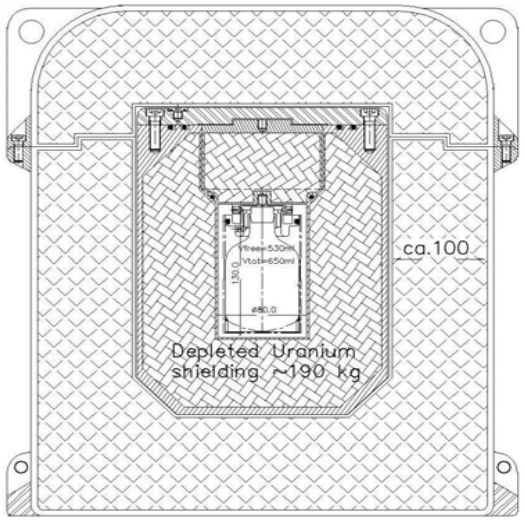
MIDUS

Type B(U) Container for Mo-99 Bulk



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Overview

- Introduction
- General information
  - Product characteristics
  - Mo-99 Bulk Production process
- MIDUS Concept
- Design / Licensing overview

Introduction

- Mallinckrodt learned in March 2005 that it will lose the ability to ship Mo-99 in October 2006.
  - Current B(U) container certificate will expire 10/2006
  - Manufacturer (certificate holder) will no longer support the product and will exit the cask business
  - The only available substitute casks have a much smaller capacity, which will result in more shipments and dose

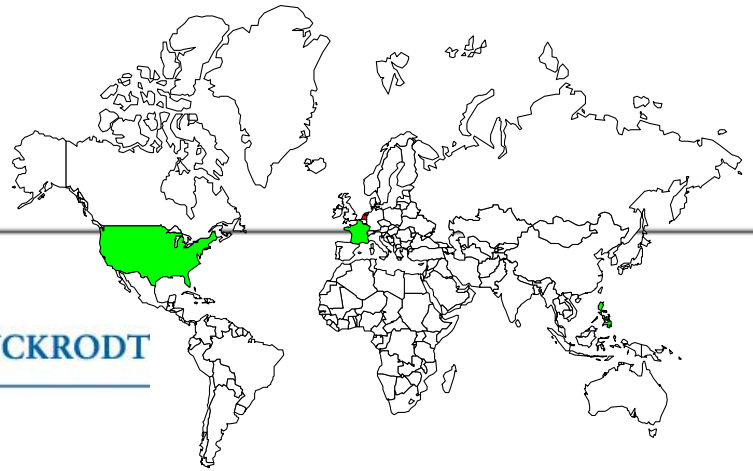
Introduction

- Mallinckrodt has taken several steps to ensure that product delivery is not interrupted
  - Created a conceptual design for a new package based on the best features of its existing cask fleet
  - Contracted BNG for U.S. certification and manufacture

- The purposes of this meeting are to:
  - Introduce the package concept and licensing plan
  - Discuss the review schedule
  - Obtain any feedback on the design and approach

General Information

- Mallinckrodt Medical is part of the Tyco Healthcare Group with manufacturing facilities in Petten (NL) and St. Louis (US). Both are producers of Radio Pharmaceuticals.
- The main pharmaceutical product of Petten is the radioactive intermediate product Molybdenum 99 (Mo-99). This product decays to Technetium 99(m) which is used for medical diagnostics.
- Forecasted in CY2006 approx. 200,000 Ci (7400 TBq) of Mo-99 will be produced which is equivalent to 20 million patient doses.
- Petten ships 150,000 Ci (5550 TBq) of Mo-99 to St. Louis annually for the US market. This is equivalent to **15 million patient doses**.



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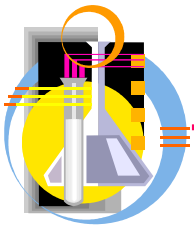
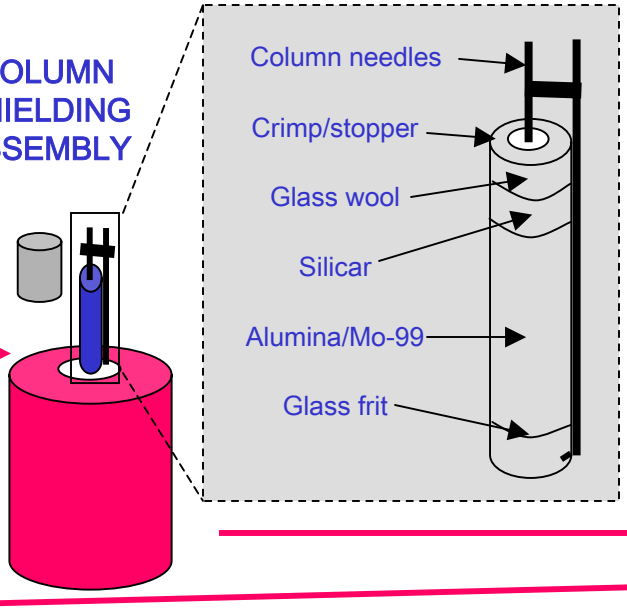
Mo-99/Tc-99 DTE Generator Production

Mo-99 PREPARATION

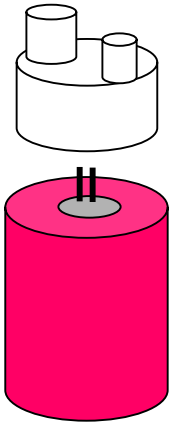
Mo-99 solution is diluted to concentration and loaded onto chromatography columns



COLUMN SHIELDING ASSEMBLY

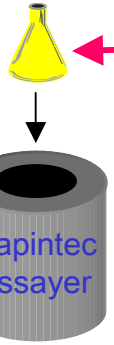


ELUTION HOOD/COLUMN CONNECTION

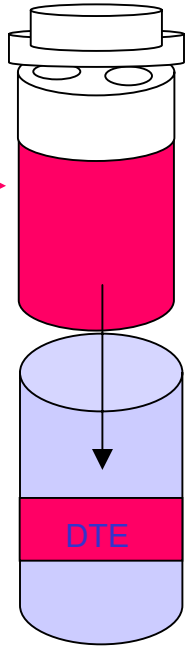


Elution hood is connected to column to complete fluid path. Saline solution flows from vial on right, through column, and out into evacuated vial on left. Mo-99 remains on the column and Tc-99 washes out with the saline solution.

ASSAY

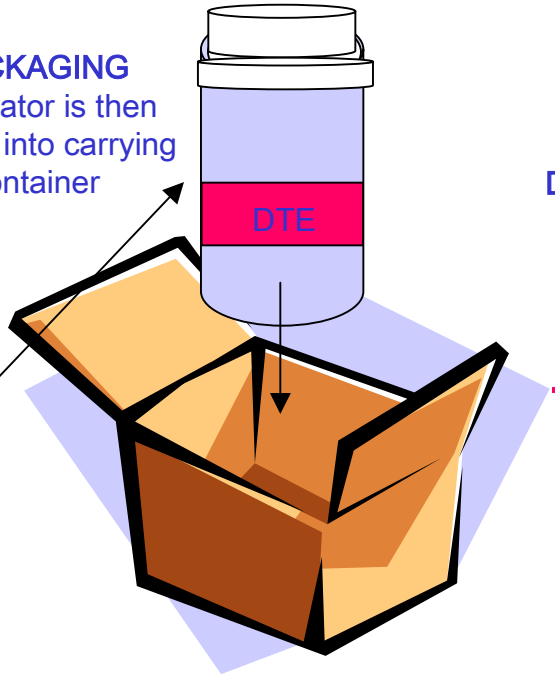


Generator is flushed with saline solution to verify Tc-99 content

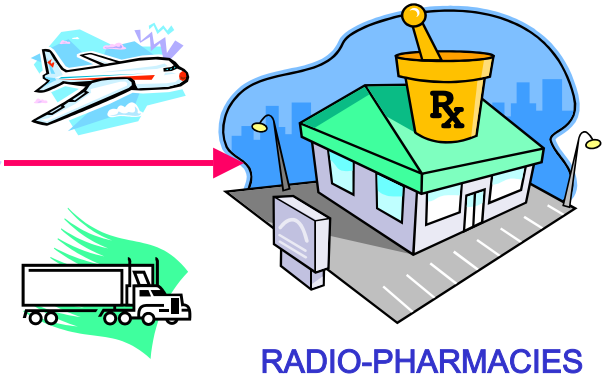


PACKAGING

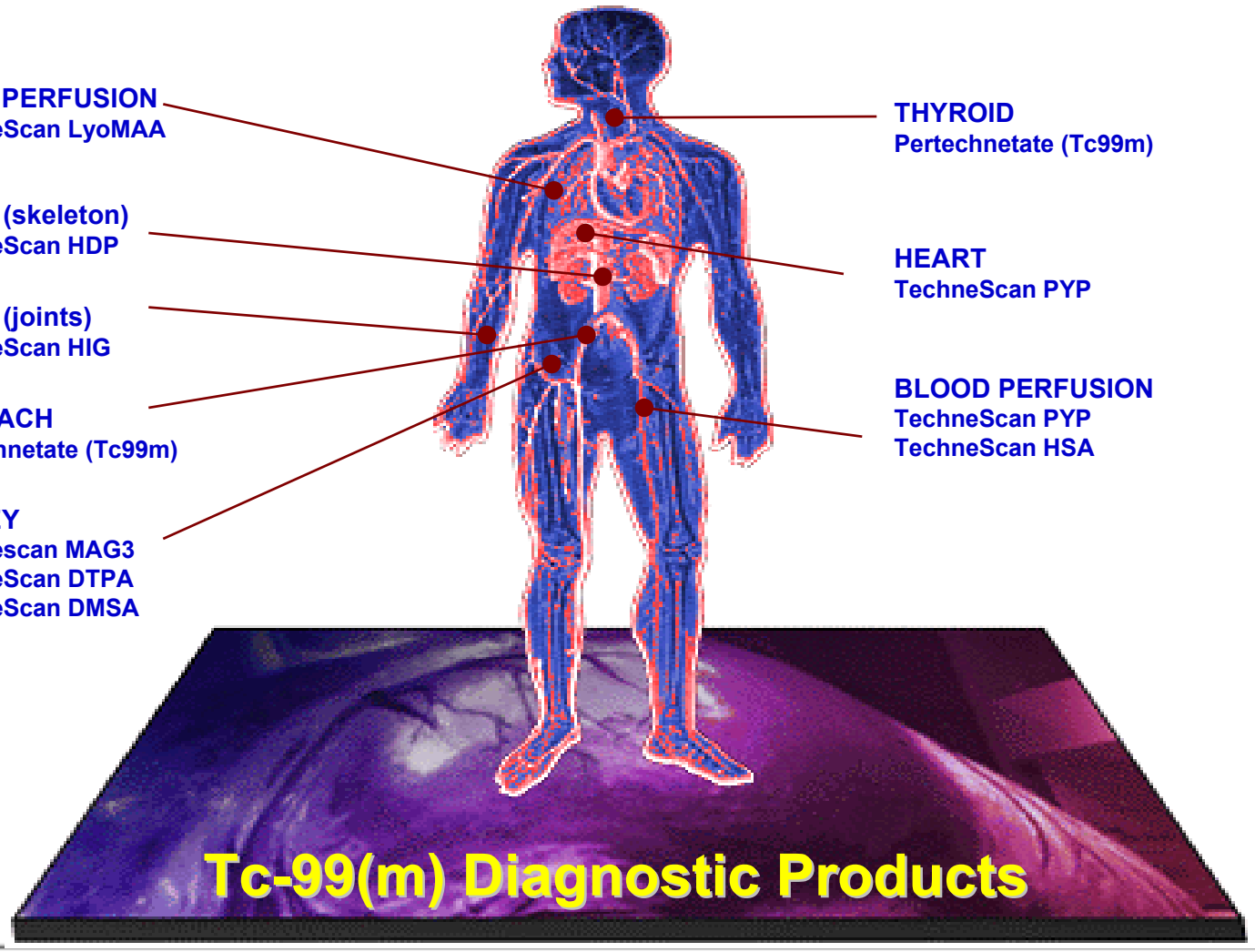
Generator is then packed into carrying container



DISTRIBUTION



RADIO-PHARMACIES



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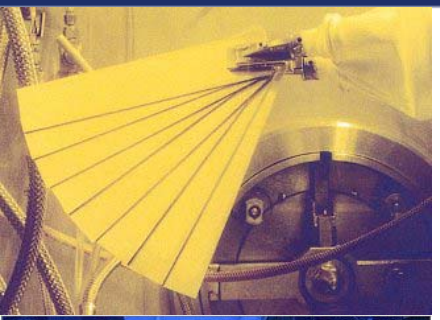
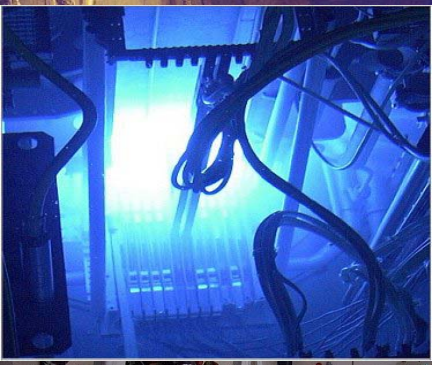
Mo-99 Bulk Production Process





- 8 targets containing 4.7 gram enriched U-235 are bombarded for 150 hours in a fission reactor with a flux of 10^{14} neutrons /m^2 * second.
- After 24 hours of cooling, the targets are processed in the Radio Chemical Centre and the Mo-99 is extracted by chemical purification into a bulk of ~80 ml solvent.
- The production process is 12 hours.
- The produced bulk contains approx. 4500 Ci dispensed into Stainless Steel flasks depending on the customer request.
- After production the Mo-99 bulk is directly shipped to the required destination in Type B(U) containers.

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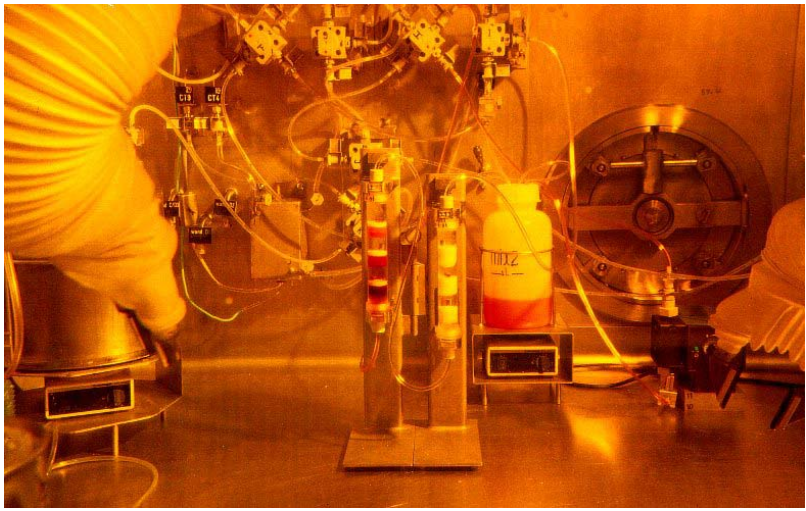
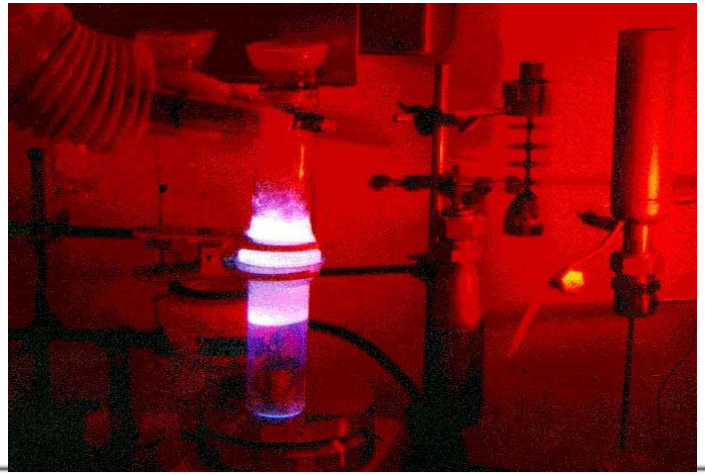
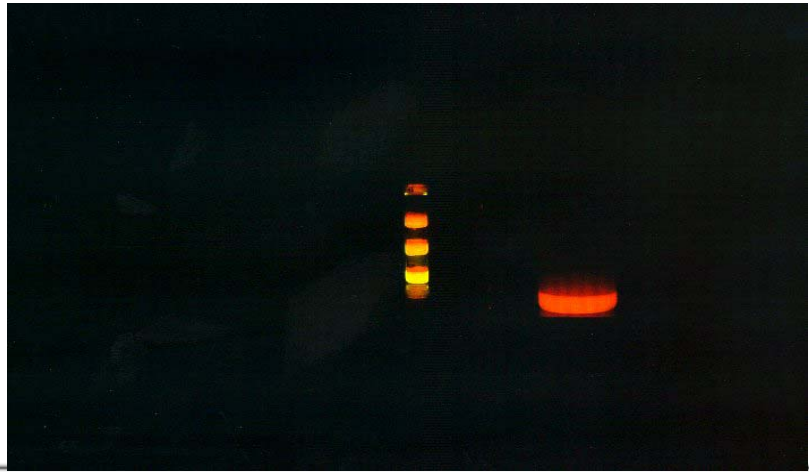
Mo-99 Production Process







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Product Characteristics

- ✓ 50 mg Mo-99 in ~80 ml liquid packed in Stainless Steel vials
- ✓ FY06: 200 Production runs
- ✓ Bulk Value
  $ 200,000 / production run
- ✓ Half-life Mo99; 66 hours
  (decay: ~ 1% per hour)

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MIDUS Concept

- 4 times a week the Mo-99 is shipped to the US in Type B(U) containers.

- Mallinckrodt / Tyco prepared a conceptual design based on the experience gained with other containers, optimizing the handling and transport issues.
  - Design has taken in account Pressure build-up due to radiolytic decomposition of liquid Mo-99.
  - Reduction of shipped containers from 9 down to 6 weekly
  - Reduction of TI from ~ 2.8 down to < 1
  - Easy handling and stowage during transport
  - Robust, simple design based on proven concepts

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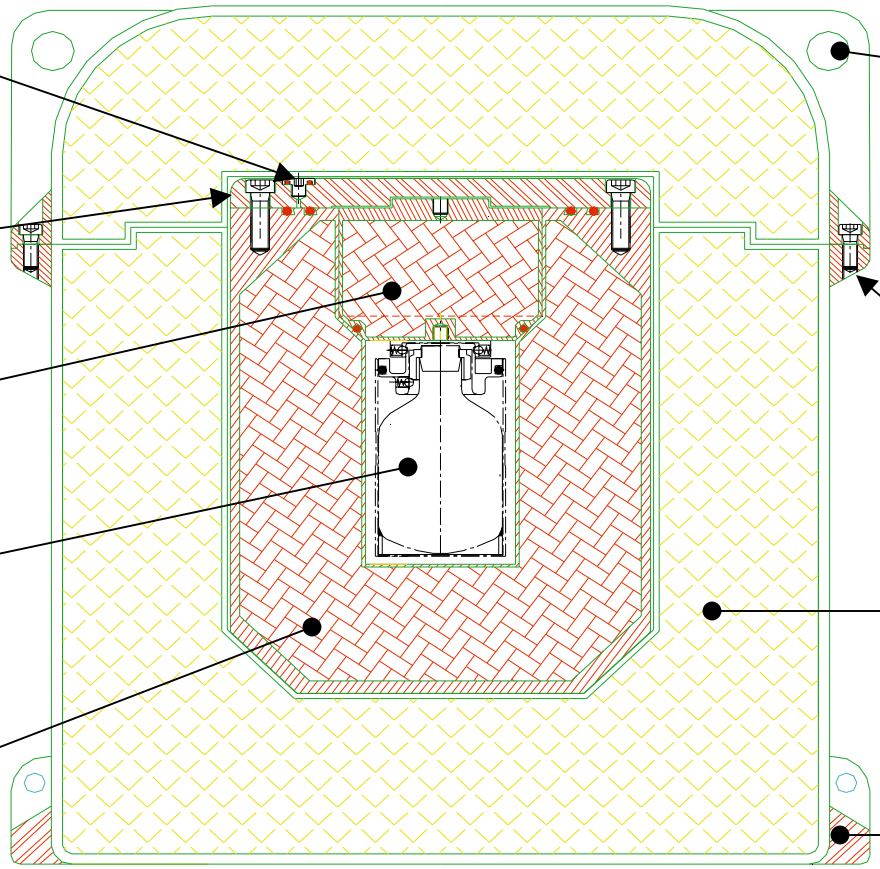
Proposed MIDUS B[U] container



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