PJLA Update Notification

Update Notification # 36
Update Notification Release Date: 2/8/17
Form/Procedure/Policy: LF-56ELAP Rev 1.4 Working Document/Checklist

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PJLA Applicant/Accredited Organizations for DoD ELAP

PJLA has recently updated the LF-56 ELAP Working Document/Checklist to include the new requirements as noted in the DoD QSM 5.1 and PJLA Update Notification #34.

Please download and closely review these changes as they will be assessed during your DoD QSM 5.1 upgrade.

- Accredited Organizations requesting to upgrade to DoD QSM 5.1 during the offsite surveillance may do so, as long as they are not adding testing from the newly added tables and revised tables in Appendix B.

- Accredited Organizations that have the PFAS tests effected by the newly added and revised tables in Appendix B, must have an onsite assessment to the QSM Version 5.1, during their next scheduled assessment.

- All Organizations must have an on-site assessment, to QSM Version 5.1, prior to January 2019.

Changes are Effective Immediately

Summary of Changes:

- Removed reference to DOE requirement throughout the checklist.

- The following items were added or language slightly modified:

	Section 4.0
4.1.1	Does the laboratory or the organization of which it is part, an entity that can be held legally responsible?
4.2.2.	Note: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.
4.2.3	d. Is top management responsible for recording all analytical and operational activities of the laboratory?
4.2.3	e. Is top management responsible for ensuring adequate supervision of all personnel employed by the laboratory?
4.2.3	f. Is top management responsible for ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored?
4.2.8.1	Are the requirements for data integrity investigation as defined in Section 4.16 TNI EL-V1M2-2009 listed?
4.2.8.1	Does management annually review data integrity procedures and update as needed
4.2.8.4	p) In addition, does the quality manager or designee review a minimum of 10% of all data packages for technical completeness and accuracy on a quarterly basis?

4.2.8.4	p) If data quality issues are discovered during the review, is the client notified within 15 business days of the discovery of the issue?
4.2.8.5	a) Do these documents include adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result?
4.2.8.5	Note: for example, documents may be equipment manuals provided by the manufacturer, or internally written documents.
4.4.4.1	Are waivers from QSM requirements requested in writing from the appropriate DoD Chemist or Contractor Project Chemist (however named) on a project-specific basis and does it include technical justification relating to the specific project for the waiver. Is documentation of approval for the waiver maintained by the laboratory and is it readily available for review?
4.5.10	Do all subcontracted or outsourced management systems elements (such as data review) or outsourced personnel comply with the laboratory's overall management system, and do they comply with the requirements of this standard, and are subject to review/approval by the DoD~~/DOE~~ customer?
4.7.2	Is the feedback used and analyzed to improve the management system, testing and calibration activities and customer service?
4.9.3	Does the laboratory upon discovery, notify within 15 business days all affected customers of potential data quality issues resulting from nonconforming work?
4.9.3	Are records of corrections taken to resolve the nonconformance submitted to the customer(s) within 30 business days of discovery?
4.9.4	Does the DoD ELAP laboratory report any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7 of the DoD QSM, to their AB within 15 business days of discovery? Discovery includes findings of such inappropriate practices by laboratory staff or customer stakeholders.
4.9.4	Does the DoD ELAP laboratory submit records of associated corrections taken or proposed corrective actions to their AB within 30 business days of discovery?
4.9.4	Note: The respective AB will then have the responsibility of informing the EDQW of the laboratory's deviation from the requirements of the QSM. If the AB is not notified within 15 business days the AB will immediately suspend the laboratory's DoD ELAP accreditation. The respective ABs and the EDQW deem these infractions as quite serious and appreciate the cooperation from all involved parties.
4.14.6	Does the review include both technical and quality systems areas?
4.14.6	Does the review include raw electronic data files derived from test reports?
4.16	Does the DoD ELAP laboratory report any instances of inappropriate and prohibited laboratory practices, as detailed in Section 5.2.7 of the DoD QSM, to their AB within 15 business days of discovery?
4.16	Does the DoD ELAP laboratory submit records of associated corrections taken or proposed corrective actions to their AB within 30 business days of discovery?
4.16	Note: The respective AB will then have the responsibility of informing the EDQW of the laboratory's deviation from the requirements of the QSM. The respective ABs and the EDQW deem these infractions as quite serious and appreciate the cooperation from all involved parties.
	Section 5.0
5.2.4	Does the laboratory maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations?
5.2.4	Do Job descriptions, as a minimum, must include as a minimum the elements in the note of 5.2.4?
5.2.4	-managerial duties
5.4.6	a) Is the reasonable estimation of uncertainty ~~make use of previous experience & validation data~~ based on knowledge of method performance and previous experience?
5.4.6	a) When estimating the analytical uncertainty, are all uncertainty components which are of importance in the given situation taken into account?\
5.5.5	h. ~~Any damage, malfunction, modification or repair to the equipment~~ Date placed in service?
5.5.5	i. ~~Date received and date placed in service (if available)~~ Condition when received (e.g., new, used, reconditioned)?
~~5.5.5~~	~~j. If available, condition when received (e.g. new, used, reconditioned)?~~
5.5.5	~~k~~ j. Operational status?
5.5.5	~~l~~ k. Instrument configuration and settings?
5.7.1	Does the laboratory not manipulate the sample material so the sample aliquot weighs exactly 1.00g ± 0.01g, as an example?
5.8.4	c. Are shipping containers and packaging opened inside a ventilation hood or other designated area that provides adequate ventilation for personnel?
5.8.8	i: Is the sample in someone's custody if the following is in place (a-d)?
5.8.8	ii) Signatures of all personnel who physically handled the samples and parent organization and physical address?

5.9.1	Are quality control samples processed in the same manner as field samples? Are they analyzed and reported with their associated field samples?
5.10.11	e) Is there qualification of numerical results with values outside the calibration range?
	Appendix A
Appendix A	· Statement of data authenticity and official signature and title of person authorizing report release, date of issuance?
Appendix A	· Describe any abnormalities deviations and failures that may affect the analytical results?
Appendix A	-Sample preservation and condition at receipt?
Appendix A	-Identification of samples and analytes for which manual integration was necessary including the justification?
Appendix A	· A cover sheet, table of contents, and case narrative including all of the information specified in the above sections are required for all stages of data reports.
Appendix A	· Stage 1: Sample results forms, chain of custody, laboratory receipt checklist?
Appendix A	· Stage 2A: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms?
Appendix A	- Stage 2B: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms, instrument QC forms, instrument and preparation logs?
Appendix A	- Stage 3: Sample results forms, chain of custody, laboratory receipt checklist, method QC forms, instrument QC forms, instrument and preparation logs, instrument quantitation forms (raw data)?
Appendix A	·Stage 4: Sample results forms, chain of custody, laboratory receipt checklist, sample related method QC forms, instrument QC forms, instrument and preparation logs, instrument quantitation forms (raw data), instrument chromatograms and spectra.
Appendix A	· In addition, standards traceability must be included in Stages 3 and 4 if a legal chain of custody is required?
	Volume 1 Module 3
1.7.1.1.1	Is a logbook or electronic record maintained with the calibrated magnification, the date of calibration, and the analyst's signature or initials recorded?
1.7.1.2.2	Is the phase-shift detection limit of the microscope checked daily and after modification?
1.7.1.3.1	a) Are both stereoscope and polarized light microscope aligned and checked for function and optimized for correct operation before every use by every analyst?
1.7.1.3.1	b) Are all alignments and function checks documented in the proper log book or electronic record?
1.7.3.1.2	e)i. Replicate. Is a second, independent analysis performed in accordance with Section 1.7.3.1.1.a?
1.7.3.1.2	e)ii Duplicate. Is a second wedge from a sample filter prepared and analyzed in the same manner as the original preparation of that sample? Are results within 2.0x of Poisson standard deviation? Is this performed at a frequency of one (1) per one hundred (100) samples?
1.7.3.1.2	e)iii Verified Analyses. Is a second, independent analysis performed on the same grids and grid openings in accordance with Section 1.7.3.1.1.c?]
	Volume 1 Module 4
1.5.1	c) Is the laboratory evaluating modified reference methods and non-standard methods (including laboratory developed methods) using quality control procedures and acceptance criteria that are consistent with those of similar standard methods or technologies, and the evaluation includes the following:
1.5.1	d) Is the use of any modified reference method or non-standard methods being approved by DoD/DOE personnel?
1.5.1	e) Are methods validated when substantive modifications are made to reference methods (i.e., stoichiometry, technology, mass tuning acceptance criteria, quantitation ions, compressing digestion or extraction timeframes, reducing reagent or solvent volumes, changing solvents, or compressing instrument runtimes)?
1.5.2.2	e) In situations where methods are setup and used on an infrequent basis, does the laboratory choose to perform LOQ verifications on a one per batch basis in lieu of quarterly verification, prior to sample analysis?
1.7.1.1	g) Do the LOQ and the highest calibration standard of a multi-level calibration curve establish the calibration range?
1.7.1.1	g) For metals analysis with a single-point calibration, do the LOQ and the calibration standard establish the calibration range, which lie within the linear dynamic range?
1.7.1.1	g) When sample response exceed the calibration range, does the laboratory dilute and reanalyze the sample (when sufficient sample volume and holding time permit) to bring results within the calibration range?
1.7.1.1	g) For metals analysis, the laboratory may report a sample result with a response above the calibration range if the laboratory analyzes and passes (within 10% of the true value) a high level check standard that exceeds the sample concentration but is within the linear dynamic range (provided the high level check standard is analyzed in the same manner as the sample and within the same calibration).
1.7.1.1	g) Are the results outside the calibration range reported as estimated values and qualified using appropriate data qualifiers that are explained in the case narrative?
1.7.2	e) iii) If the laboratory cannot immediately analyze two CCVs, then is corrective action(s) performed and repeat the CCV and all associated samples since the last successful CCV.?

1.7.3.3.1	b) If adequate sample material is not available, is the lack of MS/MSDs (MDs) noted in the case narrative, and is a LCS Duplicate (LCSD) used to determine precision?
1.7.4.1	a) i) The concentration of any target analyte (chemical of concern) in the blank exceeds 1/2 the LOQ or is greater than 1/10th the amount measured in any associated sample, or 1/0th the regulatory limit, whichever is greater?
1.7.4.1	b) If a method blank is contaminated as described above, then does the laboratory reprocess affected samples in a subsequent preparation batch, except when sample results are below the LOD? If insufficient sample volume remains for reprocessing, are the results reported with appropriate data qualifier?
1.7.4.2	d) DoD/~~DOE~~ considers the same analyte exceeding the LCS control limit two (2) out of three (3) consecutive LCS to be indicative of non-random behavior., Is corrective action taken and reanalysis of the LCS performed?
	Volume 1 Module 6
1.5.2.1.1	c) i. Is the appropriate blank subtraction the mean blank value of the blank population?
1.5.2.1.1	c) i. Is the implementation of blank populations for calculation of MDAs described in detail in a SOP?
1.5.2.1.1	c) i. It is acceptable to use a constant of 2.71 in situations where that factor is built into instrument software without an option to use 3. In that case, does the laboratory obtain permission from the DoD/~~DOE~~ client and document the use of 2.71 in the Case Narrative or in procedures available to the client?
1.5.2.1.1	c) ii. Without a Blank Population: MDA for samples without a blank population can be determined if based on appropriate Currie or MARLAP calculations, such as: 3.29* Tb+Tb MDA= S B+3 K K *TS Where: K = efficiency * e -λ t * aliquot fraction * tracer Recovery*Yield TS = count time of the sample in minutes TB = count time of the background in minutes b = background count rate in cpm Is fhe above equation used when sample and background count times are different? Other equations, where sample and background count times are the same may also be used. The above equation for MDA has the units of dpm/sample. Are other units appropriately conversion. - Site specific requirements may be provided for other MDA formulations. - MDAs for samples without a blank population can be determined if based on appropriate L. A. Currie or MARLAP calculations.
1.5.2.1.1	a) Does the laboratory handle samples with elevated activities according to the following requirements: i) The appropriate aliquot size shall be determined based on the activity level in the sample. The aliquant shall be large enough to generate data, which meet the following criteria:
1.5.4	Are results reported at the 95% confidence level, which is 1.96-sigma (often abbreviated as 2-sigma)?
1.5.4	Is the uncertainty of a count estimated as the square root of counts except when there are zero (0) counts? (In the case of zero (0) counts, the uncertainty of the count is assumed to be the square root of one count.) For counting methodologies where very low counts are possible, the MARLAP 19.57 equation may be used with acceptance by the client.
1.6.2.2	f) Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with b).
1.7.1	a) viii.When sources used for determinations for detection efficiency are not prepared from NIST/international traceable standards, they shall be "working reference materials" defined as follows: a reference material with one or more properties sufficiently well established to be used for calibration or assessment of a measurement method. Working reference materials may be prepared by the laboratory for their own use. (See ASTM C1128)
1.7.1	b) If a performance check fails, does the laboratory immediately analyze two additional consecutive performance checks (immediately is defined as starting a consecutive pair within one hour; no samples can be run between the failed performance check and the two additional performance checks). This approach allows for spurious failures of analytes to be reported without reanalysis of samples. Any corrective actions that change the dynamics of the system requires that all samples since the last acceptable performance check be reanalyzed.
1.7.1	b) Do both of these performance checks meet acceptance criteria in order for the samples to be reported without reanalysis?
1.7.1	b) If either of these two performance checks fail, are the associated samples cannot be reported and reanalyzed?
1.7.1	b) If the laboratory cannot immediately analyze two performance checks, perform corrective action(s) and repeat the performance check. Are all associated samples since the last successful performance check reanalyzed?
1.7.1	b) Does recalibration occur if the above scenario fails? Are all affected samples since the last acceptable performance check reanalyzed?

1.7.1	b) Flagging of data for a failed performance check is only appropriate when the affected samples cannot be reanalyzed. Does the laboratory notify the client prior to reporting data associated with a failed performance check?
1.7.1	b) Is the Full-Width-Half-Maximum (FWHM) resolution of the alpha or gamma detector evaluated prior to instrument use and following repair or loss of control (MARLAP 18.5.6.2).Is the measured FWHM resolution trended?
1.7.1	b) It is important to use calibration or QC sources that will not cause detector contamination from recoil atoms from the source.
1.7.1	b) i For systems using sample changers and/or long count times that run more than a day, is the energy calibration checked before each analytical batch?
1.7.1	b)ii Detector response (counting efficiency) determinations shall be performed when the check source count is outside the acceptable limits of the control chart (reference ANSI N42.23, Annex A5).
1.71	b) iv) For radon scintillation detectors, is efficiency verified at least monthly, when the system is in use.
1.7.1	v)Are Background Subtraction Count (BSC) measurements conducted after calibration and monthly thereafter and monitored for trends to ensure that a laboratory maintains its capability to meet required project objectives?
1.7.1	vi) Successive long background measurements may be evaluated in lieu of shorter background check measurement.
1.7.1	vii) Low levels of contamination not detected in a shorter background counting time may bias the results of sample analyses. The duration of the background check measurement shall be of sufficient duration (i.e., at least as long as the sample count time) to quantify contamination that may impact routine sample measurements.
1.7.1	viii) The background check frequency may be extended to accommodate long sample count times.
1.7.1	ix) If the background check is conducted less frequently than daily, any associated sample results shall not be released for use until a (bracketing) background check is measured and has met all acceptance criteria. An Instrument Contamination Check (ICC) for alpha spectroscopy can be a shorter measurement that can be performed on a weekly basis, in which case reporting sample results is not contingent on bracketing ICC checks.
1.7.1	x) A background check shall also be collected before and after any counting chamber changes are made (i.e., cleaning, liner replacement, or instrument modification).
1.7.1	xi) For gamma spectroscopy systems, long background measurements (to be used for background corrections) shall be performed on at least a monthly basis. The duration of the background measurement shall be sufficient to quantify contamination that may affect routine sample measurements (the count time for the background measurement shall be at least as long as the sample count time.)
1.7.1	xii) For alpha spectroscopy systems, monthly background determinations shall be performed for each Region of Interest (ROI). The duration of the background measurement shall be sufficient to quantify contamination that may affect routine sample measurements
1.7.1	xii) Labs must have procedures in place to define high activity and counting procedures to check for gross contamination from high activity samples.
1.7.1	xiii) For gas-proportional counters, long background measurements (to be used for background corrections) shall be performed on a monthly basis, at minimum (but some clients may specify TNI 1.7.1.c) iii) – weekly).
1.7.1	xiii) Labs must have procedures in place to define high activity.
1.7.1	xiv) For scintillation counters, the duration of the background measurement shall be sufficient to quantify contamination that may affect routine sample measurements.
1.7.1	xiv) The daily instrument check (each day of use) shall include a check with an unquenched, sealed background vial (which should never be used to correct sample results for background measurements, since it is not in the same configuration as samples)
1.7.2	Note: The “same instrument calibration parameters, instrument analysis algorithms, etc.” implies that these parameters for a given instrument shall not be changed for the samples in that batch, counting shall be at the same time, with the same count time duration. It is understood that for multiple detectors, the parameters may not be identical.
1.7.2.2	j) Is the LCS counted for a sufficient time to quantify the activity level of the LCS?
1.7.2.2	m) LCS Selection and Level: Does the LCS contain at least one analyte reported for samples by that analytical method (separation chemistry and decay mechanism) and should be at least five times, but not greater than 20 times, the RL with the following exceptions
1.7.2.2	m) i) Some programs may require, following TNI, at least 10 times the MDA and at a level compatible with routine samples.
1.7.2.2	m) ii) For RLs of low activity, the analyte shall be at a level where the random counting error does not exceed 10% in the counting time required to attain the RL.
1.7.2.2	m) iii) Analytes for gamma spectroscopy need not be the same as the sample analyte but should fall in the approximate energy region of the spectrum (i.e., low, mid-range, and high energy) of the reported analytes.
1.7.2.2	m) iv) For gross alpha and/or gross beta analysis, the analytes in the LCS shall be the same analytes used for the calibration curve.
1.7.2.2	m) v) If a laboratory standard containing the reported analyte is not available, an LCS analyte having similar separation chemistry, energy and decay mechanisms shall be used unless otherwise agreed to by the client.

1.7.2.2	n) Is the LCS traceable to the NIST or accepted international standard, or a working reference material as described in1.7.1 a) viii)? (it may be used repeatedly for different analytical batches as long as it is appropriate for the matrix and geometry of the batch)
1.7.2.3	a) xi) Acceptance Criteria: Matrix spike recoveries shall be evaluated using the following criteria: If the activity of the sample is less than 5 times the spiking level, matrix spike recoveries shall be within the control limits of 60 - 140%, or as specified by the client. If the activity of the sample is greater than 5 times the spiking level, |ZMS | ≤ 3 shall be used (MARLAP 18.4.3).
1.7.2.3	a) xii) Matrix Spike Selection and Level: Is the matrix spike added at a concentration of at least five, but not greater than 20 times the RL? (For samples having known significant activity of the targeted radionuclides, more than 20 times the RL may be added to minimize the effect of the sample activity on determination of spike recoveries.) Some programs may require, following TNI, at least 5 times the MDA.
1.7.2.3	b) i. Replicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this analysis indicate the precision of the results for the specific sample using the selected method. Replicates provide the most useful measure of precision when target analytes are found in the sample chosen for replication.
1.7.2.3	iii) The purpose of the Duplicate sample analysis is to assess laboratory precision by providing information on the laboratory's reproducibility and the homogeneity of the sample.
1.7.2.3	iv) The Duplicate activity shall not be averaged with the corresponding sample activity when reporting results.
1.7.2.3	v) Are samples identified as Field Blanks not used for Duplicate sample analysis?
1.7.2.3	vi) Is at least one Duplicate sample prepared and analyzed with every Analytical Batch of samples.
1.7.2.3	vii) Is the Duplicate counted for the same duration to meet the required detection limit?
1.7.2.3	viii) When the sample does not contain significantly elevated activity, are QC samples counted for a duration equal to that of the associated original sample?
1.7.2.3	c) iv. Tracer yield requirements for isotope direct yield methods: (usually alpha spectroscopy) Does the chemical yield for isotope dilution methods fall within the range 30% - 110% or as specified by the client?
1.7.2.7	d) Are background contamination monitoring samples analyzed at a sufficiently low level of detection to confirm that no impacts to client samples have occurred due to cross-contamination?
1.7.2.7	d) Are samples segregated by activity levels in sample receipt, processing areas, and storage areas?
1.8.1	c) Blank Correction: Does the laboratory ensure that blank corrections are not performed, except where required by client and fully documented in the Case Narrative.?
1.8.1	d) i) a. If the tracer recovery for the sample does not fall within 30% - 110%, reanalysis is required, beginning with preparation but see 1.7.2.3 c) i) through iii))?
1.8.1	d) i) b. If the FWHM for the tracer peak exceeds 100 keV and/or the peak energy does not fall within ± 50 keV of the known peak energy, reanalysis is required?
1.8.1	e) Instrument Calibration: Does the calibration of each alpha spectrometry detector used to produce data include channel vs. energy calibration, detector response, efficiency determination and background determination for each ROI.?
1.8.1	j) v) Are any manual integration or adjustment of ROIs fully discussed in the Case Narrative?
1.8.2	a) SOPs for sample analyses by Lucas Cell shall incorporate and adhere to EPA Method 903.1 (current version), Radium-226 in Drinking Water Radon Emanation Technique. Performance shall be in accordance with the standard unless otherwise defined in this document or as documented by the laboratory and accepted by clients. Reference is to the current version of the method. \
1.8.2	When references are updated, is an implementation schedule determined by the lab?
1.8.2	e) Is the bubbler used for radium-226 standardization not used for sample analysis?
1.8.3	d) Instrument Background: Is the instrument background vial for all tritium matrices prepared with low-tritium or "dead" water unless the laboratory can demonstrate suitably small background or blank effects from other sources of water.

Thank you