

Quality Systems Manual Version 5.0
Frequently Asked Questions
(FAQ)s

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New FAQs for QSM/QSAS (General)

Why are there no DCB surrogate results for methods 8081/8082 in the LCS Study?

ANS: There were not enough data points collected for DCB to reliably produce valid control limits. DCB can still be reported for 8081/8082, but a lab would be responsible for using their in-house control limits.

I assume you guys are aware of Update V? Do you think that will change the QSM at all?

ANS: Not at this time. QSM version 5.0/QSAS 3.0 incorporated parts of all EPA updates thru update IV, which was extensively reviewed. Update V will be completely reviewed and incorporated during the next revision cycle.



New FAQs for QSM/QSAS (General)

QSM 5.0/QSAS 3.0 does not clearly state which analytes are to be used for surrogates for each method. Appendix C (LCS Limits tables) lists all analytes by method alphabetically. There is nothing to distinguish which analytes are intended to be surrogates.

ANS: Surrogates were not listed in the appendix C LCS limits tables. They should be based on each individual SW-846 method.

I have been asked if for the GC/MS for drinking water (524, 525) and waste water (624, 625) methods the QSM/QSAS tables trumps the method. Since drinking water and waste water methods are dictated by law, do the QSM/QSAS tables apply? The QSM/QSAS tables are typically for RCRA.

The age old problem still exists, that projects do not always clearly define their data quality objectives, and often simply defer to the QSM/QSAS. Projects will request drinking water (524, 525) and waste water (624, 625) methods but not actually be using them for regulatory purposes.

ANS: The QSM/QSAS method tables do not apply to drinking water/waste water methods. Regulations (and regulatory methods) and project requirements defined in a QAPP supersede the QSM/QSAS.



New FAQs for QSM/QSAS (Chemistry)

We cannot find clarification about what is meant by the ICAL midpoint standard. Some individuals count the number of standards being used (e.g., 5) and say the midpoint is standard #3. Others (me included) interpret the criterion to mean the middle of the calibration range (i.e., the concentration range). Is it possible to get clarification on the intent of the criterion?

ANS: A laboratory can use either the middle of the concentration range (i.e., the mean of the low and high standard concentrations) or the mid-point calibration standard as long as that standard is less than or equal to the middle of the concentration range.

Which control limits should be used for a surrogate in the CCV- the surrogate limits or the CCV limits?

ANS: When surrogates are in the CCV, the CCV acceptance criteria limits apply.

CCV minimum frequency is every 10 samples and at the end of the prep Batch (Table 14 CWA). Interpretation of "at the end of the prep batch" means to me if I received 1 soil sample from Project A and another soil sample from Project B an hour later that I would need CCVs separating the two samples. Any thoughts?

ANS: The intent of the standard was "analytical" sequence in this example. Thus, two samples from two different batches could be run together with a single closing CCV.



New FAQs for QSM/QSAS (Chemistry)

We have a basic question for QSM QSAS version 5.0/3.0. DL and LOD are defined the same way as MDL was traditionally, and not 2X MDL, in the definition section (Module 2, pages 8 and 9).

It looks now like MDL = LOD, is that correct?

**ANS: We have not changed the basic terminology of LOD/LOQ in QSM/QSAS Version 5.0/3.0. It is still the same as you have currently implemented: MDL (99% confidence as in 40CFR, 136),
LOD = (2 x MDL).**

There is a difference in definitions of DL and LOD. DL = "different from zero" at 99% (which means it may or may not actually be present), and LOD = "must be present" in a sample at 99%. So this means DL= MDL and 2 X DL/MDL = LOD. It must be noted that LOD = 2X DL ONLY if the criteria for LOD in Module 4, section 1.5.2.1.f.i) is met.

DL is the baseline to determine the LOD since you can use the MDL or any other information you have collected (such as blank studies) without forcing you into an annual MDL study. Once you have determined a DL you only need verify the DL with an LOD spiked approximately 2 times the DL every quarter.



New FAQs for QSM/QSAS (Chemistry)

Could you provide some clarification on the hold time for 8330B soil explosives? The method is a little vague.

ANS: Sample hold time starts when the sample is removed from nature (i.e. after the samples are collected). In the case of Method 8330B, soil samples should be treated just like the analysis of base neutral acids (semi-volatiles) in soil samples, which require that hold time start after samples are collected in the field. Sample hold time ends at the start of solvent addition.



New FAQs for QSM/QSAS (Chemistry)

Questions on reporting dioxin/furan data: The dioxin method and the QSM/QSAS are not compatible in the reporting requirements. So is there still a requirement to publish an LOD for dioxin methods, even though the LODs would never be reported or used to determine flagging levels? Or should dioxins be reported to an LOD instead of the EDL/EQL, which could inflate TEQ values by a factor of 10 or more?

How are you guys reporting Total TEQ for dioxins/furans when the Total TEQ is a calculation (no DL, LOD, or LOQ) and the DL/LOD/LOQ is a required field? The DL, LOD and LOQ are fixed numbers that are reassessed every quarter. The EDL EQL and EMPC are evaluated every injection and can change.

ANS: Dioxins/furans are not treated differently with regard to reporting results and they do have LODs, as well as method required EDLs/EQLs/EMPCs. Laboratories shall follow the requirements for DL/LOD/LOQ (plus the method-specified EDL/EQL) as shown in the QSM/QSAS table. It is acceptable to report non-detect values to the EDL in lieu of the LOD, but that would be a project specific requirement only, and will not alleviate the need to determine the LOD. Project specific reporting requirements and flagging using the EDL/EQL/EMPC is permissible.

For calculating the TEQ, the method specified requirements shall be followed, unless the project team has agreed upon using a different calculation.



New FAQs for QSM/QSAS (Radiochemistry)

The previous version of the QSAS required tracer and carrier yields determined by indirect measurements to be within 40 - 110%. The current QSM/QSAS specifies 30 - 110%. Was the change intentional, and was there a specific driver for it?

ANS: Yes. The change was intentional to align the QSAS with the new QSM/QSAS and make all criteria consistent.

Can a laboratory use a CCV as a LCS for any radiochemical analysis that does not involve any preparation steps?

ANS: Yes. For methods that do not involve any preparation steps between a Continuing Calibration Verification (CCV) and a Laboratory Control Sample (LCS), such as Gamma Spectroscopy and Alpha/Beta wipes, a CCV can be used in place of a LCS or vice versa. When one sample serves as both CCV and LCS, the laboratory must use the method-specified acceptance criteria for CCV evaluations AND the laboratory's in-house statistically established control limits for LCS evaluations. The laboratory must also use their CCV for trending purposes if they use the CCV as a LCS.



New FAQs for QSM/QSAS (Radiochemistry)

In the new QSM/QSAS, Section 1.7.2.3, there is discussion about the acceptability of reporting results when tracer or carrier yields are less than 30% (three conditions must be met in order for results to be considered quantitative and acceptable). However, the tables for Alpha Spectrometry (Table 16), Gas Flow Proportional Counting (Table 18), and Liquid Scintillation Counter Analysis (Table 19) simply list the lower acceptance limits for tracers and carriers as 30%, without provisions for reporting when yields are less than 30%. Here the main body text has additional details. Are we correct in assuming that in this instance the additional details in the text in the main body can be applied when evaluating the acceptability of carrier and tracer yields, even though those details are not in the tables?

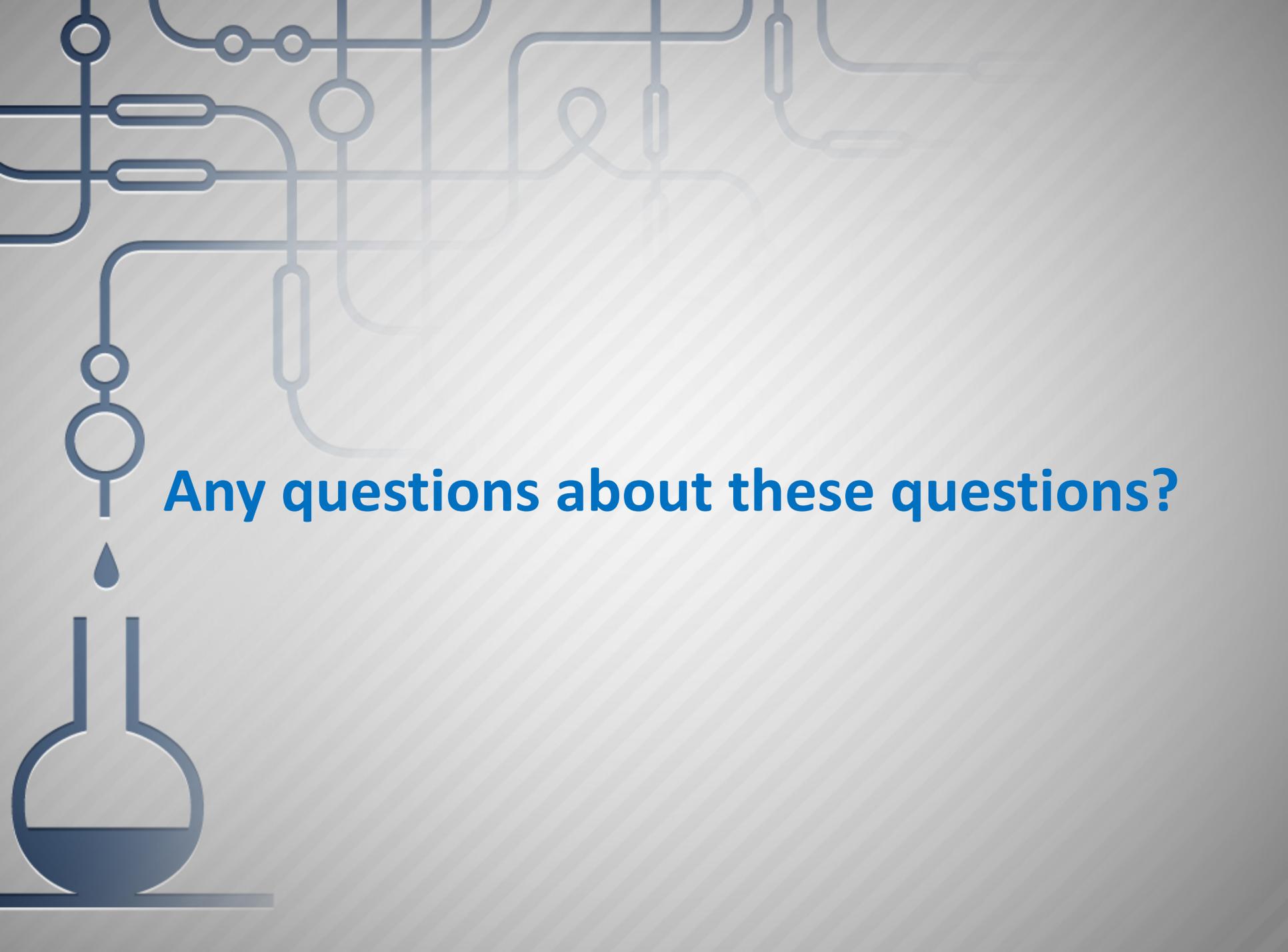
ANS: Yes, you are correct. Additional details in the text can be applied. The tables themselves do not expand beyond basic QC requirements.



New FAQs for QSM/QSAS (Radiochemistry)

We noticed that in the radiochemistry tables that MARLAP requirements have been inserted as an option? Can our laboratory use the MARLAP definitions such as MDC instead of MDA?

ANS: Yes. In Module 6 (Radiochemistry), section 1.3 the QSM/QSAS provides a clarification that the terms, definitions, and requirements of MARLAP Manual July 2004 can be used.



Any questions about these questions?