A Summary of Changes of the DoD/DOE ELAP QSM Version 6.0 and PJLA Transition Requirements

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Who Are We?

Perry Johnson Laboratory Accreditation is cross-sector accreditation body recognized in the areas of testing, calibration and medical laboratories, inspection bodies, reference material producers and proficiency test providers

ISO/IEC 17025

ISO/IEC 17020

ISO 15189

ISO/IEC 17043

ISO 17034

Governmental Schemes

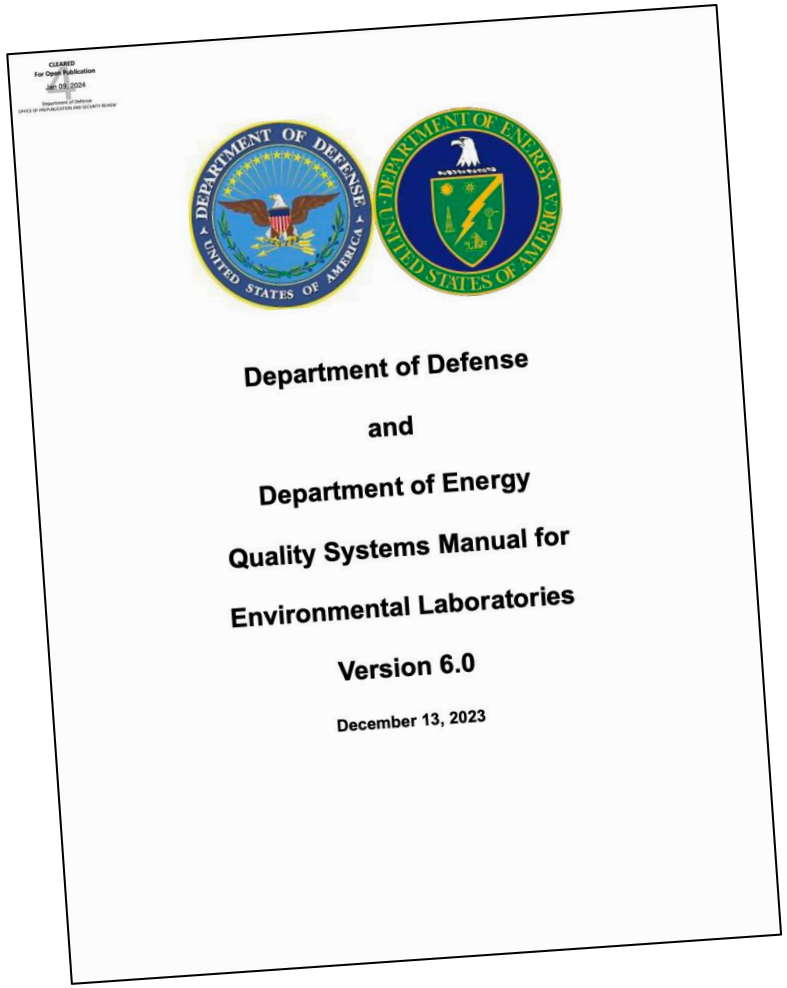
Disclaimer

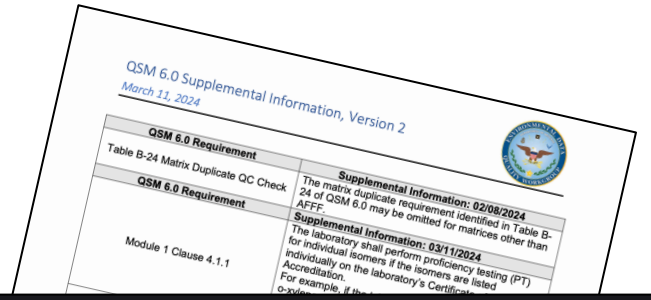
- This webinar is intended to be informational
- This webinar is intended to provide a summary some changes
- For details of specific requirements, refer directly to the standard
- Due to time constraints, this presentation only covers an overview of changes and is not intended to be all inclusive
- I do not speak on behalf of DoD or DOE, for interpretation of specific consult the EDQW and DOE

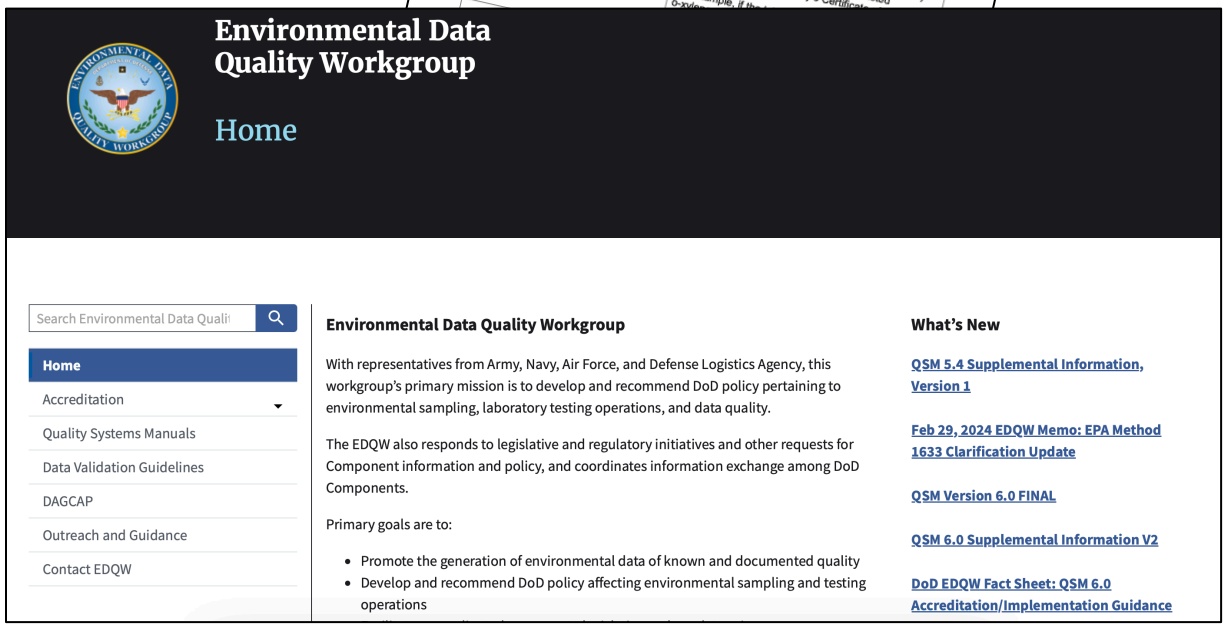
PJLA Transition Policy to QSM 6.0

- Transition
  - SA or RA or EOA
  - Additional time for SAs
- Performed on-site
- Organizations must be accredited by June 30, 2026
  - Assessments no later than February 28, 2026
    - Regardless of routine schedule

QSM 6.0 and Supplemental Information







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QSM 6.0 Structure

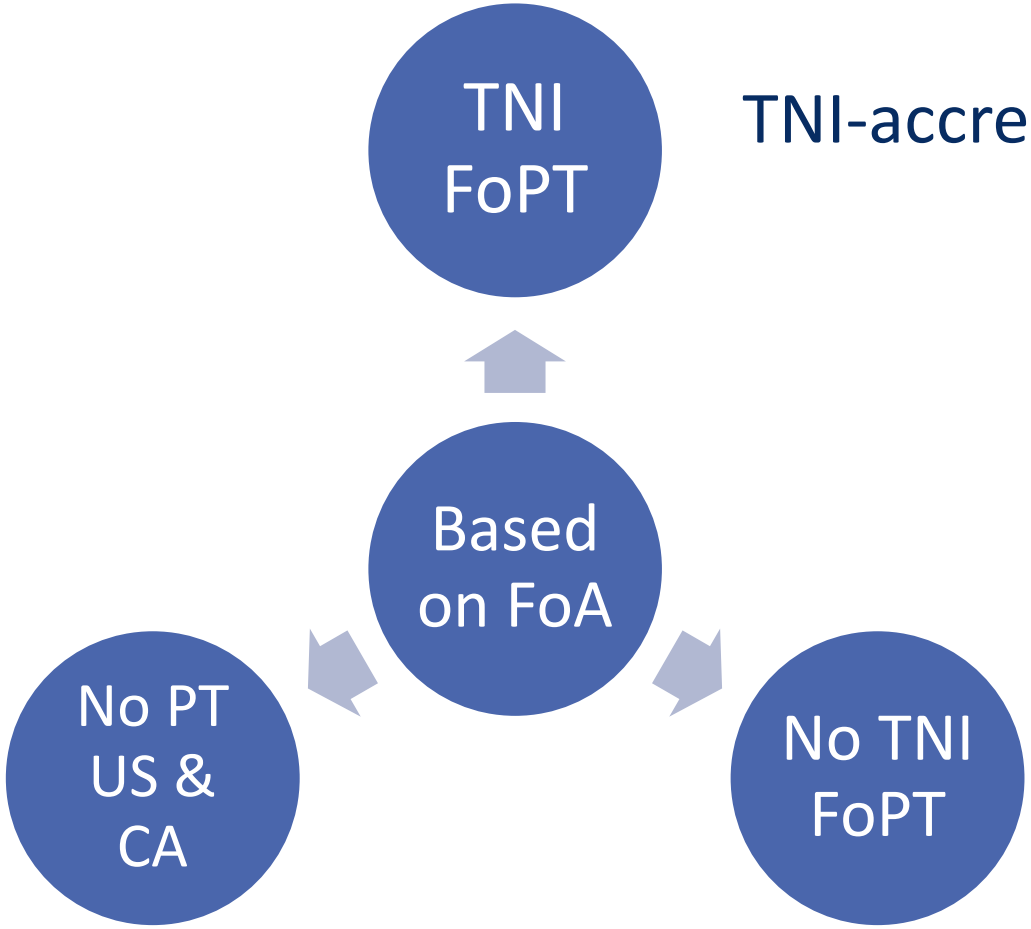
- Module 1 Proficiency Testing
- Module 2 Quality Systems General Requirements
- Module 3 Asbestos Testing
- Module 4 Chemical Testing
- Module 5 Microbiological Testing
- Module 6 Radiochemical Testing
- Module 7 Toxicity Testing
- Module 8 Industrial Hygiene Testing

- Appendix B Technology QC Requirements
- Appendix C LCS Limits

Appendices A, D & E removed from document

Module 1 Proficiency Testing

ISO/IEC 17043
PT worldwide,
Non accredited
PT, Precision and
bias studies



TNI-accredited PTP

US and CA-based
ISO/IEC 17043 PTP

Module 1 Proficiency Testing

- Methods w/suite of analytes
  - If all FoA analytes are not in study
    - Additional FoA analytes met by successful analysis of FoPT study for method
      - Unless PTs exist for specific analytes not in full PT-mix

Module 1 Proficiency Testing

- If laboratory reports single method to represent a technology for an analyte, and multiple combinations of preparation/analytical methods are used for analysis
  - Laboratory follows a documented schedule
    - Rotate combinations used each PT study
  - Every combination used
    - Minimum of once every three years
    - For each matrix

DW by Method!

Module 1 Proficiency Testing

- Precision and Bias
  - Submit in writing to AB, a list of items
    - No suitable commercial PT is available
  - **(DOE-only requirement)** Laboratory submit this in writing to all impacted DOE Customers
  - Procedure required
  - Records specified
  - Performed twice per year (timing requirements of PT studies)
  - Additional requirements on approach identified

Module 2 Quality Systems General Requirements

Definitions = requirements

Assessors may cite definitions as basis of a non-conformance

- Review Definitions (and definition clarifications)
  - Annually
  - Mid-Range
  - Multi-level Calibration vs Multi-point Calibration
  - Quality System Matrix

Module 2 Quality Systems General Requirements

- Maintain a documented program to detect and deter improper, inappropriate, or prohibited actions
  - Records shall be maintained to demonstrate compliance with schedule of items to be reviewed
- DOE Only kept named roles, clarified duties (TM or QM)

Module 2 Quality Systems General Requirements

- Personnel dealing with radioactive samples
  - Training in radioactive sample receipt,
  - Waste management,
  - Materials shipping and handling and radioactive material control, as applicable to their duties.
- This is not “DOE-Only Requirement”
  - Radioactive samples are samples sent by customer for radiological testing (See supplemental info V2, EDQW March 11, 2024)

Module 2 Quality Systems General Requirements

- Requires use Certified Reference Materials from a reference material producer accredited to ISO 17034 for calibration standards or Standard Reference Materials from NIST

When CRMs from an accredited provider are used, second source calibration verification is no longer required

Module 2 Quality Systems General Requirements

- Waivers
  - Records of approval for waiver shall be maintained by laboratory and included in all **affected data packages**
- Reporting requirements
  - LOQ and P/B, when required
  - Before and after chromatograms, rationale for MI
  - LOD/LOQ verifications when infrequent method option is used

Module 2 Quality Systems General Requirements

- DOE-Only Requirement-Section 9
- Hazardous and Radioactive Materials Management and Health and Safety Practices
  - Radioactive Materials Management Plan
  - Waste Management Plan
  - Chemical Hygiene Plan
  - Sample Receiving and Control
  - Records
  - Training

Module 3 Asbestos Testing

- Minimal updates

Module 4 Chemical Testing

- Modified or non-reference method customer approval **before use**
- When modification includes changes to sample preparation steps, validation shall include:
  - Analysis of field samples in matrices of concern
  - Field samples shall represent a range of characteristics encountered/ expected in samples
    - Examples of characteristics to consider include organic matter content, clay content, moisture content, pH, and dissolved/suspended solids
  - Validation shall include parallel studies to compare performance of reference method to modified method, where possible

Module 4 Chemical Testing

- Field samples shall contain target analytes either found natively in samples or spiked into sample
  - Validation shall include multiple levels of target analyte concentrations
  - Where method includes more than 45 target analytes, a representative subset of at least 45 analytes used
  - If a subset of analytes is used for validation, subset shall include all chemistries and target analytes that show most bias when analyzed using reference method
- Where modifications to only analytical portion of method are planned, laboratory shall take into consideration any matrix effects impacting analysis as part of its risk assessment

Module 4 Chemical Testing

- For calibrations evaluated using correlation coefficient or coefficient of determination, evaluate:
  - Relative Error (%RE)
  - Relative Standard Error (%RSE)
- Neg Control
  - Considered contaminated if target analyte in blank:
    - Exceeds 1/2 the LOQ, or
    - 1/10th the amount measured in any associated sample
      - **Whichever is greater**

Module 4 Chemical Testing

- Positive Control
  - Acceptance criteria
    - Use customer-provided acceptance criteria
    - If customer- provided acceptance criteria are not available, use Appendix C limits
    - If Appendix C limits are not available, use laboratory-developed acceptance criteria

Module 4 Chemical Testing
DL

QSM 5.4

- Frequency
  - Each matrix-method-analyte combination
  - Initially
  - Whenever there is a change in the method
- Procedure
  - EPA MDL one example of an approach
- Criteria
  - Meet requirement for false positive rate (1%)

QSM 6.0

- Frequency
  - Each matrix-method-analyte combination
  - Verified w/changes
- Procedure
  - Compliant with EPA MDL revision 2
- Criteria
  - As stated in EPA MDL revision 2
  - Estimates a 1% false positive rate

Module 4 Chemical Testing
LOD

QSM 5.4

- Frequency
  - Initial and quarterly verifications
  - Per batch basis for infrequently used methods
- Procedure
  - Spike LOD at 2-4x DL
  - Spike sets LOD until next spike
- Criteria
  - S/N ratio >3
  - Meet all requirements for identification

QSM 6.0

- Frequency
  - Initially determined
  - Ongoing verifications quarterly
  - When method altered (other than routine maintenance)
  - Verification per batch basis for infrequently used methods
    - Whichever verification frequency is chosen continued a minimum of 12 months
- Procedure
  - Initially the spike – sets the LOD
  - Ongoing spikes such that

  1/2x LOD ≤ Ongoing LOD Spike ≤ 2x LOD)
- Criteria
  - S/N ≥ 3 or Signal > MDLb (EPA 821-R-16-006)
  - Meet all requirements for identification

Module 4 Chemical Testing
LOQ

QSM 5.4

- Frequency
  - Quarterly verifications
  - Per batch basis for infrequently used methods
- Procedure
  - Within calibration range, no lower than lowest calibration point
  - LOQ > DL, should be LOQ > LOD
  - Empirically demonstrate Precision and Bias
- Criteria
  - Precision and bias meet client requirements

QSM 6.0

- Frequency
  - Verification quarterly
  - Per batch basis for infrequently used methods
    - Whichever verification frequency is chosen shall be continued for a minimum of 12 months.
  - If the method is modified, precision and bias at the new LOQ shall be demonstrated
- Procedure
  - Select LOQ such that

  LOD or 1/2 LOQ ≤ LOQ spike ≤ 2x LOQ
  - Empirically demonstrate Precision and Bias
  - Multiple Instruments same LOQ, spikes distributed
- Criteria
  - S/N ≥ 3 or Signal > MDLb (3 SD above MB)
  - Fall within 3 SD of mean historical data
  - No wider than LCS criteria ± 20%
  - ≥ 10% on lower end
  - Precision and bias meet client requirements

Module 4 Chemical Testing

- DL, LOD, and LOQ summary information available
- Precision and Bias
  - Procedure required
  - Evaluated across analytical calibration range of method
- Every data package
  - Precision and Bias at LOQ
  - LOD and LOQ verification data (infrequent method option)

Module 4 Chemical Testing

- Previous QSM exception allowing two passing CCVs to negate one failing CCV removed

- If a cause for CCV failure is identified that impacts only CCV (e.g., a missed autosampler injection)
  - Analysis may proceed if a second CCV is analyzed (within one hour and no samples analyzed)
  - Result is within acceptance criteria

Module 4 Chemical Testing

- When a modification of a method includes changes to sample preparation steps, validation process shall include analysis of field samples in matrices of concern
  - Field samples shall represent a range of characteristics encountered or expected in customer samples.
    - Characteristics to consider: organic matter content, clay content, moisture content, pH, and dissolved/suspended solids
- Validation shall include parallel studies to compare performance of reference method to modified method, where possible

Module 5 Microbiological Testing

- Minimal updates

Module 6 Radiochemical Testing

- Criteria clarifications
  - See supplemental memo EDQW
    - March 11, 2024

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QSM 6.0 Supplemental Information, Version 2
March 11, 2024

QSM 6.0 Requirement	Supplemental Information: 02/08/2024
Table B-24 Matrix Duplicate QC Check	The matrix duplicate requirement identified in Table B-24 of QSM 6.0 may be omitted for matrices other than AFFF.
QSM 6.0 Requirement	**Supplemental Information: 03/11/2024**
Module 1 Clause 4.1.1	The laboratory shall perform proficiency testing (PT) for individual isomers if the isomers are listed individually on the laboratory's Certificate of Accreditation. For example, if the laboratory lists m and p-xylene and o-xylene separately on the Certificate, the analytes shall be reported separately during PT, but If the laboratory only lists total xylene on the Certificate, only total xylenes shall be reported.
Module 2 Clause 6.2.10	"Radioactive samples" are samples sent by a customer for radiological testing.
Module 6 Clause 7.1.5.c.ii.c	Background subtraction measurements for gas-proportional and semiconductor alpha/beta detectors shall be performed monthly. Changed from quarterly.
Module 6 Clause 7.3.3.a.x.b	The Duplicate Error Ratio (DER) between the sample and the Matrix Duplicate is ≤ 3. Changed from < 3.
Module 6 Clause 7.3.3.a.x.c	The relative percent difference (RPD) is less than or ≤ 25%. Changed from < 25%.
Module 6 Clause 8.5.1.c.ii	Each Cell/Detector pair efficiency shall be verified at least annually. The continuing efficiency for each Cell/Detector pair shall be within 25% of the initially determined efficiency. Changed from + 25%.
Module 6 Clause 8.5.3.a.v	The acceptance criteria for the method blank shall be |ZBlank| ≤ 3 or within laboratory-developed criteria of ±3 standard deviations of the mean. Changed from |ZBlank| < 3 and + 3 standard deviations.

CLEARED
For Open Publication
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OFFICE OF PREPUBLICATION AND SECURITY REVIEW

Module 7 Toxicity Testing

- Minimal updates

Module 8 Industrial Hygiene Testing

- PT requirements for IH
  - External
  - Round robin (AB notification)
  - No round robins (AB notification)
    - Procedure requirements
  - No internal PT program (AB concurrence to meet PT by QC)
    - Procedure requirements
- B-Tables for IH Technologies
- Module aligns closer to American Industrial Hygiene Association (AIHA) application of IH

Appendix B Technology-Based QC Requirements

- Quality controls
  - Required unless listed as optional
- Calibration options are shown (Unless not allowed)
- Evaluation of relative error in calibration
- MB criteria updated
- LCS criteria updated

READ TABLES CAREFULLY

UPDATE SOPs ACCORDINGLY

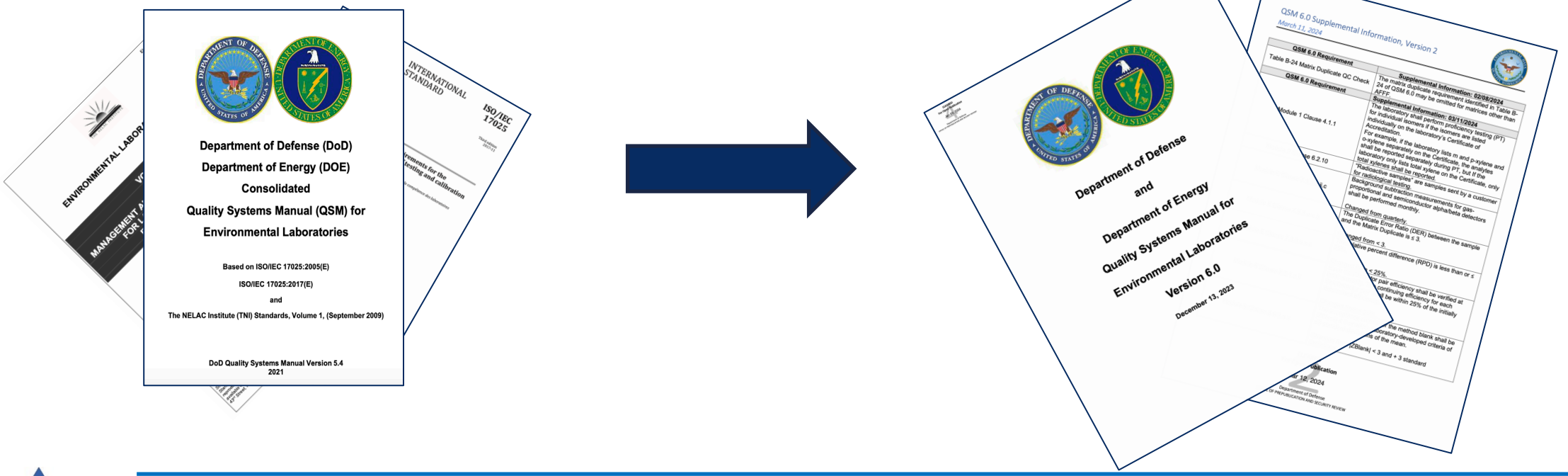
Appendix C LCS Limits

- Updated LCS Limits
  - Remember from Appendix B Tables
    - LCS limits: Customer specified, Appendix C, then lab-developed limits, if not in Appendix C
- Surrogate Spikes
  - Laboratory shall evaluate surrogate spike recoveries using acceptance criteria provided by customer, or if customer requirements are not provided, using the appropriate Appendix C limits

In Summary

Paradigm Shift

It may be easier to think of this as a new standard!



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