| **Original Text** | **Suggested Change** | **Justification** | **Comment/Suggestion – Send by 10/2/20** |
| --- | --- | --- | --- |
| 6.4.6 ISO  5.5.13.1 Support Equipment  This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices). | The list should either be removed or included as a note. | The list is not all-inclusive and does not need to be in the standard. There may need to be a guidance document created for this section. There is a section in the small lab handbook that discusses support equipment.  Whenever lists are presented in the Standard, they cause issues because people incorrectly look at them as an all-inclusive thing. How can we better make use of lists in the Standard? |  |
| 7.5.1 ISO  4.13.3 Additional Requirements  a) The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts. | No Change suggested | Audit trail is mentioned in 4.13.2.1  Gray area does exist, however the language is as clear as we can make this. We are open to suggestions for changes. |  |
| 7.2.1.2 ISO  4.2.8.5   1. Documents that contain sufficient information to perform the tests, do not need to be supplemented or rewritten as internal procedures if the documents are written in a way that they can be used as written. Any changes, including the use of a selected option, shall be documented and included in the laboratory’s records.   e) The laboratory shall have and maintain an SOP for each accredited analyte or method.  f) The SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each method shall include or reference the following topics where applicable:   1. identification of the method; 2. applicable matrix or matrices; 3. limits of detection and quantitation; 4. scope and application, including analytes to be analyzed; 5. summary of the method; 6. definitions; 7. interferences; 8. safety; 9. equipment and supplies; 10. reagents and standards; 11. …… | Clarify that paragraph f is not a required outline, all topics must be covered when applicable but exact wording of headers and specific order is not required.  Modify the language from F to clarify that it applies to method procedures and add G for “administrative” SOPs  Work on language for the final sentence of f)  Clarify the difference between types of procedures for instance: administrative SOP and Method/Analytical SOP may not require all of the same components listed. | SOPs can be written in any format that includes all of the information necessary to accomplish what is defined in the standard. The formatting and language needs to be modified so laboratory understand there are many ways to accomplish this requirement.  Again, this is a list. Not all of these items are required, and since this list is written for methods, these bullets don’t apply to non-method SOPs |  |
| 7.4.2 ISO  5.8.5 Additional Requirements – Documentation  The following are essential to ensure the validity of the laboratory’s data.  a) The laboratory shall have a documented system for uniquely identifying the sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates.  b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned to each sample.  c) The laboratory ID code shall be placed as a durable mark on the sample container.  d) The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation. | Look at the word unique and whether the word should just be removed. | Identifying the sample and being able to track it through the quality systems do not necessarily require every container to be uniquely identified.  A unique identifier is required for each sample, and sub-samples need to be tied back to the sample. These are two different requirements |  |
| 8.8.2 ISO  4.14.5. c) The Internal audit schedule shall be completed annually, | Remove “schedule" .Remove the word annual/quarterly and insert language for the specific time frame intended  Suggested Language:  Instead of annually use every 12 months not to exceed 18 months or Internal audit must be performed every calendar year not to exceed 18 months | There does not seem to be a uniformity in what annually means. We need to clarify this statement. |  |
| 5.8.7.1 The laboratory shall implement procedures for verifying and documenting preservation. | Change from implement to have and implement. | This change is to insure that procedures are documented and not just implemented. |  |
| 5.10.11 c) Any non-accredited tests shall be clearly identified as such to the client when claims of  accreditation to this Standard are made in the analytical report or in the supporting electronic  or hardcopy deliverables. | Any results that are generated for non-accredited tests shall be clearly identified as such in the analytical report or in the supporting electronic or hardcopy deliverables when claims of accreditation to this Standard are made. | The rewording is to clarify that this only applies when claims of accreditation to this standard are made. |  |
| Multiple references to Quality Manual, the first is 1.1 introduction | Remove the requirement of a Quality Manual | Hold off on this change, as many states require it in their regulations. Work towards this goal.  It’s possible to have all of these items in multiple places, especially as more information is stored on-line or in ‘the cloud’. If the Quality Manual went away, it wouldn’t mean that the requirements contained in it would go away |  |
| *ISO 8.8.2 d) implement appropriate correction and corrective actions without undue delay;* | Define undue delay | Up to the laboratory to define. Clarify that the corrective action process needs to be begin immediately (as soon as practicable), but the actual action taken can be any appropriate timeframe as defined within the individual corrective action. |  |
| 4.13.3 b) The laboratory shall retain all records for a minimum of five (5) years from generation of the  last entry in the records. | Change the word entry to use or add a part in the section about personnel training and initial demonstration and or all training records on the analyst until 5 years after they leave the company. | Training records are different than other laboratory records and need to have clarification within this section.  Make a guidance document for records and time frames that are required for keeping (IDOC, maintenance records on instruments) |  |
| 4.4.1 c) the appropriate test and/or calibration method is selected and is capable of meeting the  customers' requirements (see 5.4.2). | No change suggested | The customer however named is the end user of the data |  |
| ISO **7.8.2.1** Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:  f) identification of the method used;  n) additions to, deviations, or exclusions from the method  **ISO 7.8.3.1** In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:  b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); | Additional Language needs to be added on what is required in the reports:  Prep methods  Need to add more language to expand on requirements in 7.8.2.1  Need more language to make sure that laboratories are identifying the revision of the methods.  Prep methods are not required on PT due to not being in table, but are required on final report by most ABs  PT executive committee looking at adding Prep methods to table.  Qualifiers  Should this go under final reports or non-conforming work.  5.10.3.2 f is language from 2005 iso standard, replaced with 7.8.2.1 n, where it talks about deviations from the method.  Additional language needs to be added for data qualifiers. | The ISO language needs to be expanded for the specific requirement within an environmental laboratory. |  |
| ISO 7.11.2  NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated. | Instrument Software Note in 17025 needs to be added as requirement. | Instrument software- verification and validation is done by using the equipment, so analytical performance would count as the instrument software validation.  DOD requires that the calculation on the instrument be validated with a known set of data and run in through the program to do some manual math checking. Should TNI follow this thinking? This is based on old thinking, so maybe we should let it go.  Need to consider before making Note 2 a requirement, laboratories do not want the same requirements for LIMS to be applied to off the shelf software, unless it has modification made by or for the laboratory. |  |
| 5.6.4.2 a) The laboratory shall retain records for all standards, reagents, reference materials, and  media, including the manufacturer/vendor, the manufacturer’s Certificate of Analysis or purity  (if available), the date of receipt, and recommended storage conditions. | No Suggested Change | Possible guidance document here  Note: C of As only available on the vendor website are by definition uncontrolled record for which labs can’t ensure record retention requirements are met without some level of contractual agreement with the vendor. |  |
| ISO 3.8 and 3.9 Definitions | No Suggested Change | Data validation/verification is already a requirement of the standard, however named. |  |
| 5.4.2 Selection of Methods | No Suggested Change | Language is ISO language and may need guidance but does not need additional language. |  |
| **ISO 8.3.1** The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.  ISO 8.3.2 d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; | Language needs to be added from the current standard ‘authorized editions’ | There needs to be language added to ensure that accredited laboratories have an authorized copy of the standard for which they have accreditation. |  |
| 5.5.13.1 d) Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available. | No Suggested Change | Open to suggested language |  |
| Continuing Operations Plans | No suggested Change | This would fall under the risk and opportunities clause. |  |
| Method validation and verification | Leave up to the technical modules to define. | The QS module needs to state that validations and verification must occur using current ISO language, how they are completed would be up to each technical module. |  |