

## MEMORANDUM

To: Dr. Jeff Flowers  
ELAB Chairman

From: Mr. Gary Dechant  
ELAB Laboratory Management Workgroup Chair

Date: August 10, 2009

Subject: Crosswalk and Comparison between the EPA OW Laboratory Certification Process and the TNI Environmental Laboratory Sector Accreditation Standard

The Environmental Laboratory Advisory Board (ELAB) Laboratory Management Workgroup is providing the text and tables that follow as a product of the charge from ELAB to prepare a crosswalk and comparison between the EPA OW Laboratory Certification Process and the TNI Environmental Laboratory Sector Accreditation Standard.

The ELAB was tasked with the comparison of the requirements of the drinking water program as specified in the Manual for the Certification of Laboratories Analyzing Drinking Water (Fifth edition EPA 815-R-05-004, January 2005) (Manual) and the requirements specified in The NELAC Institute (TNI) Quality Systems Standard (QS). The Manual is intended to assist EPA in certifying laboratories for the analysis of drinking water contaminants under the Safe Drinking Water Act. The Manual is also used by State certification programs as guidance, as noted in the Disclaimer of the Manual. The Manual is a program quality plan specific developed to support the SDWA program. The TNI Standard is a consensus standard intended to support the TNI National Environmental Laboratory Accreditation Program, including accreditation drinking water laboratories. The Standard is a quality systems document developed to address general quality practices and does not address any specific program requirements.

An initial comparison of the documents was done by Eastern Research Group (ERG) and the results were submitted to ELAB. ELAB then assigned the Laboratory Management Workgroup (LMW) to review the comparison and submit a draft to ELAB for consideration. The LMW workgroup petitioned the laboratory and regulatory stakeholders and created the final review committee that consisted of ELAB members, TNI members, state accreditation authorities, drinking water laboratories, members of AWWA and members of the EPA drinking water certification group.

The Manual is considered by the EPA to be a guidance document for drinking water labs. The word "should" in the Manual does not connote a requirement but does indicate EPA's strongly preferred approach to ensure the quality of laboratory results. Generally the term "must" in this manual refers to elements that are required by the National Primary Drinking Water Regulations or the promulgated drinking water test methods. The Manual uses the term "should" to describe criteria and procedures that in OGWDW's judgment are necessary for laboratories to produce data that are scientifically valid and defensible, and are of known and acceptable precision and accuracy. Many States have incorporated all or part of the Manual into their State regulations, and in those State regulations, the word "should" is replaced by "must" to indicate requirements.

The accreditation standards developed by (TNI) are standards used by TNI National Environmental Laboratory Accreditation Program Accreditation Bodies (NELAP ABs) for accrediting laboratories.

OGWDW has recognized the TNI standard as an alternative guidance to the Manual, and has accepted the TNI accreditation as equivalent to EPA's Laboratory Certification for drinking water compliance samples.

The LMW, tasked with comparing the Drinking Water Program (which includes the Manual) to the TNI standard determined that using the assumption that the Manual is being implemented as a requirement, rather than guidance, greatly facilitated this process. In addition, the LMW did not attach significance to any item. The LMW acknowledges that many items cover issues that are of significantly greater cost or have a much greater impact on the data quality in support of the drinking water program than do other items and would stress that the significance of issues be included in any final evaluation. The LMW also did not address any issues covering health and safety. Although both documents do address safety in some fashion, the extent to which it is assessable was undetermined.

A significant limitation in this study is that it was not possible to examine all the requirements found in the individual methods. The Office of Water laboratory certification program is based on the laboratory using only methods from a list of specific regulated methods. The methods listed in Federal Regulation often contain important information, such as quality control and quality assurance procedures, which may not be present in the Manual. In addition, it incorporates regulatory reporting and monitoring requirements that are outside the quality scope specific to the TNI Standard. On the other hand, TNI does not have a fixed, specified set of approved methods and accredits to most analytical methods with the regulated drinking water methods being a sub-set of the total methods available for accreditation. Because of the general nature of the TNI Standards it may contain elements not found in the Manual but which are contained in individual methods or it may contain elements not applicable to drinking water samples. Thus a side by side comparison of the TNI Standards and the Office of Water Certification Manual may indicate missing features and requirements that are actually present in the individual methods or may not be applicable at all.

The TNI Standard assumes that the methods chosen for accreditation are commonly used, are readily available and contain the specific directions, including QA/QC procedures, necessary to produce relevant and meaningful data. The TNI Standard makes general reference to the utilization of standard methods, but does not specifically recommend that a method be chosen from a specific set of methods. The EPA 5th Edition Lab Certification Manual differs from the TNI Standard in that the EPA CM provides additional guidance for using Rule-approved methods, including additional guidance on those methods that may not be included in the method itself. Much of this ancillary information contained in the EPA CM is not described in TNI Standard. The TNI Standard assumes that methods will have all technical information and QA/QC included in the procedure. Occasionally, this is not the case. When using Rule-approved methods the lab may have to refer to the 5th Edition CM for additional details on running the analyses. Additionally, some state drinking water certification programs supplement the Office of Water requirements with additional state specific requirements when they feel that there are inadequacies in the individual methods. In this case neither document may capture the requirement.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Implementation</b>						
Document Titles	Environmental Laboratory Sector TNI Standards Adopted December 22, 2007		<b>Manual for the Certification of Laboratories Analyzing Drinking Water</b> (Fifth edition)(Manual)(EPA 815-R-05-004, January 2005), <b>Supplement 1 to the Fifth Edition of the Manual for the Certification of Drinking Water</b> (Supplement 1)(EPA 815-F-08-006, June 2008) and 40 <b>CFR</b> Part 141 (which includes by reference <b>Technical Notes on Drinking Water Methods</b> (EPA/600/R-94/173, October 1994) and promulgated <b>Test Methods</b> ).			<p>The TNI standard is a set of requirements for laboratory accreditation.</p> <p>The Office of Water Certification Manual was issued as a Guidance Document that has been incorporated by rule in many state programs.</p> <p>The comparisons in this table between the TNI standard and the OW CM is based on the assumption that all of the guidance in the CM is a requirement when states implement the program..</p>
Evaluation of Certification Program	EL-VIMI-2008.1		Manual Chapter III Section 1		Similar sections, different programmatic roles. The Office of Water Certification Manual (OW CM) and the NELAC Institute (TNI) Standard both describe the roles, the responsibilities, and the structures of their respective programs.	Differences in the standards reflect the differences between the overall programs. TNI Standard outlines aspects of its program in greater detail by incorporating ISO language and addressing matrices other than drinking water.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Requirements for Certification of Laboratories - Proficiency Testing	EL-V1M1-2008.1, EL-V2M1-ISO-2008 Section 7.11 and EL-V2M2-2008.1	Almost all of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011	Manual Chapter III Sections 2, 13.1 and 14, Chapter IV Section 7.2.1, Chapter V Section 7.2, and Chapter VI Section 7.4	40 CFR Parts 141.23, 141.24, 141.89 and 141.131	Both programs require successful analysis of PT samples as part of their approval and ongoing conformance to their requirements. Both programs require that the PT samples be handled as routine samples. Both programs require that the PT samples be obtained from an approved provider.	OW-CM requires the laboratory to pass one PT sample by analyte and method (matrix implied as DW) per year based on pass/fail criteria published in 40CFR141. OW-CM defines the target analyte list based on regulated analytes. OW-CM requires that the laboratory should be able to provide documentation that the person analyzing the samples is a laboratory employee who routinely analyzes drinking water compliance samples. The TNI standard requires the laboratory to analyze two PT per year per fields of proficiency testing (FoPT) with a successful PT performance history of 2 out of 3. FoPT is defined as matrix, technology /method and analyte. FOPT analytes can only be changed, approved and required by TNI. TNI lists several specific areas covering how data is obtained and used. TNI accredits PT providers under a TNI standard. TNI lists actions that should not be taken with PT samples, such as subcontracting, analyzing PT samples for other labs to gain accreditation, obtaining results from PT providers, or discussing PT results with other labs.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Individual(s) Responsible for the Certification Program	EL-V1M1-2008.1 Section 3.1 and EL-V2M1-ISO-2008 Section 3.2, TNI By-Laws and TNI SOP 3-003-r8.6	Almost all of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011	Manual Chapter III Sections 3 and 10, 40 CFR Part 142.10(b)(3)(i)	40 CFR Part 142.10	Each program has officers or authorities empowered to certify or accredit laboratory programs.	<p>The certification program is a requirement of primacy for the States. EPA HQ delegated some of the responsibility in 142.10(b)(3)(i) to the Regions. The OW CM defines the role of the EPA, Regions and States. The Certification Authority (CA), Certification Program Manager (CPM), and Certification Officer(s) (CO) may represent the State and Regional personnel. The role of the laboratory personnel, laboratory director/manager or technical manager, and quality assurance manager are also defined</p> <p>TNI Standard has Accreditation Bodies whose authority is generally derived from regulatory authority acceptance of the accreditation process. TNI assigns the responsibility for accrediting states (AB's) to the NELAP board. This authority cannot be delegated.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
On-Site Laboratory Audit Team	EL-V2M3-ISO-2008.1 Sections 4.2.3, 4.2.4, and 4.2.5	Almost all of TNI Standard Reference EL-V2M3-ISO-2008 is ISO/IEC 17011	Manual Chapter III Section 4.1		Both programs require appropriate education/training.	<p>OW CM requires that auditors have a Bachelor's degree or equivalent education/experience in the field they certify. OW CM requires that the CO complete the appropriate EPA laboratory training course. OW CM has no requirement for supervised assessments.</p> <p>TNI states an assessor shall hold at least a Bachelor's degree in a scientific discipline or have commensurate experience acquired by having performed verified assessments of environmental laboratories, and have completed and attained a passing score on the written examination of courses approved by the employing accreditation body on assessing quality systems and all technical disciplines comprising a technology or combination of method and technology that the assessor will assess. Also states that an assessor needs to have participated in one or two on-site assessments under the supervision of a qualified assessor before performing an unsupervised assessment.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Third Party Auditors	EL-V2M1-ISO-2008.1 Sections 3.1 and 7.4.2	Almost all of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011	Manual Chapter III Sections 3, 4.2 and Appendix D		Both standards state the Accreditation Body (AB) may use a third-party assessor if outside expertise is required, so long as the body verifies the third party is free of conflict of interest and competent to perform the assessment.	Appendix D of the OW CM manual discusses EPA's policy on third party auditors and potential for conflict of interest.  TNI takes full responsibility for all subcontracted assessments and assess the potential for conflict of interest.
Plans for Certification of Laboratories and Certification Process	EL-V2M1-ISO-2008 Sections 4.6, 7.7.2	Almost all of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011	CW Manual Chapter III Sections 5 & 7		OW CM's CPM and TNI's AB have similar responsibilities for planning assessments.	The TNI standard has pre-specified procedures for certification. These procedures are detailed for the laboratory in Volume 1 and Volume 2. OW CM refers to CPM as the individual responsible for developing and recording certification plans, schedules, etc. A similar comparison can be made to a TNI Assessment Board (certifying, auditing, and auditing record keeping elements), who establishes the plans and procedures for on-site assessments.  The OW CM is a guidance manual where the process is less prescriptive, using terms like should and may.
Principal State Laboratories	Not Found		Manual Chapter III Section 6	40 CFR Part 142.10(b)(4) as a condition of primacy		TNI does not require that states operate a laboratory capable of performing analytical measurements for federally mandated contaminants.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Terminology:</b> Certified, Accredited, Provisionally Certified, Not Certified, Interim Certification	EL-V2M1-2008 Section 7.0	Almost all of TNI Standard Reference EL-V2M1- ISO-2008 is ISO/IEC 17011	Manual Chapter III, Sections 8, 13, & 14		Both programs address entry, suspension, revocation and reinstatement for the programs and both specify the requirements for these actions	<p>OW CM uses certified and interim certification for entry into the program, provisional certification for labs during deficiency corrective action process and not certified for revocation. Appeals and reinstatement is conducted by the certification authority.</p> <p>TNI uses accreditation for entry and suspension for resolution of serious interm findings and withdrawal for removal from the program. Suspension is used for short term or temporary removal from the program until issues are resolved usually with a particular analyte and does not require reapplication. Revocation or voluntary withdrawal requires reapplication. There is no status change when a laboratory is correcting deficiencies not significant enough to apply suspension. The application process is more formally documented and TNI has a formal list of reasons for denial. The appeals process allows for evaluation by an independent group. There are more reasons under the TNI program for suspensions or revocation. TNI does not address interim certification.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Detection Limits Requirements	EL-V1M6-2008 Section 1.5.2.2 (MDL)		Manual Chapter III Section 11.9, Chapter IV Sections 6.7, 7.2.9 and 7.2.11, Tables IV-7, IV-8 and IV-9, Chapter VI Sections 1.5, 3.1, 7.3, 7.7.1, 7.7.2, and 8.5.10, Appendix C, and promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both programs require methods that meet the client's requirements.	<p>OW CM, 40 CFR Part 141 and promulgated Test Methods specify MCLs and list typical MDLs. MDLs must be at or sufficiently below the MCLs. The procedure for calculating MDLs is also given.</p> <p>The TNI standard does not specify a procedure for determining the LOD (EL-V1M4-2008, 1.5.2) merely that if a procedure is mandated by a method or regulation, that that procedure is to be used and it is to be properly documented. While the TNI does not require the use of the fixed reporting limits specified in 40 CFR 141, it does require that the data meet the requirements of the contract for testing and that the LOD be verified on each instrument prior to use.</p>

DRAFT

9/16/09

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Laboratory Quality Assurance Plan	EL-V1M2-ISO-2008 Sections 4.2.2 & 5.9	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	OW CM recommends a quality plan, TNI requires a quality plan.	<p>OW CM-laboratory must adhere to the quality control required by the methods and should prepare a quality plan. OW CM does not require that QA Plan format include an identifier, page number, etc. OW CM does not state that the QA Plan contain information on review of new work requests, a policy for deviations from documented procedures or method specifications. OW CM does not state that major equipment or electronic signatures be included in the QA Plan. Nor does it state that procedures for dealing with complaints or protecting confidentiality be included. OW CM does reference EPA order 5360.1 A2 as a guide for developing a QA plan (see Chapter III Section 11).</p> <p>TNI requires a quality system and quality manual (however named).</p>
Laboratory organization and responsibility	EL-V1M2-ISO-2008 Section 4.1, 4.2, 5.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.1 and formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2.		Programs are similar for technical management and QA management.	<p>Other than the Technical Manager, TNI does not specify positions or type/amount of education, experience, and/or training needed, only "appropriate".</p> <p>OW CM does not indicate whether the person responsible for preparing a document may or may not review the report for final release.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Methodology	EL-V1M2-ISO-2008 Section 4.4.1c	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 13.2, formal Quality Management system (ISO/EIC 17025) recommended in Supplement 1 Chapter III Section 2 and former Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Both programs require methods that meet client requirements.	OW CW requires the laboratory to use federally mandated methods as specified in 40CFR141 and in the CM. Alternative methods must be approved by the EPA/OGWDW.  TNI recommends national or international methods but requires the laboratory follow the methods prescribed by the client. Clients can specify modifications to methods, which must be agreed upon and documented.
On-Site Assessment Frequency	EL-V1M1-2008.1 Section 4.0, EL-V2M2-2008.1 Sections 5.1.1, 5.2.1, & 5.2.3, EL-V2M3-ISO-2008 Section 5.1	Almost all of TNI Standard Reference EL-V2M2-ISO-2008 is ISO/IEC 17011	Manual Chapter III Sections 2 and 13.3		Both programs require onsite assessment.	OW CM suggests that an on-site assessment be conducted once every three years and sooner if the laboratory previously did not do well during an audit or has had a major change.  For TNI , the interval between the surveillance on-site assessments should not exceed 2 years, with the first surveillance on-site assessment carried out no later than 12 months from the date of initial accreditation.
Notification of Certifying Authority (CA) of Major Changes	EL-V2M1-ISO-2008 Section 8.1.2	Almost all of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011.	Manual Chapter III Section 13.4		Both programs require notification	TNI requires changes be documented in the appropriate laboratory documents.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Certification or Accreditation Status Review	EL-V2M1-ISO-2008 Section 7.0	Most of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011	Manual Chapter III Sections 14.1 & 14.2		Both programs use PT performance as a means to downgrade certification or accreditation status.	<p>OW CM states that a laboratory should be downgraded to provisionally certified. An OW CM laboratory may continue to do work but have to note suspension in writing on any report. OW CM states that EPA or the state provide technical assistance to help identify and resolve the problem.</p> <p>TNI may suspend a laboratory for failure to comply with PT analysis requirements. A TNI accredited laboratory can not continue as a certified laboratory after failure to comply and suspension. TNI mentions due process, TNI discusses other aspects like personnel requirements that may cause suspension.</p> <p>Both TNI Standards and OW CM specify their own procedures and criteria for downgrading/revoking certification status. TNI and OW CM both require analysis of PTs and penalize for falsification; but TNI provides more detail.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Criteria/ Procedures for Revocation	EL-V2M1-ISO-2008 Sections 7.5.6.1, 7.9.1 & 7.9.4.2 and EL-V2M2-2008.1 Section 10.0	Almost all of TNI Standard Reference V2M1-ISO-2008 is ISO/IEC 17011.	Manual Chapter III Sections 14.3 & 14.4		Both programs have procedures for revocation of certificates.	OW CM states that a laboratory is not certified if it has deficiencies and cannot produce valid data. Due process in reference to certification status is not discussed in OW CM, but in other sections it does state that the laboratory has the right to heard by EPA.  TNI lists the deficiencies that lead to revocation. TNI mentions due process.
Upgrading or Reinstatement of Certification	EL-V1M1-2008.1 Section 8.0 and EL-V2M1-ISO-2008 Section 7.9.5	Almost all of TNI Standard Reference V2M1-ISO-2008 is ISO/IEC 17011.	Manual Chapter III Section 14.5		Both standards require the facility to pass accreditation status before upgrading or reinstatement can be done.	OW CM requires a written request from the laboratory seeking upgrading or reinstatement of certification.  TNI requires the laboratory to meet the requirements for continued accreditation to be reinstated after suspension, . Under TNI, to reinstate accreditation after revocation, the laboratory must meet the requirements for initial accreditation.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Reciprocity	EL-V1M1-2008.1 Section 7.5.2		Manual Chapter III Section 16		Both programs promote reciprocity between state programs.	<p>OW CW strongly endorses reciprocity between states and encourages states to incorporate reciprocity within their laws and regulations.</p> <p>TNI requires recognition between primary and secondary accreditation bodies from the aspect of quality assessments but allows secondary accreditation bodies to apply fees for secondary accreditation</p>
Alternate Test Procedures (ATPs)	EL-V1M3-2008 Section 1.4, EL-V1M4-2008 Sections 1.4 & 1.5.e.b., EL-V1M5-2008 Section 1.4, EL-V1M6-2008 Section 1.4, and EL-V1M7-2008 Section 1.4		Manual Chapter III Section 18	40 CFR Part 141.27	Non-standard methods must be validated for certification in both programs.	<p>The OW CM requires new methods or modified methods be approved by the EPA OGWDW via written submission. TNI only requires that the new/modified method be validated through laboratory analysis, documented for review, and be approved by the client for use.</p> <p>TNI recognizes the Tier I, Tier II, and Tier III requirements established by U.S. EPA Office of Water as possible Alternate Test Procedure (ATP) approval processes, where Tier I and Tier III apply to the Clean Water Act and Tier II applies to drinking water only.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Organization</b>						
Activities carried out according to a defined standard	EL-V1M2-ISO-2008 Section 4.1.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025.	Manual Chapter II, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	40 CFR Part 141	Both programs require activities performed to the standards.	OW CM states that the EPA encourages the States to base certification of drinking water laboratories either upon criteria contained in the manual or upon state-developed equivalents that are at least as stringent as the manual.  TNI states that laboratories should carry out activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.
Quality system	All of EL-V1M2-ISO-2008, EL-V2M1-ISO-2008 Section 5.7.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011.	Manual Chapter III Sections 2 & 11, Chapter IV Section 7, Chapter V Section 7 and Chapter VI Section 7, formal Quality Management System (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control Program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141.	With the Supplement to OW CM, both standards require a quality system to be implemented. The Supplement of OW CM requires a quality system to be implemented and encourages quality systems based on ISO 9001 and ISO/IEC 17025. It specifically encourages third party certification to ISO 17025 and list several acceptable organizations including TNI. All test methods require quality systems.	TNI requires that the effectiveness of the required quality system be reviewed in the annual internal audit.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Management system that covers other facilities (temp. or mobile)	EL-V1M2-ISO-2008 Section 4.1.3	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025.	Manual Chapter III Section 11.4, formal Quality Management System (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Both standards require the management system to cover temporary facilities of all types.	OW CM does not discuss management of mobile or field activities, however it does describe the similar concept of field work throughout the standard.  TNI -The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent laboratory facilities, or in associated temporary or mobile laboratory facilities.
Conflict of interest between laboratories and AB's	EL-V1M2-ISO-2008 Section 4.1.4, EL-V2M1-ISO-2008 Section 7.4, EL-V2M3-ISO-2008 Section 4.3.3	Almost all of TNI Standard Reference V1M2-ISO-2008 is ISO/IEC 17025 and almost all of TNI Standard References EL-V2M1-ISO-2008 and EL-V2M3-ISO-2008 are ISO/IEC 17011	Manual Appendix D and formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2 and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Both standards emphasize the importance in preventing conflicts of interest between the laboratory and the accrediting body.	TNI-The accreditation body, shall identify, analyze and document the relationships with related bodies to determine the potential for conflict of interest, whether they arise from within the accreditation body or from the activities of the related bodies. Where conflicts are identified, appropriate action shall be taken.  OW CM- Conflict of Interest is found in Appendix D addressing sensitivity to potential conflict of interest, but no real discussion of conflict of interest.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Laboratory Managers and Other Personnel: Education, Experience, Responsibilities and Reporting Hierarchy	EL-V1M2-ISO-2008 Sections 4.1.5.a, 4.1.5.b, 4.1.5.h, & 4.1.7.1	Almost all of TNI Standard Reference V1M2-ISO-2008 is ISO/IEC 17025.	Manual Chapter III Sections 10.2 & 10.3 Chapter IV Section 1.1, Chapter V Section 1.1, Chapter VI Section 1.1, and formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2 and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both standards require the QA manager be independent and have access to senior management.  Both programs have specifications for personnel performing analysis. Neither standard indicates whether or not a technical manager documents personnel qualifications.	OW CM supervisors and personnel working at a specific type of lab (chemist, micro., and radio.) have their specifications of education etc. listed under appropriate section. OW CM does not have credit hour requirements in chemistry or analysis.  TNI standard 5.2.6.1 for technical managers requires a BS with 24 credit hours in chemistry and 2 years in analysis, a year experience or masters/doctorate. TNI technical managers of limited laboratories (covering only one field) have an associate's degree in specific type with 16 hours college credit hours and 2 years in analysis in appropriate field.
Ensure internal and external pressure does not affect personnel	EL-V1M2-ISO-2008 Section 4.1.5.b, 4.1.5.h	Almost all of TNI Standard Reference V1M2-ISO-2008 is ISO/IEC 17025.	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2 and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		TNI-(4.1.5.b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;  OW CM does not discuss the issue of internal and external pressure that would impede on competence, integrity, or impartiality.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Organization (lab and larger entity) structure and job specification of personnel	EL-V1M2-ISO-2008 Section 4.0	Almost all of TNI Standard Reference V1M2-ISO-2008 is ISO/IEC 17025.	Manual Chapter III Section 11.1, and formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2 and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Both standards mandate that the laboratory structure and personnel job specifications should be outlined in the Management Plan (TNI) or Quality Assurance Plan (OW CM.)	

DRAFT

9/16/2009

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
QA manager who is independent but has access to upper management	EL-V1M2-ISO-2008 Sections 4.1.5.i, 4.1.7.1	Almost all of TNI Standard Reference V1M2-ISO-2008 is ISO/IEC 17025.	Manual Chapter III Sections 10 & 11, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2 and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both standards ask that quality assurance managers have direct access to upper management and be independent from the management.	<p>OW CM does not indicate whether or not the QA manager has functions independent from laboratory operations for which they have QA oversight. It does state that the QA manager should be independent from the laboratory management, if possible. The OW CM plan does not state that the QA manager is responsible for conducting internal audits or for corrective actions (section III.11 indicates that the QA plan should state who that person is). OW CM supervisors and personnel working at a specific type of lab (chemist, micro., and radio.) have their specifications of education etc. listed under appropriate sections. The OW CM document does not elaborate on the specific requirements of the QA manager position.</p> <p>TNI does not specify that the QA manager needs to have a bachelors degree and a year of experience in quality assurance. TNI states that the technical director may also be the QA manager; (the QA manager has functions independent from laboratory operations for which they have QA oversight (4.1.7.1.b)).</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Appoint deputies for key managerial personnel like the technical director and quality manager	EL-V1M2-ISO-2008 Section 4.1.5.j	Almost all of TNI Standard Reference V1M2-ISO-2008 is ISO/IEC 17025.	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2 and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141		TNI requires the laboratory to appoint deputies for key managerial personnel (NOTE: Individuals may have more than one function and it may be impractical to appoint deputies for every function).  OW CM plan does not discuss appointing deputies for key management staff.
<b>Quality System</b>						
Quality Assurance	EL-V1M2-ISO-2008 Section 4.2.8.3, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11, Chapter IV Section 4.5, Chapter V Section 7, Chapter VI Section 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both include QA specific to individual methods.	Individual differences are covered in specific technical sections of the standards.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Laboratory documentation to ensure quality	EL-V1M2-ISO-2008 Sections 1.1, 4.2.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11, Chapter IV Section 7, Chapter V Section 7, Chapter VI Section 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141		<p>The TNI standard provides specific details for the required elements of each of the quality documents for the quality system.</p> <p>The EPA program references other EPA documents that provide more detail.</p>
Objectives included in QA plan	EL-V1M2-ISO-2008 Sections 4.2.2, 4.2.8.3.g, 4.2.8.3.h	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11, Chapter IV Section 7, Chapter V Section 7, Chapter VI Section 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141		<p>TNI standard indicates that a quality policy statement should be issued under the authority of top management.</p> <p>OW CM QA Plan does not include the laboratory's objectives but requires project data quality objectives per EPA QA/R-5.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Quality manual inclusions	EL-V1M2-ISO-2008 Sections 4.2.2, 4.2.5, 4.2.6, 4.2.8.3, 4.2.8.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11, Chapter IV Section 7, Chapter V Section 7, Chapter VI Section 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both list the required inclusions.	<p>The OW CM does not have specific title page and table of contents instructions. OW CM does not state that the quality manual should state the structure of QA plan. OW CM does not state that the QA manual should provide a reference of exceptions from the manual for managers to follow. The OW CM does refer to other EPA QA documents as guidelines.</p> <p>TNI does have specific title page and table of contents procedures and requires exceptions to be referenced or documented: 4.2.8.4.m).</p>
Manual should include responsibilities of the QA manager.	EL-V1M2-ISO-2008 Sections 4.2.6, 4.2.8.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 10.3, 11, 11.1 and 11.3, Chapter IV Section 7, Chapter V Section 7, Chapter VI section 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both include responsibilities of the QA manager.	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
List schedules of internal and external system and data quality audits and interlaboratory comparisons in the quality manual.	EL-V1M2-ISO-2008 Sections 4.0 (interlab comp), 4.1.7.1.f, 4.11.5, 4.14, 4.2.8.4.c	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.10, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both programs have requirements for internal QA checks.	OW CM states that the QA Plan should list schedules of internal and external system and data quality audits and interlaboratory comparisons (may reference SOP).  TNI states the quality manual shall contain or reference verification practices, which may include interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes (4.2.8.4.c)
<b>Document Control</b>						
Control of all documents in the quality system	EL-V1M2-ISO-2008 Section 4.3	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both programs address control documents.	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Revision status of QA manual	EL-V1M2-ISO-2008 Sections 4.2, 4.3.2.1, EL-V2M1-ISO-2008 Section 5.7.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of TNI Standard Reference EL-V2M1-ISO-2008 is ISO/IEC 17011	Manual Chapter III Section 11, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both programs require review and update of the QA manual/plan.	<p>The OW CM manual requires annual review of both the QA plan and all SOPs.</p> <p>Where practicable, TNI requires an annual review of the quality manual during the internal audit. TNI also requires identifying the current revision, which OW CM does not address.</p>
Specification of outdated/function/availability of QA manual	EL-V1M2-ISO-2008 Section 4.3.2.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11, Chapter IV Section 7.1.1, Chapter V Section 7.1.1, Chapter VI section 7.1.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141		<p>OW CM does not have a requirement that deals with handling invalid manuals once revisions are conducted. Section III.11 simply states that it is the responsibility of the QA manager to conduct periodic revisions of the manual and make sure appropriate information is always included.</p> <p>TNI has defined procedures for handling obsolete documents.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Control Document Identification and Format	EL-V1M2-ISO-2008 Sections 4.3.2.3, 4.3.3.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		<p>The OW CM manual does not specifically state that QA manuals should include an identifier, page number, etc as required in EPA QA/R-5. OW CM requires the date of last revisions of SOPs.</p> <p>TNI recommends QA Plan document format with identifier, page number, revision, etc.</p>
Review of documents (who and do they have references)	EL-V1M2-ISO-2008 Sections 4.1.7.1, 4.3.2, 4.3.3.1	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141		<p>TNI-Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval (4.3.3.1).</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Altered text highlighted and hand amendments, process for changing electronic documents	EL-V1M2-ISO-2008 Sections 4.3.3.2, 4.3.3.3, 4.3.3.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.5 and 11.13, Chapter IV Sections 8.2 and 8.6, Chapter V Section 8.2, Chapter VI Sections 8.2 and 8.6, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		OW CM has control of electronic data throughout, however does not address altered text in electronic documents or QA documents.  TNI requires that, where practicable, the altered or new text to be identifiable in the document or the appropriate attachments (4.3.3.2). As well as procedures to describe how changes in documents maintained in computerized systems are made and controlled (4.3.3.4).
<b>Review of Requests, Tenders and Contracts</b>						
Reviews of contract and work statements	EL-V1M2-ISO-2008 Section 4.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		CM OW does not address review of contracts.  TNI discusses it in detail.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Subcontracting</b>						
Subcontracting	EL-V1M2-ISO-2008 Section 4.5, EL-V2M1-ISO-2008 Section 7.4, EL-V2M3-ISO-2008 Section 6.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of EL-V2M1-ISO-2008 and EL-V2M3-ISO-2008 are ISO/IEC 17011	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		OW CM does not discuss the issue of subcontracting.  TNI discusses subcontracting in detail.
<b>Purchasing Services and Supplies</b>						
Procedures for purchasing, reception, and storage of reagents and standards	EL-V1M2-ISO-2008 Sections 4.6 and 5.6.4.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter VI Section 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141		In the radiochemistry method of the OW CM, it is stated that the QA program should encompass the purchase of supplies. This is the only mention of a purchasing procedure in the OW CM.  TNI requires a laboratory policy/procedure for the selection and purchasing of services and supplies.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Chain-of-Custody Procedures	EL-V1M2-ISO-2008 Sections 5.8.7.4, 5.8.7.5, 5.8.8, EL-V1M3-2008 Section 1.7.8.1	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 12 and Appendix A, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both discuss chain-of-custody procedures.	
<b>Service to Client</b>						
Laboratory service to client and confidentiality	EL-V1M2-ISO-2008 4.7, EL-V2M1-ISO-2008 4.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of EL-V2M1-ISO-2008 is ISO/IEC 17011	Manual Chapter III Section 11.2, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141		OW CM has "Process used to identify clients' Data Quality Objectives" listed as a QAP inclusion, but provides no details on the confidentiality or laboratory response to client complaints.  TNI requires a laboratory to cooperate with the client, monitor their performance in relation to the work performed for that client, and provide confidentiality.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Control of Nonconforming Environmental Testing and/or Calibration Work</b>						
Policy and procedure for nonconformity with own procedures	EL-V1M2-ISO-2008 Sections 4.9, 4.11, EL-V2M1-ISO-2008 Sections 5.5, 5.6	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of EL-V2M1-ISO-2008 is ISO/IEC 17011	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		TNI requires laboratories to have a policy/procedure to implement in the event of work that does not conform to testing procedures.  OW CM does not require such a policy.
Corrective actions	EL-V1M2-ISO-2008 Section 4.11, EL-V2M1-ISO-2008 Section 5.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of EL-V2M1-ISO-2008 is ISO/IEC 17011	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Both programs require laboratories to have a policy/procedure to implement corrective actions when work does not conform to test procedures.  OW does not specifically mention the term nonconformance but has procedures for nonconfirming tests.	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Preventive Action</b>						
Preventive action	EL-V1M2-ISO-2008 Section 4.12, EL-V2M1-ISO-2008 Section 5.6	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of EL-V2M1-ISO-2008 is ISO/IEC 17011	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		TNI requires laboratories to have a procedure to identify potential sources of nonconformity.  OW CM does not require such a policy.
<b>Control of Records</b>						
Record system	EL-V1M1-2008.1 5.3, EL-V1M2-ISO-2008 4.13, 5.8.7 (records are mentioned throughout Vol 1)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.13 & 15, Chapter IV Section 8, Chapter V Section 8 and Chapter VI Section 8, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods		Both include a list of required records. Both have a similar minimum length of record storage.	OW CM states that records should be maintained for a minimum of 6 years. OW CM requires record keeping procedures should be documented in the QA Plan.  TNI requires record retention for a minimum of 5 years. TNI requires that a laboratory establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. TNI includes records of subcontractors, disposal of records, legibility, and storage environment, preventing unauthorized access, archiving files, naming files, or overwriting/obliterating old files, electronic data storage, OW CM does not.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Data access and disposal procedures and other criteria	EL-V1M2-ISO-2008 Section 4.13	ISO/IEC 17025	Manual Chapter III Sections 5, 11.12, 11.13 & 15, Chapter IV Section 8, Chapter V Section 8 and Chapter VI Section 8, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods			OW CM does not describe disposal of records, legibility, and storage environment or procedures for preventing unauthorized access. OW CM does not have a set format for archiving files, naming files, or overwriting/obliterating old files.  TNI discusses control of records in detail.
History of records	EL-V1M2-ISO-2008 Sections 4.13.3.a, 4.13.3.f	ISO/IEC 17025	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.			TNI requires laboratories to establish a record keeping system shall allow the history of the sample to be readily available.

Subject	Requirement Source			CFR Reference	Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference			
Raw data	EL-V1M2-ISO-2008 Section 4.13.3.f.i	ISO/IEC 17025	Manual Chapter IV Sections 8.2 & 8.4, Chapter V Sections 8.2 & 8.4 and Chapter VI Sections 8.2 & 8.4, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods		Both programs discuss raw data management.	

DRAFT

9176109

Subject	Requirement Source			CFR Reference	Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference			
Mistakes and alterations	EL-V1M2-ISO-2008 Section 4.13.2.3	ISO/IEC 17025	Manual Chapter IV Sections 8.2, 8.3 & 8.4, Chapter V Sections 8.2, 8.3 & 8.4 and Chapter VI Sections 8.2, 8.3 & 8.4, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods		Both programs have similar requirements	

DRAFT 9/16/09

Subject	Requirement Source			CFR Reference	Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference			
Security of records	EL-V1M2-ISO-2008 Sections 4.13.3.f.xv, 4.13.3.e, 4.13.1.2, 4.13.1.3, 4.13.1.4	ISO/IEC 17025	Manual Chapter III Sections 11.8 & 11.13, Chapter IV Sections 2 & 8.2, Chapter V Section 8.2 and Chapter VI Sections 2.1 & 8.2, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.		Both require a suitable environment and security of electronic data.	

DRAFT 9/16/09

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Samples	EL-V1M2-ISO-2008 Section 4.13.3	ISO/IEC 17025	Manual Chapter III Sections 11.4, 11.5 & 11.12, Chapter IV Sections 6 & 8.3, Chapter V Sections 6 & 8.3, Chapter VI Sections 6 & 8.3 and Appendix A, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods		Both require similar sample/data documentation, but TNI provides more detail.	
Retention of raw data, final reports, SOPs, PT	EL-V1M2-ISO-2008 Section 4.13.3.f	ISO/IEC 17025	Manual Chapter I and Chapter III Sections 11.8, 11.13 & 15, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods		Yes	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Sampling, analytical and administrative records	EL-V1M2-ISO-2008 Section 4.13.3.f	ISO/IEC 17025	Manual Chapter III Sections 10.1, 11.1 & 12, Chapter IV Sections 8.3 & 8.4, Chapter V Sections 8.3 & 8.4 and Chapter VI Sections 8.3 & 8.4, , formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods		Similar, but TNI requires more detailed sample/data records.	
Reconstruction of Data	EL-V1M2-ISO-2008 Section 4.13.3.f	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 8.5, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both require adequate information be available to allow the auditor to reconstruct the final results for compliance samples and PT samples.	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Steps taken after audit finds errors or deficiency	EL-V1M2-ISO-2008 Sections 4.14.2, 4.14.3, 4.14.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		TNI requires that in the event of audit findings, the laboratory shall take timely corrective action, record the findings and corrective actions, and follow-up.
<b>Management Reviews</b>						
Management Reviews	EL-V1M2-ISO-2008 Section 4.15, EL-V2M1-ISO-2008 Section 5.8	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025 and almost all of EL-V2M1-ISO-2008 is ISO/IEC 17011	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141		OW CM does not discuss reviews that are conducted by quality assurance managers.  TNI requires a management review of the (Laboratory Quality Management System) QA/QC program in a laboratory.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Data Integrity</b>						
Data integrity and follow-up of audits	EL-V1M2-ISO-2008 Sections 4.2.8.1, 4.2.8.1, 4.16	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Supplement 1 Chapter 3 Section New, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	
<b>Personnel</b>						
Personnel	EL-V1M2-ISO-2008 Section 5.2 and 6.2 a and c.	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 10 & 11.1, Chapter IV Section 1, Chapter V Section 1 and Chapter VI Sections 1 & 4.1.1.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both address educational exceptions for the technical manager. Waiver of academic training is discussed in both programs	The OW CM includes specific education and/or experience requirements for many key positions.  TNI only specifies technical education/experience requirements for the technical director.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Contracted Personnel	EL-V1M2-ISO-2008 Section 5.2.3	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter V Section 1.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	-	<p>TNI-The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.</p> <p>OW CM only discusses contracted personnel for the supervisor/consultant position in the critical elements for microbiology chapter.</p>
Personnel Job Descriptions	EL-V1M2-ISO-2008 Section 5.2.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Similar Requirements	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Personnel Records	EL-V1M2-ISO-2008 Section 5.2.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 10.2 & 11.1, Chapter IV Sections 1 & 8.4.6, Chapter V Section 1 and Chapter VI Section 1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Similar Requirements	
Non-Testing Activity Documentation	EL-V1M2-ISO-2008 Section 4.1.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.7, Chapter IV Section 8, Chapter V Section 8 and Chapter VI Section 8, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Similar in regard to documenting the method and QC procedures used.	TNI-If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Data Integrity Training	EL-V1M2-ISO-2008 Section 5.2.7	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Supplement 1 Chapter III Section New, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	
Laboratory Analyst and Technician	Individual technical modules Section 1.6  See also TNI Management Responsibility in TNI Module 2		Manual Chapter IV Sections 1.2 & 1.3		Both programs address analyst and technician competency.	OW CM specifies required education and experience for the laboratory analyst and technician, in addition to specialized training for the operation of analytical instrumentation. Additional requirements apply for the analysis of compliance samples.  TNI-The analyst (s) shall demonstrate on-going capability by meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. TNI does not discuss educational or experience requirements for the laboratory analyst and technician.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Sampling Personnel	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.2, 5.2.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 1.4, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>OW CM requires that personnel who collect samples should be trained in the proper collection technique for all types of samples which they collect. Their technique should be reviewed by experienced sampling or laboratory personnel.</p> <p>TNI-The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization (s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.</p>

DRAFT 9/16/09

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Waiver of Academic Training Requirement	EL-V1M2-2008 Section 5.2.6.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 1.5, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Similar with some exceptions	OW CM-The certification officer may waive the need for specified academic training, on a case-by-case basis, for highly experienced analysts.  TNI -A person who does not meet the technical manager education credential requirements, but meets the listed requisites can be a technical manager. TNI also does not have a "Waiver".
<b>Accommodations and Environmental Conditions</b>						
Facilities and Control of Environmental Conditions	EL-V1M2-ISO-2008 Section 5.3	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.4, 11.11 & 11.12, Chapter IV Section 2, Chapter V Section 2 and Chapter VI Section 2, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both require measures to prevent cross contamination.	TNI is not as specific as the OW CM in the standards for measures to prevent cross contamination. TNI does not describe the specific environment of the laboratory (i.e. cleanliness, instrument location, area for sample preparation, safety, and cleaning of glassware).

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Preventive maintenance procedures and schedules	EL-V1M2-ISO-2008 Sections 5.5.3, 5.5.5.g, 5.5.6, EL-V1M5-2008 Section 1.7.3.7.b.ii	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.11, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>OW CM mentions that the preventative maintenance procedures and schedules should be addressed in the QA plan.</p> <p>TNI mentions that the laboratory shall have procedures for use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.</p>
<b>Environmental Test and Calibration Methods and Method Validation</b>						
Environmental Test and Calibration Methods and Method Validation	EL-V1M2-ISO-2008 Sections 5.4, 5.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.4, 11.5, 11.6, 11.7, 11.8 & 11.9, Chapter IV Sections 3 & 5.1, Chapter V Section 3 and Chapter VI Sections 3 and 7.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>OW CM states that the QA Plan should include processes to identify clients' data quality objectives (DQOs). OW CM presents QC such as calibrations as method-specified and discusses use of only EPA-approved methods or EPA-approved alternatives.</p> <p>TNI requires laboratories to perform testing in such a way to meet the needs of the client and regulatory authorities or organizations. TNI discusses client-specified and laboratory-approved methods. TNI discusses that deviation from environmental test and calibration methods should occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
SOPs with dates of last revision	EL-V1M2-ISO-2008 Sections 4.2.8.5.c, 5.4.1	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.3, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both require review, signatures, and dated revisions.	TNI requires archive of SOPs so previous data can be paired with SOP requirements in force at the time of analysis.
Methods manual	EL-V1M2-ISO-2008 Sections 5.4.1 and 5.9.3, and EL-V1M7-2008 Section 1.7.1.1d(tox)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11 and Chapter IV Section 5.1, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both require manuals to be available, and have provisions for using non-standard methods.	TNI specifies the items to be included or referenced for each test method. The quality control protocols specified by the laboratory's SOP shall be followed (see Section 4.2.8.5 in this Standard). The laboratory shall ensure that the essential standards outlined in the individual Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed.  OW CM states that laboratories should prepare a written description of its QC activities.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Acceptable Methods	EL-V1M2-ISO-2008 Section 5.4.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141 and ATP in 40 CFR Part 141.27	No	<p>TNI requires that the laboratory use methods as specified or defined by the client.</p> <p>OW CM mandates the use of only those methods specified in 40 CFR 141.</p>
Most Current Method/Standard	EL-V1M2-ISO-2008 Sections 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Title page, Chapter IV Sections 5 & 8.2, Chapter V Sections 5 & 8.2 and Chapter IV Sections 5 & 8.2, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141 and ATP in 40 CFR Part 141.27	No	<p>TNI uses the terms "method" and "standard" interchangeably and requires that, when possible, the most current version of the method or standard be used.</p> <p>40 CFR Part 141 specifies the test methods and revisions that are approved for drinking water compliance monitoring. Only method/revisions that are promulgated in the Federal Register or approved through the ATP process may be used. There is no requirement or preference for a given method/revision over another one. The OW CM does say that version 5 supersedes earlier versions.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Method Confirmation and Demonstration	EL-V1M2-ISO-2008 Section 5.4, Individual technical modules Section 1.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.9 and Chapter V Sections 5.6.1.4.1 & 5.6.1.4.5, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>EPA does test method validation prior to approving promulgated methods (this is part of the reason that EPA does not allow the use of non-promulgated methods for drinking water compliance). The OW CM does not need to discuss this. OW CM specifies certain procedures that require initial and continuing demonstration of method capability and performance.</p> <p>TNI states that all methods should require those demonstrations and includes specific documentation and time requirements. TNI also addresses method validation in the individual technical modules.</p>
Uncertainty	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.4.1, 5.4.6	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter VI Sections 7, 8.4.7 & 8.5.9, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	<p>OW CM only discusses uncertainty in the critical elements for radiochemistry chapter.</p> <p>TNI-The laboratory shall retain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty. The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope, including where appropriate, an estimation of the measurement uncertainty.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Calculations and Data	EL-V1M2-ISO-2008 Sections 4.13.2.2, 5.4.7.1, 5.9.3.a.v, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.3, 11.8, 11.9 & 11.13, Chapter IV Sections 8.2 & 8.6, Chapter V Sections 8.2 and Chapter VI Sections 7.6, 8.2 & 8.6, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	

DRAFT 9/16/09

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Laboratory Software Configuration or Modification Validation	EL-V1M2-ISO-2008 Sections 4.13.3.f.xv, 5.4.7.2, 5.5.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.13, Chapter IV Section 8.6 and Chapter VI Section 8.6, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Yes	
Quantitation of Multicomponent Organic Analytes	EL-V1M4-2008 Sections 1.7.2.b, 1.7.3.2.3.b (chem)		Manual Chapter IV Section 7.2.10		Both have provisions for quantitation of multicomponent organic analytes using a representative number of components.	OW CM (chemistry) indicates the analyst's professional judgment should be used and refers to EPA SW 846 for more information. A representative number (5-9) of peaks is suggested.  TNI (chemistry) indicates that for continuing calibration and LCS for multi-component analytes, a representative chemical related substance or mixture can be used.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Low Level Quantitation	EL-V1M4-ISO-2008 Sections 1.5.2, 1.5.2.1, and 1.5.2.2		Manual Chapter IV Section 7.2.12		No	<p>OW CM-Minimum reporting limits (MRL) must be below the MCL. Laboratories should run a Laboratory Fortified Blank (LFB) at their MRL every analysis day and should not report contaminants at levels less than the level at which they routinely analyze their lowest standard.</p> <p>TNI-For low level samples the laboratory may analyze duplicate laboratory control samples or a replicate matrix spike to determine reproducibility within a preparation batch in place of a sample replicate.</p>
<b>Equipment</b>						
Laboratory Equipment and Instrumentation	EL-V1M2-ISO-2008 Section 5.5, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 3, Chapter V Section 3 and Chapter VI Section 3, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both standards cover equipment and instrumentation	<p>OW CM does not mention the use of equipment outside of a laboratories permanent control.</p> <p>TNI does not mention specific types of equipment and/or specific maintenance/calibration requirements.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Calibration	EL-V1M2-ISO-2008 Sections 5.5, 5.5.1, 5.9.3.a.iii, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.6, Chapter IV Sections 3, 4, 5, 6 & 7, Chapter V Sections 3, 4, 5, 6 & 7 and Chapter VI Sections 3, 4, 5, 6 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>TNI requires laboratories to perform calibration in such a way to meet the needs of the client and regulatory authorities or organizations. Calibration requirements in the TNI standards are divided into two parts (analytical support equipment and instrument calibration). TNI-Instrument calibration requirements presented in the technical modules.</p> <p>OW CM presents QC such as calibrations as method-specific. Calibration requirements in the OW CM standards are found within the equipment, general laboratory practices, analytical methodology, sample, and quality control sections of each critical elements chapter (Section 3, 4, 5, 6, and 7 of Ch. IV, V, and VI).</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Support Equipment	EL-V1M2-ISO-2008 Sections 5.5, 5.5.13.1	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.9, 11.11 & 11.12, Chapter IV Sections 3 & 7.1, Chapter V Sections 3 & 8.5 and Chapter VI Sections 3 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	OW CM specifies type of equipment, proper maintenance, and calibration for certain pieces of equipment needed in each critical element chapter.  TNI does not mention specific types of equipment and/or specific maintenance/calibration requirements.
Specific Device Accuracy	EL-V1M2-ISO-2008 Section 5.5.13.1.e	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 7.1.6, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	OW CM does not discuss mechanical volumetric dispensing devices or glass microliter syringes.  TNI-Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) must be checked for accuracy on a quarterly basis.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Autoclave	EL-V1M5-2008 Section 1.7.3.7.b.ii		Manual Chapter V Section 3.5		Both require autoclave operation records.	<p>OW CM only mentions the use of an autoclave in the critical elements for microbiology chapter. OW CM does not state that pressure should be recorded for each run of the autoclave.</p> <p>TNI-Records of autoclave operations shall be maintained for every cycle. Records shall include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials.</p>
Instrument Calibration	EL-V1M2-ISO-2008 Section 5.5, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.3, 11.9 & 13.2, Chapter IV Sections 3 & 7, Chapter V Sections 3 & 7 and Chapter VI Sections 3 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Similar but not identical	<p>TNI requires a standard from a second manufacturer or manufacturing lot as initial calibration verification for chemical testing and radiochemical testing. TNI standard does not specify detailed procedural steps for calibration, but establishes the essential elements for selection of the appropriate techniques. TNI-the lowest cal point shall be at or below the LOQ. (1.7.1.1.f for chem)</p> <p>OW CM does not discuss verification of initial instrument calibrations by a standard obtained from a second manufacturer or lot (TNI 1.7.1.1.d for chem)(1.7.1.a.iv for radio). OW CM does not state if the lower calibration standard should be above the detection limit.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Zero point and single point calibration standard	EL-V1M1-2008.1 Section 5.2.1.b, EL-V1M4-2008 Section 1.7.1.1.h (chem)		Calibration section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	OW CM does not discuss instrument technology with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard. This is discussed in and only allowed if specified in the promulgated Test Methods.
Calibration Results	EL-V1M2-ISO-2008 Sections 5.5.2	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.9 & 11.12, Chapter IV Sections 3 & 7, Chapter V Sections 3 & 7 and Chapter VI Sections 3 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Equipment use and maintenance	EL-V1M2-ISO-2008 Sections 5.5.6, 5.5.7	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.11 & 11.12, Chapter IV Sections 3, 4, 5, 6 & 7, Chapter V Sections 3, 4, 5, 6 & 7 and Chapter VI Sections 3, 4, 5, 6 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	OW CM states that corrective actions are performed, described, and documented. OW CM does not discuss a “control of nonconforming work” procedure (TNI 5.5.7).

DRAFT 9/16/09

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Equipment Records	EL-V1M2-ISO-2008 Sections 5.4.1, 5.5.3, 5.5.4, 5.5.5, 5.5.13.1, EL-V1M5-2008 Section 1.7.3.7.b.ii (microb)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.11, Chapter V Section 8.5 and Chapter VI Section 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	OW CM's microbiology and radiochemistry sections require equipment records similar to TNI.	OW CM specifies that preventative maintenance documents should be kept for five years. OW CM does not specify the exact items needed in records for equipment or labeled on equipment.  TNI requires that the laboratory must have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both.
Continuing instrument calibration verification	EL-V1M2-ISO-2008 Sections 5.9.3.a.iii, 5.5.10, 5.6.3.3, individual technical modules, EL-V1M4-2008 Section 1.7.2 (chem), EL-V1M5-2008 Section 1.7.2 (microb), EL-V1M6-2008 Section 1.7.1.b (radio)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.6, Chapter IV Section 7.2.4 and Chapter VI Sections 3.1.2 & 3.1.5, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	OW CM requires daily variation in the concentration of continuing calibration standards. Promulgated test methods require second source.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Measurement Traceability</b>						
Measurement Traceability	EL-V1M2-ISO-2008 Sections 5.6.1, 5.6.2 and 5.6.3	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Sections 3, 4, 5, 6 & 7, Chapter V Sections 3, 4, 5, 6 & 7 and Chapter VI Sections 3, 4, 5, 6 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	

DRAFT 9/16/09

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Testing Laboratories	EL-V1M2-ISO-2008 Sections 5.4.6, 5.9.3, EL-V1M7-2008 Sections 1.7.1.1(tox),1.7.1.6.q	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.6 & 11.13, Chapter IV Sections 3, 4, 5, 6 & 7, Chapter V Sections 3, 4, 5, 6 & 7 and Chapter VI Sections 3, 4, 5, 6 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	

DRAFT 9/16/09

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Reference Standards and Materials	EL-V1M2-ISO-2008 Sections 4.2.8.4, 5.6.3, 5.6.4, 5.9.1, 5.9.3, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.3 & 11.13, Chapter IV Sections 3 & 7, Chapter V Sections 3 & 7 and Chapter VI Sections 3 & 7, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	OW CM specifies the type of standard or reference material used for calibration for testing of water quality parameters measured by non-certified labs (exception in IV 5.2) and in some radiochemistry tests.  TNI requires traceability to national or international standards of measurement or to national or international standard reference materials, unless such reference materials are not available.
Records and Label	EL-V1M2-ISO-2008 Sections 5.6.4.2, 5.8.5, 5.8.6, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.6, 11.7, 11.9 & 11.13, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	OW CM does not specify the exact items needed in records or labeled for all standards, reagents, reference materials and media.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Record keeping procedures	EL-V1M1-2008.1 Section 5.3, EL-V1M2-ISO-2008 Sections 4.13, 5.8.7, (records are mentioned throughout Vol1)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.13 & 11.15, Chapter IV Sections 8.1 & 8.2, Chapter V Sections 8.1 & 8.2 and Chapter VI Sections 8.1 & 8.2, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both have lists of inclusions for their individual record keeping procedures. Have similar record retentions - OW CM 6 years and TNI 5 years.	OW CM-records should be maintained for 6 years. A list of inclusions is provided.  TNI-records should be maintained for 5 years. Provides a list of information necessary for reconstruction of data.
<b>Sampling</b>						
Sampling	EL-V1M2-ISO-2008 Sections 5.4.1, 5.4.2, 5.5.2, 5.7, 5.8.4 Note 2, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.4, 11.5, 11.9 & 11.13, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Sample Collector	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.2.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 6.5 and Appendix A, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	OW CM makes a general statement about sample collector training requirements. The records must include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results. Sample collector name is mentioned in items for sample collection in Appendix A of the OW CM.  TNI requires name of collector to be documented
Sample Compositing	Not Found		Manual IV Chapter 6.7		No	OW CM—Compositing must be done in the laboratory, and only if the laboratory detection limit is adequate for the number of samples being composited (maximum of five).

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Handling of Samples</b>						
Sample Identification	EL-V1M2-ISO-2008 Sections 5.8.2, 5.8.5	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Sections 11.4 & 11.5, Chapter IV Section 6, Chapter V Section 6, Chapter VI Section 6 and Appendix A, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Yes	
Sample Temperature	EL-V1M2-ISO-2008 Sections 5.3.2, 5.8.4, 5.8.9.a.i, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 6.2 and Chapter V Section 6.3, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods.	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>TNI mentions regulatory or method criteria for temperature, but gives a general guide for sample temperature if none is given. Also has more information in individual technical modules.</p> <p>OW CM is more specific than TNI on shipping and storage temperature. Sample temperatures are also addressed in the promulgated Test Methods.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Neutralization of Residual Chlorine	EL-V1M2-ISO-2008 Sections 5.8.4, 5.8.9.a, EL-V1M5-2008 Sections 1.7.5.b (microb)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter V Section 3.15.4, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	OW CM and TNI specify that sodium thiosulfate should be added to each container to neutralize any residual chlorine.	OW CM and TNI standards specify that sodium thiosulfate should be added to each container to neutralize any residual chlorine.  OW CM does not list minimum concentrations that samples should be neutralized to.  TNI instructs laboratory to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples.
Maximum Holding Times	EL-V1M2-ISO-2008 Sections 4.13.3.f.v, 5.10.11.a, EL-V1M7-2008 Section 1.7.1.6.s(tox)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 6.3, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Similar for drinking water samples. TNI offers other options for other matrices.	OW CM has a general statement indicating that holding times are to be followed according to the specific method being used. Holding times are more specifically addressed in the promulgated Test Methods.  TNI also specifies hold time prescribed by the method and approved by the regulatory agency. However, TNI presents some specific hold times for toxicity testing beyond the scope of the OW CM. (EL-V1M7-2008 1.7.1.6.s).

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Sample Collection and Transport	EL-V1M2-ISO-2008 Sections 5.4, 5.7, 5.8, individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 6.4, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both OW and TNI make general statements and indicate that sample collection is to be followed as specified in the method being used.	
Chain-of-Custody	EL-V1M2-ISO-2008 Sections 5.8.7.2.b.i, 5.8.7.4, 5.8.7.5, 5.8.8, EL-V1M3-2008 Section 1.7.8.1(asbestos)	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 8, Chapter V Section 8, Chapter VI Section 8 and Appendix A, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both discuss chain-of-custody procedures.	TNI is not as specific in the chain-of-custody procedures for handling of samples and does not include examples of chain-of-custody forms in their standards.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Sample Acceptance and Rejection	EL-V1M2-ISO-2008 Sections 5.8.3, 5.8.6, and 5.8.7.2.a	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 6.1, Chapter V Section 6 and Chapter VI Section 6, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	OW CM states the laboratory must have a procedure for accepting samples.  TNI requires the laboratory to develop a sample acceptance policy.	
Handling/Storage of Samples	EL-V1M2-ISO-2008 Sections 5.8.1 – 5.8.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.4 & 11.5, Chapter IV Section 6, Chapter V Section 6, Chapter VI Section 6, Appendix A and Appendix D, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Storage Temperature	EL-V1M2-ISO-2008 Sections 5.8.1 – 5.8.4, 5.8.9	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.5 and Chapter IV Section 6.2, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both discuss storing samples at appropriate temperatures.	Temperature requirement is only discussed in the critical elements for chemistry chapter of the OW CM standards.  TNI discusses it more broadly, mentions using method specified temperatures for storage.
<b>Reporting the Results</b>						
Data reduction, validation, reporting and verification	EL-V1M2-ISO-2008 Section 5.10, Individual technical modules	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.8, Chapter IV Section 8, Chapter V Section 8 and Chapter VI Section 8, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both specify requirements to meet traceability and legal defensibility	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Sample Report	EL-V1M2-ISO-2008 Sections 5.10.2, 5.10.3	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.8, Chapter IV Section 6.6, Chapter VI Section 8.5 and Appendix A, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both OW CM and TNI identify the minimal requirements of what should be included in sample reports.	OW CM discusses sample report format in the chemistry and radiochemistry methods.  TNI encompasses all methods and requires more information for the Sample Report, such as consecutive page numbers, accreditation statements, management signatures etc.
Analytical Results	EL-V1M2-ISO-2008 Sections 5.10.1, 5.10.2, 5.10.4	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 8.5 and Chapter VI Section 8.5, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Subcontractor Reports	EL-V1M2-ISO-2008 Section 5.10.6	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	<p>OW CM does not discuss reporting requirements for work performed by contractors. OW requirements for subcontractors are the same as those for primary laboratories.</p> <p>TNI-When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically. When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.</p>
Electronic Transmission of Results	EL-V1M2-ISO-2008 Sections 5.4.7, 5.10.7	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	<p>OW CM does not discuss requirements in the case of transmission of environmental test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means.</p> <p>TNI-In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the standard requires conformance to the International Standards Organization requirement (see also 5.4.7).</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Understandable Format	EL-V1M2-ISO-2008 Section 5.10.8	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter III Section 11.13, Chapter IV Section 8, Chapter V Section 8, Chapter VI Section 8 and Appendix A, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	TNI-The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.
Amendment to Test Reports and Calibration Certificates	EL-V1M2-ISO-2008 Section 5.10.9	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	OW CM standards do not discuss requirements for amendments to test reports or calibration certificates.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Action in Response to Noncompliant Laboratory Results	EL-V1M2-ISO-2008 Section 5.10.3.1.b	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 9, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141, 40 CFR Part 141	No	<p>TNI requires laboratories to follow all relevant regulations required by the sponsoring program including state regulations regarding the reporting of exceedences.</p> <p>Although not specified as a requirement, the OW CM mentions prompt reporting and re-sampling if under contract to do so. There are reporting and record keeping requirements throughout 40 CFR Part 141</p>
<b>Demonstration of Capability</b>						
Initial Demonstration of Capability (DOC)	Individual technical module Section 1.6.2		Manual Chapter III Section 11.9, Chapter IV Sections 7.2.9, 7.2.11 & 8.4.6 and Chapter V Section 5.6.1.41	Promulgated Test Methods in 40 CFR Part 141	Both programs require Demonstration of Capability	<p>TNI requires an IDOC if the test method has not been performed within a twelve (12) month period. The TNI standard also requires a demonstration of ongoing proficiency on an annual basis.</p> <p>Requirements of the promulgated Test Methods must be followed. OW CM states that IDC must be performed before the analysis of compliance samples for each method, for each instrument, and for each analyst</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
DOC Sample Preparation and Documentation	Individual technical module Sections 1.6.2.2, 1.6.3		Manual Chapter IV Sections 7.2.9 & 8.4.6 and Chapter V Section 5.6.1.4			<p>OW CM does not indicate that the samples used are from outside sources. OW CM does not indicate the steps that need to be taken if the initial DOC fails.</p> <p>For biological testing, TNI does not specifically state that the DOC test consists of ten reagent water samples spiked with enumerated sewage or equivalent at 1-2 PFU per sample for each coliphage type used or for each coliphage type analyzed, three field samples are spiked with 1-2 PFU, however it does give guidelines to prepare DOC samples. TNI provides non-specific requirements for initial and on-going DOC in each test module.</p>
<b>Essential Quality Control Requirements: Chemical Testing</b>						
Availability of QC Information	EL-V1M2-ISO-2008 Section 4.13.3.c	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 7.1.2, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	All quality control information should be readily available for inspection by auditors.	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Balances and Weights	EL-V1M2-ISO-2008 Section 5.5.13.1	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 7.1.3, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Should be appropriate for the application to be used; balances should be calibrated at least annually. TNI requires that support equipment be calibrated or verified at least annually.	
Color Standards	Not Found		Manual Chapter IV Section 7.1.4		No	TNI has no specific information about color standards.
Temperature Measuring Devices	EL-V1M2-ISO-2008 Section 5.5.13.1, EL-V1M5-2008 Section 1.7.3.7.b.i	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 7.1.5, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both require calibration or calibration verification.	OW CM has more detail and additional (more frequent calibration) requirements for digital thermometers, thermocouples, and infrared detection devices.  TNI requires that support equipment be calibrated or verified at least annually.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Traceability of Calibration	EL-V1M2-ISO-2008 Section 5.6.3	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter IV Section 7.1.6, formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Both require calibrations of all measurement devices be traceable to national standards whenever applicable.	
Blanks	EL-V1M4-2008 Section 1.7.3.1		Manual Chapter IV Section 7.2.5	Promulgated Test Methods in 40 CFR Part 141	Both require a blank.	OW CM-blank should be analyzed as required by the method.  TNI requires one method blank analysis at a minimum per preparation batch.
Laboratory Control Samples	EL-V1M4-2008 Section 1.7.3.2		Manual Chapter IV Section 7.2.6	Promulgated Test Methods in 40 CFR Part 141	Both require Laboratory Control Samples (LCS) and reporting limit verifications.	The OW CM uses the term Laboratory Fortified Blank (LFB) and requires it to be prepared from a second source. The OW CM uses the term Reporting Limit Verification.  TNI uses the term Laboratory Control Sample (LCS) and does not require it be prepared from a second source. TNI uses the term Limit of Quantitation (LOQ).  Reporting Limit Verification and LOQ are equivalent.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Matrix Spikes	EL-V1M4-2008 Section 1.7.3.3		Manual Chapter IV Sections 7.2.7 & 7.7.1	Promulgated Test Methods in 40 CFR Part 141	Both require a Matrix Spike (MS).	Both OW CM and TNI mention that the test method specifies the frequency of MS analysis.
Detection Limits	EL-V1M4-2008 Section 1.5.2		Manual Chapter IV Sections 7.2.9 & 7.2.11	Promulgated Test Methods in 40 CFR Part 141	Yes	OW CM is much more specific than TNI in stating the procedures and requirements for determining detection limits.
Quality Control Sample (QCS)	EL-V1M4-2008 Section 1.7.3		Manual Chapter IV Section 7.2.2	Promulgated Test Methods in 40 CFR Part 141	Both require initial calibration verification (ICV) and a second source standard for quality control samples (QCS)	OW CM specifies a quarterly analysis of a QCS and procedures for detection limit studies of quality control samples (QCS).  TNI requires analysis of an ICV after every initial instrument calibration.
Analytical Method Selection	EL-V1M4-2008 Section 1.4 for method selection and 1.5 for method validation.		Manual Chapter IV Section 5	Promulgated Test Methods in 40 CFR Part 141	No	OW requires that one of the methods specified in 40 CFR 141 be used unless another test method is approved by the EPA and the state.  TNI-If there is not a regulatory requirement for the parameter/method combination, the parameter/method combination need not be validated under 1.5.1.b as a non-standard method if it can be analyzed by another similar standard method of the same matrix and technology.
Detection Documentation	EL-V1M4-2008 Section 1.5.2		Manual Chapter IV Section 8		Yes	

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Data Reduction Documentation	EL-V1M4-2008 Section 1.7.3.4		Manual Chapter IV Sections 7 & 8		Yes	OW CM specifies the process and method of documentation.  TNI specifies that the procedures for data reduction shall be documented.
Quality of Standards and Reagents	EL-V1M4-2008 Section 1.7.3.5		Manual Chapter IV Sections 4.1.1, 4.2.1 & 4.3.1	Promulgated Test Methods in 40 CFR Part 141	Both specify the reagents must meet the method requirements.	TNI specifies that the quality of water sources shall be monitored, documented, and shall meet method specified requirements.  Reagent requirements are specified in OW promulgated Test Methods.
Verification of Titrants	EL-V1M4-2008 Section 1.7.3.5.c			Promulgated Test Methods in 40 CFR Part 141		OW CM does not discuss the verification of concentrations of titrants in the manual but procedures require this verification.  OW only allows promulgated Test Methods to be used for compliance drinking water testing.
Glassware preparation	Not Found		Manual Chapter IV Sections 4.2.2 & 4.2.3		No	OW CM refers glassware cleaning requirements to those specified in the methods (summaries provided).  TNI does not discuss glassware preparation in this technical module.
Analytical Methods - Analyses approved by the State	EL-V1M4-2008 Section 1.4		Manual Chapter IV Section 5.2		No	TNI states "When a laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a standard method".

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Microbiology Testing Detailed Method Review</b>						
Sterility Checks and Blanks	EL-V1M5-2008 Section 1.7.3.1		Manual Chapter V Sections 3, 4, 5, 5.1.6.4 and V.5.4.1.2		Both require the use of beginning and ending blanks. Both indicate series ends after 30 min time elapses between sample filtrations.	TNI requires a method blank to be inserted after 10 samples.
Sterilization of MF Filtration Equipment	EL-V1M5-2008 Sections 1.7.3.1.a.i, 1.7.3.1.a.ii, 1.7.3.1.b.ii, 1.7.3.1.b.v		Manual Chapter V Sections 5.4.1.2 and V.5.4.1.3		Both discuss rinsing the filtration funnels.	OW CM states that the funnel may be exposed to UV light at specified wavelength and time. OW CM states to test for growth and all data must be rejected if the control indicates contamination.
Container Sterility	EL-V1M5-2008 Section 1.7.3.1.b.iii		Manual Chapter V Section 4.2		Both specify one check per lot (commercial) or batch (lab-prepared).	TNI does not specify the procedure for confirming container sterility such as amount and type of broth, incubation, etc.
Reagent grade water	EL-V1M5-2008 Section 1.7.3.5.c		Manual Chapter V Section 4.3		Both have specific parameters with associated frequencies for testing.	OW CM states that reagent water is to be used for preparation of media, reagents and dilution/rinse water.
Dilution Water Sterility	EL-V1M5-2008 Section 1.7.3.1.b.iv		Manual Chapter V Section 4.4.3		Both specify one check per lot (commercial) or batch (lab-prepared).	TNI does not specify the procedure for confirming sterility such as amount and type of broth, incubation, etc.
Dilution/rinse Water	Not Found		Manual Chapter V Section 4.4 (except 4.4.3 above), and V.5.3.2.1.1		No	TNI does not specify that dilution/rinse water be of the same quality as reagent water.  OW CM does state that reagent water is the basis for dilution/rinse water.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
MF Colony Count Verification	EL-V1M5-2008 Section 1.7.3.2		Manual Chapter V Section 5.4.2.8		Both require 10% agreement between comparative counts	<p>TNI's analyst comparison for test variability and reproducibility is method independent.</p> <p>The OW is specific to coliform and fecal coliform membrane filters only.</p>
Control Cultures	Not Found		Manual Chapter V Sections 4 and 5		No	<p>OW CM specifically lists control cultures.</p> <p>TNI does not.</p>
Media	EL-V1M5-2008 Sections 1.7.3.5.a, 1.7.3.5.b, 1.7.3.5.d		Manual Chapter III Section 11 and Manual Chapter V Sections 5.1.6 and 5.1.6.4		Yes	<p>OW CM requires both lab-prepared and commercial medium be tested with positive &amp; negative culture controls &amp; for sterility per lot/batch. Additionally, each lot of Chromogenic/Fluorogenic media is to be tested with 365-366 nm UV for auto-fluorescence.</p> <p>TNI requires lab-prepared media be tested for performance with a suggested partial list of testing parameters.</p>
Media (Product) Shelf Life	EL-V1M5-2008 Section 1.7.3.5		Manual Chapter V Sections 5.1.6.1, 5.1.6.2, and 5.1.6.3		Yes	<p>OW CM notes that caked or discolored dehydrated media should be discarded. Media may not be used after expiration date.</p> <p>TNI mentions using media during its shelf life. TNI allows use of media after shelf live has expired if it is verified.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Media Documentation	EL-V1M5-2008 Section 1.7.3.5.d		Manual Chapter V Sections 5.1.6.2 and 5.1.6.3		Yes	For media prepared in the laboratory and media prepared commercially, OW CM does not state that the manufacturer, the amount of media prepared, and the expiration date must be documented.  TNI does not state that sterilization time and temperature must be recorded.
Selectivity	EL-V1M5-2008 Section 1.7.3.6		Manual Chapter V Sections 5.1.6.4 and V 5.1.6.2		OW CM uses the term "control organisms" while TNI uses "reference cultures."	OW CM does not mention the preservation, preparation, and use of reference/stock stocks.
Temperature Measuring Devices	EL-V1M5-2008 Section 1.7.3.7.b.i,		Manual Chapter V Sections 3.3 and 5.5.13.1		Both require annual verification.	OW CM states the actual calibration, record, etc. requirements for temperature measuring devices and discusses when to discard temperature measuring devices. OW requires reference thermometer verification every 5 years.  TNI requires verification of temperature monitoring devices yearly.
Autoclaves	EL-V1M5-2008 Section 1.7.3.7.b.ii		Manual Chapter V Sections 3.5.1 and 3.5.2		Yes	OW CM does not discuss initial evaluation of the autoclave.  TNI does not discuss time requirements for the autoclave and does not mention slow depressurization to avoid media boiling/bubbles.
Autoclave Temperature	EL-V1M5-2008 Section 1.7.3.7.b.ii		Manual Chapter V Section 3.5.4		Yes	OW CM does not discuss the use of temperature sensitive tape.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Autoclave Records and Maintenance	EL-V1M5-2008 Section 1.7.3.7.b.ii		Manual Chapter V Section 3.5.3		Yes	OW CM does not discuss or require a pressure check and calibration of the temperature device during annual maintenance of the autoclave.  TNI lists the autoclave operation records that must be maintained. TNI requires annual maintenance and includes a pressure check and calibration of the temperature device.
Autoclave Timing	EL-V1M5-2008 Section 1.7.3.7.b.ii		Manual Chapter V Section 3.5.5		Yes	
Autoclave Parts	Not Found		Manual Chapter V Section 3.5.6		No	TNI does not mention autoclave door seals and drain screens.
Volumetric Equipment	EL-V1M5-2008 Section 1.7.3.7.b.iii		Manual Chapter V Sections 3, 3.11.2, and 3.13.4		Yes	OW CM specifies types of volumetric equipment and requirements for each. OW lists accuracy tolerance levels.  TNI requires volumetric equipment with movable parts be verified for accuracy quarterly, other volumetric equipment verified once per lot prior to first use.
UV Instruments; Germicidal	EL-V1M5-2008 Section 1.7.3.7.b.iv		Manual Chapter V Section 3.16.2		Yes	
UV, Germicidal, Cleaning	Not Found		Manual Chapter V Section 3.16.1		No	TNI does not discuss the frequency or process for cleaning the UV instruments.
Incubator, Water Baths, and Ovens	EL-V1M5-2008 Section 1.7.3.7.b.v		Manual Chapter V Section 3.4.1, 3.4.2, and 3.6.1		Both require the temperature of incubators and water baths to be documented twice daily each day of use	OW CM specifies temperature and time in incubators, ovens, and water baths.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Oven	EL-V1M5-2008 Section 1.7.3.7.b.v.2		Manual Chapter V Section 3.6.3 and 3.4.2		Yes	
Glassware	EL-V1M5-2008 Section 1.7.3.7.b.vi		Manual Chapter V Section 3.14.1 and 5.3.1.3		Yes	TNI does not discuss plastic items. TNI does not discuss prohibition on use of auto fluorescent glassware and should not contain inhibitory residue.  OW states that all glass and plastic-ware used in testing must be sterile, contain no inhibitory residue and must not auto-fluoresce.
Glassware Inhibitory Residue Test	EL-V1M5-2008 Section 1.7.3.7.b.vi.3		Manual Chapter V Section 4.5.3		Both require annual inhibitory residue testing and with every change in washing procedure (the source for the test procedure is not defined). OW refers to Standard Methods 9020B for Inhibitory Residue Test.	
Glassware pH Reaction	EL-V1M5-2008 Section 1.7.3.7.b.vi.4		Manual Chapter V Section 4.5.4		Yes	OW CM specifies the procedure for this test.  TNI requires this test at least once daily each day of washing
Glassware Washing	EL-V1M5-2008 Section 1.7.3.7.b.vi		Manual Chapter V Section 4.5.1		Yes	Similar, however TNI does not specify the use of distilled or de-ionized water for the final rinse.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Laboratory equipment and supplies	EL-V1M5-2008 Section 1.7.3.7.b		Manual Chapter V Sections 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11, 3.12, 3.13, 3.14, 3.15, 3.17, and 5.3.2.1.2.		No	<p>OW CM is more specific in discussing laboratory equipment in general. Such as the temperature monitoring devices, OW CM discusses having a QC record book for specific temperature device information. OW CM contains separate sections in the standard for volumetric glass and pipettes. OW CM specifies that pipettes have a precision and accuracy within 2.5%. OW CM contains separate standards for each type of UV instrument. In most cases, OW CM was more specific in the maintenance and calibration requirements. OW also discusses QC of Quanti-Tray sealer.</p> <p>TNI discusses volumetric equipment as a whole and not pipettes specifically. TNI discusses UV Instruments in general. TNI does not discuss size of containers sufficient for fermentation media, legible markings in graduated cylinders and pipettes (2.5% tolerance), and tube closings. The listed OW CM sections that were not previously discussed regarding laboratory equipment and supplies are either not found or only briefly discussed in the TNI standard.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
<b>Radiochemical Analysis Detailed Method Review</b>						
Laboratory Supervisor/Technical Manager	EL-V1M2-2008 Section 5.2.6.1	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter VI Section 1.1, Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Similar requirements for Laboratory Supervisor/Technical Manager.	TNI standard 5.2.6.1 requires a BS with 24 credit hours in chemistry and 2 years experience in analysis or only one year experience with a masters/doctoral.  OW CM does not have credit hour requirements and requires only one year of experience. TNI does list several exceptions to this depending on the particular lab environment.
Laboratory Analyst, Technician, and Sampling Personnel	Not Found		Manual Chapter VI Sections 1.2, 1.3, and 1.4		No	OW CM gives specific education, training and experience requirements for an analyst.  TNI does not give specific requirements for an analyst, but does for a technical director in 5.2.6.1
Initial and Ongoing Demonstration of Proficiency for Analysts and Technicians	EL-V1M6-2008 Section 1.6.2		Manual Chapter VI Section 1.5		Both require annual DOC's.	The OW CM specifies MDL studies or an alternate procedure.  TNI specifies applicable procedures.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Method Blanks	EL-V1M6-2008 Section 1.7.3.1		Manual Chapter VI Section 1.5			<p>OW CM mentions instrument and reagent blanks. OW CM requires an instrument blank to check background analyzed on each day. Instrument must be placed out of service if blank is out of control.</p> <p>TNI requires at a minimum one method blank per batch (of no more than twenty samples). Data with a failing method blank should be reprocessed for analysis or flagged with the appropriate data-qualifying codes.</p>
Data Produced by Analysts and Technicians in Training			Manual Chapter VI Section 1.6		No	<p>OW CM states that this data must be reviewed by a fully qualified analyst or the lab supervisor.</p> <p>TNI requires final data review and release by a Technical Director.</p>
Waiver of Academic Training	EL-V1M2-2008 Section 5.2.6.2.c	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter VI Section 1.7, Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>OW CM offers an academic waiver to highly-experienced analysts.</p> <p>TNI does not have a "waiver", but does require twelve months prior laboratory management experience at the time of application for certification if academic requirements are not met.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Positive, negative, and other controls	EL-V1M6-2008 Section 1.7.3		Manual Chapter VI Section 3.1.5, 4.2, and 7.3		Yes	<p>See method blank discussion above concerning negative controls.</p> <p>Positive controls have specific criteria in the OW CM. OSW details matrix spike requirements for field collection, which TNI omits.</p> <p>TNI details these as "laboratory control samples" that are spiked with an analyte of interest and analyzed to meet specific performance criteria. TNI includes criteria for surrogate spikes, which the OSW omits.</p>
Radiation Counting Instruments	EL-V1M6-2008 Section 1.7.1		Manual Chapter VI Section 3.1		Detection limits are similar.	
Liquid Scintillation Counting (LSC) system Background Check	EL-V1M6-2008 Sections 1.7.1.a, 1.7.1.b, 1.7.1.c		Manual Chapter VI Section 3.1.1		Both agree that background checks should be performed daily.	<p>The OW CM specifies background check frequency.</p> <p>The TNI generally references background contamination and does not specify frequency.</p>
Gas-flow Proportional Counting System Background Check	EL-V1M6-2008 Section 1.7.1.c		Manual Chapter VI Section 3.1.2		Both agree that background checks should be performed daily.	<p>The OW CM specifies background check frequency.</p> <p>The TNI generally references background contamination and does not specify frequency.</p>
Alpha Scintillation Counting System Background Check	Not Found		Manual Chapter VI Section 3.1.3		No	<p>The OW CM specifies background check frequency.</p> <p>The TNI generally references background contamination and does not specify frequency.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Scintillation Cell System Background Check	EL-V1M6-2008 Section 1.7.1.c		Manual Chapter VI Section 3.1.4		No	<p>The OW CM specifies background check frequency.</p> <p>The TNI generally references background contamination and does not specify frequency.</p>
Gamma Spectrometer Systems Background Check	EL-V1M6-2008 Section 1.7.1.c		Manual Chapter VI Section 3.1.5		Both agree that background checks should be performed monthly.	<p>The OW CM specifies background check frequency.</p> <p>The TNI generally references background contamination and does not specify frequency.</p>
Alpha Spectrometer Systems Background Check	EL-V1M6-2008 Section 1.7.1.c		Manual Chapter VI Section 3.1.6		Both agree that background checks should be performed monthly.	<p>The OW CM specifies background check frequency.</p> <p>The TNI generally references background contamination and does not specify frequency.</p>
Other Radiation Instrumentation Background Checks	Not Found		Manual Chapter VI Section 3.1.7		No	<p>OW CM states that the calibration and background checks should be consistent with the method being used and the manufacturer's recommendation.</p> <p>TNI wrote the section on Radiation Counting Instruments to be all-inclusive, thus this is not applicable to that standard.</p>
Chemicals/ Reagents	EL-V1M6-2008 Section 1.7.2.5		Manual Chapter VI Section 4.1	Promulgated Test Methods in 40 CFR Part 141	Yes	OW CM does not discuss standards for purchasing from outside US commercial suppliers.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Reagent Water	EL-V1M6-2008 Section 1.7.2.5		Manual Chapter VI Section 4.2	Promulgated Test Methods in 40 CFR Part 141	No	TNI requires that reagent water meet the standards of the method in use.  OW CM has more specific parameters required for reagent water.
Analytical Methods: Standard Operating Procedures (VI.5.1)	EL-V1M2-2008 Sections 3.0, 4.2.8.5	Almost all of TNI Standard Reference EL-V1M2- ISO-2008 is ISO/IEC 17025	Manual Chapter VI Section 5, Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	Yes	The OW CM states that the methods cited in 40 CFR parts 141.25 (a) and (b) must be used. OW CM also includes a table listing those methods.  TNI does mention requirements for SOPs in general.
Sample Collection, Handling, and Preservation: Composited Samples (VI.6)	Not Found		Manual Chapter VI Section 6.1	Promulgated Test Methods in 40 CFR Part 141	No	TNI does not include composite samples.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Matrix spikes and duplicates (replicates), low level samples	EL-V1M6-2008 Sections 1.7.2.3.a, 1.7.2.3.b		Manual Chapter I Section 7.3.3.a and Manual Chapter VI Sections 7.7.1, 7.7.2, and 7.2.12	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>See above discussion about positive controls for matrix spike comparison.</p> <p>Duplicates in the OW CM are described as replicate analysis of the same sample. The OW CM also describes the process in more detail. Concerning low level samples, the OW CM states that target levels below the MRL should not be reported.</p> <p>TNI defines duplicates as a replicate piece of sample carried through the entire sample process. TNI asks that an instrument duplicate be run to determine data reproducibility to assess the accuracy of low level samples.</p>
Laboratory control samples	EL-V1M6-2008 Sections 1.6.1, 1.6.2.2, 1.6.3, 1.7.2.2		Manual Chapter VI Section 7.7.3	Promulgated Test Methods in 40 CFR Part 141	Yes	<p>TNI does not state that the batch has to be thrown away if samples are recounted and LCS (if LCS assessments have already exceeded the limits) assessment is still unsatisfactory. TNI requires at a minimum one per batch. TNI does not describe the process in detail.</p>

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Activity level and source of matrix spikes and LCS	EL-V1M6-2008 Sections 1.7.2.2.g, 1.7.2.3.a.vii		Manual Chapter VI Section 7.7.2	Promulgated Test Methods in 40 CFR Part 141	Yes	The TNI states that the matrix spikes should be spiked at a level five times the minimum detectable activity (MDA) and an LCS should be spiked at ten times the MDA. The OM CW requires the matrix spikes to be spiked at ten times the anticipated sample activity level and handles the LCS samples in the same way. The TNI also states that a matrix spike can be used in place of an LCS.
LCS or matrix spike for more than one isotope	EL-V1M6-2008 Sections 1.7.2.2.g, 1.7.2.3.a.vii		Not Found	Promulgated Test Methods in 40 CFR Part 141	No	The OM CW does not address this issue.
Initial demonstration of capability	EL-V1M6-2008 Section 1.6.2		Manual Chapter VI Section 1.5	Promulgated Test Methods in 40 CFR Part 141	Both standards require an IDC to be performed for each instrument and at times when a change of personnel or method occurs.	
PT	EL-V1M2-2008 Section 5.0, EL-V1M5-2008 Sections 1.5, 1.71	Almost all of TNI Standard Reference EL-V1M2-ISO-2008 is ISO/IEC 17025	Manual Chapter VI Section 7.4, Formal Quality Management system (ISO/IEC 17025) recommended in Supplement 1 Chapter III Section 2, and formal Quality Control program requirement specified in the Quality Control section of promulgated Test Methods	Promulgated Test Methods in 40 CFR Part 141	No	TNI does not discuss in detail mixed alpha and mixed beta/gamma PT studies.

Subject	Requirement Source				Similarities	Differences
	TNI Standard Reference	ISO Reference	OW/DWLCP Reference	CFR Reference		
Instrument Calibration (general)	EL-V1M6-2008 Section 1.7.1.1, 1.7.1.b.i, 1.7.1.b.ii, 1.7.1.b.iii, 1.7.1.b.iv		Manual Chapter III Section 11.6 and Manual Chapter VI Sections 3.1.1, 3.1.2, 3.1.3, 3.1.5, and 3.1.6	Promulgated Test Methods in 40 CFR Part 141	Both documents cover the basic parameters required in calibration of instrumentation and use similar methods to monitor the stability of calibration over time. Both require similar calibration verification processes.	The standards differ in background check requirements.
Background measurements	EL-V1M6-2008 Section 1.7.1.c		Manual Chapter VI Sections 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.5, 3.1.6, and 7.8		Neither standard provides specific procedures to determine background measurements for radiation counting instruments.	TNI does not state background measurements for every type of radiation counting instrument.
Detection limit	EL-V1M6-2008 Section 1.5.2.1		Manual Chapter VI Sections 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.5 and 3.1.6		Yes	The OW CM does not list specific procedures for detection limit determination or requirements other than the limits mentioned in the CFR.  TNI describes very specific requirements for detection limits.
Results with uncertainties reported	EL-V1M6-2008 Section 1.5.4		Manual Chapter VI Section 8.4		Both documents require results to be reported with uncertainties.	
Aspects of records and data reporting	EL-V1M6-2008 Section 4.13		Manual Chapter VI Section 8.2, and 8.3, and parts of Sections 8.4, 8.5, and 8.6		No	TNI specifies a five-year hold time on all data.  The OW CM requires a ten year hold time. The OW CM also specifies on what medium data may be backed up.
Instrument and Method Performance Charts/Records	EL-V1M6-2008 Section 1.7.1.b		Manual Chapter VI Section 7.8		Both discuss control charting.	TNI specifies control charting methods for each type of radiation counting instrument.