



Changes to QSM

Module 6

QUALITY SYSTEMS FOR RADIOCHEMICAL TESTING

PRESENTED AT THE DOE ASP WORKSHOP AUGUST 2021

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Summary

- ▶ **TNI 2009 which reference ISO 17025 v 2005 was updated to TNI 2016 – renumbered / rearranged to match**
- ▶ **Eliminated redundant text: Moved some requirements from text to Appendix B only**
- ▶ **Tried to align contents of Table B-16 through B-20**

Disclaimer



**Many, many small changes
and moves**



**Each laboratory should review
in detail to ensure continued
compliance**

Details

Terms and definitions (MDA, Decision Level, Tracers and Carriers) were moved to 1.3 from other locations

Terms and definitions (z-blank, z-DUP, etc.) moved to appropriate locations in the body of the module

Equations for DL and MDA can also be in program documents, not just SOPs.

- Since project can select alpha and beta risk factors other than 0.05 the lab must confirm they got them right

Sample-specific MDAs are considered a standard practice as in QSM 5.3. Nominal detection limits must be noted when used

Clarification: before "MDA Optimization" had a 10% limit on uncertainty now is titled "MDA Requirements for Elevated Samples"

Details

New sentence in “Decision Levels” - Decision levels are used as the default detection threshold. Alternatively, the client may use/specify detection thresholds that meet project/site-specific requirements.

Now contains “Evaluation of Selectivity” referenced in TNI 2016 with no further text

Dropped material balance checks for alpha spectrometry sources

When performance check fails and either of two performance checks following fail, “laboratory shall perform corrective actions”

Dropped sentence on “systems using sample changers and/or long count times that run more than a day “

Dropped detector source check requirement from ANSI N42.23 as redundant

Details

For Radon systems, changed monthly check to annual and added “cell /detector pairs” as evidence of continuing calibration

Dropped four paragraphs / sentences from the background check section

Dropped certain prep batch restriction (same time frame batch) which were in QSM 5.3 1.7.2

Dropped batch blank requirement (less than reporting limit unless five times. . .)

Clarified batch blank matrices

Dropped LCS matrix documentation requirement

Details

Dropped LCS Selection and Level section

Dropped MS added “as early as possible” and “not required when tracers are utilized...” and sentence on spiking higher than 20X RL

Added: other client specifications for MS must be documented

Dropped purpose of duplicates, one per batch requirement, and requirement to document matrix-related failures in case narrative

Dropped “tracers added at very beginning - . . grinding, sieving...”

“should” to “shall” and other editorial changes in tracer section

Dropped entire description of carriers and incorporated with “tracers and carriers chemically mimic...” - redundant text

Details



- ▶ Clarified “The laboratory shall investigate the cause of recurrent negative results. Records of these investigations shall be maintained. All instances of negative results shall be discussed in the Case Narrative.”
- ▶ Dropped water purity requirement as redundant
- ▶ Changed annual verification of standards from “logbook” to “maintain records”
- ▶ Throughout – “site shall approve” has been eased to “maintain documentation” – example alpha spec – correction of tracer contribution to other ROIs

Details – Appendix B

Tried to eliminate having the same criterion in two places.

Made all sections similar as far as possible

Included “Flagging is only required if reanalysis is not possible” throughout

Moved many comments into Requirements and Minimum Frequency – when appropriate

Alpha Spec - Details

Alpha spectrum slope and intercepts “shall be recorded” rather than “documented”

Dropped Blank Correction “shall not be performed”

Changed “site accepted” to “documented” for the lab’s method for correction of tracer into other regions of interest

Dropped energy calibration – 3 isotopes at 3 to 6 MeV and slope 15 MeV/channel

Dropped background count times equal to or longer than sample count

Dropped 2000 (check source) and 3000 (efficiency) tracer counts

Alpha Spec Details

Moved FWHM < 100
and Centroid < 50 keV
to B-16

Moved alpha spec
“conditions requiring
reanalysis” such as
tracer recovery outside
30-110%, tracer FWHM,
tracer centroid to B-16

Reanalysis required for
activity higher than
tracer causing
interferences --- remains
in body of text

Reanalysis still required
for interferences with
tracer or analyte ROI

Lucas Cell / Radon details

Either EPA 903.1 or ASTM D3454 may be used. Removed restrictive language on exact method compliance

New: "CCV requirements in Table B-20 only apply to cell/detector pairs for DOE samples"

Voltage plateau slope requirement moved to Appendix B-20

Dropped new cell calibration "monthly for 6 months"

LCS samples may be used for evidence of continuing calibration

Lucas Cell / Radon details

Defined batch QC – MB, LCS,
MS, DUP

Clarified MB is not used to
correct sample activities

B-20 – changed monthly
cell/detector CCV to annual

B-20 dropped instrument
contamination check

Gamma Spec Details

- ▶ Removed details on NaI detectors and reference ANSI N42.12

Gas Flow Proportional Counting Details

- ▶ ANSI N42.25 – dropped “shall adhere to” but still reference for calibration
- ▶ Gas bottle change – B-18

Liquid Scintillation Details

- ▶ Simplified description of vials
- ▶ Dropped ANSI N42.15
- ▶ Details in instrument background paragraph simplified and moved to B-18
- ▶ Added discussion of quench
- ▶ Storage under fluorescent lights and in sunlight prohibited



QUESTIONS?