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Reactor Based Mo-99 Supply System Project: Cask Certification Plans

Washington, D.C., June 28, 2016

NON PROPRIETARY PART 1



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NON PROPRIETARY: PART 3

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QA Program

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Nordion's QA Program



- Full QA Program Approval prior to 2012
 - In support of several C of C's
- 2012 – Limited Scope QA Program
 - Use, Maintenance, Repair, Procurement
 - No active C of C's
- 2016 – Require full scope
 - Support C of C for F-339 package

- **F-339 Package**
 - Design phase < 2012 – under QAP Approval
 - 1 package (s/n 8) manufactured 2012, no QAP Approval
 - No changes to manufacturing controls/oversight
 - New packages (s/n 9, 10) to be manufactured
 - Will QAP Approval cover off s/n 8? How to address?
- **Need to amend QAP to broaden scope**
 - Do we just address specific elements or full program?
 - Regulatory Guide 7.10

- **Additional Questions**
 - Full scope approval for all products (special and normal form)
 - 2012 approval only lists special form
 - Nordion does ship non-special form into US
 - Timeline
 - Do we need QAP prior to submission for C of C or concurrent?



Discussion

Agenda

- Project Introduction
- High Level Process Description
- Cask Certification Plans (Proprietary)
- QA Program

Mo-99 Production by Selective Gas Extraction (SGE)

Leveraging World-Class Capabilities and Existing Nuclear Infrastructure



About Nordion



Nordion is a health science company that provides market-leading products used for the prevention, diagnosis and treatment of disease.

We've been **delivering safe, high-quality products** to global customers for more than 60 years.

To best serve the diversity of our customers' requirements, we are organized into two business units—**Sterilization Technologies** and **Medical Isotopes**.

APPROXIMATELY

375 EMPLOYEES

SUPPLY OVER

500 CUSTOMERS

AROUND

30 PRODUCTS

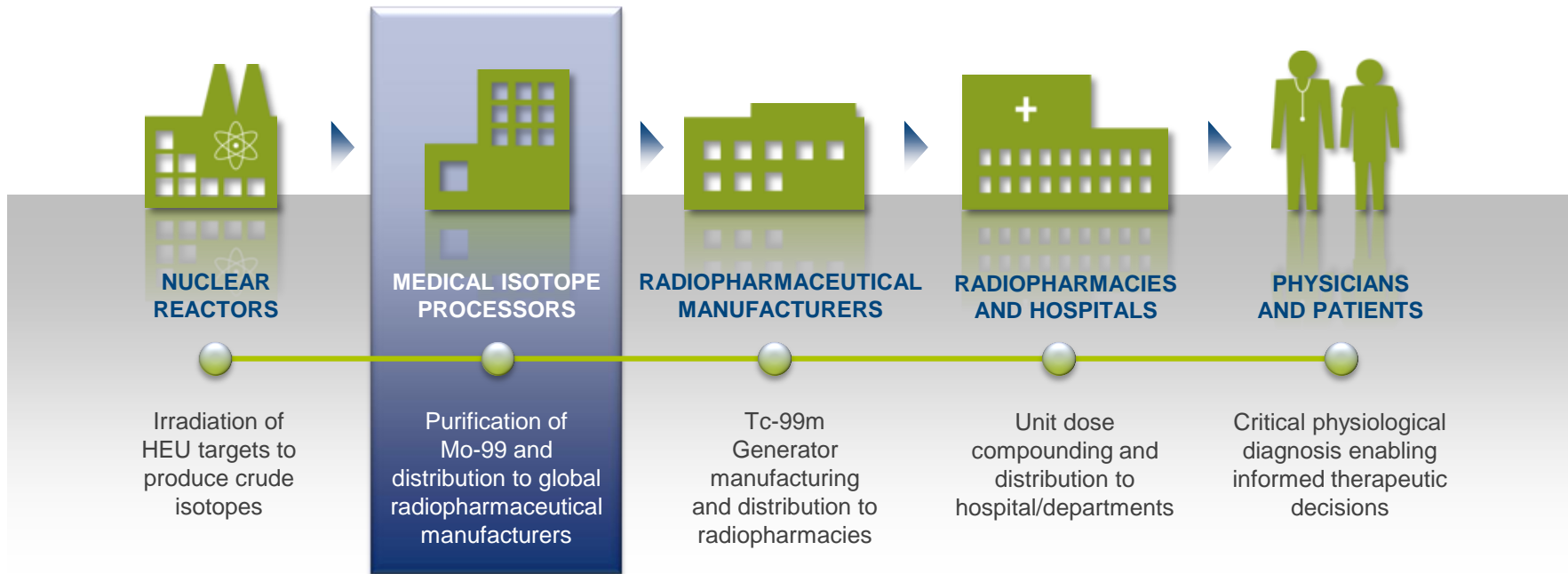
ACROSS MORE THAN

40 COUNTRIES



Medical Isotopes

Experts in the Critical Supply Chain (Mo-99)



- Established, reliable facilities providing high-quality isotopes to global customers
- Specialty skills in operations, regulatory affairs and global logistics
- Nordion has been manufacturing Mo-99 for over 40 years

Nordion Current Mo-99 Supply

- Nordion's current supply chain utilizes the National Research Universal (NRU) reactor operated by Canadian Nuclear Laboratories (CNL)
- The NRU is scheduled to cease routine production of Mo-99 in November 2016.
- Government of Canada announced on February 6, 2015 its support of the extension of the NRU operations until March 31, 2018 to help support global medical isotope demand in the unexpected circumstances of shortages during this time.
- Nordion supports the efforts of the Canadian Government to operate the NRU and provide a standby Mo-99 capability during the period of transition as new supply capacity comes online.



Partnership with General Atomics and the Missouri University Research Reactor (MURR)

- Mo-99 supply utilizing proprietary Selective Gaseous Extraction (SGE) technology
- Leverages existing reactor, processing facility and licensed shipping container infrastructure and capabilities



Energy & Environment New Nuclear Regulation & Safety Nuclear F

US-Canadian partnership for isotopes

23 February 2015

A Canadian-US partnership has been announced to create a "new, reliable supply" of medical isotopes for use worldwide.



Project Organization



General Atomics

Target and reactor systems design and manufacturing

- Trusted resource of high-technology systems
- Experts in nuclear fuel cycle, including uranium mining and processing
- Experts in reactor design: GA TRIGA® research reactors in operations around the world for over 50 years
- Developer of LEU technology utilizing novel reusable target design

Missouri University Research Reactor (MURR)

Premium Reactor Operator and Research Center

- 10 megawatt facility; the largest university research reactor
- Operates 52 weeks a year
- 35+ years of successful and innovative radiopharmaceutical R&D and collaborations with industry
- Strong record of regulatory compliance (US NRC, US FDA)
- Experts in volume radiochemical processing and international shipping
- Nordion's partner in supply of TheraSphere for over 20 years

Nordion

Premier Isotope Producer and Distributor

- Experts in Mo-99 purification into medical grade product since 1975
- Strong record of regulatory compliance (US FDA, EMEA, Health Canada)
- cGMP/GLP - licensed facility
- Global leading supplier of Mo-99 with extensive marketing, sales & distribution expertise
- Global licensed transport container fleet



NNSA Awards Mo-99 Cooperative Agreement to General Atomics

September 30, 2015

WASHINGTON, DC – Today, the Department of Energy’s National Nuclear Security Administration (DOE/NNSA) announced that it will award a cooperative agreement to General Atomics (GA) to support its project for domestic production of molybdenum-99 (Mo-99) without highly enriched uranium (HEU).

Mo-99 is the parent isotope of technetium-99m, which is the most widely used radioisotope in medical diagnostic imaging and is used in approximately 80 percent of nuclear diagnostic imaging procedures in the United States, equating to about 50,000 medical procedures every day. The United States currently does not have a domestic production capability for Mo-99 and must import its supply from foreign producers. Under the American Medical Isotopes Production Act of 2012, and through its long-standing nonproliferation mission, NNSA is working to support the establishment of reliable supplies of Mo-99 while minimizing the use of HEU in civilian applications. This project with General Atomics meets both of these important goals.

Process Overview

