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Evaluation of a compact automated system for filling syringes in a nuclear pharmacy.

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Introduction

- Dispensing radiopharmaceuticals involves aseptic handling practices while ensuring the radiation safety of pharmacists and technicians performing these activities.
- **RescueDose (Israel)** is a compact automated system for drawing radiopharmaceuticals from a multi-dose vial into patient specific unit-dose syringes.
- Objectives of this work were to evaluate RescueDose in an operational nuclear pharmacy setting for:
  1. Precision and speed of filling syringes
  2. Radiation exposure to personnel during filling
  3. Environmental certification of the PEC equipped with RescueDose under dynamic conditions

Methods

- **Precision and Time:** Four operators processed 80 simulated prescriptions. The time to process a prescription and the precision of the activity (mCi) for each prescription were recorded.
- **Exposure:** GM radiation survey readings were taken in the Primary Engineering Control (PEC) aka "hood" before, during and after processing of syringes and with differing amounts of activity from three different marketed vials.
- **Contamination (PEC):** Surface sampling was conducted after cleaning/disinfecting using 2 contact TSA LP80 plates on smooth areas of the device and sterile swabs streaked onto plates for 2 irregular surfaces (shielded vial area and syringe clamp area). Smoke pattern test was performed during dynamic filling of syringes and examined for turbulence and refluxing at critical sites. The particle counts were measured downstream of the RescueDose pivoting arm, which was determined by smoke pattern.
- **Contamination (Product):** A media fill test was conducted with 3 x 30 mL TSB media simulating multi-dose vials with 15 different volumes drawn into syringes and incubated for 14-days at 25°C and examined for turbidity.
- **Product Stability and BUD:** Radiochemical ITLC purity testing was performed 12 to 24 hours after bubbling approximately 180 mL of 99% oxygen through kits of tetrofosmin, sestamibi, and MDP for kit degradation.

Precision and Time

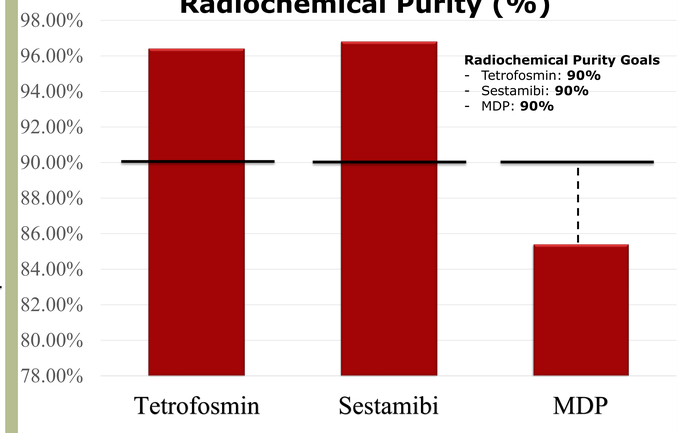
Precision (%)

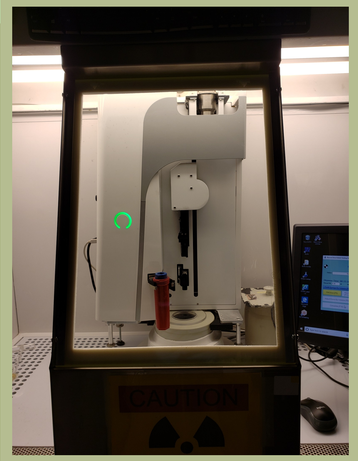
Average Drawing Time

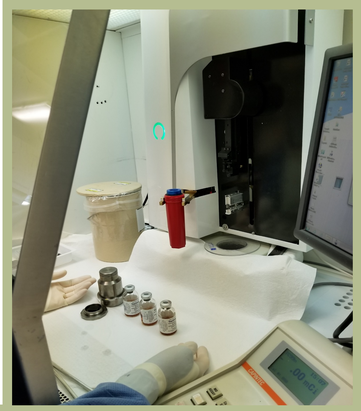
15 seconds

Product Stability and BUD

Radiochemical Purity (%)







Results

- **Precision:** Syringe volume requested was within ±0.01 mL for 99% of measurements.
- **Time:** The average time to draw a dose into a syringe was 15 seconds.
- **Exposure:** Radiation exposure was very low in the range of 0.02 to 2 mR/hr, with one spot at 5 mR/hr.
- **Contamination (PEC):** There was zero contamination in the PEC. Smoke pattern confirmed uniform air flow away from the critical area. Average particle count (n=4) was 38.25/m^3 (SD±39.93).
- **Microbacterial Contamination (Product):** Media fill test was negative for turbidity in all 45 syringes.
- **Product Stability and BUD:** Twenty-two kits were tested for radiochemical purity with the following mean results:
  - **Tetrofosmin** (n=9; >18 hr) 96.4%
  - **Sestamibi** (n=4; >18 hr) 96.8%
  - **MDP** (n=9; **<**12 hr) 85.4%

Discussion and Conclusion

- This work demonstrated RescueDose reproducibly filled syringes with high precision.
- Radiation exposure was significantly low to the operator.
- No radioactive contamination was detected anywhere in the PEC or on equipment or shields.
- Passed ISO 5 particle count and smoke pattern test.
- Passed aseptic media fill simulation.
- The filling process adds a percent of the drawing volume as air. We purged 8x the volume using 99% oxygen. One of the three kits fell below 90% at our previously established beyond use date.
- The syringe volume filling equipment met all our criteria for implementation into dispensing routine.
- Future analysis of overall impact on morning run and long term monitoring of efficiency.

References

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