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Supplementary Information

Written submission from Best Theratronics Limited

Renseignements supplémentaires

Mémoire de Best Theratronics Limited

In the Matter of the

Best Theratronics Limited

Application for the renewal of the Class IB Nuclear Substance Processing Facility Operating Licence

Commission Public Hearing

May 16, 2019

À l'égard de

Best Theratronics Limited

Demande de renouvellement du permis d'exploitation d'une installation de traitement de substances nucléaires de catégorie IB

Audience publique de la Commission

Le 16 mai 2019

Canada

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Overview

The purpose of this document is to address matters raised following the Applicant's request for Class II Facility/NSRD licences, and succinctly state the issues for the Commission's consideration.

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1.0 Matters for Consideration

The Applicant has appreciated the CNSC staff's support though the renewal process as well as their input and courteous communications throughout. This notwithstanding, the Applicant and CNSC Staff have come to a respectful disagreement regarding the Applicant's request to replace its current Class 1B license with Class II Facility/NSRD licenses. The difference of opinion turns on somewhat technical interpretations of the applicable regulations, as well as the broader policy objectives of the legislation.

There are essentially three questions of interpretation before the Commission:

(a) Does the Applicant's facility include a particle accelerator "**that is capable**" (emphasis added) of producing nuclear energy of more than 50 MeV per atomic mass unit for certain beams of particle?
(b) Does the Applicant manage, store or dispose **waste** "containing radioactive nuclear substances at which the resident inventory of radioactive nuclear substances **contained in the waste** is10^{15} Bq" or more?
(c) Does the Applicant "**process or use**" nuclear substances in a quantity in excess of 10^{15} Bq in a year?

1.1 Issue of "Capacity"

As the evidence will show, the Applicant manufactures particle accelerators that are designed to produce nuclear energy of more than 50 MeV, but is incapable of doing so on the manufacturing floor of the facility. The operation is physically inhibited. Once an end user purchases the product and takes delivery, that end user has the option of removing the physical impediments to operate the accelerator to create the capacity to produce nuclear energy of more than 50 MeV. The unit's capability is enabled only after the end user exercises this option.

1.2 Issue of "Waste"

Paragraph 19 (a) of the *General Nuclear Safety and Control Regulations* define a nuclear facility for the purposes of Section 2(i) of the *Act* as a facility for the management, storage or disposal of **waste** containing radioactive nuclear waste at **which the resident inventory of waste** is 10^{15} Bq or more. The regulatory framework effectively pulls this definition into the definition of a Class 1 Facility as CNSC Staff have correctly pointed out.

However, the entire focus of paragraph 19(a) is on waste, which is defined by the International Atomic Energy Agency as "material... for which no further use is foreseen".

The Applicant's evidence will show that, while it stores returned double encapsulated sealed sources for periods of time which exceeds 10^{15}Bq activity annually, such inventory is for resale, future use, recycle and disposal, and as such, not all returned sources meets the definition of "waste".

1.3 Issue of "Processing and Use"

With the exception of one research and development Class II prescribed equipment, loaded with a double encapsulated cobalt source, with an activity 0.189 x 10^{15} Bq, the Applicant is essentially a distributor of radioactive material and does not process or use nuclear material.

The Applicant manufactures blood irradiators, but contracts with Nordion for the purpose of loading the sources in the blood irradiators. The Applicant also manufactures cobalt teletherapy equipment, but the cobalt sources are manufactured by Nordion or other manufacturers in the United States. Finished sources are delivered in Type B(U) transport packages and shipped to the end user/customers in the same Type B(U) containers.

2.0 Legislative Objectives and Risk

The Applicant respectfully submits that its technical legal interpretations are sound standing on their own, but even more persuasive when considered in the context of the purposes of the legislation.

Section 3 of the *Act* provides that its purpose is the limitation of risk "to a **reasonable level and in a manner that is consistent with Canada's international obligations**". The objects of the Commission are stated in Section 9 of the *Act* to include the prevention of "**unreasonable risk**" and **conformity** with **international obligations and measures of control** (emphases added)**.**

The Applicant is a low risk licensee that produces a particle accelerator that is not capable of operating at a Class 1 level, while on the Applicant's premises. With the greatest of respect, the Applicant believes that taking an overly broad view of the meaning of the word "capability" is inconsistent with the Act's purpose of limiting risk to a reasonable level. If the accelerator cannot be operated at a Class 1 level in any practical sense, how does requiring a Class 1 license reduce risk in any reasonable way? How is that consistent with the Commission's mandate to prevent unreasonable risk when there

is no risk at all? And in the absence of any international conventions in respect of particle accelerators, how is that in conformity with international obligations and controls?

Likewise, all of the radioactive material stored at the Applicant's facility are contained in double encapsulated sealed sources and are always shielded inside self-shielded blood irradiators or in Type B(U) transport containers**.** This is because the Applicant is merely a distributor, with the exception of the one R& D prescribed equipment mentioned above, and in stark contrast to licensees that process or use such material or are waste management facilities. The Applicant never uses or processes unshielded material. Requiring the Applicant to secure a Class 1B license as though it were a facility to process or use nuclear material, or be considered as waste management facility, is also inconsistent with the legislative policy framework that requires risk limitation **to a reasonable level.** The concern raised was based on articulating a broad interpretation of the word "waste" that is inconsistent with Canada's international obligations and not in conformity with the definition promulgated by the International Atomic Energy Agency.

3.0 Arguments against a Consolidated Licence

A suggestion was presented that a consolidated Class 1B licence, instead of Class II Facility/NSRD licences, is more efficient and financially beneficial to both the CNSC and the Applicant. However, these arguments are lost on the Applicant as extremely intense oversight on a low risk operation supports neither efficiency nor the achievement of financial benefits. The enormous difference in licensing costs will only serve to erode the Applicant's ability to compete internationally against entities with similar risk profiles that are less much intensely regulated by the jurisdictions in which they operate.

4.0 Conclusion

As per arguments presented above, following extensive review of the NSCA and relevant regulations, the Applicant believes regulatory oversight by Class II Facility/NSRD directorates, as it was prior to Class 1B license, is appropriate for current and future operations.