Issue date
23 September 2022

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, managers and staff of:
- Medical Imaging
- Nuclear Medicine

Expert Reference Group
Content reviewed by:
LHD Nuclear Medicine Clinicians
Representatives from:
ACI Nuclear Medicine Network

Clinical Excellence Commission
Tel: 02 9269 5500
Email: CEC-MedicationSafety@health.nsw.gov.au

Intranet
Internet

Review date
January 2023

Quarantine required – glass vials supplied with ANSTO Tc-99m generators

Situation

Australian Nuclear Science & Technology Organisation (ANSTO) has advised of a quality issue with the glass vials used in several nuclear medicine products. An unexpected residue of unknown origin has been found inside the glass vials. The issue is limited to vials provided as part of their Tc-99m generators. The impact, if any, of the residue on patient safety has not been fully determined.

ANSTO is working with the supplier and the TGA to quantify any risk to patient safety and will advise of the recall action, if any. In the interim, affected vials should be quarantined pending further advice from ANSTO and the TGA. The Technelite evacuated vials are not impacted and can continue to be used.

The batch numbers of the impacted vials are –

5 mL saline	
ANSTO batch number	*Vendor batch number*
1002970	4164
1003083	4180
10 mL saline	
ANSTO batch number	*Vendor batch number*
1002861	4134
1002971	4160
1003023	4169
1003054	4172
1003070	4174
1003086	4179
1003149	4184
30 mL EVAC	
ANSTO batch number	*Vendor batch number*
1002899	4141
1003009	4157
1003047	4165
1003071	4166
1003093	4182
1003151	4167

Clinical Recommendations

- Quarantine the affected vials pending further advice from ANSTO and the TGA.
- If available within your facility, continue to use unaffected batches of sterile saline vials which are currently in date.
- Alternative vials containing sterile saline that are fitted with a rubber stopper, and fit within the generator's vial holder, can also be used.
- Sites with sterile manufacturing facilities may be able to produce a suitable alternative aseptically.

PTO

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant departments, clinicians and other staff involved in performing nuclear scans. Include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment and develop strategies to mitigate the risk of this issue.
3. Report any incidents associated with this medicine into the local incident management system (e.g., ims+) and to the TGA.
4. Confirm receipt and distribution of this Safety Notice by **COB Monday 26 September** to CEC-MedicationSafety@health.nsw.gov.au