five years. The applicant would then be in a position to come back after five years and argue that LEU target development has been delayed, so it requires another five-year supply of HEU. This would undermine the incentive structure envisioned by the Schumer Amendment, would essentially nullify the law, and would pave the way for perpetual exports of HEU to Canada.

It would be far more prudent for the Commission to limit any exports of HEU fuel to the applicant to a one-year supply, subject to renewal annually if the Commission determines that the applicant is continuing to facilitate the active development of an LEU target that can be used in the Maple reactors. Such an arrangement would maintain the incentive structure envisioned by the Schumer Amendment. As President Ronald Reagan put it, "Trust, but verify."

Conclusion

Since the Schumer Amendment was enacted in 1992, it has had a major impact in reducing HEU exports and influencing reactor operators to convert to LEU. Most recently, just last month, the operator of the Petten reactor announced that he would proceed with conversion to LEU to ensure supply of fresh fuel that had been restricted by the Schumer Amendment.

Thus, how the Commission decides the pending license application will affect not only exports of HEU to Canada but will set a precedent as to whether the Schumer Amendment is to be enforced or can be evaded. Reactor operators and medical-isotope producers around the world who are still wavering over whether to convert to LEU are watching this case very closely. We urge the Commission to enforce the Schumer Amendment in its full letter and spirit by rejecting the applicant's request for advance approval of a 5-year supply of HEU and by deciding this matter in a way that conditions any supply of HEU on actual and continuing cooperation to fulfill the requirements of the Schumer Amendment.

NCI

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STATEMENT OF PAUL L. LEVENTHAL AND ALAN J. KUPERMAN
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2. Original NCI Plan -- In its submissions before the Commission, NCI suggested that commencement of isotope production in the Maple reactors could be deferred until LEU targets were qualified and the NPF modified to handle them, requiring two to five years. In the interim, the NRU could continue to produce such isotopes. (It already is envisioned as a back-up facility in case of problems at the Maple facilities, meaning that extra waste can be dealt with.) Once LEU targets were qualified and the NPF modified, the Maple reactors and NPF could commence operation using LEU targets, and the NRU would be shut down. This approach would have the effect of terminating HEU exports to Canada as quickly as possible, without interrupting the supply of medical isotopes, fulfilling the Schumer Amendment's intent.

3. Modified NCI Plan – The applicant expresses concern that a potential five-year delay in commencing operations at the Maple reactors could endanger the supply of isotopes because the NRU is aging. The legitimacy of this concern is called into question by recent publications indicating that the NRU can operate for at least five more years. Nevertheless, there is a way to accommodate this concern while meeting the requirements of the Schumer Amendment. Start-up of the Maple reactors and NPF could be deferred just until completion of the modification of the NPF to handle LEU targets (in addition to planned HEU targets). This option would entail conducting an assessment of the modifications necessary at the NPF to accommodate LEU targets, which among other differences have a five-fold larger amount of uranium than HEU targets. It might turn out that no modifications would be necessary, based on preliminary assessments that the concentration of uranium in solution can be increased, so that the volume is unchanged. Any modifications found necessary would be relatively inexpensive to implement because the facility would not yet be radioactive, and they could be completed in less than two years, prior to final qualification of the LEU targets. Then, the Maple reactors and NPF could commence operation with HEU targets, converting to LEU targets as soon as they were successfully qualified.

4. NRC Proposal -- In its invitation to this hearing, the Commission asked witnesses to evaluate an alternate proposal. Under this option, the applicant would commence isotope production using HEU targets at one new Maple reactor and the NPF, but the other Maple reactor would be kept on stand-by until LEU targets were developed. The benefit of this option is that it would provide the applicant an incentive to develop the LEU target to earn a return on its investment in the second Maple reactor. The drawback is that it would permit operation of the NPF with HEU targets prior to its modification to accommodate LEU targets. As noted, the NPF would become radioactive, thereby significantly increasing the cost of future conversion to accommodate LEU targets, and potentially providing the applicant an excuse not to convert and to use HEU targets in the second Maple reactor, as well.

Maple reactors and funds entirely the necessary modifications to the applicant's processing facilities, there cannot be an active LEU target development program. Under such circumstances, it would be reasonable for the Commission to conclude that there is no real commitment by the applicant to convert. In this case, the Schumer Amendment requirements are not fulfilled and the pending application should be rejected.

Trust, but Verify

The applicant has requested a five-year supply of HEU fuel, based on its promise to continue cooperating towards expeditious development of and conversion to LEU targets. The problem is that if such an export is granted, the applicant will have little incentive to continue such cooperation over the next five years. The applicant would then be in a position to come back after five years and argue that LEU target development has been delayed, so it requires another five-year supply of HEU. This would undermine the incentive structure envisioned by the Schumer Amendment, would essentially nullify the law, and would pave the way for perpetual exports of HEU to Canada.

It would be far more prudent for the Commission to limit any exports of HEU fuel to the applicant to a one-year supply, subject to renewal annually if the Commission determines that the applicant is continuing to facilitate the active development of an LEU target that can be used in the Maple reactors. Such an arrangement would maintain the incentive structure envisioned by the Schumer Amendment. As President Ronald Reagan put it, "Trust, but verify."

Conclusion

Since the Schumer Amendment was enacted in 1992, it has had a major impact in reducing HEU exports and influencing reactor operators to convert to LEU. Most recently, just last month, the operator of the Petten reactor announced that he would proceed with conversion to LEU to ensure supply of fresh fuel that had been restricted by the Schumer Amendment.

Thus, how the Commission decides the pending license application will affect not only exports of HEU to Canada but will set a precedent as to whether the Schumer Amendment is to be enforced or can be evaded. Reactor operators and medical-isotope producers around the world who are still wavering over whether to convert to LEU are watching this case very closely. We urge the Commission to enforce the Schumer Amendment in its full letter and spirit by rejecting the applicant's request for advance approval of a 5-year supply of HEU and by deciding this matter in a way that conditions any supply of HEU on actual and continuing cooperation to fulfill the requirements of the Schumer Amendment.

NCI

Meeting with the Nuclear Regulatory Commission

June 16, 1999

Transnuclear, Inc.

Atomic Energy of Canada Limited

MDS Nordion Inc.

(Export of 93.3% Enriched Uranium)

Dkt. No. 11005070, Lic. No. XSNM 03060

Introduction and Overview

- **Introduction--AECL**
  - **Dr. Jean-Pierre Labrie, General Manager, Research and Isotope Reactor Business**
- **Presentation--MDS Nordion**
  - **Dr. Iain C. Trevena, Senior Vice President, Nuclear Medicine**

Agenda

- **Overview of MDS Nordion Medical Isotope Business**
- **MMIR Project**
- **Conversion to LEU Targets**
- **Cooperation with Argonne National Laboratory**

Applications

- **Non invasive diagnosis of disease**
- **In the U.S. 36,000 diagnostic procedures use Technetium-99m daily**
- **New radiopharmaceuticals pinpoint malignant tumours and provide dynamic information on the function of the brain and heart**

MDS Nordion's Supply Obligations

Isotope	Percent*	Application
Molybdenum-99	**65%**	**Diagnosis**
Iodine-131	**>90%**	**Therapy**
Xenon-133	**>95%**	**Diagnosis**
Iodine-125	**70%**	**Therapy**

*Data expressed as % of world market requirements

Reactor Isotope Production

- **NRU operating since 1957**
- **NRU Mo-99 production will cease in 2000**
- **Last major shutdown 1991 (11 months)**
- **Monthly 5 day shutdown for maintenance**
- **Routine supply managed through inventory build-up**
- **Reliable supply of custom product**
- **Superior service to Nuclear Medicine**
- **Short lived isotopes require uninterrupted supply**

MMIR Project

- **Two 10 MW reactors**
- **Dedicated to isotope production**
- **Secure supply assured through back-up**
- **MAPLE 1 Start-up 1999**
- **MAPLE 2 Start-up 2000**

MMIR Project

Processing Facility:

- **Hot cells for processing product and solidifying waste**
- **New Mo-99 process reduces waste, eliminates long term storage of liquid waste**

Cost:

- **$140 million since 1996 for capital**

HEU As Target Material

- **Proven technology**
- **Fastest way to security of supply**
- **Drug regulatory approval straightforward**
- **Production using HEU targets is essential to assure uninterrupted supply**
- **Failure to start production with HEU targets will put MMIR project in jeopardy**

LEU As Target Material

- **No economically feasible LEU targets are currently available**
- **Increased target mass (factor of 5)**
- **Increased volume of high level liquid waste (factor of 5)**
- **Different raw material requires higher level of testing to obtain Drug Regulatory Approval**

Other Reactors Used For High-Level Molybdenum-99 Production

- **Commissioned in 1965 or earlier**
- **Multi-purpose Research Reactors**
- **Government Funding Required for Continued Operation**
- **GE Reactor Shut Down** **1980**
- **Cintichem Reactor Shut Down** **1990**
- **NRX Reactor Shut Down** **1993**

HEU/LEU Conversion

Reactor Considerations:

- **Modify current design to achieve 5X target mass**
- **Model safety of new design**
- **Test new design in a test reactor, e.g. NRU**
- **Obtain AECB approval for testing in MAPLE**
- **Test new targets up to full power in MAPLE**
- **Submit test results to AECB and obtain approval**

No issues with having HEU targets in the reactor prior to the conversion

HEU/LEU Conversion

NPF/Process Considerations:

- **NPF on critical path when project initiated**
- **Current high level waste tanks full end 2000**
- **Current facility unable to process targets from MAPLE**
- **NPF construction 60% complete**
- **NPF tank storage capacity already maximized**
  - **More than double original plan**

New process chemistry required

- ***To reduce volume of liquid waste during processing***
- ***Achieve product purity with 5X uranium concentration***
- ***Eliminate high levels of transuranics***

Cooperation with Argonne National Laboratory

November 5, 1998

- Agreement on LEU target based on Atomic Energy Canada Limited (AECL) target concept

January 12, 1999

- MDS Nordion (MDSN) proposal presented to demonstrate technical and commercial viability of LEU target/process in MMIR facilities:
  - Prepare confidentiality agreement
  - Prepare scope of work
  - Determine commercial terms

Cooperation with Argonne National Laboratory

January 19, 1999

- Argonne National Laboratory (ANL) submitted draft generic plan to develop LEU conversion needs for target/process

March 2, 1999

- MDSN informed ANL that technical information prepared
- Confidentiality agreement submitted to ANL

April 17, 1999

- ANL counsel forwarded to MDSN a proposed addendum to the existing ANL-AECL Non-Disclosure Agreement, which includes MDSN as a party to the Agreement in a single, tripartite arrangement

Cooperation with Argonne National Laboratory

May 6, 1999

- **MDSN re-submits amended confidentiality agreement to ANL**

May 13, 1999

- **MDSN/ANL confidentially agreement duly executed**

May 14, 1999

- **MDSN authorizes AECL to submit technical information to ANL**

May 20, 1999

- **AECL forwards technical information to ANL**

Views of the Executive Branch

On Application XSNM03060 for Export of HEU to Canada for Medical Isotope Production

Presentation Before the Nuclear Regulatory Commission

June 16, 1999

Views of the Executive Branch

On Application XSNM03060
for Export of HEU to Canada
for Medical Isotope Production

Presentation Before the
Nuclear Regulatory Commission

June 16, 1999

Madame Chairman, Commissioners, Ladies and Gentlemen:

My name is Richard Stratford and I am the Director of the Office of Nuclear Energy Affairs in the Department of State's new Bureau of Nonproliferation. I have been asked to present the Executive Branch's views on the issuance of an export license for authorization to export to Canada 130.65 kilograms of highly enriched uranium (HEU) in the form of UO2 targets for the production of medical isotopes in the Maple 1 and 2 reactors currently under construction by Atomic Energy of Canada Limited's (AECL) Chalk River Nuclear Laboratories.

As I noted in my letter of March 5, 1999 to NRC's Acting Director of International Programs, the Executive Branch reviewed the application carefully and concluded, as we have many times in the past, that the export of HEU targets to one of our closest friends for medical isotope

production would not be inimical to the common defense and security of the United States. In making this determination, we reviewed the license application carefully in light of applicable statutes, regulations and policy and we have considered (both before and after I forwarded the Executive Branch views to the Commission) the points raised by the intervenors and by the applicant in this case.

As a result of our review, the Executive Branch concluded that the conditions of the Atomic Energy Act, as amended, are fully met for this export. These conclusions included a determination that physical protection measures are adequate against possible diversion of the HEU by terrorists or proliferant countries. In making that particular determination, we consulted with the Department of Defense to confirm that physical protection measures will be adequate to deter theft, sabotage and other acts of international terrorism which would result in diversion of the material during the export. Moreover, the Government of Canada has provided written physical protection assurances, which have been verified by visits of U.S. experts to Canadian facilities.

The preeminent issue for this hearing would seem to be whether or not the conditions set forth in Section 134 of

the Atomic Energy Act are met (i.e. the Schumer Amendment). In our judgment, the three conditions of the Schumer amendment are met. First, with respect to the availability of a low-enriched uranium (LEU) target, the Department of Energy has confirmed that no LEU target is currently available that can be used as an alternative to HEU for Canadian isotope production. Second, with respect to a commitment to convert to the use of LEU, the U.S. and Canada have exchanged diplomatic notes confirming agreement that whenever an LEU target has been qualified by the relevant authorities and does not result in a large percentage increase in the total cost of operating a reactor, including necessary associated equipment, for the production and processing of medical isotopes, such an alternative LEU target will be used in that reactor after required equipment has been installed and the necessary licenses have been obtained. Third, with respect to a U.S. development effort on LEU targets, the Argonne National Laboratory has an active DOE-funded program underway for the development of LEU targets.

The intervenors had expressed the view that the requirements of Schumer are not met because Argonne lacks the information it needs to determine if the LEU targets it

is currently developing are compatible with the Canadian isotope production process. In this connection, the intervenors have stated that the Canadian producers, MDS Nordion and Atomic Energy of Canada, Limited, have refused to permit visits by Argonne to the isotope production facility or to furnish information about the Canadian process. However, our information is that visits, meetings and exchanges of information are taking place. Moreover, representatives of MDS Nordion told us in a meeting earlier this year, and later reiterated in writing, the company's commitment to convert to LEU production targets. In light of these developments, we believe that current Canadian cooperation with Argonne clearly meets Schumer amendment requirements.

The intervenors also suggest that there is no reason why Canada cannot continue to meet medical isotope production requirements by use of the NRU reactor while reconfiguring the Maple reactors for use of LEU targets. We find Canadian concerns to be reasonable regarding the risks of having to depend on the 43 year-old NRU reactor as the sole source of medical isotopes for an indefinite period, particularly given our inability to predict how long it will take to develop an LEU target for the Maple reactors that meets both nuclear and medical safety and regulatory

standards. Moreover, we have concluded that the proposed export is clearly in the interest of the United States since Canada, through its HEU target process, currently supplies more than 60 percent of U.S. medical requirements for molybdenum-99.

Madame Chairman, Commissioners, now I come to the point that I really want to make. It is clear that the Executive Branch, the NRC, the Congress and the intervenors all desire as great a reduction as possible and, eventually, the elimination of the use of HEU in civil nuclear commerce. But to make that happen, we need the voluntary cooperation of foreign research reactor operators and medical isotope producers in ongoing efforts to convert from use of HEU to low enriched uranium (LEU) fuel and targets. That voluntary cooperation is key to the success of our effort and, to a large extent, that cooperation has been forthcoming. However, we need to bear in mind that even when reactor operators and isotope producers are prepared to convert to LEU, they will need HEU to carry them through the interim period until the necessary steps for successful conversion to LEU can be completed. And if I were a reactor operator or an official in the nuclear establishment of another government, I would want to know that fuel and target material for my reactor were going to be supplied on a

reliable and predictable basis.. If we expect reactor operators and isotope producers to make serious efforts to convert to LEU, we need to make equally serious efforts to ensure a predictable and reliable supply of HEU until conversion can be accomplished.

We expect operators or producers seeking interim supplies of HEU to cooperate in good faith with the DOE RERTR Program in efforts to develop an alternative LEU fuel or target that can be used in a particular reactor. By the same token, when it is clear that there is no currently available LEU fuel or targets that can be used in a particular reactor or isotope production process, and that operators or producers are cooperating with DOE in good faith, we do not seek to second-guess how such producers run their operation. We expect that they will exercise good business judgement in seeking a timely supply of usable nuclear fuel or targets and that it is normal to assure redundant capability. That does not mean, however, that we do not exercise an independent look at whether the requirements of our law are being met. We have looked at, and we will continue to look at, whether a government's or an operator's cooperation with the RERTR development program is going forward in a productive manner.

I think it is important to note that as we negotiate the conversion of the last remaining HEU-fueled reactors and isotope production to LEU, we can expect that there will be more applications for supply of HEU, not less. The remaining reactors to be converted are the "big ones," and the ones posing the most technically difficult challenges. We are now making substantial progress in gaining the commitment of these operators and governments to conversion. But I have to tell you that the diplomatic notes that pertain to these conversions are a bit more complex and more reciprocal than in the Canadian case. In the case of Grenoble, for example, in return for a commitment to convert (and assuming an active U.S. LEU development program), we committed to make best efforts to sell HEU to the operator and to support issuance of the corresponding export licenses. If during the conversion period, each HEU application became the subject of intense debate and second guessing of operator/producer motives, we would not be perceived as a reliable supplier, and our ability to satisfy the obligations we undertook would be called into question. In which case, the operator or government would certainly seek alternative sources of HEU supply. If that happens, there will be no incentive to convert to LEU and the fundamental goal of the RERTR Program and U.S. efforts to limit uses of HEU globally will be undercut.

In short, ladies and gentlemen, we are moving ever more in the direction of a two-sided bargain -- a governmental commitment to LEU conversion, when and if possible, in return for a reliable and predictable basis on which to continue operation of existing facilities pending conversion. We think that is a fair bargain. And we firmly believe that the Government of Canada and the Canadian isotope producers are prepared to carry out their side of the bargain. For that reason, we believe that the issuance of the subject export license supports, not undercuts, our nonproliferation and nuclear supply policies.

Thank you for giving me the opportunity to make this presentation.

Title: Briefing on Proposed Export of High Enriched Uranium to Canada

Scheduled: 9:00 a.m., Wednesday, June 16, 1999 (PUBLIC)

Duration: Approx 1 1/2 hrs

Participants:

Panel 1

Applicant — 30 mins**

- Dr. Iain C. Trevena, Senior Vice-President
  Nuclear Medicine, MDS Nordion
- Dr. Jean Pierre Labrie, General Manager
  Research and Isotope Reactor Business
  Atomic Energy of Canada, Ltd. (AECL)

Panel 2

Nuclear Control Institute — 30 mins**

- Paul Leventhal, President
  Nuclear Control Institute (NCI)

Panel 3

Executive Branch — 30 mins**

- Richard J. K. Stratford, Director
  Office Nuclear Energy Affairs
  Nonproliferation Bureau, State Department (DOS)
- Tricia Dedik
  Director, Nuclear Transfer and Supplier Policy Division
  Office of Arms Control and Nonproliferation
  Department of Energy (DOE)
- Leonard S. (Sandy) Spector, Director
  Office of Arms Control and Nonproliferation, DOE
- Samit K. Bhattacharyya
  Technology Development Director
  Argonne National Laboratory (ANL)

  or
- Armando Trevelli
  RERTR Program Manager
  Argonne National Laboratory (ANL)
- Jim Snelgrove
  Coordinator for Engineering Applications
  Argonne National Laboratory (ANL)

(Cont. next page)

** Includes time for questions and answers.

Other People Attending:

MDS Nordion:

- Grant R. Malkoske, Vice President, Engineering & Technology
- David L. Nicholds, General Counsel & Corporate Secretary

AECL:

- Greg Sayer, Legal Counsel
- James A. Glasgow, Legal Counsel
  Morgan, Lewis & Bockius, LLP
- John E. Mathews, Legal Counsel
  Morgan, Lewis & Bockius, LLP

DOE/ANL

- Richard Goorevich,
  Nuclear Transfer and Supplier Policy Division
  Office of Arms Control and Nonproliferation, DOE

- Armando Travelli, Manager
  Reduced Enrichment in Research and Test Reactors (RERTR)
  Program, Argonne National Laboratory

- Jim Snelgrove, Senior Physicist
  Argonne National Laboratory

- Grant Bill Zagota
  RERTR Program
  Argonne National Laboratory

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U.S. Nuclear Regulatory Commission

SECRETARIAT

SCHEDULE

June 11, 1999
(Announced in Fed. Reg.)

Week of June 14

MONDAY 06/14

9:30 AM Annette Stacc Mtg Bill

2:00PM 4:00PM — BRIEFING ON 10 CFR PART 70 - PROPOSED RULE FOR REVISED REQUIREMENTS FOR THE DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL
Speaker: (Staff/NEI) (Public Meeting)
(See Scheduling Notes)

TUESDAY 06/15

10:30AM NOON — ALL EMPLOYEES MEETING (Public Meeting)
("The Green" Plaza Area) Ken

1:30PM 3:00PM — ALL EMPLOYEES MEETING (Public Meeting)
("The Green" Plaza Area) Bill

WEDNESDAY 06/16

(Awards Ceremony - 2:00 p.m.)

9:00AM 10:30AM — BRIEFING ON PROPOSED EXPORT OF HIGH ENRICHED URANIUM TO CANADA (Public Meeting) Ken
Speaker: (Applicant/NCI/DOS/ANL/DOE)
(See Scheduling Notes)

THURSDAY 06/17

9:00AM 11:00AM — BRIEFING ON STATUS OF URANIUM RECOVERY Ken
Speaker:(NRC/DOE/CRCPD/Fuel Cycle Facilities
Utah/NMA/Wyoming Mining Association)
(See Scheduling Notes)

11:00AM 11:05AM — AFFIRMATION/DISCUSSION AND VOTE (Public Meeting) Ken
(if needed)

11:05AM 11:30AM — AGENDA PLANNING SESSION (Exempt Session) Bill
(Executive Conference Room)

1:30PM 2:30PM — DISCUSSION OF MANAGEMENT ISSUES Ken
(Executive Conference Room) (Closed--Ex. 2 and 6)

FRIDAY 06/18

→ 9:00 a.m.

9:30AM 11:30AM — BRIEFING ON NRC INTERNATIONAL ACTIVITIES Bill
Speaker: (OIP/NRR/RES/NMSS) (Public Meeting)
(Briefing package due 6/11)

All meetings in Commissioners' Conference Room unless otherwise indicated.

11:30 Affirmation:
- Kansas Gas and Electric (Wolf Creek)
- Maintenance Rule

NUCLEAR CONTROL
INSTITUTE

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E-mail nci @access.digex.net Web http://www.nci.org

June 21, 1999

The Honorable Shirley Ann Jackson
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Madam Chairman:

Thank you again for the opportunity to testify at this past Wednesday's public meeting on the proposed export of highly enriched uranium to Canada. The meeting was extremely useful for establishing facts and encouraging cooperation from the applicant. We would like to underscore some key points of our presentation and to amplify on one in particular. We request that this letter be made a part of the official meeting record.

As stated in our presentation, the Nuclear Control Institute's goal is to facilitate the phase-out of Canada's reliance on highly enriched uranium (HEU) targets and its conversion to low-enriched uranium (LEU) targets -- in accord with the 1992 Schumer amendment -- without any interruption in the supply of vital medical isotopes to the United States and Canada. We wish to underscore that our proposed course of action would enable this outcome, whereas the applicant's would work against it.

The applicant intends to begin operations at its New Processing Facility using HEU targets. Once that facility becomes radioactive, according to an affidavit submitted by the applicant, any modifications necessary to accommodate conversion to LEU targets "would require the shutdown of the existing facilities for an extended period of time." (Joint affidavit of Dr. Forrest J. Remick and Mr. Harold D. Bengelsdorf, at 15.) An extended shutdown of the processing facility would interrupt the supply of isotopes, unless an entire second processing facility were constructed at significant expense. The applicant has argued that such a significant increase in cost would be cause not to convert to LEU. Thus, the applicant's proposed course of action leads inevitably to a stark choice: interruption in the supply of medical isotopes or perpetual reliance on HEU targets.

By contrast, our plan is to delay start-up of isotope production at Canada's new Maple reactors with the new Maple HEU targets and the NPF until a feasibility study and any required modifications are completed at the NPF to accommodate LEU targets. This approach would enable eventual conversion to LEU targets without an interruption in the supply of medical isotopes. Our plan would significantly reduce the cost of conversion to LEU targets and thus make that conversion more likely, in accord with the intent of the Schumer Amendment. In the interim, we have suggested the Canadians continue to rely on the NRU reactor and its associated

processing facility to produce isotopes. We believe this is a feasible option, given Canadian plans to maintain operation of the NRU reactor through 2005.

At the public meeting, a legitimate question was raised as to the availability of backup production capability -- in the event of an unanticipated interruption in the operation of the NRU reactor – in order to ensure an uninterrupted supply of vital medical isotopes to the United States and Canada. We replied that in addition to potential foreign isotope sources in Europe and South Africa, there is the possibility that the Maple reactors themselves, held on standby, could provide such backup capacity. We would like to amplify on this proposed contingency plan.

If the NRU reactor were to shut down unexpectedly, the NRU targets could be irradiated in one or both of the Maple reactors and then processed at the NRU processing facility. This approach would not require new FDA approval because both the target and the process would be the same as have been used for years and already have FDA approval. Canadian nuclear regulatory approval presumably would be required to insert the NRU targets in the Maple reactors, but this approval could be obtained in advance as a contingency plan in the context of the ongoing licensing proceeding for the Maple reactors. This arrangement would be superior to the situation in which the applicant finds itself today, relying on the aging NRU reactor without any other back-up reactor in the event of a shut down.

The only remaining question is the adequacy of waste storage capacity at NRU in the event of continued operation of the NRU processing facility. We understand that remediation efforts already are underway to free up capacity in the waste storage tank of the NRU processing facility. It is possible that additional storage capacity or regulatory approval also would have to be sought by the applicant. The applicant should pursue these options rather than insist that the Commission relax enforcement of the Schumer Amendment.

In addition, we were gratified that Ambassador Stratford responded positively to our contention that approving an export license for a five-year supply of HEU targets was inadvisable because it could undermine the applicant's incentive to proceed with conversion to LEU targets. We are troubled, however, by his suggestion that the Commission proceed with approval of a five-year license and then merely engage in annual reviews with the Executive Branch of the applicant's cooperation toward meeting the Schumer requirements. The best way to maintain an effective incentive structure is for the Commission to avoid granting any license for more than a one-year supply of HEU targets. To address the applicant's stated concern about licensing costs, the Commission could assess a one-time licensing fee for all one-year licenses that may be approved during the five-year period. However, in our view it is essential that the Commission assert its prerogative to act affirmatively on each one-year license, based on the applicant's cooperation at that time. This approach is far more likely to achieve the desired result than trying to jerry-rig a new procedure under which a five-year license would be granted subject to annual reviews.

In conclusion, we believe that there is a prudent, feasible path forward that can ensure continued supply of medical isotopes while fulfilling the Schumer Amendment's intent to phase out remaining HEU exports:

1. At a minimum, the Commission should withhold action on the proposed license until applicant has completed a feasibility study and made any necessary modifications to the NPF to accommodate LEU targets when qualified. As stated in our presentation, the Executive Branch should also be requested to submit a formal plan that includes an assessment of conversion costs and an agreement as to how these costs will be shared between the U.S. and Canadian governments and the applicant.

2. In the meantime, applicant can continue to rely on the NRU facilities to produce isotopes.

3. In the event of an unplanned outage of the NRU reactor, the NRU targets could be irradiated in the Maple reactors and processed in the NRU processing facility.

4. After the NPF is modified to accommodate LEU targets in addition to HEU targets, isotope production can commence in the Maple reactors and in the NPF using the Maple's new HEU targets with subsequent conversion to LEU targets, or production could be delayed slightly and then commenced with LEU targets.

Thank you for your attention to this important national-security and public-health matter.

Sincerely,

Alan J. Kuperman
Senior Policy Analyst

Paul L. Leventhal
President

cc: Commissioner Greta Joy Dicus
Commissioner Nils J. Diaz
Commissioner Edward McGaffigan, Jr.
Commissioner Jeffrey S. Merrifield
Annette Vietti-Cook, Secretary of the Commission