MIDUS
Type B(U) Container for Mo-99 Bulk
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.
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**
- Column needles
- Crimp/stopper
- Glass wool
- Silicar
- Alumina/Mo-99
- Glass frit

**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**
DTE

**RADIO-PHARMACIES**
Capintec Assayer

DTE
THYROID
Pertechnetate (Tc99m)

HEART
TechneScan PYP

BLOOD PERFUSION
TechneScan PYP

TechneScan HSA

LUNG PERFUSION
TechneScan LyoMAA

BONE (skeleton)
TechneScan HDP

BONE (joints)
TechneScan HIG

STOMACH
Pertechnetate (Tc99m)

KIDNEY
Technescan MAG3
TechneScan DTPA
TechneScan DMSA

Tc-99(m) Diagnostic Products
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 $/m^2 \cdot$ 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.
Mo-99 Production Process
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)
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
Proposed MIDUS B[U] container

- Test Port
- Bolted Closure Lid + O-rings
- Shield Plug
- SS 316L Product Bottle
dU shielded Containment
- Over pack
- Stable Base Integral Tie-down points
- Integral Lifting / Tie-down points
- Bolted Over-pack closure
- Bolted Over-pack closure
- Integral Lifting / Tie-down points