



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

CNSC Readiness for licensing of Facilities for Medical Isotope Production

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Outline



- Expert Panel Report
- CNSC Input to the Expert Panel
- Readiness for Licensing Facilities for Producing Isotopes

Expert Panel- Background



The Government of Canada established an expert panel in June 2009 to provide advice on medium- and long-term options for the production of medical isotopes in Canada.

Expert Panel Report - Findings



- A new multi-purpose research reactor.
- The MAPLE Project is more than 2-years away from being an option and the economics are questionable.
- Existing reactors using HEU targets should be considered as responses to short-term supply shortages.
- Photo-fission with linear accelerators
 - Poor economics and significant generation of nuclear waste
- Mo-100 transmutation with linear accelerators
 - Poor economics, but would not generate nuclear waste.
 - Mo-100 recycling and generator R&D is required
- Cyclotrons with commercial production beginning between 2011 and 2014
 - would only serve hospitals and radiopharmacies in close proximity,
 - R&D on target design and Mo-100 recycling are needed.

Expert Panel Report - Recommendations



General recommendations:

- Strive for diversity and redundancy throughout the supply chain.
- Leverage multi-use infrastructure.
- Continue with international coordination, and seek processing standardization within North America; and
- Recognize that HEU options are viable only in the short to medium-term.

Expert Panel Report - Recommendations



Technology-specific recommendations:

- Replace the NRU reactor with a new multi-purpose research reactor.
- Support an R&D program for cyclotron-based Tc-99m production; and
- Achieve better use of Tc-99m supply through advanced medical imaging technologies.

CNSC Input to the Expert Panel



- CNSC staff member seconded to NRCan
- Expert panel requested CNSC to assess samples of the proposals:
 - 3 for accelerators/cyclotrons
 - 3 for reactors

CNSC Input to the Expert Panel



Assessment Criteria:

- Licensability: *“Is the proposal licensable?”*
- Applicable Regulations: *“[Have] High level licensing requirements [been] identified?”*
- Timelines: *“[Are] Timelines for regulatory approval reasonable?”*
- Information in Support of Timelines: *“Is the information provided to address timelines, high-level regulatory requirements, and expectations sufficient?”*
- Other Comments: *“Are there any major omissions (e.g., waste management) and technical challenges that have been overlooked, not adequately addressed?”*



Key Findings for the Accelerator Based Submissions:

- All accelerator based submissions do not present significant licensing risk or obvious regulatory issues.
- The viability of each project relies primarily on the result of development work to demonstrate its capability and on other factors related to processing and waste management.



Key Findings for the Reactor Based Proposals:

- All proposals could be licensable provided that the submissions are supported by adequate safety cases.
- Where substantial changes were proposed to existing designs of reactors, or the use of cores of unproven design.
 - The licensing of such facilities would require substantive new safety cases and related regulatory assessments.



Since the proposals were not a licence application

- CNSC will require specific information for:
 - the processing aspects of irradiated targets.
 - the management and stabilization of high level radioactive waste.

Readiness for Licensing of Facilities for Producing Isotopes: Timelines



Estimated timelines for licensing of:

- Accelerators & Cyclotrons
- Reactors
- Processing Facilities ($> 10^{15}$ Bq/a, $< 10^{15}$ Bq/a)
 - pre-requisites for meeting timelines documented

Readiness for Licensing of Facilities for Producing Isotopes: Regulatory Framework



In order to support licensing of various types of reactors, accelerators, cyclotrons and processing facilities:

- CNSC staff carried out a review of existing:
 - Regulations, Regulatory Documents (RDs), Guidance Documents (GDs)
 - Industrial codes and standards
- CNSC staff have identified
 - No regulatory amendment is required
 - RDs & GDs are required to support licensing of new facilities for isotope production
 - We will build on recent past experience and not reinvent the wheel.

RDs & GDs to Support Assessment of Licence Applications



- Existing Accelerators & Cyclotrons documents
 - “Class II Non-medical Accelerator Licence Application Guide”
 - “Certification of Radiation Devices or Class II Prescribed Equipment”
 - RD-327, “Nuclear Criticality Safety”

RDs & GDs to Support Assessment of Licence Applications



Reactors

- Licence to Prepare Site Application for Class 1A Reactors with Thermal Output Greater than 5 MW - Guidelines - under development
- RD-308, Safety Analysis Requirements for Small Reactors - under development
- RD-367, Design Requirements for Small Reactors- under development
- Construction Licence Application for Small Reactors: Guidelines - to be developed, building on Construction Licence Application for Nuclear Power Plants: Guidelines, RD-308, RD-367, IAEA documents for research reactors
- Operating Licence Application for Small Reactors: Guidelines - to be developed, building on RD-308, RD-367, IAEA documents for research reactors, IAEA document GS-G-4.1, Format and Content of Safety Analysis Reports

RDs & GDs to Support Assessment of Licence Applications



Processing Facilities with throughput $< 10^{15}$ Bq/a:

- RD-52, "Design Guide for Nuclear Substance Laboratories and Nuclear Medicine Rooms"
- RD-327, "Nuclear Criticality Safety"

RDs & GDs to Support Assessment of Licence Applications



Processing Facilities with throughput $> 10^{15}$ Bq/a:

- Safety Analysis Requirements for Processing Facilities - to be developed, build on requirements for New Processing Facility at AECL-CRL
- Design Requirements for Processing Facilities - to be developed, build on requirements for New Processing Facility at AECL-CRL
- Application Guidelines for Site Preparation for Processing Facilities - to be developed, build on Licence to Prepare Site Application for Class 1A Reactors with Thermal Output Greater than 5 MW - Guidelines
- Application Guidelines for Construction of Processing Facilities - to be developed, build on Construction Licence Application for Nuclear Power Plants: Guidelines
- Operating Licence Application for Processing Facilities:
 - to be developed, building on
 - RD-308, RD-367 presented to the Commission in January 2010;
 - IAEA documents for research reactors, IAEA document GS-G-4.1, Format and Content of Safety Analysis Reports

Summary



- Expert Panel provided clear recommendations to the Canadian government (multi-purpose reactor, cyclotrons)
- CNSC provided direct support to NRCan
- CNSC provided support to Expert Panel, report delivered on schedule
- Readiness for licensing facilities for isotope production:
 - Timelines estimated
 - Regulatory framework elements currently available to support facility licensing identified
 - Identified regulatory framework elements to be developed to support facility licensing



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