Purpose: This fact sheet summarizes the results of the 2013 Department of Defense (DoD) Environmental Data Quality Workgroup (EDQW) Laboratory Control Sample (LCS) Control Limits Study and discusses different types and applications of LCS data.

Background: In 1999, the DoD EDQW initiated its first LCS Study, in cooperation with the American Council of Independent Laboratories (ACIL) to evaluate how well contract laboratories performed with SW-846 methods in a routine fashion. ACIL solicited and collected LCS data representing nine SW-846 methods and 454 analyte-matrix-method combinations from over 20 DoD-approved laboratories.

The LCS data were used to generate laboratory performance criteria (expressed in terms of LCS control limits) that EDQW believed good-performing laboratories should be able to meet, in the absence of project-specific requirements. The LCS control limits were calculated as the sample mean recovery ± 3 sample standard deviations. The study also produced some important findings:

1) Recoveries of certain analytes are consistently poor when unmodified SW-846 methods are used.

2) Method modification may be needed in order to meet measurement performance criteria (MPC) for project-specific analytes and matrices; however, this is not typically done.

Laboratory Control Sample (LCS):

An LCS is an analyte-free matrix spiked with target analytes and used to document laboratory performance on a specific analytical method. An LCS is typically prepared and analyzed with each batch of 20 or fewer samples and processed through the entire sample preparation and analysis sequence. For this reason, an LCS sample evaluates the performance of the analytical system as a whole (i.e., analyst, reagents, prep methods, instrumental conditions, etc.) A laboratory may use analyte recovery from the LCS sample to evaluate analytical bias and the difference between analyte recovery on duplicate LCS samples to evaluate analytical precision.

2013 DoD LCS Study: As part of efforts to consolidate laboratory quality systems requirements, the EDQW determined that there would be a benefit to update the LCS Study with larger sample sizes from laboratories currently participating in either the DoD Environmental Laboratory Accreditation Program (ELAP) or the DOE Consolidated Audit Program (DOECAP). Of the 114 DoD ELAP-accredited and DOE-approved laboratories, 52 laboratories provided their LCS data. After removing erroneous data and outliers, data sets were available for 1,258 analyte-matrix-method combinations representing 23 methods. LCS control limits were calculated in the same manner as those from the 1999 LCS Study. The updated LCS control limits are published in the DoD EDQW LCS Study Report (2013).

The following discusses different types and applications of LCS control limits, including ***method-specific LCS control limits***, a laboratory's ***in-house LCS control limits***, ***project-specific LCS control limits***, and the ***DoD/DOE QSM LCS limits.***

How should method-specific LCS control limits be used? ***Method-specific LCS control limits*** provide information about method performance under controlled conditions defined in the method (e.g., single laboratory trials). Many standard methods publish method performance data in terms of the recoveries and standard deviations of LCS samples in various matrices and at various concentration levels. They

are useful for comparing and selecting different methods. As a benchmark for comparison with a laboratory's in-house LCS control limits, they are also a useful tool for evaluating laboratory capabilities.

How should a laboratory's in-house LCS control limits be used? According to the DoD/DOE QSM, laboratories must determine their ***in-house LCS control limits*** by compiling LCS recovery data for specific analyte-matrix-method combinations over time (at least 30 samples). Laboratories accredited in accordance with DoD ELAP or approved under DOECAP must establish in-house, statistically established LCS control limits for all analyte-matrix-method combinations listed on their scope of accreditation/approval. The procedures that a laboratory uses for calculating the LCS limits must be documented. The in-house LCS limits must meet all requirements specified in paragraph 1.7.3.2.3 (c) of Volume 1, Module 4 of the DoD QSM Version 5.0. Laboratories must use their in-house LCS control limits to monitor and control their method performance and to estimate the minimum laboratory (analytical system) contribution to measurement uncertainty. Laboratories must analyze an LCS sample for each analytical batch of 20 or fewer samples, if applicable to the method. By routinely monitoring LCS recoveries using software tools or control charts, laboratories can detect trends and prevent out-of-control situations.

For the purposes of selecting laboratories, the project chemist should compare a laboratory's in-house LCS control limits with project-specific MPC for precision and bias, for each analyte-matrix-method combination of concern, with special attention given to analytes of primary concern (e.g., risk drivers). Project teams may use the QSM LCS control limits in place of project-specific MPC if they will satisfy project-specific data quality objectives (DQOs). In order to generate data capable of meeting the project's DQOs, the laboratory's in-house LCS control limits for both precision and bias must meet the project-specific MPC (or the QSM LCS control limits) for both precision and bias. Because an LCS sample is prepared in a clean matrix, it represents the best-case scenario for precision and bias. Performance in actual samples is generally worse.

How should the project-specific LCS control limits be used? For DoD and DOE projects, the project teams shall establish ***project-specific LCS control limits*****,** which serve as part of project-specific MPC on data precision and bias, during the project planning process. If DoD QSM LCS control limits meet project DQOs, a project may adopt the QSM LCS control limits as project-specific LCS control limits. The project-specific LCS control limits may be used as criteria for assessing and selecting analytical methods and laboratories. Any laboratories with in-house LCS control limits outside the project-specific LCS control limits do not meet project DQOs and should not be allowed to perform analytical services.

How should the QSM LCS control limits be used? For DoD and DOE projects, unless project-specific LCS control limits are specified, laboratories must use the **QSM LCS control limits** (specified in the QSM Appendix C) for both batch quality control and data reporting. The laboratories' in-house LCS control limits should be within the project-specific LCS control limits if available or the QSM LCS control limits if not available. If project-specific analytes are not included in Appendix C, then laboratories must use their in-house LCS control limits for these purposes.

If using the QSM LCS control limits for evaluating method or laboratory performance, it is important to consider the following: 1) The QSM LCS control limits were calculated from data pooled from multiple laboratories using their own SOPs and hence the QSM LCS control limits would be wider than a single laboratory's in-house LCS control limits. 2) In most cases the LCS samples were prepared by spiking analytes at a single concentration at or near the mid-point of the calibration curve, which is typically much higher than a project's decision level and may show better data quality than that at the project's decision level. 3) Because only three classes of analytes (metals, explosives, and PAHs) were evaluated using more than one method, the QSM LCS data permits method performance comparisons for only those classes of analytes. 4) For any given analyte, it may be possible to achieve better performance by modifying the method to achieve optimum performance for that analyte. Depending on the extent of the modification, however, method validation and client and regulatory agency approval may be required prior to its application to DoD/DOE projects.