Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

CMD 21-H100.1B

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Supplementary Information

Renseignements supplémentaires

Written submission from Bruce Power

Mémoire de Bruce Power

In the Matter of

À l'égard de

Application to allow the production of lutetium-177(Lu-177) at the Bruce Nuclear Generating Station (NGS)

Demande de modification de permis visant à permettre la production de lutécium 177 à la centrale nucléaire de Bruce

Public Hearing - Hearing in writing based on written submissions

Audience Publique - Audience fondée sur des mémoires

July 2021

Juillet 2021

Canada

July 14, 2021

BP-CORR-00531-01830

Mr. M. Leblanc
Commission Secretary
Canadian Nuclear Safety Commission
P.O. Box 1046
280 Slater Street
Ottawa, Ontario
K1P 5S9

Dear Mr. Leblanc:

Bruce B: Response to Questions from Commission Panel Members, CMD 21-H100Q

The purpose of this letter is to respond to the applicable questions from the Commission Panel Members on Bruce Power's Lutetium-177 (Lu-177) Isotope Production system, as requested in Reference 1.

Bruce Power's responses to questions 1 to 5 from Table 1 of CMD 21-H100Q are provided in Attachment A.

If you require further information or have any questions regarding this submission, please contact Peter McDermid, Director, Medical Isotopes and Business Development, at (226)-930-1551 or peter.mcdermid@brucepower.com.

Yours truly,

Maury Burton
Chief Regulatory Officer,
Bruce Power
2021.07.14 11:13:31 -04'00'

Maury Burton
Chief Regulatory Officer
Bruce Power

cc: CNSC Bruce Site Office

Attach.

Reference:

1. Email, L. Sigouin to M. Burton, "CMD 21-H100Q - Commission Panel Questions - Bruce NGS Lu-177", June 30, 2021, BP-CORR-00531-01832.

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Attachment A

Bruce Power Responses to CMD 21-H100Q

Attachment A: Bruce Power Responses to CMD 21-H100Q

CNSC Question 1:

"If there is a breach in the pneumatic delivery system, Bruce Power notes that contaminated inert carrier gas would be directed to the exhaust stack and be contained by the high-efficiency particulate air (HEPA) filters. Furthermore, releases through the stack would be detected by the continuous monitoring system.

Question: It is not mentioned how the carrier gas would become contaminated, but HEPA filters are designed for particulate matter capture. Therefore, is the HEPA filter sufficient to capture the contaminated carrier gas?"

Bruce Power Response 1:

As described in Section 4.1 of the Environmental Risk Assessment Gap Analysis for Isotope Production Activities (Reference A1), the carrier gas could contain activated beta-gamma emitting particulates and Ar-41. Ar-41 is an activation product of Ar-40 that can be present in small quantities in the system during normal operation. When there is a breach of the pneumatic delivery system, additional Ar-41 can be generated due to air ingress. The particulates will be attenuated by the HEPA filters, but the Ar-41 will not as it is a noble gas. All releases to the stack, including the particulates and the noble gases, will be continuously monitored by the stack monitor and will be reported as per routine environmental reports. Based on estimations, the expected increase in noble gas activity released through the stack is negligible.

CNSC Question 2:

"Bruce Power will be shipping the irradiated targets to a third party, name withheld due to commercial confidentiality that is a licensed entity outside of Canada. Although it is stated that the recipient of the irradiated targets is a licensed entity, can CNSC staff confirm that it has validated these credentials, and that the entity is in fact known and in good international standing? The purpose of this question is not to place in doubt the business dealings of Bruce Power, but solely to ensure that withholding names of recipients of nuclear materials for business reasons does not prevent CNSC from doing its due diligence investigation for safety and international obligations. The name does not need to be revealed, the only request is for confirmation that CNSC has in fact investigated and approved the recipient."

Bruce Power Response 2:

It has been determined that the identity of the third party can be released. Isotopen Technologien Munchen (ITM) is a privately owned biotechnology and radiopharmaceutical company dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radioisotopes for use in cancer treatment. ITM was founded in Munich Germany in 2004 and pioneered the commercial production of high quality non-carrier added Lutetium-177. ITM currently utilizes an international network of research reactors for the irradiation of Ytterbium-176 to produce Lutetium-177. ITM is in good standing with the German nuclear regulator and holds the required licences to obtain, process and distribute Lu-177. ITM must maintain this licence to receive Lu-177 originating from any reactor internationally, including Bruce Power.

CNSC Question 3 (i):

"Under Design Background in CNSC's CMD it was mentioned that targets that become stuck in the carrier tubes would remain in place until the unit's next outage.
Questions:
(i) Would such a blockage prevent any further irradiation of targets, making the system inoperative, and"

Bruce Power Response 3 (i):

A new batch of targets for the next weekly production cycle will not be inserted into the system if a blockage of targets is detected inside the Target Finger Tubing (TFT); therefore, further irradiation of new targets will not occur. Until removed, the targets that are stuck in the TFT will continue to be irradiated if they reside in the section of the TFT that is positioned inside the calandria reactor core.

Target blockages inside the TFT would not make the entire system inoperative; however, the function of inserting new target batches would not be available until the stuck targets are removed from the core. The system's containment boundary valves will still be operable and will close keeping the irradiating targets isolated inside containment. The system will also be capable of continuing the processing of already harvested targets from the previous production cycle that are waiting in the shielded Decay Zone (DZ), Queue Zone (QZ) or Target Interface Skid (TIS) for transport out of Bruce B, as these portions of the system would not be impacted by targets blocked inside the core.

CNSC Question 3 (ii):

"Under Design Background in CNSC's CMD it was mentioned that targets that become stuck in the carrier tubes would remain in place until the unit's next outage.
Questions [continued]:
(ii) Would the targets be highly radioactive after such prolonged exposure, and what would the handling and disposal implications be?"

Bruce Power Response 3 (ii):

While activity will continue to increase the longer targets are irradiated in the core, the activity of the targets will plateau after 30 days of residency in the core. Further irradiation beyond this time period will not result in increased target activity.

The Decay Zone (DZ) where newly irradiated targets are initially transferred to when first harvested from the reactor core has been conservatively designed to shield against the maximum target activity that could be produced (i.e. 30 days of irradiation) at higher than normal reactor power levels. The target stop valve permissive in the decay zone will also not allow the release of these targets for further processing and flasking until the activity has decreased to acceptable safe levels. For these reasons there are no handling implications as a result of prolonged target exposure in the reactor core.

In respect to disposal implications, all harvested targets will return to ITM regardless of whether the target activities are suitable for medical use, recycling or waste disposal.

CNSC Question 4:

"Related to the previous issue, if targets become stuck in the delivery system, is there any risk of pressure build-up due to trapped delivery gas heating, or the possibility of the delivery tube bursting and releasing contaminated gas?"

Bruce Power Response 4:

If targets become stuck in the delivery system, pressure can increase as a result of the blockage due to loss of venting and heating of the helium gas around the stuck irradiated targets. Consideration of this event has been incorporated into the design as targets will need to be stationary in isolatable sections of the system (such as in the TFT for irradiation, in the Decay Zone for activity decay and in the Queue Zone for target flasking), therefore the design pressure of the system was selected to envelope the expected rise in pressure that would result in the event of a stuck or stopped target.

There is no possibility that the system tubing would burst releasing contaminated gas as a result of a stuck target because the system has been designed to withstand higher pressures, which is demonstrated by design stress analysis and pressure testing after construction to pressure boundary requirements.

CNSC Question 5:

"What happens to the target in the event of an unplanned shutdown? Can it be retrieved, or left in place to complete its irradiation as planned and then retrieved? Has this scenario been planned for?"

Bruce Power Response 5:

In the event of an unplanned unit shutdown, targets can either be retrieved for early harvesting (contingent on system accessibility which could be hindered by the forced shut down) or left in the core for further irradiation following the outage. The decision to retrieve or leave the targets would be based on commercial requirements and would not impact the safety of the system or reactor.

This scenario has been planned for as analysis has been performed to demonstrate the targets can be safely left inside the core for 3.5 calendar years before the next planned outage occurs where future target retrieval can occur if required.

<u>Reference:</u>

A1: Letter, M. Burton to M. Leblanc, "Application for the Amendment of the Power Reactor Operating Licence", November 25, 2020, BP-CORR-00531-00982.