

Notice of Intent to Establish or Modify a TNI Standard

Expert Committee:	Chemistry Expert Committee	Proposal Date:	September 1, 2021	CSDEC Approval Date:	October 1, 2021
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TNI Volume/Module	Section(s)
V1	M4

Potentially impacted stakeholders/stakeholder groups:
Laboratories, Accrediting Bodies and Other

Nature of the standard to be established or complete Attachment 1 if change to existing standard:
<p>V1M4 is reaching the 5-year re-evaluation point and has had numerous Standard Interpretation Requests (SIR) requiring the Chemistry Expert Committee to clarify sections of the Module. While the entire Module will undergo review and potential changes, the sections of the Module determined to require specific attention are those relating to Calibration, LOD/LOQ, and Demonstration of Capabilities for both analysts and laboratories.</p> <p>The revisions to the Module will improve the module by resolving previously submitted SIRs, add clarity and useability of the Module to laboratories and Accrediting Bodies.</p> <p>Attachment 1 per SOP 2-100, Rev. 3.4 information is not presented as this level of detail of potential changes required in Attachment 1 are not yet available. This information will be supplied upon presentation of the DS summary and justification documentation.</p>

If a new standard, justification or need for the standard:
Not Applicable; not a new standard/module.

Any potential conflicts with the other standards and/or Modules of TNI Standards:
None anticipated but committee will work with other Expert committees, particularly Quality Systems Expert Committee, to ensure no potential conflicts arise in development of the revised module.

Potential economic impact:
No substantial economic impacts anticipated

Other potential suitability issues (enforceability, implementability, auditability):
No substantial issues anticipated

Signature of proposal representative:

Date:

Standard Update - Summary of Suggested Changes and Justification

Original Text	Suggested Change	Justification
<i>Include current reference and language. (If presented for public view, ISO language should only be referenced.)</i>	<i>Don't need to work on specific language - just summarize change needed.</i>	<i>Why does this need to be changed/updated?</i>

Note: This table can be used to prepare for a public meeting to seek stakeholder input.

Note: When the standard has been developed and is presented as a Draft Standard, a new version of this table is prepared noting the actual changes made to the standard. The "Suggested Change" column will include the actual language from the DS. The "Original Text" column will include the language from the previous (if any) standard. The "Justification" column states the reason for the change and provides any additional comments the expert committee thinks are pertinent.