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Written submission from David Winfield

Mémoire de David Winfield

In the Matter of

À l'égard de

Application for a licence amendment to authorize activities related to the production and possession of Molybdenum-99 (Mo-99) at the Darlington Nuclear Generating Station (NGS)

Demande de modification de permis en vue d'obtenir l'autorisation de produire du molybdène 99 (Mo-99) à la centrale nucléaire de Darlington

Public Hearing - Hearing in writing based on written submissions

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Comments on Ontario Power Generation (OPG) licence amendment application for the Darlington Nuclear Generating Station (DNGS) in order to carry out activities related to the production and possession of molybdenum-99 radioisotope

Reference 2021- H-107

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Executive Summary

In the absence of any evaluation of economic feasibility being provided, we have concluded that the project is strongly technology driven, regardless of similar Mo-98 activation based projects which were not financially viable, [10] and [11]. As a result the Isotope Irradiation System (IIS) project appears to be a high-risk project for a government agency, with the possibility of inadequate oversight of commercial viability, at the pre-construction stage. Sections 1, 2 and Appendices 2 and 3 provide examples for this concern. While the IIS is on a smaller financial and technical scale than the failed MAPLE Mo-99 program, the same structural mix of a government agency, private sector partners and a First-Of-A-Kind (FOAK) project, are again all present and for the identical overall Tc-99m end product. Meanwhile the integrated technology and market used for fission-product Mo-99 / Tc-99m generators and eluted Tc-99m unit doses sold to hospitals have been well-proven for decades.

In our opinion, notwithstanding that the Mo-99 generator program is still under development, in order for the low specific activity Mo-99 obtained from natural molybdenum activation to compete with existing Mo-99 producers, as well as two new fission product Mo-99 projects now underway in Europe, would appear to require a significant increase in the production available from a single DGNS reactor. The IIS Unit 2 production capability has not been disclosed, so further insight is precluded.

The activation irradiation phase to Mo-99 is well known and technically demonstrated internationally. In principle then the basic concept of the IIS seems technically sound, although no details or alternative design rationales are discussed. However, the proposed FOAK technical method for insertion and removal of targets appears to be overly complex and perhaps susceptible to more component failures that a simpler design might avoid. By contrast the simpler conventional and well-proven hydraulic and pneumatic capsule systems of the NRU and SLOWPOKE reactors have established many decades of successful commercial operational experience for short-lived isotope production. The FOAK licensing and commissioning phase might then be particularly costly because of the absence of prior design and operational history and due to installation in a power reactor dedicated to power production.

Safety relevant information for the IIS itself is extremely brief, so a comprehensive review is not possible. Important examples of potential IIS failure events that are not addressed in any detail would be a stuck capsule, or other failures that could result in an in-core string of capsules that could not be removed with Unit 2 at power. Whether such capsules could then be safely left in core, disrupting Mo-99 production, until the next scheduled shutdown is not discussed. A similar example could be a hydraulic system piping failure and whether a leak of 2 Ci / kg water could be left until the next scheduled shutdown to clean up and repair. Appendix 1(i) provides comments on using 2 Ci / kg heavy water, with regard to ALARA. Appendix 1(ii) information implies that no capsule irradiation performance testing will be performed prior to commissioning the IIS. If so, this does not appear to be a prudent approach.

Section 4 indicates that the requested Mo-99 licence activity limit for Unit 2 seems to exceed the production capability by a large factor. The activity limit should be related to the corresponding number of irradiated capsules, which can then be operationally verified for compliance.

Finally, we suggest that it would be in the public interest for the Commission to request a preliminary cost / benefit analysis of the integrated Darlington IIS project as part of the first regulatory hold point, prior to equipment installation on the reactor, under protection of a non-disclosure agreement.

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1. Background

Within the limited technical detail of the information provided, our comments are twofold:

(1). To assess: (i) whether the DNGS irradiation proposal licence amendment appears technically sound, (ii) identify potential safety concerns that may not have been addressed and (iii) any potential detraction or conflict with the power production mandate of DNGS Unit 2.

(2). To identify any concerns that might limit the overall scope of the Mo-99 production, processing and medical usage cycle. The project should provide confidence that the irradiation proposal is commercially viable and capable of providing adequate specific activity (Ci ^{99}Mo / g Mo) after processing, of medical grade Tc-99m, while recognizing uncertainties of approvals needed from Health Canada and the US Food and Drug Administration (FDA) may lead to unrealistic schedules, [1].

The project recognizes that the potential isotope production capabilities of CANDU units offer some advantages, compared with other power reactor types and also many research reactors. There is thus no reason in principle that this irradiation capability, operating along with the primary mission of power production, should be discouraged. In general the basic concept of the IIS facility is technically sound. However, with the substantial Tc-99m processing chain and medical treatments being dependent upon a single CANDU unit and a single Moly-99 IIS there might well be a longer-term issue of production reliability.

Ignoring cost recovery / commercially viability at this stage, deemed out of scope in the submissions [2], is though problematic and should, we suggest, be of concern to the Commission. This concern arises from recollection of the MAPLE reactor project failure and subsequent lawsuits between BWXT Medical Ltd.'s predecessor, MDS Nordion and AECL. This experience should initiate a very cautionary approach, especially as the same final identical high-purity Tc-99m product is again the overall objective. Obscuring any technical or commercial flaw from inadequate oversight at an early stage must be avoided to prevent a repeat of this past experience that resulted in hugely wasteful expenditures of public and private sector funds and loss of credibility for the industry, [3]. In 2010 the Federal Government responded to a report of the Expert Panel on Medical Isotope Production of March 31, 2010, specifically on the Canadian production of Mo-99 by the MAPLE reactor project. The Federal Government concluded that dependence on government-funded reactors for the supply of Tc-99m supply was unsustainable and that no more public funds would be invested in Mo-99 proposals, unless the private sector covered full costs, liabilities and risks without further public investment. As with the MAPLE project the IIS project also involves a similar complex mixture of a Crown Corporation funded reactor and private sector partners, but now with a more diverse and still developing international Mo-99 supply chain, involving numerous other private sector players.

In Sections 2 to 4 and Appendix 1 we identify concerns and comments on a number of management, production, design and testing aspects of the project. Appendices 2 and 3 identify concerns with potential conflicting production priorities (power and isotope production) as these are not addressed by either OPG or CNSC. CNSC concludes that the IIS would have a negligible impact on existing reactor operations, [4]. OPG states that the IIS has no impact on safe operation, [5].

2. International picture

The Mo-99 / Tc-99m business is highly complex and competitive. We have concern that neither the CNSC nor OPG submissions provide any summary of past and current international proposals that use the same activation process as the IIS. The contribution to the current international progress and impact that the IIS might potentially make is thus lacking.

If it is appropriate for OPG to present '*Made in Ontario Solution'* information [6], it should also surely be appropriate to provide an overview of the current international Mo-99 production status, to give a perspective of the potential impact of DNGS's proposed production, [7]. For example, a new dedicated medical isotope production reactor in Europe is being constructed, on a commercial basis, as were the two ill-fated MAPLE reactors at Chalk River. In February 2020 BWXT announced that the University of Missouri Research Reactor (MURR) had performed irradiations on proprietary BWXT natural molybdenum targets [8] as part of developmental testing for Tc-99m production. More recently, an October 2020 announcement [9] was made for a reliable US domestic production capability of Mo-99, supplied from natural molybdenum targets, also using irradiations at MURR. A recent summary of various US and international proposals would have been helpful to understand the shortage and the evolution of the current commercial market for supplying the ^{99}Mo / ^{99m}Tc generator systems. Some linking therefore of the many current competing developments should have been presented to provide a broader perspective to OPG's *'Made in Ontario Solution'* proposal. Past experience with the neutron activation production method in particular would also have been useful. One of the recent activation production proposals using light water power reactors failed to materialize, due to lack of commercial viability, [10]. MURR is reported to have first used the activation method for Mo-99 in 1967 until 1980, but ceased production when the process became uneconomic, [11]. Reference [10] conclusions provides a comprehensive summary of the challenges facing current efforts to provide new Mo-99 supply routes, including agreement among all OECD countries to move towards full cost recovery. This agreement introduces an additional fundamental uncertainty for new Mo-99 projects producing low specific activity Mo-99 that is not mentioned or addressed in [6].

3. Management structure

OPG's submission did not provide a management organization chart of the IIS project. Relevant items of responsibilities however can be found in various sections of OPG CMD 21-H107.1:

- Laurentis Energy Partners (LEP) is the Project Owner of the Mo-99 IIS, [12],
- OPG and LEP have joint oversight role for project execution, (Section 2.1.6),
- OPG will be responsible for IIS operation, (Section 2.1.6),
- Corrective maintenance to be provided predominately by BWXTC-NEC maintenance staff, with OPG-oversight, (Section 2.6.3.1),
- Preventative maintenance, testing and critical equipment inspections (these during unit planned outages) to be provided using OPG's ECC process, (Section 2.6.3.2), and
- OPG is ultimately responsible for safety, (Section 2.8.4), [13].

From this list it is not clear if ownership of the IIS facility equipment resides with OPG, or its wholly-owned subsidiary LEP. It is also not clear why predominant responsibility for corrective maintenance resides with BWXTC-NEC staff as Section 2.6.3.1 implies, rather than OPG staff trained on reactor system maintenance, who, as per Section 2.1.6, are responsible for IIS operation. OPG indicate (Section 2.1.6) that additional staff may be required. This implies perhaps that these costs will be borne by OPG, not the project owner LEP. At this stage of the project we would expect, given the advance need for hiring and training, that at least the minimum facility operational and maintenance personnel requirements would have been defined in the OPG submission.

4. Production capability

The overall production viability from the very low specific activity neutron capture targets should give confidence that the proposal is both technically and financially viable. The submissions however provide no information on the expected useful potential production in terms of 6-day Curies, the fundamental Mo-99 production unit [14].

OPG's response [15] to the regulatory requirement Section 3(i) of the proposed license amendment: *'The quantity of activated Mo-99 will not exceed 8,766 TBq'*, we submit is an inadequate definition of the intended on-site Mo-99 activity limit. No material form or relevant time scale is defined in the OPG response. The chemical form of the target in the capsule (natural molybdenum metal, [16]), should be specified in Section 3(1)(c), as required by the Act. Sometimes, irradiated targets have material inside the cladding to facilitate capsule/cladding heat transfer. The capsule description [17] provides no mention if this is the case or not. The four-figure 1 TBq precision implied in the proposed 8,766 Bq activity limit is unrealistically small and cannot be technically justified or verified.

A maximum Mo-99 activity unit by itself does not provide a directly-measurable criterion for compliance. To provide this, the Licence Condition Handbook (LCH) should relate the maximum activity to the equivalent allowable number of irradiated capsules in Unit 2. No information is provided to show how the proposed licence activity limit has been derived and, importantly, what the capsule limit will be in each individual adjuster port location.

Published specific activity values of Mo-99 achievable from natural molybdenum metal irradiated in a thermal flux of 2×10^{14} neutrons / cm^2 / sec for 7 days are about 1 Ci Mo-99 / g Mo. The proposed licence limit of about 240,000 Ci (8,766 TBq) could then be equivalent to about 240 kg of irradiated natural molybdenum metal. If a guesstimate target weight of 250 g of molybdenum metal and the same flux were assumed, the proposed limit would then represent around 1,000 targets irradiated for 7 days. No public information was provided to confirm either this guesstimated target weight or the average thermal neutron flux. The uncertainty of our estimated target number is therefore unknown. Notwithstanding this lack of information, the proposed licence activity limit on site would appear to considerably exceed the source term activity requested in the licence amendment. The maximum in-situ capsule loading of all four IIS irradiation positions with capsules after a 7-day irradiation and conservatively allowing for some removed irradiated targets before shipment off site[1], would seem to be very much fewer than 1,000 targets. Notwithstanding this discrepancy we suggest that the maximum Mo-99 activity not to be exceeded on site should be explained in the LCH in terms of the verifiable equivalent number of 7-day-irradiated capsules in Unit 2.

[1] Also conservatively allowing for 20% extra for any unplanned over-irradiation of a few more days at power, after which equilibrium neutron activated Mo-99 would be achieved. If a much extended irradiation period occurred there is no information regarding any other consequences of over-irradiation.

Appendix 1: Design and testing overview

(i) Design

CNSC states that the design has identified and incorporated existing OPEX [18], but that there is no OPEX for an equivalent target delivery system in an operating CANDU reactor [19]. The latter claim would presumably be self evident as CNSC states numerous times that such irradiations are FOAK for a CANDU reactor for the unique IIS system, [20]. We are then concerned that neither the CNSC nor OPG submissions refer to the design and operational experience of the Hydraulic Capsule Facility (HCF) of the NRU reactor. The HCF operated successfully as an extremely reliable source of commercial isotopes based on the same principles to those planned for the IIS [21] in a large heavy-water-moderated reactor with vertically-cooled fuel channels, for more than 50 years. Features of the HCF design and historical operational experience would thus seem particularly relevant to the IIS. The design and safety analysis information from international irradiation experience that has been demonstrably considered by OPG, [18], is though not referenced[2].

A design feature mentioned in the OPG submission is to operate with 2 Ci / kg heavy water for hydraulic propulsion of the targets [22] and to use higher tritium concentration moderator water for in-core cooling of targets in an elevator. No description of the elevator, basket system, hydraulic system, pneumatic system or capsule drying system is provided. The use of what seems to be three capsule transfer sub-systems appears rather complex, compared to using a single pneumatic or hydraulic transfer system, as used in research reactors. Lack of any design rationale details precludes a review of the basic design. What can be commented on from the NRU HCF hydraulic-only design is that, by contrast, the HCF used only very low tritium concentration water, maintained over time with makeup additions from virgin heavy water, to mitigate tritium releases and doses. The use of 2 Ci / kg water for the IIS does not seem to be a good example of ALARA[3], particularly for initial commissioning and first target irradiations, before system heavy water make up losses and hence tritium releases are established, does not seem prudent. No upper limit on this concentration is given in the submission, nor was any indication provided that the hydraulic system heavy water may, or may not be, subject to any significant neutron flux, potentially increasing the tritium concentration.

While the NRU HCF did not have a containment system to penetrate, other basic HCF design features, would also have been relevant for OPG to consider with respect to safety-relevant design information. Such design features, needed for hydraulic system coolant flow / temperature control, pressure and surge tank control, heavy water make up, ion exchange system, radiolytic gas production, IIS process alarms, IIS reactor trip requirement, are all absent in the OPG submission.

(ii) Testing

CNSC staff concluded that OPG has addressed requirements associated with problem identification [23]. We found however no mention in the CNSC or OPG submissions any evidence that capsule irradiation testing will be performed prior to IIS commissioning in Unit 2. If this is the case, we submit this is a significant omission. For a FOAK irradiation to be performed in an 880 MWe CANDU unit with no prior irradiation testing (in a research test reactor) does not seem a very prudent approach to demonstrate either:

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[2] In addition to the NRU HCF, the most appropriate international information source we would suggest would be the IAEA Incident Reporting System for Research Reactors, IRSRR, which is not mentioned.

[3] ALARA is emphasized and claimed in numerous locations in the submissions of CNSC staff and OPG.

(i) capsule safe performance for 7-day irradiations and over-irradiation periods, and

(ii) adequacy of the irradiated Mo-99 product activity and purity for subsequent product processing to medical grade Tc-99m [4].

In contrast to the CNCS staff position therefore we do not agree that commissioning tests in an operating unit should be used to demonstrate satisfactory capsule irradiation performance. CNSC staff claim that proof of concept component tests will have been performed, [24]. There is no mention of the need for routine vacuum testing of all capsules or dimensional tolerance checking, which would also be expected.

OPG claims the IIS will be implemented based on proven engineering and a robust safety case, [25]. Absence of satisfactory target irradiation testing is not, in our view, an example of proven engineering, nor of a robust safety case.

Information from [8] indicates that MURR has performed recent test irradiations on natural molybdenum targets for BWXT. Neither the OPG nor CNSC submissions mention these BWXT target irradiations in MURR. It is therefore not clear if these undisclosed BWXT irradiations are being claimed by CNSC as proof-of-concept component tests as part of existing OPEX experience for the IIS-specific targets, [26], as any MURR contributions are not acknowledged in the '*Made in Ontario Solution',* [6]. Lack of any safety-relevant information on the target capsule irradiation performance precludes any further review comments on the capsules.

Appendix 2: Impact on normal operation

No information is provided to clarify that, if some IIS corrective maintenance is needed, whether a forced Unit 2 outage would be called. It appears however plausible that the following IIS failure events, taken from the hazard analysis summary [27], might well need an unscheduled unit shutdown for repair and clean up:

(1), (2) …release of damaged target fragments into moderator,
(7) …failure of target hydraulic system pressure boundary,
(9) …failure to position targets at required in-core locations,
(11) …failure to recombine D_2 and O_2 gases in IIS adjuster thimbles,
(12) …stuck targets in hydraulic tubing, and
(26) …loss of D_2O.

As mobile components in the IIS system, stuck capsules, could be expected to be one of the system dominant failure modes[5] albeit with low frequency, as it was with the HCF. The HCF did not use a mechanical winch / elevator sub-system, but with these IIS moving components it might also be expected that failures in this sub-system would require a unit outage to repair.

OPG also postulates an IIS system piping failure [28], implying this is the same as failures 7 and 26 noted by the CNSC above. The OPG statement that a piping failure in the hydraulic system would not require any operational response for up to 8 hours seems questionable. That the IIS will have a negligible and / or <u>no</u> effect on safe operation [4] and [5], also seems questionable for the

[4] The abandoned MAPLE reactor project had issues, amongst others, at a late stage, with both of these two basic items (i) and (ii) for fission-produced Mo-99.
[5] Causes could be inadequate capsule dimension tolerances (mitigated by pre-loading testing) and capsule swelling / distortion problems, the latter possibly also causing failure modes (1) and (2).

above failure events if they cannot be entirely discounted and forced outages may be needed.

Generally we find the CNSC IIS system design, operations and safety case summary reviews [29] brief and incomplete for public review. Safety seems more focused on secondary effects that the presence of the IIS may have on the reactor SCA's, e.g. effects on existing special safety trip setpoints and effect on an existing reactor accident progression [30] rather than on potential failures within the IIS system itself. There is no mention in the submissions whether the IIS requires any process alarms to help mitigate any of the postulated failure events listed, [27]. Alarm provision and possibly trip protection is common for non-fuel material irradiations performed in research and test reactors by irradiation systems (e.g. pneumatic, hydraulic and movable rod inserts). The NRU HCF required a system-specific reactor trip protection. The IIS failure mode Table 2 listing does not though provide enough information to judge, even qualitatively, event frequencies and consequences, such as would be provided in a failure mode effects and consequence analysis (FMECA).

The CNSC LCH highlights the existence of reactor operating limits in Section 3, yet there is no mention of any limits or conditions for the IIS itself, such as the maximum simultaneous number of capsules allowed, allowable reactor residence time and administrative controls in place to ensure compliance. CNSC mentions cooling of targets, [31], but there is complete absence of any design requirements for heat production in the capsules. Maximum expected temperature in the target material is not mentioned, yet irradiated capsule heat removal for total capsule loading would be expected to be a dominant safety parameter of concern for capsule irradiation integrity. The CNSC discussion of the IIS effect on a reactor corium melt with no mention of the IIS target heat load under normal or loss of hydraulic cooling conditions, seems curiously out of balance.

Appendix 3: Operational priorities

As noted in Appendix 2 above, a stuck capsule, a failure of the elevator system, or a piping failure might possibly require unscheduled Unit 2 shutdowns to repair. The operational priority in the event of such potential failures should be explicit. It is not clear from the CMD submissions[6] that a stuck capsule and other postulated failures, would all be fail-safe. Fail-safe in the context of IIS failure modes could be defined as events allowing continued Unit 2 reactor operation for an indeterminate time, until the next planned reactor outage. Whether Unit 2 normal operation and shutdown schedule would be thus compromised by an unscheduled shutdown for IIS repair, should be clarified in the IIS Operating Manual, [32]. The technical inconvenience of an unscheduled shutdown could well be viewed to have safety implications. There could also be a large economic penalty for loss of power production to maintain isotope production, as well as concern for prioritisation of private sector commercial interests, possibly at the expense of OPG ratepayers. With OPG having ultimate responsibility for safety this may seem to absolve private sector partners for any design problems, potential power production revenue losses and reactor related repair costs. If all such costs are to be borne by OPG this should be made clear.

The analysis conclusions seem to imply mainly that IIS normal operation has no impact on safe reactor operation. For normal operations we accept, within the limitations of the details available, that with the relatively benign nature of the target material, this conclusion is likely valid. Without more information however we cannot conclude that the impact assessment on normal reactor operation has covered the identified failure modes of Appendix 2.

[6] Safety analysis references are confidential.

References

[1] https://www.world-nuclear-news.org/RS-Darlington-to-supply-molybdenum-99-2106187.html
[2] CNSC CMD 21-H107, Section 2.2, Table 2.
[3] The North Renfrew Times, June 2 2021 'This Week in History', June 6 2001: *"The CNSC says it accepts part of the blame for problems with the Maple reactor project at Chalk River".*
[4] CNSC CMD 21-H107, p.1, para. 5.
[5] OPG CMD 21-H107-1, Section 2.3.2, para. 2.
[6] OPG CMD 21-H107.1, Section 1.4.
[7] CMD 21-H5.6 in the matter of BWXT Medical Ltd., Application for a Class 1B Licence, notes the importance from a world-wide public health perspective, yet the public is presented with no information or references in the current CMD submissions.
[8] https://www.bwxt.com/news/2020/02/25/BWXT-Successfully-Demonstrates-Labeling-of-Cold-Kits-with-its-Mo-99--Tc-99m-Technology
[9] https://www.frost.com/news/press-releases/northstar-commended-by-frost-sullivan-for-its-radiogenix-system/
[10] Annu. Rev. Nucl. Part. Sci, 2020, 70:77-94. The Shortage of Technetium-99m and Possible Solutions, T.J. Ruth, TRIUMF, Vancouver, B.C.
[11] IAEA Nuclear Energy Series No. NF-T-54, Non-HEU Production Technologies for Molydenum-99 and Technetium-99^{m}, Section 4.3, Vienna, 2013.
[12] CNSC CMD 21-H107, p.44 does not clarify whether LEP is also the IIS facility owner. OPG CMD 21-H107.1 does not identify the Project Owner.
[13] Both CNSC staff (CMD 21-H107, pp. 44-45) and OPG (CMD 21-H107-1, pp. 12-13) emphasize that OPG has committed to document in the DNGS Mo-99 IIS Operating Manual (OM) a policy that continued safe reactor operation will always take priority over medical isotope production, with safety having overriding priority over schedule, cost and production.
[14] Recognizing there are different ways the 6-day Curie is defined (*'Six problems with the 6-day Cu*rie', Journal of Radioanalytical and Nuclear Chemistry, 305, 13-22, 2015) this unit nevertheless is widely used.
[15] OPG CMD 21-H107.1, page 4 of 17, Section 3(1)(c).
[16] OPG CMD 21-H107.1, Section 1.5 states natural molybdenum is predominately Mo-98. More correctly Mo-98 contributes only 24.4% to natural molybdenum; one of the reasons the activation process produces a low specific activity product.
[17] OPG CMD 21-H107.1, Section 1.5.1.
[18] CNSC CMD 21-H107, Section 3.1 and 4.5.1.
[19] CNSC CMD 21-H107, p.43.
[20] CNSC CMD 21-H107, p.1, Section 1.1, Section 3.1, p.43.
[21] OPG CMD 21-H107.1, Sections 1.5 & 2.1.7 and CNSC CMD 21-H107, Section 3.5.
[22] CNSC CMD 21-H107-1, B.9.
[23] CNSC CMD 21-H107, p. 14.
[24] CNSC CMD 21-H107, Section 3.1, p.62, para 1.
[25] OPG CMD 21-H107.1, Section 1.1.
[26] CNSC CMD 21-H107, p.28.
[27] CNSC CMD 21-H107, p.57, as numbered in Table 2.
[28] OPG CMD 21-H107.1, Section 2.10.2.7.
[29] CNSC CMD 21-H107, Section 3.1 to 3.5.
[30] OPG CMD 21-H107.1, Section 2.3, 2.3.2 and 2.4.3.
[31] CNSC CMD 21-H107, p. 14, Section 3.2.
[32] OPG CMD 21-H107.1, Section 2.1.3 indicates continued safe reactor operation will take priority over medical isotope production.