# DoD/DOE QSM Version 5.4 Waivers

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# ISO/IEC Clause

- 4.4 Review of Requests, Tenders and Contracts (ISO/IEC 17025/2005(E), Clause 4.4)

  The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

  a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

  b) the laboratory has the capability and resources to meet the requirements;

  c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2). Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.

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# QSM Requirement

- 4.4.4.1 DoD/DOE Requirement

    Waivers from DoD/DOE QSM requirements must be requested in writing from the appropriate DoD or DOE Chemist or Contractor Project Chemist (however named) on a project-specific basis and shall include technical justification relating to the specific project for the waiver. Documentation of approval for the waiver must be maintained by the laboratory and readily available for review.

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# DoD ELAP and DOE Accreditation

**Must meet all requirements of the QSM for accreditation**

How must this be done for waivers?

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# What is a Waiver?

- A waiver is a REQUEST made by the laboratory to the DoD or DOE Chemist or Contractor Project Chemist prior to contract award.

- The waiver can be accepted by the DoD or DOE Chemist or Contractor Project Chemist on a case by case / project basis.

- The waiver should only be accepted if the data quality objectives of the project can be achieved.

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# What is not a Waiver?

- A waiver is not a blanket list of deviations from QSM requirements that is submitted with every project.
  - Examples:
    - No closing CCVs
    - Broader acceptance limits than those allowed for in the QSM for calibrations
    - Not running the required frequency of Batch Quality Control Samples
- A waiver is not a method modification.

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# Waivers and Accreditation

- The laboratory must have documentation from the DoD or DOE Chemist or Contractor Project Chemist accepting the requested waiver along with the technical justification.

  - Example – Our project is just for screening data and investigational purposes

- The documentation must be readily available for review during the assessment.

- The waiver should be included in data packages.

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# Proposed Changes to QSM Version 6.0

- Require documentation of waivers in all Data Packages.

- Require waivers to be documented in the Case Narrative.

- DoD or DOE Chemist or Contractor Project Chemist will change to:

  - "The appropriate DOE or DoD Chemist or identified technical point of contact".

- Waiver must be requested and accepted prior to contract award.

# Questions

Thank you!

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