**Record of Technical Anomaly**

**Technical Anomaly No: TA425**

**PART 1: Issue, impact assessment and signing open**

**Raised by: Hannah Ford** **Date: 02/02/22**

**OP / Method: OP221/222**

**Analytical sequence(s) affected** *(where appropriate)***: 42/21 - current**

**Details** *(please tick relevant box(es) and provide supplementary information where required)***:**

□ QC point(s) above/below ±2SD □ Bracketing standard(s) outside limits

□ QC point(s) above/below ±3SD □ QC Recovery outside limits

□ QC point(s) outside expanded uncertainty R Other *(add details below*

DMA5000M linearity check was performed on 02/07/21 using ERM standards that had passed their expiry date. Standards used were:

|  |  |  |
| --- | --- | --- |
| **%abv** | **SWRI Chemical number** | **Expiry Date** |
| 5% | C7236 + 7237 | 30/10/2020 |
| 15% | C-7216 + 7217 | 23/10/2020 |
| 40% | C-7629 | 15/03/2022 |
| 70% | C-7230 + 7228 | 29/10/2020 |

All standards were stored in fridge and unopened until use. Linearity check passed so indication is that integrity of the standards had not been compromised.



Expiry dates were not noticed by either analyst or run checker – discrepancy only came to light when reviewing data and paperwork prior to Feb 2022 UKAS audit.

NB. Covid-19 pandemic lockdown in 2020 had lead to ERM standards being stored for longer than usual before use – in future it is unlikely that standards would not be used up before their expiry date.

□ No apparent reason for this anomaly

**Recommended Action:**

□ No action required out with the usual close monitoring of the Quality Control data in subsequent runs.

Conforming linearity check is to be performed as soon as the required standards are in stock.

Recordkeeping procedure for ERM checks is to be reviewed, possibly incorporating standard expiry date into Form 65, but more extensive overhaul may be more advantageous including the phasing out of paper records in favour of digital records.

**Explanation why the issue does not impact data quality & why it isn’t a departure:**

Linearity check passed so indication is that integrity of the standards had not been compromised. All reported data since the linearity check is backed up by passing daily instrument checks, Quality Control checks, and quarterly 40% ERM checks.

**Management Review:**

***I agree to open this Technical Anomaly and confirm that this would not prevent results from being reported.***

**Authorised by:**

**(Technical/Services/Quality Manager)**

**Date:**

**PART 2: Follow-up actions and close-out**

**Follow-up actions conducted:**

□ No follow up required

**Signed off & closed by Quality Manager:**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_**

