## MEMORANDUM

To: Lara Autry, US EPA

From: Raymond G. Merrill, Eastern Research Group, Inc.

Date: December 15, 2008

Subject: Draft 2008 Crosswalk between the OW Certification Manual and the TNI Environmental Laboratory Sector Accreditation Standard

The text and tables that follow are a comparison of EPA Office of Water's Fifth Edition (January 2005) Manual for the Certification of Laboratories Analyzing Drinking Water and the 2008 NELAC Institute (TNI) Standards for accreditation of environmental laboratories. As an addition to the review, ERG also provides input on whether TNI standards conform to the International Standards Organization (ISO) requirements in related areas. This review and comparison updates the previous comparison completed by Versar Inc. in May of 2006. We've summarized the major differences in the two programs below and we've also provided detailed tables describing the similarities and differences. If you have any questions or comments please feel free to contact me.

## **Comparison of TNI and OW Laboratory Assessment Standards**

The following tables present a comparison between the EPA Office of Water Fifth Edition (January 2005) Manual for the Certification of Laboratories Analyzing Drinking Water (OW CM) including Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-F-08-006, June 2008) and the 2008 TNI Standards (December 2007).

Review and keywords searches were performed on the TNI Standards and the Supplement to the OW CM primarily. The previous comparison of OW CM certification standards performed by Versar was used to capture some of the original OW CM requirements that were not changed with the publication of the June 2008 supplement.

Tables are formatted with six columns identifying the:

- assessment subject,
- TNI citation,
- TNI Citation conformance to ISO 17025,
- OW CM citation,
- similarities and
- differences

"Not Found" as noted in the tables indicates that a requirement or topic in one assessment standard was not located in the comparison standard. If the TNI reference was found to be ISO/IEC 17011 or ISO/IEC 17025 compliant, this was noted in the appropriate column of the table.

The purpose of this comparison is to define the technical differences between the two programs. In doing so, the differences between the two programs can be evaluated by Environmental Laboratory Advisory Board (ELAB) to formulate advice to EPA on future improvements to laboratory compliance or accreditation programs. This effort will in turn provide information needed to improve the National

Program for laboratory accreditation and promote a single onsite inspection and assessment process rather than the current certification process requiring independent multiple states assessment.

With the recent update to the TNI Standards and the Supplement to the OW CM, the two standards moved toward the goal of a unified process for certification or accreditation. The recent Supplement to the OW CM refers to TNI. Also the TNI standard update includes some SWDA-based requirements from the drinking water program.

The organization of the contents of the OW CM and TNI Standard differ. Chapters in the OW CM include an Introduction (I), Responsibilities (II), Implementation (III), Critical Elements of Chemistry (IV), Critical Elements of Microbiology (V), and Critical Elements of Radiochemistry (VI). The updated TNI standard consists of 4 Volumes, two of which contain a number of Modules.

The TNI volumes cover laboratory assessment requirements for more than drinking water laboratory assessment (e.g., solid waste, air) The first volume the of the TNI standard entitled "Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis," contains Module 1 (Proficiency Testing), Module 2 (Quality Systems General Requirements), Module 3 (Quality Systems for Asbestos Testing), Module 4 (Quality Systems for Chemical Testing), Module 5 (Quality Systems for Microbiological Testing), Module 6 (Quality Systems for Radiochemical Testing), and Module 7 (Quality Systems for Toxicity Testing). Volume 2, General Requirements for Accreditation Bodies Accrediting Environmental Laboratories, contains Module 1 (General Requirements), Module 2 (Proficiency Testing), and Module 3 (On-Site Assessment). Volume 3 is General Requirements for Environmental Proficiency Test Providers. Volume 4 is General Requirements for an Accreditor of Environmental Proficiency Test Providers.

Both standards are valid approaches to assess laboratories and improve quality programs in laboratories analyzing environmental samples. The OW CM is more focused on drinking water programs and requires a laboratory to adhere to the quality control defined by the method and to prepare a quality plan that reflects that control. No attempt has been made to summarize the quality requirements in OW methods or to compare the method specific requirements with the TNI standard. Therefore, some of the differences noted in the two standards may be accounted for in the OW methods.

TNI requires a quality system and a quality manual (however named) that documents the system. The TNI standard requires laboratories to meet requirements in the contract they sign with their client(s). If specific quality requirements are not listed in the contract then the quality requirements in the methods coupled with the laboratory's Quality Plan have primary authority for setting specific quality requirements during sample analysis. OW CM certification are restricted to meeting the quality requirements in prescribed methods for drinking water in contrast to TNI which has greater scope and is geared toward the needs of individual clients and their data quality requirements. Therefore, differences between the OW CM and TNI standards related to specific QC requirements listed in the methods are of less importance than the broader program requirements for each group.

TNI standard tends to require more documentation and detail on QA/QC requirements since there is no standard set of methods to reference. TNI accreditation evaluates laboratories on their quality program responding to client or contract agreements and the methods referenced in the contract agreements. OW CM evaluates laboratories on the performance of reference methods which contain the body of QC details required by the program.

The education and experience required for the personnel who perform methods evaluated by either of the two assessment approaches (manuals) a significant different. The OW CM provides more detail on individual positions and education/experience levels in the method sections. Other than the technical

manager, TNI does not provide education or experience requirements for laboratory personnel. TNI focuses on documentation of qualifications for analysis and demonstration of proficiency by the laboratory analysts rather than formal education and degrees.

Documentation required from a certified or accredited laboratory is a topic where the two manuals have significant differences. The TNI requires much more documentation than the OW CM. Differences include the TNI requirement for a comprehensive Quality Manual for laboratory operation and responsibility for program management. The OW requirement for a Quality Plan is much more like a project specific project plan. While the OW requirement can include all that the TNI standard requires, the OW CM does not list in detail the requirements for either the Quality Plan or method SOPs.

TNI does not address several important topics to the drinking water program covered by OW such as Principal State Laboratories, Interim Certification, reciprocity, and numerous method specific technical details.

The two approaches also differ in several non-technical areas. OW CM does not discuss subcontracting, management reviews, internal audits, data integrity training, electronic transmission of results, preventative action, and client confidentiality, TNI includes specific requirements for each of these topics.

Subject	The NELAC	ISO	<b>OW/Drinking</b>	Similarities	Differences
v	Institute (TNI)	Reference	Water		
	<b>Standard Reference</b>		Laboratory		
			Certification		
			Program		
			(DWLCP)		
			Reference		
			Implementati	on	
Document Titles			Manual for the		
			Certification of		
			Laboratories		
			Analyzing		
			Drinking Water		
			and Supplement		
			1 to EPA 815-		
			R-05-004		
Evaluation of	Environmental	,	III.1	Similar sections, different	Differences in the standards reflect
Certification	Laboratory Sector			programmatic roles. The	the differences between the overall
Program***	TNI Standards			Office of Water Certification	programs. TNI Standard outlines
	Adopted December			Manual (OW CM) and the	aspects of its program in greater
	22, 2007			NELAC Institute (TNI)	detail than OW CM.
	Management and			Standard both describe the	
	Technical			roles, the responsibilities,	
	Requirements for			and the structures of their	
	Laboratories			respective programs.	
	Performing				
	Environmental				
	Analysis				
Requirements for	EL-V1M1-2008		III.2	Both require Proficiency	OW CM requires passing a PT for
Certification of	Section 4.0, EL-			Test (PT) samples, Programs	each analyte/each method once a
Laboratories	V2M2-2008 Sections			differ on the initial and	year. The National Environmental
	5.1.1, 5.2.1, 5.2.3,			ongoing requirements.	Laboratory Accreditation
					Conference Institute (TNI)
	EL-V2M3-ISO-2008				standard, handles PTs in much
	Section 5.1				more detail. TNI has differing
					requirements for initial (2
					successful PTs for each matrix,
					technology/method, and analyte),
					continuing (2 successful PTs per

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Subject	The NELAC	ISO	OW/Drinking	Similarities	Differences
	Institute (TNI)	Reference	Water		
	Standard Reference		Laboratory		
			Certification		
			Program		
			(DWLCP)		
			Reference		
	1		Implementati	on	
					year for each matrix,
					technology/method, and analyte),
					and experimental PTs (2 PTs for
					each matrix, technology/method,
					and analyte).
Requirements for	EL-V1M1-2008		III.2	Both programs require onsite	Programs differ regarding on-site
Certification of	Section 4.0, EL-			assessment.	audit frequency; OW CM requires
Laboratories	V2M2-2008 Sections				once every three years with
	5.1.1, 5.2.1, 5.2.3,				questionnaires given on other years,
	EL-V2M3-ISO-2008				TNI requires onsite assessment
	Section 5.1				once every two years.
Individual(s)	EL-V1M1-2008	ISO/IEC	III.3	Each program has officers or	The program structures also differ
Responsible for the	Section 3.1, EL-	17011		authorities empowered to	slightly by definition and duties of
Certification Program	V2M1-ISO-2008			certify or accredit laboratory	authorities within the program.
	Section 3.2			programs.	OW CM has Certification
					Authority (CA), Certification
					Program Manager (CPM), and
					Certification Officers (CO) that
					may represent the state and regional
					personal. TNI Standard has
					Accreditation Bodies whose
					authority is generally derived from
					regulatory authority acceptance of
					the accreditation process.
On-Site Laboratory	EL-V2M3-ISO-2008		III.4.1	Both programs require	OW CM requires that auditors have
Audit Team	Sections 4.2.3, 4.2.4,			appropriate	a Bachelor's degree or equivalent
	4.2.5			education/training.	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

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program	Similarities	Differences
			(DWLCP)		
			Reference		
	I		Implementati	on	
					supervised assessments. 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.
Third Party Auditors	EL-V2M1-ISO-2008	ISO/IEC	111.3, 111.4.2, Appendix D	Both standards state the	Appendix D of the OW CM manual discusses EDA's policy on third
	Sections 5.1, 7.4.2	1/011	Арренанх D	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.	party auditors and potential for conflict of interest. TNI takes full responsibility for all subcontracted assessments and assess the potential for conflict of interest.

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program	Similarities	Differences
			Reference		
			Implementati	on	
Plans for Certification of Laboratories and Certification Process	EL-V2M1-ISO-2008 Sections 4.6, 7.7.2	ISO/IEC 17011	Ш.5, Ш.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 process is less prescriptive, using terms like should and may. The OW program allows the CPM to make program decisions based on the audit assessment.

Subject	The NELAC	ISO	<b>OW/Drinking</b>	Similarities	Differences
Ŭ	Institute (TNI)	Reference	Water		
	Standard Reference		Laboratory		
			Certification		
			Program		
			(DWLCP)		
			Reference		
			Implementati	on	
Principal State	Not Found		III.6	No	TNI omission.
Laboratories					
(Laboratories that					
have available					
facilities capable of					
performing analytical					
measurements for all					
federally mandated					
contaminants					
specified in the State					
Primary Drinking					
Water Regulations)					
Terminology:	EL-V1M1-ISO-2008		III.8.1	Both programs address	TNI uses the term accredited, OW
Certified vs.	Section 4.0			laboratory assessment.	CM uses the term certified. TNI
Accredited					stipulates differences between the
					accreditation process of initial and
					continuing accreditation.
					Participation in the TNI process is
					voluntary.
Provisionally	EL-V2M1-ISO-2008	ISO/IEC	III.8.2	Both programs address	TNI uses the term suspension- the
Certified	Section 3.0, EL-	17011		performance and	laboratory can not perform analysis
	V1M1-ISO-2008.1			nonperformance issues in	for which field it is suspended. OW
	Section 3.0			laboratories.	CM allows the laboratory to
					conduct the analysis if the client is
					aware of its certification status.
					unless the evaluation team believes
					that the laboratory can perform the
					analysis within acceptable limits.
					TNI provides additional causes for
					suspension (i.e. failure to maintain
					a quality system); OW CM lists the

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory	Similarities	Differences
			Certification Program (DWLCP)		
			Reference		
			Implementati	on	
					cause as being deficiencies either in PT studies or on-site visits. TNI- The status can be reversed if compliance is demonstrated to the primary AA. TNI also mentions the right to due process.
Not Certified	EL-V2M1-2008.1 Sections 7.5.6.1, 7.9, EL-V2M2-2008.1 Section 10.0		Ш.8.3	Both programs state that deficiencies prevent laboratories from becoming certified.	OW CM states that a laboratory is not certified if it has deficiencies and cannot produce valid data. TNI includes an outline of deficiencies that prevent a laboratory from becoming accredited. It also categorizes these deficiencies in three categories: suspended, withdrawn, or reduced accreditation. TNI mentions due process. Due process in reference to certification status is not discussed in OW CM, but in other sections is does states that the laboratory has the right to be heard by EPA.
Interim Certification	Not Found		III.8.4	No	OW CM states that an on-site audit should be made as soon as possible but not later than 3 years after an interim certification is granted.
Drinking Water Laboratories	EL-V1M6-2008 Section 1.5.2.2 (MDL)		III.9	Both programs require methods that meet the client's requirements.	OW CM-Laboratories that analyze drinking-water samples for Safe Drinking Water Act (SDWA) compliance monitoring shall use methods whose detection limits

Subject	The NELAC	ISO	<b>OW/Drinking</b>	Similarities	Differences
U	Institute (TNI)	Reference	Water		
	Standard Reference		Laboratory		
			Certification		
			Program		
			(DWLCP)		
			Reference		
			Implementati	on	
					meet the requirements of 40 CFR
					141. Although TNI does not have
					specific subsections or sections
					dealing with this exact subject
					matter, TNI does stipulate that
					laboratories must meet federal
					agency requirements, and the
					requirements of the methods they
					use, which would include the Safe
					Drinking Water Act.
Laboratory Quality	EL-V1M2-2008		III.11	OW CM recommends a	OW CM-laboratory must adhere to
Assurance Plan	Sections 4.2.2, 5.9			quality plan, TNI requires a	the quality control required by the
				quality plan.	methods and should prepare a
					quality plan, while TNI requires a
					quality system and quality manual
					(however named). 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.
Laboratory	EL-V1M2-ISO-2008	ISO/IEC	III.11.1	Programs are similar for	Other than the Technical Manager,

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Subject	The NELAC	ISO	OW/Drinking	Similarities	Differences
	Institute (TNI)	Reference	Water		
	Standard Reference		Laboratory		
			Certification		
			Program		
			(DWLCP)		
			Reference		
	I	ſ	Implementati	on	
organization and	Section 4.1, 4.2, 5.2	17025		technical management and	TNI does not specify positions or
responsibility				QA management.	type/amount of education,
					experience, and/or training needed,
					only "appropriate". Waiver of
					academic training is also not
					discussed in the TNI standards.
					OW CM does not indicate whether
					the person responsible for preparing
					a document may or may not review
					the report for final release. OW
					CM describes the internal audit
					process through a certification
					program. OW CM does not
					specifically state that laboratory
					personnel can conduct internal
					audits to check compliance with
					certification or accreditation
					standards.
Methodology	EL-V1M2-ISO-2008		III.13.2	Both programs require	OW CM requires Federal
	Section 5.4			methods that meet client	Reference Methods listed in
				requirements.	specific sections of IV, V, I (and
					specified in 40 CFR part 141). TNI
					states that methods published in
					international, regional, or national
					standards shall preferably be used,
					but that the laboratory use methods
					which meet client requirements.
On-Site Evaluation	EL-V2M3-ISO-2008	ISO/IEC	III.13.3	Both programs require onsite	OW CM suggests that an on-site
	Sections 5.0, 6.0	17011, most		assessment.	assessment be conducted once
		of Section			every three years and sooner if the
		6.0 is			laboratory previously did not do

Subject	The NELAC	ISO	OW/Drinking	Similarities	Differences
, i i i i i i i i i i i i i i i i i i i	Institute (TNI)	Reference	Water		
	Standard Reference		Laboratory		
			Certification		
			Program		
			(DWLCP)		
			Reference		
			Implementati	on	
		ISO/IEC			well during an audit or has had a
		17011			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	Not Found		III.13.4	No	TNI does not require accrediting
Certifying Authority					authority be notified that major
(CA) of Major					changes have occurred. TNI
Changes					requires changes be documented in
_					the appropriate laboratory
					documents.
PT Criteria	EL-V2M1-ISO-2008	Most of TNI	III.14.1, 14.2	Both programs require PT	TNI requires the laboratory to
	Section 7.0	Standard		sample analysis as a means	conduct two PT studies for each
		Section 7.0 is		to evaluate laboratory	field of proficiency testing per year
		ISO/IEC		conformance to the standard.	for "matrix-technology/method-
		17011			analyte/analyte group". OW CM
					requires PT samples to be analyzed
					at least annually for "regulated
					contaminants for which they wish
					to be certified, by each method for
					which they wish to be certified
					(OW CM I Introduction)".
Certification or	EL-V2M1-ISO-2008		III.14.1, 14.2	Both programs use PT	OW CM states that a laboratory
Accreditation Status	Section 7.0			performance as a means to	should be downgraded to
Review				downgrade certification or	provisionally certified, whereas,
				accreditation status.	TNI may suspend a laboratory for
					failure to comply with PT analysis

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Subject	The NELAC	ISO	OW/Drinking	Similarities	Differences
	Institute (TNI)	Reference	Water		
51	tandard Reference		Laboratory		
			Program		
			(DWLCP)		
			Reference		
			Implementatio	on	
					requirements. An OW CM
					laboratory may continue to do work
					but have to note suspension in
					writing on any report. A TNI
					accredited laboratory can not
					continue as a certified laboratory
					after failure to comply and
					suspension. 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. TNI mentions due
					process, OW CM states that EPA or
					the state provide technical
					assistance to help identify and
					resolve the problem. TNI discusses
					other aspects like personnel
					requirements that may cause
Critario/Drocaduras EI	L VOM1 2000 1		III 14 2 14 4	Both programs have	Suspension, UW UM does not.
for Develoption	L-V 21VI1-2008.1		111.14.3, 14.4	boun programs have	Ow CIVI states that a laboratory is
I or Kevocation Se	0.1, 7, 0, 4, 2, 51			procedures for revocation of	not certified if it has deficiencies
	7.1, 1.7.4.2, EL-			certificates.	and cannot produce valid data. TNI
	21012 - 2000.1				revocation TNI mentions due
Se					process. Due process in reference
					to certification status is not
					discussed in OW CM but in other

Subject	The NELAC	ISO Defenence	OW/Drinking	Similarities	Differences
	Standard Reference	Kelerence	Laboratory		
			Certification		
			Program		
			(DWLCP)		
			Reference	on	
			Implementati		laboratory has the right to heard by
					EPA.
Upgrading or	EL-V1M1-2008.1		III.14.5	Both standards require the	OW CM requires a written request
Reinstatement of	Section 8.0, EL-			facility to pass accreditation	from the laboratory seeking
Certification	V2M1-2008.1			status before upgrading or	upgrading or reinstatement of
	Section 7.9.5			reinstatement can be done.	certification. INI-requires the
					for continued accreditation to be
					reinstated after suspension Under
					TNI, to reinstate accreditation after
					revocation, the laboratory must
					meet the requirements for initial
					accreditation.
Record Keeping	EL-V1M2-ISO-2008	ISO/IEC	III.15	Both programs address	OW CM states that records should
	Section 4.13	17025		records maintenance.	be maintained for a minimum of 6
					years and INI states a minimum of
					s years. Ow CW addresses that the
					be documented in the OA Plan
					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
					unauthorized access archiving
					files naming files or
					overwriting/obliterating old files,

Subject	The NELAC Institute (TNI) Standard Reference	ISO Reference	OW/Drinking Water Laboratory Certification Program (DWLCP) Reference	Similarities	Differences
			Implementati	on	
					electronic data storage, whereas OW CM does not.
Reciprocity	Not Found		III.16	No	Although TNI does support reciprocity between states and regions, no statement was found in the standard regarding reciprocity.
Alternate Test Procedures (ATPs)	EL-V1M4-ISO-2008 Section 1.5.3.d		III.18	Non-standard methods must be validated for certification in both programs.	The OW CM requires new methods or modified methods be approved by the EPA via written submission. TNI only requires that the new/modified method be validated through laboratory analysis and documented for their review. TNI offers Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) as a possible approval process.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
		PT Studies	s, and Use of .	Accreditation	
Analysis of PT	EL-V1M1-2008.1		III.13.1,	Both TNI and OW CM state	OW CM also states that the
samples and use of	Section 5.1		III.14.3,	that the PT sample shall be	laboratory should be able to provide
own laboratory PT			IV.7.2.1,	analyzed in the same manner	documentation that the person
results			V.7.2, VI.7.2	as routine samples.	analyzing the samples is a
					laboratory employee who routinely
					analyzes drinking water compliance

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
		PT Studies	s, and Use of .	Accreditation	
					samples. 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. OW CM does not discuss these issues.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
· ·	Reference	Reference	Reference		
		conform to			
		ISO?			
			Organizatio	n	
Legal responsibility	EL-V1M2-ISO-2008		IV.8.1, V.8.1,	No	The OW CM does not discuss the
	Section 4.1.1, EL-		VI.8.1		legal responsibility of the
	V2M1-ISO-2008				accreditation body. TNI states that
	Section 4.1				the accredited laboratory or
					organization can be held legally
					responsible. It also discusses the
					legal responsibility of the AB.
Activities carried out	EL-V1M2-ISO-2008		П	Both programs require	OW CM states that the EPA
according to a defined	Section 4.1.2			activities performed to the	encourages the States to base
standard				standards.	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.
Instrument testing &	EL-V1M2-ISO-2008		111.11.6	Both programs have	INI requires laboratories to
calibration.	Section 4.1.2		(calib.),	requirements for calibration.	perform testing in such a way to
			111.11.2		meet the needs of the client and
			(client		regulatory authorities or
			objective)		organizations. UW CM states that
					the QA Plan should include
					processes to identify clients data
					CM presents OC such as
					civi presents QC such as
					canorations as method-specified.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
, i i i i i i i i i i i i i i i i i i i	Reference	Reference	Reference		
		conform to			
		ISO?			
	1		Organizatio	n	
					TNI requires laboratories to perform calibration in such a way to meet the needs of the client and regulatory authorities or organizations.
Quality system	All of EL-V1M2- ISO-2008, EL- V2M1-ISO-2008 Section 5.7.4	Most of the V1M2 (if not all) is ISO/IEC 17025	III.2, III.11, IV.7, V.7, VI.7	With the Supplement to OW CM, both standards require a quality system to be implemented.	TNI requires that the effectiveness of the required quality system be reviewed in the annual internal audit.
Management system that covers other facilities (temp. or mobile)	EL-V1M2-ISO-2008 Section 4.1.3	ISO/IEC 17025	III.11.4	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 facilities, or in associated temporary or mobile facilities.
Conflict of interest (between data quality/compliance with other topics)	EL-V1M2-ISO-2008 Section 4.1.4, EL- V2M1-ISO-2008 Section 7.4	ISO/IEC 17025,ISO/IEC 17011	Appendix D	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	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference conform to ISO?	Reference		
			Organizatio	n	
Personnel with authority and resources to carry out work and see deviations from quality system	EL-V1M2-ISO-2008 Sections 4.1.5.a, 4.1.5.b, 4.1.5.h	ISO/IEC 17025	III.10.2 and III.10.3	Programs are similar although worded differently.	TNI discusses that the laboratory must have technical management who have the authority and resources to carry out work and see departures from the management system and initiate preventive actions. OW CM states the QA Manager should be independent from lab management and have access to senior management.
Protect client confidentiality and storage of data	EL-V1M2-ISO-2008 Sections 4.1.5.c, 4.7.1, 5.4.7.2	ISO/IEC 17025	IV.8.2, V.8.2, VI.8.2	No	OW CM does not discuss client confidentiality, but does discuss reporting stored results to clients before removal. TNI discusses protecting confidential information, both discuss records retention.
Ensure internal and external pressure does not affect personnel	EL-V1M2-ISO-2008 Section 4.1.5.b	ISO/IEC 17025	Not Found	No	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.
Organization (lab and larger entity) structure and job specification of personnel	EL-V1M2-ISO-2008 Sections 4.1.5.e, 4.1.5.f, EL-V1M2- ISO-2008 Section 4.0	ISO/IEC 17025	III.11.1	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.)	

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		180?	Organizatio		
			Organizatio		
Adequate supervision, supervision by personnel who are familiar with test. Technical managers document personnel qualifications?	EL-V1M2-ISO-2008 Sections 4.1.5.g, 4.1.5.h	ISO/IEC 17025	III.10.2, IV.1.1, V.1.1, VI.1.1	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. 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. OW CM does not have credit hour requirements in chemistry or analysis. 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
QA manager who is independent but has access to upper management	EL-V1M2-ISO-2008 Sections 4.1.5.i, 4.1.7.1	ISO/IEC 17025	III.10.1-3, III.11	Both standards ask that quality assurance managers have direct access to upper management and be independent from the management.	In appropriate field. 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). TNI does not specify that the QA manager needs to have a bachelors degree

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Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences					
, i i i i i i i i i i i i i i i i i i i	Reference	Reference	Reference							
		conform to								
		ISO?								
Organization										
					and a year of experience in quality					
					assurance. 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					
					the technical director may also be					
					the $\Omega \Lambda$ manager: (the $\Omega \Lambda$ manager					
					has functions independent from					
					laboratory operations for which					
					they have OA oversight					
					(4.1.7.1.b)).					
Appoint deputies for	EL-V1M2-ISO-2008	ISO/IEC 17025	Not Found	No	TNI requires the laboratory to					
key managerial	Section 4.1.5.j				appoint deputies for key managerial					
personnel like the					personnel (NOTE: Individuals may					
technical director and					have more than one function and it					
quality manager					may be impractical to appoint					
					deputies for every function). OW					
					CM plan does not discuss					
					appointing deputies for key					
					management staff.					
PT Testing	EL-VIMI-2008.1,		III.13.1,	Both require PT testing and	TNI - Volume 1, Module 1 provides					
	EL-V2NI2-ISO-2008		111.14,	obtaining P1 samples from	the requirements for laboratory					
			1V./.2.1,	suppliers	Tasting (DT) program To obtain					
			v./.2, v1./.4	suppliers.	initial accreditation, the laboratory					
					shall successfully analyze two					
					unique TNI compliant PT samples					
					(FoPT) for each field of					
					accreditation being sought. The					

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences					
Organization										
					laboratory must obtain PT samples from a PTOB/PTPA approved PT provider. The results from the PT studies must be returned to the PT provider for analysis. The accrediting authority (AA) should have access to the results of the PT testing. OW CM-sites a CFR for maintaining certification status through proficiency testing. Drinking water labs must satisfactorily analyze a PT sample at least annually for chemical contaminants. The lab must obtain PT samples from a supplier acceptable to the appropriate certification authority (CA).					

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
			<b>Quality Syste</b>	em	
Quality Assurance	EL-V1M2-ISO-2008 Section 5.9, individual technical modules	ISO/IEC 17025	III.11, IV.4.5, V.7, VI.7	Both include specific QA in individual method sections.	In general, OW CM specifies that laboratories should maintain a Quality Assurance Plan and lists the topics for inclusion in the plan. QA is discussed throughout the TNI document with requirements for a quality management plan for the laboratory operation. (Section EL- V1M2-ISO-2008 Section 5.9) as a technical requirement of

Subject	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences
		conform to ISO?			
			<b>Quality Syste</b>	em	
					accreditation.
Laboratory documentation to ensure quality	EL-V1M2-ISO-2008 Sections 1.1, 4.2.2	ISO/IEC 17025	III.11, IV.7, V.7, VI.7	Quality documentation is required: OW CM's QA Plan, TNI 's QA Manual	OW CM states that laboratories must adhere to the method required QC and document these activities in a QA Plan. TNI states the laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). OW CM suggests a QA Plan, whereas TNI requires a OA Manual.
Objectives included in QA plan	EL-V1M2-ISO-2008 Sections 4.2.2, 4.2.8.3.g, 4.2.8.3.h	ISO/IEC 17025	III.11, IV.7, V.7, VI.7	No	TNI standard indicates that a quality policy statement should be issued under the authority of top management. OW CM QA Plan does not include the laboratory's objectives but requires project data quality objectives per EPA QA/R-5.
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	ISO/IEC 17025	III.11, IV.7, V.7, VI.7	Both list the required inclusions.	The OW CM does not have specific title page and table of contents instructions, TNI does. 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. TNI requires exceptions to be referenced or documented: 4.2.8.4.m).
Manual should include responsibilities of the QA manager.	EL-V1M2-ISO-2008 Sections 4.2.6, 4.2.8.2	ISO/IEC 17025	III.11.1 and III.10, IV.7, V.7, VI.7	Both include responsibilities of the QA manager.	

Subject	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences
		conform to ISO?			
			<b>Quality Syste</b>	em en	
List schedules of internal and external system and data quality audits and interlaboratory comparisons	EL-V1M2-ISO-2008 Sections 4.0 (interlab comp), 4.1.7.1.f, 4.11.5, 4.14, 4.2.8.4.c	ISO/IEC 17025	III.11.10	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 inter- laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes (4.2.8.4.c)

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
		D	ocument Cor	ntrol	
Control of all documents in the quality system	EL-V1M2-ISO-2008 Section 4.3	ISO/IEC 17025	III.11 (intro)	Yes	
Revision status of QA manual	EL-V1M2-ISO-2008 Sections 4.2, 4.3.2.1, EL-V2M1-ISO-2008 Section 5.7.4	ISO/IEC 17025	III.11 for QA plan and III.11.3 for procedures	Both programs require review and update of the QA manual/plan.	The OW CM manual requires annual review of both the QA plan and all SOPs. 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.
Specification of outdated/function/ availability of QA manual	EL-V1M2-ISO-2008 Section 4.3.2.2	ISO/IEC 17025	III.11, IV.7.1.1, V.7.1.1, VI.7.1.1	No	OW CM does not have a requirement that deals with handling invalid manuals once revisions are conducted. Section

Subject	TNI Standard	TNI	<b>OW/DWLCP</b>	Similarities	Differences				
U	Reference	Reference	Reference						
		conform to							
		ISO?							
Document Control									
					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.				
					TNI has defined procedures for				
					handling obsolete documents.				
Identification of QA	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11	No	The OW CM manual does not				
Manual documents	Sections 4.3.2.3,				specifically state that QA manuals				
and ID type text	4.3.3.2				should include an identifier, page				
					number, etc as required in EPA				
					QA/R-5. OW CM requires the date				
					of last revisions of SOPs. This				
					format with identifier page				
					number, revision, etc.				
Review of documents	FL-V1M2-ISO-2008	ISO/IEC 17025	III 11 1	No	TNI-Changes to documents shall be				
(who and do they	Sections 4 1 7 1	150/1EC 17025	111.11.1	110	reviewed and approved by the same				
have references)	4.3.2. 4.3.3.1				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).				
Altered text	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.5,	No	OW CM has control of electronic				
highlighted and hand	Sections 4.3.3.2,		III.11.13,		data throughout, however does not				
amendments, process	4.3.3.3, 4.3.3.4		IV.8.2,		address altered text in electronic				
tor changing			IV.8.6, V.8.2,		documents or QA documents. TNI				
electronic documents			v1.8.2, v1.8.6		requires the altered or new text to				
					the appropriate attachments				
					the appropriate attachments $(4, 2, 3, 2)$ As well as presedures to				
					(4.5.5.2). As well as, procedures to				
			1		describe now changes in documents				

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Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences		
	Document Control						
					maintained in computerized systems are made and controlled (4.3.3.4).		

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
		Review of Req	uests, Tende	rs and Contracts	
Reviews	EL-V1M2-ISO-2008 Section 4.4	ISO/IEC 17025	Not Found	No	CM OW does not address review of contracts. TNI discusses it in detail.
					· · ·

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences		
	Reference	Reference	Reference				
		conform to					
		ISO?					
	Subcontracting						
Subcontracting	EL-V1M2-ISO-2008	ISO/IEC	Not Found	No	OW CM does not discuss the issue		
	Section 4.5, EL-	17025,			of subcontracting.		
	V2M1-ISO-2008	ISO/IEC 17011					
	Section 7.4, EL-						
	V2M3-ISO-2008						
	Section 6.2						

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences		
	Reference	Reference	Reference				
		conform to					
		ISO?					
Purchasing Services and Supplies							
Procedures for	EL-V1M2-ISO-2008	ISO/IEC 17025	VI.7	No	In the radiochemistry method of the		
purchasing, reception,	Section 4.6, EL-				OW CM, it is stated that the QA		
and storage of	V1M2-ISO-2008				program should encompass the		

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Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
		Purchasi	n <mark>g Services</mark> a	nd Supplies	
reagents and standards	Section 5.6.4.2				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.
Chain-of-Custody	EL-V1M2-ISO-2008	ISO/IEC 17025	III.12,	Both discuss chain-of-	OW CM gives a detailed example
Procedures	Sections 5.8.7.4,		Appendix A	custody procedures.	of the chain-of-custody procedure
	5.8.7.5, 5.8.8, EL-				in Appendix A. TNI also contains a
	V1M3-2008 Section				detailed requirement for COC.
	1.7.8.1				
		1			

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
			Service to Cli	ent	
Laboratory service to client and confidentiality	EL-V1M2-ISO-2008 4.7, EL-V2M1-ISO- 2008 4.4	ISO/IEC 17025, ISO/IEC 17011	III.11.2	No	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.

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Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
	Control of None	conforming Er	vironmental	Testing and/or Calibration	n Work
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	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	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.
Action required for nonconformance	EL-V1M2-ISO-2008 Section 4.11, EL- V2M1-ISO-2008 Section 5.5	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	TNI requires laboratories to have a policy/procedure to implement corrective actions when work does not conform to testing procedures. OW CM does require a corrective action procedure in the laboratory QAP, but does not mention nonconformance.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
		F	Preventive Ac	tion	
Preventive action	EL-V1M2-ISO-2008	ISO/IEC	Not Found	No	TNI requires laboratories to have a
	Section 4.12, EL-	17025,			procedure to identify potential
	V2M1-ISO-2008	ISO/IEC 17011			sources of nonconformity. OW CM
	Section 5.6				does not require such a policy.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
		С	ontrol of Rec	ords	
Record system	EL-V1M1-2008.1	ISO/IEC 17025	III.11.13,	Both include a list of	
	5.3, EL-V1M2-ISO-	except Sect.	III.15, IV.8.2,	required records. Both have	
	2008 4.13,	5.3	V.8.2, VI.8.2,	a similar minimum length of	

Reference   Reference     conform to	
conform to	
ISO?	
Control of Records	
5.8.7(records are IV.8.1, V.8.1, record storage, OW CM: 6	
mentioned VI.8.1 years, TNI: 5 years.	
throughout Vol1)	
Data access and EL-V1M2-ISO-2008 ISO/IEC 17025 III.5, No OW CM does not describe of the second does not does not describe of the second does not describe of the second does not describe of the second does not does	isposal
disposal procedures Section 4.13 III.11.12, of records, legibility, and sto	orage
and other criteria environment or procedures f	or
V.8, VI.8, preventing unauthorized acc	ess.
III.11.13 OW CM does not have a set	format
I for archiving files, naming fi	files, or
TNI discusses control of rec	ords in
detail	orus m
History of records FL-V1M2-ISO-2008 ISO/IEC 17025 Not Found No. TNI requires laboratories to	
Sections 4 13 3 a	vstem
4.13.3.f	sample
to be readily available.	
Raw data EL-V1M2-ISO-2008 ISO/IEC 17025 IV.8.4, V.8.4, Both programs discuss raw	
Section 4.13.3.f.i VI.8.4, data management.	
IV.8.2, V.8.2,	
VI.8.2	
Mistakes andEL-V1M2-ISO-2008ISO/IEC 17025IV.8.3, V.8.3,YesAll records of analyses must	be
alterationsSection 4.13.2.3VI.8.3,available for inspection by	
IV.8.2, V.8.2, accrediting authorities. OW	СМ
VI.8.2 manual does not have this	
requirement.	• •
Security of records EL-VIM2-ISO-2008 ISO/IEC 17025 IV.2, IV.8.2, Both require a suitable OW CM provides general g	indance
Sections 4.13.3.1.xv, V.8.2, VI.2.1, environment and security of for security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the security and maintenance v.8.2, VI.2.1, environment and security of the s	10 9
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$	rements
4.15.1.5, 4.15.1.4 III.11.0, III.1.1.0, III.1.1.2 III.1.1.2 III.1.1.2	n uata
- III.11.15 Such as indexing of records	and
Samples FL-V1M2-ISO-2008 ISO/IEC 17025 III 11.4 Both require similar OW CM discusses required	records
Section 4.13.3 III.11.5 Sample/data documentation throughout the manual but	not as a

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences				
	Reference	Reference	Reference						
		conform to							
		ISO?							
Control of Records									
			III.12,	but TNI provides more	list of required records. TNI				
			Appendix A,	detail.	requires sample/data documents				
			IV.6, V.6,		that allow the history of the sample				
			VI.6, IV.8.3,		to be readily understood and list				
			V.8.3, VI.8.3		what is to be included.				
Retention of raw data,	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.8,	Yes					
final reports, SOPs,	Section 4.13.3.f		III.11.13,						
PT			III.15,						
			Introduction						
Sampling, analytical	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.8.4, V.8.4,	Similar, but TNI requires	TNI requires more records				
and administrative	Section 4.13.3.f		VI.8.4,	more detailed sample/data	including all manual calculations				
records			IV.8.3, V.8.3,	records.	and a log of signatures for				
			VI.8.3,		personnel authorized to sign				
			III.10.1,		laboratory records or deliverables.				
			III.11.1, III.12		OW CM does not discuss required				
					records at the same level of detail.				
Reconstruction of	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.8.5	Both require adequate					
Data	Section 4.13.3.f			information be available to					
				allow the auditor to					
				reconstruct the final results					
				for compliance samples and					
				PT samples.					
Internal audits	EL-V1M2-ISO-2008	ISO/IEC 17025	Not Found	No	According to TNI, the laboratory				
	Section 4.14				shall periodically conduct internal				
					audits of its activities.				
Steps taken after audit	EL-V1M2-ISO-2008	ISO/IEC 17025	Not Found	No	TNI requires that in the event of				
finds errors or	Sections 4.14.2,				audit findings, the laboratory shall				
deficiency	4.14.3, 4.14.4				take timely corrective action, record				
					the findings and corrective actions,				
					and follow-up.				

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		

		conform to ISO?			
		Ma	nagement Re	views	
Management Reviews	EL-V1M2-ISO-2008 Section 4.15, EL- V2M1-ISO-2008 Section 5.8	ISO/IEC 17025, ISO/IEC 17011	Not Found	No	OW CM does not discuss reviews that are conducted by quality assurance managers. TNI requires a management review of the QA/QC program in a laboratory.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences				
	Data Integrity								
Data integrity and follow-up of audits	EL-V1M2-ISO-2008 Sections 4.2.8.1, 4.2.8.1, 4.16	ISO/IEC 17025	Not Found	No	TNI requires the laboratory to establish and maintain a documented data integrity system Laboratories maintain SOPs that accurately reflect current laboratory activities, such as assessing data integrity.				

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
			Personnel		
Personnel	EL-V1M2-ISO-2008 Section 5.2	ISO/IEC 17025	III.10, III.11.1, IV.1, V.1, VI.1, 4.1.1.1	Similar Programs	TNI does not specify positions (NOT including technical directors, Sect. 5.2.6.1) or type/amount of education, experience, and/or training needed, only "appropriate". Waiver of academic training is also not discussed in the TNI standards.
Contracted Personnel	EL-V1M2-ISO-2008 Section 5.2.3	ISO/IEC 17025	V.1.1	Vague	TNI-The laboratory shall use personnel who are employed by, or under contract to, the laboratory.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences					
-	Reference	Reference	Reference							
		conform to								
		ISO?								
Personnel										
					Where contracted and additional					
					technical and key support personnel					
					are used, the laboratory shall ensure					
					that such personnel are supervised					
					in accordance with the laboratory's					
					management system OW CM only					
					discusses contracted personnel for					
					the supervisor/consultant position					
					in the critical elements for					
					microbiology chapter.					
Personnel Job	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.1	Similar Requirements						
Descriptions	Section 5.2.4									
Personnel Records	EL-V1M2-ISO-2008	ISO/IEC 17025	III.10.2,	Similar Requirements						
	Section 5.2.5		III.11.1, IV.1,							
			V.1, VI.1,							
Un to Date Training	Individual technical		IV.0.4.0	Similar requirements of	OW CM only mentions ongoing					
Op to Date Training	modules Section		VI.1.3, IV 7 2 9	ongoing demonstration of	demonstrations of proficiency for					
	1.6.3		11.7.2.9	competence in the chemistry	analysts and technicians in the					
				and radiochemistry sections.	critical elements for chemistry and					
				J.	radiochemistry chapter. TNI					
					addresses ongoing demonstrations					
					of proficiency in individual					
				~	technical modules.					
Activity	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.7, IV.8,	Similar in regard to	TNI-If the laboratory is part of an					
Documentation	Section 4.1.4		V.8, VI.8	documenting the method and	organization performing activities					
				QC procedures used.	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					

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Reference	Reference	Reference		
		conform to			
		ISO?			
			Personnel		
					to identify potential conflicts of
					interest.
Data Integrity	EL-V1M2-ISO-2008	ISO/IEC 17025	Not Found	No	OW CM does not discuss data
Training	Section 5.2.7				integrity training.
Laboratory Analyst	Individual technical		IV.1.2 and	No	OW CM specifies required
and Technician	modules Section 1.6		IV.1.3		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.
Sampling Personnel	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.1.4	Yes	OW CM requires that personnel
	Sections 4.13.2.1,				who collect samples should be
	5.2, 5.2.5				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.
					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

Subject	TNI Standard Reference	TNI Reference conform to	OW/DWLCP Reference	Similarities	Differences
		ISO?			
			Personnel		
					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.
Waiver of Academic Training Requirement	EL-V1M2-2008 Section 5.2.6.2		IV.1.5	Similar with some exceptions	Similar, but TNI does not have a "Waiver". 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.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference conform to	Reference		
		ISO?			
	Ac	commodation	s and Enviro	nmental Conditions	
Facilities and Control of Environmental Conditions	EL-V1M2-ISO-2008 Section 5.3	ISO/IEC 17025	IV.2, V.2, VI.2, III.11.4, III.11.11, III.11.12	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 glass wear).
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	ISO/IEC 17025	III.11.11	Yes	OW CM mentions that the preventative maintenance procedures and schedules should be addressed in the QA plan. 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.
Laboratory Safety	EL-V1M2-ISO-2008 Section 4.2.8.5.f.viii	ISO/IEC 17025	IV.4.4, V.4, VI.4.4	Similar	OW suggests that laboratory personnel apply general and customary safety practices as a part of good laboratory practices. Each laboratory is encouraged to have a safety plan as part of their SOP. Where safety practices are required in an approved method, they must be followed. For radiochemistry, OW CM requires certain protective equipment. TNI just states that safety shall be included or referenced in each test method.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference conform to ISO?	Reference		
	Environmen	tal Test and C	alibration Me	thods and Method Valida	tion
Environmental Test and Calibration Methods and Method Validation	EL-V1M2-ISO-2008 Sections 5.4, 5.5	ISO/IEC 17025	III.11.4, III.11.5, III.11.6, III.11.7, III.11.8, III.11.9, IV.3, V.3, VI.3, IV.5.1, VI.7.1	Yes	OW CM discusses use of EPA- approved methods, whereas 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. OW CM does not.
SOPs with dates of	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.3	Both require annual review,	TNI requires archive of SOPs so
last revision	Sections 4.2.8.5.c, 5.4.1			signatures, and dated revisions.	previous data can be paired with SOP requirements in force at the time of analysis.
Methods manual	EL-V1M2-ISO-2008 Section 5.9.3, EL- V1M2-ISO-2008 Section 5.4.1, EL- V1M7-2008 Section 1.7.1.1.d(tox)		III.11, IV.5.1	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

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences					
Environmental Test and Calibration Methods and Method Validation										
					prepare a written description of its QA activities.					
Methods for clients	EL-V1M2-ISO-2008 Section 5.4.2	ISO/IEC 17025	III.11.2	No	OW CM has "Process used to identify clients' Data Quality Objectives" listed as a QAP inclusion, but provides no details on the topic. TNI discusses that the laboratory shall use methods that meet the needs of the customer.					
Standards and Methods	EL-V1M2-ISO-2008 Sections 5.4.1, 5.4.2, 5.4.3, 5.4.4, 5.4.5	ISO/IEC 17025 except 5.4.4 and 5.4.5	IV.5, V.5, VI.5, IV.8.2, V.8.2, VI.8.2	Yes	OW CM does not discuss if laboratories must use the latest valid edition of a standard.					
Method Confirmation and Demonstration	EL-V1M2-ISO-2008 Section 5.4, Individual technical modules Section 1.5	ISO/IEC 17025 except technical modules	III.11.9, V.5.6.1.4.1, V.5.6.1.4.5	Yes	OW CM does not discuss test method confirmation and validation (TNI 5.4.2, 5.4.5). OW CM specifies certain procedures that require initial and continuing demonstration of method capability and performance. 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.					
Environmental Test and Calibration Methods	EL-V1M2-ISO-2008 Section 5.4	ISO/IEC 17025	Not Found	Similar	OW CM discusses use of EPA- approved methods, whereas TNI discusses client-specified and laboratory-approved methods.					
Uncertainty	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.4.1, 5.4.6	ISO/IEC 17025 except Sect. 5.4.6	VI.7, 8.4.7, 8.5.9	No	OW CM only discusses uncertainty in the critical elements for radiochemistry chapter. TNI-The laboratory shall retain sufficient					

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
, i i i i i i i i i i i i i i i i i i i	Reference	Reference	Reference		
		conform to			
		ISO?			
	Environmen	tal Test and C	alibration Me	thods and Method Valida	tion
					information to facilitate, if possible,
					identification of factors affecting
					the uncertainty. The laboratory
					procedures for all tests and/or
					calibrations within its scope.
					including where appropriate, an
					estimation of the measurement
					uncertainty.
Calculations and Data	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.3,	Yes	
	Sections 4.13.2.2,	except Sect.	III.11.8,		
	5.4.7.1, 5.9.3.a.v,	5.4.7.1	III.11.9,		
	individual technical		111.11.13,		
	modules		$1 \times .0.2,$ $1 \times 8 \times 6 \times 8 \times 2$		
			VI 7 6		
			VI.8.2. VI.8.6		
Laboratory Software	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.13,	Yes	
Configuration or	Sections 4.13.3.f.xv,	except Sect.	IV.8.6, VI.8.6		
Modification	5.4.7.2, 5.5.5	5.4.7.2			
Validation					
Calibration Curve	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.7.2.3	Yes	
	Sections $5.5.1$ ,				
	5.9.5.a.III, Individual				
Calibration Check	FL-V1M2-ISO-2008	ISO/IEC 17025	IV 7 2 4	Ves	
Cultoration Check	Sections 5.9.3.a.iii.	except Sect.	1		
	5.5.10, 5.6.3.3,	5.6.3.3 and			
	individual technical	technical			
	modules, EL-V1M4-	modules			
	2008 Section 1.7.2				
	(chem), EL-V1M5-				
	2008 Section 1.7.2				
	(microb), EL-V1M6-				

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
	Environmen	tal Test and C	alibration Me	thods and Method Valida	tion
Quantitation of Multicomponent	2008 Section 1.7.1.b(radio) EL-V1M4-2008 Sections 1.7.2.b.		IV.7.2.10	Both have provisions for quantitation of	OW CM (chemistry) indicates the analyst's professional judgment
Organic Analytes	1.7.3.2.3.b (chem)			multicomponent organic analytes using a representative number of components.	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.
Low Level Quantitation	EL-V1M6-2008 (radiochem)		IV.7.2.12	No	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. 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.

Subject   TNI Standard   TNI   OW/DWLCP   Similarities   Diff     Reference   Reference   Reference   Image: Conform to image: Conform	fferences
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			Equipment		
Laboratory	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.3, V.3,	Both standards cover	OW CM does not mention the use
Equipment and	Section 5.5,	except	VI.3	equipment and	of equipment outside of a
Instrumentation	individual technical	technical		instrumentation	laboratories permanent control.
	modules	modules			TNI does not mention specific
					types of equipment and/or specific
					maintenance/calibration
					requirements.
Calibration	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.3, 4, 5, 6,	Yes	Calibration requirements in the TNI
	Section 5.5		7; V.3, 4, 5, 6,		standards are divided into two parts
			7; VI.3, 4, 5,		(analytical support equipment and
			6, 7; III.11.6		instrument calibration). TNI-
					Instrument calibration requirements
					presented in the technical modules.
					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).
Support Equipment	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.9,	Yes	OW CM specifies that preventive
	Sections 5.5, 5.5.13.1		III.11.11,		maintenance documents should be
			III.11.12,		kept for five years. TNI does not
			IV.3, IV.7.1,		mention specific types of
			V.3, V.8.5,		equipment and/or specific
			VI.3, VI.7		maintenance/calibration
					requirements. OW CM specifies
					type of equipment, proper
					maintenance, and calibration for
					certain pieces of equipment needed
					in each critical element chapter.
Specific Device	EL-V1M2-ISO-2008	ISO/IEC 17025	Not Found	No	OW CM does not discuss
Accuracy	Section 5.5.13.1.e				mechanical volumetric dispensing
					devices or glass microliter syringes.
					TNI-Volumetric dispensing devices
					(except Class A glassware and
					Glass microliter syringes) must be

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference conform to ISO?	Reference		
	l		Equipment	t	
					checked for accuracy on a quarterly basis.
Autoclave	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5	Both require autoclave operation records.	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. 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.
Instrument Calibration	EL-V1M2-ISO-2008 Section 5.5, individual technical modules	ISO/IEC 17025 except technical modules	III.11.3, III.11.9, IV.3, 7; V.3, 7; VI.3, 7, III.13.2	Similar but not identical	TNI standard does not specify detailed procedural steps for calibration, but establishes the essential elements for selection of the appropriate techniques. 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. TNI-the lowest cal point shall be at or below the LOQ. (1.7.1.1.f for chem)
Zero point and single point calibration standard	EL-V1M1-2008.1 Section 5.2.1.b, EL- V1M4-2008 Section	ISO/IEC 17025 except technical	Not Found	No	OW CM does not discuss instrument technology with validated techniques from

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Kelerence	conform to ISO?	Kelerence		
			Equipment		
	1.7.1.1.h (chem)	modules			manufacturers or methods employing standardization with a zero point and a single point calibration standard.
Calibration Results	EL-V1M2-ISO-2008 Sections 5.5.2		III.11.9, III.11.12, IV.3, 7; V.3, 7; VI.3, 7	Yes	
Equipment use and maintenance	EL-V1M2-ISO-2008 Sections 5.5.6, 5.5.7		IV.3, 4, 5, 6, 7; V.3, 4, 5, 6, 7; VI.3, 4, 5, 6, 7; III.11.11, III.11.12	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).
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)	ISO/IEC 17025 except technical modules	III.11.11, V.8.5, VI.7	OW CM's microbiology and radiochemistry sections require equipment records similar to TNI.	OW CM does not specify the exact items needed in records for equipment or labeled on equipment. TNI-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), V1M6 Section 1.7.1.b (radio)	ISO/IEC 17025 except Sect. 5.6.3.3 and technical modules	III.11.6, IV.7.2.4, VI.3.1.2, VI.3.1.5	No	In OW CM continuing instrument calibration verification is discussed in the chemistry and radiochemistry methods of the OW CM. TNI requires a standard from a second manufacturer or lot as continuing calibration verification for chemical testing and radiochemical testing.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
		Meas	surement Trac	ceability	
Measurement	EL-V1M2-ISO-2008		IV.3, 4, 5, 6,	Yes	
Traceability	Section 5.6		7; V.3, 4, 5, 6,		
			7; VI.3, 4, 5,		
			6, 7		
Testing Laboratories	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.6,	Yes	
	Sections 5.4.6, 5.9.3,	except Sect.	III.11.13,		
	EL-V1M7-2008	5.4.6 and	IV.3, 4, 5, 6,		
	Sections	technical	7; V.3, 4, 5, 6,		
	1.7.1.1(tox),1.7.1.6.q	modules	7; VI.3, 4, 5,		
			6, 7		
Reference Standards	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.3, IV.7,	Yes	OW CM specifies type of
and Materials	Sections 4.2.8.4,	except Sect.	V.3, V.7,		equipment, reference material, and
	5.6.3, 5.6.4, 5.9.1,	5.6.3 and	VI.3, VI.7,		calibration for certain pieces of
	5.9.3, individual	technical	III.11.3,		equipment needed in each critical
	technical modules	modules	III.11.13		element chapter. TNI does not
					mention a specific type of reference
					standard or material and/or specific
					calibration requirements, however it
					states "Where possible, traceability
					shall be to national or international
					standards of measurement or to
					national or international standard
					reference materials" (TNI
					5.6.4.1.b).
Records and Label	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.6, 11.7,	Yes	OW CM does not specify the exact
	Sections 5.6.4.2,	except Sect.	11.9, 11.13		items needed in records or labeled
	5.8.5, 5.8.6,	5.6.4.2 and			for all standards, reagents, reference
	individual technical	technical			materials and media.
	modules	modules			
Record keeping	EL-V1M1-2008.1	ISO/IEC 17025	III.11.13,	Both have lists of inclusions	OW CM-records should be
procedures	Section 5.3, EL-	except Sect.	III.15, IV.8.2,	for their individual record	maintained for 6 years. A list of
	V1M2-ISO-2008	5.3	V.8.2, VI.8.2,	keeping procedures. Have	inclusions is provided. TNI-records

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences		
	Measurement Traceability						
	Sections 4.13, 5.8.7, (records are mentioned throughout Vol1)		IV.8.1, V.8.1, VI.8.1	similar record retentions - OW CM 6 years and TNI 5 years.	should be maintained for 5 years. Provides a list of information necessary for reconstruction of data.		

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to ISO?			
			Sampling		
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	ISO/IEC 17025 except technical modules	III.11.4, III.11.5, III.11.9, III.11.13	Yes	
Sample Collector	EL-V1M2-ISO-2008 Sections 4.13.2.1, 5.2.5	ISO/IEC 17025	IV.6.5	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. TNI requires name of collector to be documented
Sample Compositing	Not Found		IV.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	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to ISO?			
		Ha	ndling of Sar	nples	L
Samples	EL-V1M1-2008.1	ISO/IEC 17025	III.11.4,	Yes	
	Sections 5.0, 5.8,	except Sect.	III.11.5, IV.6,		
	individual technical	5.0 and	V.6, VI.6		
	modules	technical			
I.I		modules	TTL 1.1.4	X	
Identification	EL-VINI2-ISO-2008	ISU/IEC 1/025	111.11.4,	Yes	
	Sections 5.6.2, 5.6.5		$V_{6} V_{16}$		
			Appendix A		
Temperature	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.6.2, V.6.3	Yes	TNI mentions regulatory or method
	Sections 5.3.2, 5.8.4,	except	·		criteria for temperature, but gives a
	5.8.9.a.i, individual	technical			general guide for sample
	technical modules	modules			temperature if none is given. Also
					has more information in individual
					technical modules. OW CM is
					more specific than TNI on shipping
Noutrolization	EL V1M2 ISO 2008	ISO/IEC 17025	V 2 15 /	OW CM and TNL specify	OW CM and TNL standards specify
(stabilization)	Sections 5.8.4	except	V.J.1J.4	that sodium thiosulfate	that sodium thiosulfate should be
(submization)	5.8.9.a. EL-V1M5-	technical		should be added to each	added to each container to
	2008 Sections 1.7.5.b	modules		container to neutralize any	neutralize any residual chlorine, but
	(microb)			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
Comula Dairatian			WC1	No	wastewater samples.
Sample Rejection	EL-V INIZ-ISO-2008	150/1EC 1/025	1 v .0.1	INO	of samples in the critical elements
	5 8 7 2 a	_			for chemistry chapter
Maximum Holding	Not Found EL -	ISO/IEC 17025	IV 6 3	No	OW CM has a general statement
Times	V1M2-ISO-2008	except Sect.			indicating that holding times are to

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
		На	indling of Sar	nples	
	Sections 4.13.3.f.v, 5.10.11.a, EL-V1M7- 2008 Section 1.7.1.6.s(tox)	5.10.11.a and technical modules			be followed according to the specific method being used. TNI specifies hold time prescribed by the method and approved by the regulatory agency. TNI does present some hold times, such as: "The maximum holding time of effluents (elapsed time from sample collection to first use in a test) shall not exceed thirty-six (36) hours; samples may be used for renewal up to seventy-two (72) hours after first use except as prescribed by the
					method and approved by the regulatory agency having authority for program oversight" (EL-V1M7- 2008 1.7.1.6.s).
Sample Collection and Transport	EL-V1M2-ISO-2008 Sections 5.4, 5.7, 5.8, individual technical modules	ISO/IEC 17025	IV.6.4	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)	ISO/IEC 17025 except technical modules	Appendix A, IV.8, V.8, VI.8	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.
Sample Acceptance	EL-V1M2-ISO-2008 Section 5.8.6	ISO/IEC 17025	IV.6.1 V.6, VI.6	OW CM states the laboratory should document its rejection criteria. TNI requires the laboratory to develop an overall sample acceptance	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
		На	ndling of Sar	nples	
				policy addressing the items listed in Section 5.8.6.	
Handling/Storage of Samples	EL-V1M2-ISO-2008 Section 5.8		III.11.4, III.11.5, IV.6, V.6, VI.6, Appendix A.D	Yes	
Storage Temperature	EL-V1M2-ISO-2008 Sections 5.8.4, 5.8.9		III.11.5, IV.6.2	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.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences			
	Reference	Reference	Reference					
		conform to						
		ISO?						
Assuring the Quality of Environmental Test and Calibration Results								
Quality Control	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11, IV.7,	Yes				
	Sections 5.9.1, 5.9.2,		V.7, VI.7					
	593							

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
		Re	porting the Re	esults	
Data reduction,	EL-V1M2-ISO-2008		III.11.8	No	OW CM only mentions that the
validation, reporting	Section 5.10,				procedure for data reduction,
and verification	Individual technical				validation, and reporting should be
	modules				included in the QA Plan.
Sample Report	EL-V1M2-ISO-2008	ISO/IEC 17025	III.11.8,	Both OW CM and TNI	OW CM discusses sample report
	Sections 5.10.2,		IV.6.6,	identify the minimal	format in the chemistry and
	5.10.3		V1.8.5,	requirements of what should	radiochemistry methods. TNI
			Appendix A	be included in sample	encompasses all methods and
				reports.	requires more information for the
					Sample Report, such as consecutive
					statements, monogement signatures
					statements, management signatures
Calibration Paparting	EL V1M2 ISO 2008	ISO/IEC 17025	IV 8 4 5	Vas	OW CM does not discuss
Requirements	Sections 5 10 1	except Sect	VI 8 4 5	103	calibration certificates or specific
Requirements	5 10 2 5 10 4	5 10 4	V1.0.4.5		reporting requirements for
	5.10.2, 5.10.4	5.10.4			calibration However OW CM
					does discuss calibration
					requirements and specifies type of
					equipment, reference material, and
					calibration for certain pieces of
					equipment needed in each critical
					element chapter. OW CM's critical
					elements of chemistry and
					radiochemistry chapters state that
					calibration and standards
					information must be reported in the
					analytical records. TNI specifies
					the actual items and circumstances
					that should be reported for
California Data	EL VINO 100 0000		Net Ee 1	N -	Calibration.
Subcontractor Reports	EL-VINI2-ISU-2008		Not Found	INO	UW UN does not discuss reporting
	Section 5.10.6				by contractors. TNL When the test
					by contractors. This when the test

Subject	TNI Standard	TNI	<b>OW/DWLCP</b>	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
		Re	porting the Re	esults	
					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.
Electronic	EL-V1M2-ISO-2008		Not Found	No	OW CM does not discuss
Transmission of	Sections 5.4.7, 5.10.7				requirements in the case of
Results					transmission of environmental test
					or calibration results by telephone,
					telex, facsimile or other electronic
					or electromagnetic means. 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).
Understandable	EL-V1M2-ISO-2008		III.11.13,	Yes	TNI-The format shall be designed
Format	Section 5.10.8		IV.8, V.8,		to accommodate each type of test or
			VI.8,		calibration carried out and to
			Appendix A		minimize the possibility of
					misunderstanding or misuse.
Amendment to Test	EL-V1M2-ISO-2008		Not Found	No	OW CM standards do not discuss
Reports and	Section 5.10.9				requirements for amendments to
Calibration					test reports or calibration
Certificates					certificates.
Action in Response to	EL-V1M2-ISO-2008	<b>ISO/IEC 17025</b>	IV.9	No	TNI does not specify the

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Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences		
		Re	porting the R	esults			
Noncompliant Laboratory Results	Section 5.10.3.1.b				notification of water authority.		

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
-	Reference	Reference	Reference		
		conform to			
		ISO?			
		Demo	nstration of C	apability	
Initial Demonstration	Individual technical		IV.7.2.9,	No	OW CM does require an Initial
of Capability (DOC)	module Section 1.6.2		IV.8.4.6,		Demonstration of Capability be
			V.5.6.1.4,		performed, but does not indicate
			III.11.9,		when it is necessary. TNI-An
			IV.7.2.11		initial DOC shall be conducted
					prior to using any test method, and
					at any time there is a change in
					instrument type, personnel or test
					method or any time that a method
					has not been performed by the
					laboratory or analyst in a twelve
					(12) month period.
Specifics of sample	Individual technical		IV.7.2.9,	No, program specific	OW CM does not indicate that the
preparation and	module Sections		IV.8.4.6,	differences exist.	samples used are from outside
reporting	1.6.2.2, 1.6.3		V.5.6.1.4		sources. 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

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
		Demo	nstration of C	apability	
					provides non-specific requirements for initial and on-going DOC in each test module. OW CM does not indicate the steps that need to be taken if the initial DOC fails. TNI does.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
~~~	Reference	Reference	Reference		
		conform to			
		ISO?			
	Essenti	al Quality Cor	ntrol Requiren	nents: Chemical Testing	
Availability of QC	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.7.1.2	All quality control	
Information	Section 4.13.3.c			information should be readily	
				available for inspection by	
				auditors.	
Balances and Weights	EL-V1M2-ISO-2008	ISO/IEC 17025	IV.7.1.3	Should be appropriate for the	
	Section 5.5.13.1			application to be used;	
				balances should be calibrated	
				at least annually. TNI	
				requires that support	
				equipment be calibrated or	
			NV 7 1 4	verified at least annually.	
Color Standards	Not Found		IV./.1.4	No	TNI has no specific information
The second se		100/000 17005	NI 7 1 5		about color standards.
Temperature	EL-V1M2-ISO-2008	ISO/IEC 1/025	1V./.1.5	Both require calibration or	OW CM has more detail and
Measuring Devices	Section 5.5.13.1, EL-			calibration verification.	additional (more frequent
	V INIS-2008 Section				calibration) requirements for digital
	1./.3./.0.1				infrared datasticn devices. TNI
					minared detection devices. TNI
					ashibitistical or verified at least
					annually
					annuany.

Subject	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences					
		ISO?								
	Essential Quality Control Requirements: Chemical Testing									
Traceability of Calibration	EL-V1M2-ISO-2008 Section 5.6.3	ISO/IEC 17025	IV.7.1.6	Both require calibrations of all measurement devices be traceable to national standards whenever applicable.						
Negative Control Purpose	EL-V1M4-2008 Section 1.7.3.1		IV.7.2.5	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		IV.7.2.2	Both require a Laboratory Control Samples (LCS).	OW CM at least one LCS should be analyzed per quarter and LFBs as required by the method. TNI requires one LCS analysis at a minimum per preparation batch.					
Matrix Spikes	EL-V1M4-2008 Section 1.7.3.3		IV.7.2.7	Both require a Matrix Spike (MS).	Both OW CM and TNI mention that the test method specifies the frequency of MS analysis, however OW CM does not mention Matrix Spike Duplicates (MSDs).					
Detection Limits	EL-V1M4-2008 Section 1.5.2		IV.7.2.9, 7.2.11	Yes	OW CM is much more specific than TNI in stating the procedures and requirements for determining detection limits.					
Quality Control Samples	EL-V1M4-2008 Section 1.7.3		IV.7.2.2	Yes	OW CM specifies frequency and procedures for detection limit studies of quality control samples.					
Analytical Test	EL-V1M4-2008 Section 1.4 (Method Selection)		Not Found	No	OW CM does not discuss the involvement of the analytical method process or the matrix of interest. TNI-If there is not a regulatory requirement for the parameter/method combination, the					

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference conform to ISO?	Reference		
	Essenti	al Quality Cor	trol Requiren	nents: Chemical Testing	
					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		IV.8	Yes	
Data Reduction Documentation	EL-V1M4-2008 Section 1.7.3.4		IV.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		IV.4.1.1, 4.2.1, 4.3.1	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.
Verification of Titrants	EL-V1M4-2008 Section 1.7.3.5.c		Not Found	No	OW CM does not discuss the verification of concentrations of titrants, TNI does.
Selectivity	EL-V1M4-2008 Section 1.7.3.6		Not Found	No	TNI lists requirements for selectivity, OW CM does not.
Glassware preparation	Not Found		IV.4.2.2, IV.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		IV.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	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences
		conform to ISO?			
	Essenti	al Quality Cor	trol Requirer	nents: Chemical Testing	
Sample Collection, Handling, and Preservation	EL-V1M2-2008 Sections 5.7, 5.8, EL- V1M4-2008 Section 1.7.5		IV.6.7	Yes	OW CM was more specific in the requirements.
Quality Control	EL-V1M4-2008 Section 1.7.3		Entire Section of IV.7 (except 7.1.1 to 7.1.3, 7.2.5, 7.2.9, and 7.2.11)	Yes	OW CM was more specific in the requirements.
Action Response to Noncompliant Laboratory Results	Not Found		Entire Section of V.9	No	The listed OW CM sections on action regarding QC failure or noncompliant lab results are either not found or only briefly discussed in TNI.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences				
	Reference	Reference	Reference						
		conform to							
		ISO?							
	Whole Effluent Testing Detailed Method Review								
Toxicity Testing	EL-V1M7-2008		Not Found	No	OW CM does not discuss or contain				
					a section regarding toxicity testing.				

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
	N	licrobiology T	esting Detaile	ed Method Review	
Supervisor/consultant	EL-V1M2-2008		V.1.1, V.1.2	TNI and OW CM have	TNI and OW CM have similar
and analyst	Section 5.2.6.1			similar educational	educational requirements, but TNI
				requirements.	requires 16 college credit hours
					microbiology and biology while

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences					
Ŭ	Reference	Reference conform to	Reference							
		ISO?								
Microbiology Testing Detailed Method Review										
					OW CM requires one course if the degree is in a field other than microbiology. OW CM also states that the supervisor needs to have two weeks of federal training of drinking water analysis or 80 hours on the job training and a laboratory may have consultants fulfill these duties if documentation showing that the consultant is acceptable to the state is presented during audits. OW CM requires that analysts have at least a high school degree; three months of microbiology testing experience in water, milk, or food media. TNI does not specify media					
Waiver of academic training	EL-V1M2-2008 Section 5.2.6.2		V.1.3	Similar	TNI does not have an experience "Waiver" for academic training. 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.					
Personnel records	EL-V1M5-2008 Section 1.6 (DOC), V1M2-2008 Section 5.2		V.1.4	OW CM and TNI require similar records for personnel.	TNI makes this the responsibility of the management and includes an analyst signature record sheet.					
Sterility Checks and Blanks	EL-V1M5-2008 Section 1.7.3.1		V.3, 4, 5, V.5.1.6.4	Yes	TNI does not list control organisms or frequency for testing					

Subject	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences						
		conform to ISO?									
	Microbiology Testing Detailed Method Review										
					commercially prepared medium. OW CM has specific requirements.						
Filtration	EL-V1M5-2008 Sections 1.7.3.1.b.ii, 1.7.3.1.b.v		V.5.4.1.2, 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. TNI does not.						
Container Sterility	EL-V1M5-2008 Section 1.7.3.1.b.iii		V.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		V.4.3	Yes	OW CM provides quality requirements. Both have specific parameters with associated frequencies for testing.						
Dilution Water Sterility	EL-V1M5-2008 Section 1.7.3.1.b.iv		V.4.4.3	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.						
Dilution/rinse Water	Not Found		V.4.4 (except V.4.4.3 above), V.5.3.2.1.1, 4.3.2, 8.2	No							
Plate Counts	Not Found		V.5.4.2.8	No	OW CM does not discuss using only one microbiology analyst for duplicate plate counts in a laboratory.						
Proficiency Test	EL-V1M2-2008 Section 5.0, EL- V1M5-2008 Sections		V.7.2, V.8.2	Yes							

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
, , , , , , , , , , , , , , , , , , ,	Reference	Reference conform to ISO?	Reference		
	Ň	licrobiology T	esting Detaile	ed Method Review	·
	1.5, 1.71				
Target Organisms	Not Found		V.4, V.5	No	
Test methods	EL-V1M5-2008		V.3, 4, 5, 6, 7	Yes	
	Section 1.4				
Media	EL-V1M5-2008		V.5.1.6,	Yes	
	Sections 1.7.3.5.a,		III.11, V		
	1./.3.5.b, 1./.3.5.d		NE1C1	N/	
Product Shelf Life	EL-VIM5-2008		V.5.1.6.1,	Yes	OW CM notes that caked or
	Section 1.7.3.5		5.1.0.2,		discolored denydrated media should
			5.1.0.5		be discarded. This mentions using
Madia Documentation	EL V1M5 2008		V5162	Vac	For modia propagad in the
Media Documentation	Section 1735 d		V.J.1.0.2, 5163	165	laboratory and media prepared
	Section 1.7.5.5.d		5.1.0.5		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		Not Found	No	OW CM does not mention the
	Section 1.7.3.6				preservation, preparation, and use
					of reference stocks.
Lab Facilities	EL-V1M5-2008		V.2	Yes	TNI does not require laboratory to
	Section 1.7.3.7.a				maintain effective separation
					between areas where activities are
					incompatible.
Temperature	EL-V1M5-2008		V.3.3	Yes	OW CM states the actual
Measuring Devices	Section 1.7.3.7.b.i				calibration, record, etc.
					requirements for temperature
					measuring devices. TNI only
					uiscusses ii devices are
		1	1		appropriate . TNI requires at least

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences					
	Reference	Reference conform to ISO?	Reference							
	Microbiology Testing Detailed Method Review									
					annual verification (see EL-V1M2- 2008, Section 5.5.13.1) OW CM gives more detail.					
Autoclaves	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5.1, V.3.5.2	Yes	OW CM does not discuss initial evaluation of the autoclave. TNI does not discuss time requirements for the autoclave.					
Autoclave Temperature	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.3.5.4	Yes	OW CM does not discuss the use of temperature sensitive tape.					
Autoclave Records and Maintenance	EL-V1M5-2008 Section 1.7.3.7.b.ii		V.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		V.3.5.5	Yes	TNI requires the autoclave mechanic timing device to be checked quarterly against a stopwatch and documented.					
Autoclave Parts	Not Found		V.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		V.3	Yes	OW CM specifies types of volumetric equipment and requirements for each. TNI requires volumetric equipment with movable parts be verified for accuracy quarterly, other volumetric equipment verified once per lot prior to first use.					

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
, i i i i i i i i i i i i i i i i i i i	Reference	Reference conform to ISO?	Reference		
	N	licrobiology T	<b>Secting Detaile</b>	ed Method Review	
UV Instruments	EL-V1M5-2008 Section 1.7.3.7.b.iv		V.3.16.2	Yes	TNI requires UV instruments tested quarterly for effectiveness
UV Cleaning	Not Found		V.3.16.1	No	TNI does not discuss the frequency or process for cleaning the UV instruments.
UV Support Equipment	Not Found		V.3	No	OW CM specifies type of calibration requirements for support equipment. TNI specifies calibration according to the method specified requirements.
Incubator, Water Baths, and Ovens	EL-V1M5-2008 Section 1.7.3.7.b.v		V.3.4.1, 3.4.2, 3.6.1	Yes	OW CM specifies temperature and time in incubators, ovens, and water baths. TNI requires the temperature of incubators and water baths to be documented twice daily each day of use
Oven	EL-V1M5-2008 Section 1.7.3.7.b.v.2		V.3.6.3, 3.4.2, 3.6.3	Yes	TNI requires ovens to be checked for sterilization effectiveness monthly.
Glassware	EL-V1M5-2008 Section 1.7.3.7.b.vi		V.3.14.1	Yes	TNI does not discuss a description of plastic items.
Glassware Inhibitory Residue Test	EL-V1M5-2008 Section 1.7.3.7.b.vi.3		V.4.5.3	Yes	TNI requires annual testing and with every change in washing procedure
Glassware pH Reaction	EL-V1M5-2008 Section 1.7.3.7.b.vi.4		V.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		V.4.5.1	Yes	Similar, however TNI does not specify the use of distilled or deionized water for the final rinse.
Laboratory equipment and supplies	EL-V1M5-2008 Section 1.7.3.7.b		V.3.3, 3.5, 3.6, 3.13,	No	OW CM is more specific in discussing laboratory equipment in

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences					
, i i i i i i i i i i i i i i i i i i i	Reference	Reference	Reference							
		conform to								
		ISO?								
Microbiology Testing Detailed Method Review										
			3.15, 3.17,		general. Such as the temperature					
			V.3.1, 3.2,		monitoring devices, OW CM					
			3.7, 3.8, 3.9,		discusses having a QC record book					
			3.10, 3.11,		for specific temperature device					
			3.12, 3.14,		information; whereas, TNI does					
			3.15, and 3.17		not. TNI and OW CM standards on					
					pipettes differ, and OW CM					
					specifies that they have a precision					
					and accuracy within 2.5%. TNI					
					discusses volumetric equipment as					
					a whole and not pipettes					
					specifically. Ow CM contains					
					separate sections in the standard for					
					discusses LIV Instruments in					
					general OW CM contains separate					
					standards for each type. 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. In					
					most cases, OW CM was more					
					specific in the maintenance and					
					calibration requirements.					
General Laboratory	Not Found		V.4.1, 4.4	No	Not found in TNI. In most cases,					
Practices					OW CM was more specific in the					
					testing and notification					
					requirements.					

Subject	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences
		ISO?			
	N	licrobiology T	esting Detaile	ed Method Review	
Analytical	EL-V1M5-2008		Entire Section	No	OW CM was more specific in the
Methodology	Section 1.4		of V.5 (except		methods requirements. TNI does
			5.1.6 to		not list specific methods as a
			5.1.6.4,		requirement, unless already
			5.4.1.2,		prescribed to meet federal or local
			5.4.1.3,		regulations.
			5.4.2.8, and		
			5.6.1.4)		
Sample Collection,	EL-V1M5-2008		Entire Section	No	OW CM was more specific in the
Handling, and	Section 1.7.5		of V.6 (except		sampling/handling/preservation
Preservation			6.5 and 6.6)		requirements.
Action Response to	Not Found		Entire Section	No	Not found in TNI. In most cases,
Laboratory Results			of V.9		OW CM was more specific in the
					testing and notification
					requirements.

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference	Reference		
		conform to			
		ISO?			
	Ra	diochemical A	Analysis Detai	iled Method Review	
Laboratory	EL-V1M2-2008		VI.1.1	Similar requirements for	TNI standard 5.2.6.1 requires a BS
Supervisor/Technical	Section 5.2.6.1			Laboratory	with 24 credit hours in chemistry
Manager				Supervisor/Technical	and 2 years experience in analysis
				Manager.	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	Not Found		VI.1.2	No	OW CM gives specific education,
					training and experience

Subject	TNI Standard	TNI	OW/DWLCP Boforonco	Similarities	Differences
	Kelerence	conform to ISO?	Kelerence		
	Ra	diochemical A	Analysis Detai	led Method Review	
Technician	Not Found		VI.1.3	Νο	requirements for an analyst. TNI does not give specific requirements for an analyst, but does for a technical director in 5.2.6.1 See above comment for laboratory
	1,001 00000		, 1110		analyst.
Sampling Personnel	Not Found		VI.1.4	No	See above comment for laboratory analyst and technician.
Initial and Ongoing Demonstration of Proficiency for Analysts and Technicians	EL-V1M6-2008 Section 1.6.2		VI.1.5	Ongoing DOCs can be performed via QC or the method by which the initial DOC was performed.	The OW CM describes specific means by which an initial DOC must be performed. TNI gives ways to complete an initial DOC if not specified by the method or regulation.
Method Blanks	EL-V1M6-2008 Section 1.7.3.1		VI.1.5	Both required a background check daily.	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. 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.
Data Produced by Analysts and Technicians in Training	Not Found		VI.1.6	No	OW CM states that this data must be reviewed by a fully qualified analyst or the lab supervisor. TNI requires final data review and release by a Technical Director.
Waiver of Academic	EL-V1M2-2008		VI.1.7	Yes	OW CM offers an academic waiver

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference conform to ISO?	Reference		
	Ra	diochemical A	Analysis Detai	iled Method Review	
Training	Section 5.2.6.2.c				to highly-experienced analysts. 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.
Positive, negative, and other controls	EL-V1M6-2008 Section 1.7.3		VI.3.1.5, VI.4.2, VI.7.3	Yes	See method blank discussion above concerning negative controls. Positive controls have specific criteria in the OW CM, while NELAC details these as "laboratory control samples" that are spiked with an analyte of interest and analyzed to meet specific performance criteria. OS CW details matrix spike requirements for field collection, which TNI omits. TNI includes criteria for surrogate spikes, which the OS CW omits.
Radiation Counting Instruments	EL-V1M6-2008 Section 1.7.1		VI.3.1	Detection limits are similar.	TNI does not provide detailed information on the overall process of calibration of each type of radioactivity counter, while the OW CM does. OW CM does not address background levels measurement. TNI goes into specific detail about this.
Liquid Scintillation Counting (LSC) system Background Check	EL-V1M6-2008 Sections 1.7.1.a, 1.7.1.b, 1.7.1.c		VI.3.1.1	Both agree that background checks should be performed daily.	TNI does not describe the check process in detail.
Gas~flow	EL-V1M6-2008		VI.3.1.2	Both agree that background	

Subject	TNI Standard Reference	TNI Reference	OW/DWLCP Reference	Similarities	Differences
		conform to ISO?			
	Ra	diochemical A	Analysis Detai	led Method Review	
Proportional Counting System Background Check	Section 1.7.1.c			checks should be performed daily.	
Alpha Scintillation Counting System Background Check	Not Found		VI.3.1.3	No	TNI does not describe the background check process in detail. OW CM mandates a background check performed each time a set of compliance monitoring samples is analyzed, or weekly.
Scintillation Cell System Background Check	EL-V1M6-2008 Section 1.7.1.c		VI.3.1.4	No	TNI states that background checks must be performed daily. OW CM states they must be performed each time a set of compliance monitoring samples is analyzed. OW CM provides more information about this technology.
Gamma Spectrometer Systems Background Check	EL-V1M6-2008 Section 1.7.1.c		VI.3.1.5	Both agree that background checks should be performed monthly.	
Alpha Spectrometer Systems Background Check	EL-V1M6-2008 Section 1.7.1.c		VI.3.1.6	Both agree that background checks should be performed monthly.	
Other Radiation Instrumentation Background Checks	Not Found		VI.3.1.7	No	OW CM states that the calibration and background checks should be consistent with the method being used and the manufacturer's recommendation. NELAC wrote the section on Radiation Counting Instruments to be all-inclusive, thus this is not applicable to that standard.
Chemicals/reagents	EL-V1M6-2008 Section 1.7.2.5		VI.4.1	Yes	OW CM does not discuss standards for purchasing from outside US

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
	Reference	Reference conform to ISO?	Reference		
	Ra	diochemical A	<b>Analysis Deta</b> i	iled Method Review	
					commercial suppliers.
Reagent Water	EL-V1M6-2008 Section 1.7.2.5		VI.4.2	No	TNI requires that reagent water meet the standards of the method in use. OW CM has more specific parameters required for reagent water.
Glassware/Plasticware	EL-V1M6-2008 Section 1.7.2.7.b		VI.4.3	Both state that glassware should be washed in accordance with the method in use.	TNI states if there is no specification in the method, then the washing procedure should be documented. OW CM includes a specific procedure to wash glassware when the correct procedure is not documented in the method.
Safety	Not Found		VI.4.4	Both standards state that proper safety measures should be addressed in the laboratory standard operating procedures.	The TNI standard does not address safety specifically for radiochemical analysis.
Analytical Methods: Standard Operating Procedures (VI.5.1)	EL-V1M2-2008 Sections 3.0, 4.2.8.5		VI.5	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		VI.6.1	No	TNI does not include composite samples.
Matrix spikes and duplicates (replicates),	EL-V1M6-2008 Sections 1.7.2.3.a,		VI.7.7.1, VI.7.7.2,	Yes	See above discussion about positive controls for matrix spike

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences					
	Reference	Reference	Reference							
		conform to								
		ISO?								
	Radiochemical Analysis Detailed Method Review									
low level samples	1.7.2.3.b		VI.7.2.12		comparison. Duplicates in the OW					
					CM are described as replicate					
					analysis of the same sample,					
					however TNI defines this as a					
					replicate piece of sample carried					
					through the entire sample process.					
					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. TNI					
					asks that an instrument duplicate be					
					run to determine data					
					reproducibility to assess the					
					accuracy of low level samples.					
Laboratory control	EL-V1M6-2008		VI.7.7.3	Yes	TNI does not state that the batch					
samples	Sections 1.6.1,				has to be thrown away if samples					
	1.6.2.2, 1.6.3, 1.7.2.2				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.					
Activity level and	EL-V1M6-2008		VI.7.72	Yes	The TNI states that the matrix					
source of matrix	Sections 1.7.2.2.g,				spikes should be spiked at a level					
spikes and LCS	1.7.2.3.a.vii				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					

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Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences
, i i i i i i i i i i i i i i i i i i i	Reference	Reference	Reference		
		conform to			
		ISO?			
	Ra	diochemical A	Analysis Detai	led Method Review	
					of an LCS.
LCS or matrix spike	EL-V1M6-2008		Not Found	No	The OM CW does not address this
for more than one	Sections 1.7.2.2.g,				issue.
isotope	1.7.2.3.a.vii				
Initial demonstration	EL-V1M6-2008		VI.1.5	Both standards require an	
of capability	Section 1.6.2			IDC to be performed for each	
				instrument and at times when	
				a change of personnel or	
				method occurs.	
PT	EL-V1M2-2008		VI.7.4	No	TNI does not discuss in detail
	Section 5.0, EL-				mixed alpha and mixed beta/gamma
	V1M5-2008 Sections				PT studies.
	1.5, 1.71				
Instrument calibration	EL-V1M6-2008		III.11.6	No	TNI goes into far more detail about
(general)	Section 1.7.1.1				instrument calibration, while the
					OW CM standard only describes
					the basic components of instrument
					calibration requirements.
Alpha and gamma	EL-V1M6-2008		VI.3.1.5,	Yes	TNI does not describe the
spectroscopy	Sections 1.7.1.b.i,		VI.3.1.6		calibration process in detail for any
calibration	1.7.1.b.ii				particular analysis.
Gas~proportional and	EL-V1M6-2008		VI.3.1.2,	Yes	TNI does not describe the
liquid scintillation	Section 1.7.1.b.iii		VI.3.1.1		calibration process in detail for any
calibration					particular analysis.
Scintillation counters	EL-V1M6-2008		VI.3.1.3	Yes	TNI does not describe the
calibration	Section 1.7.1.b.iv				calibration process in detail for any
					particular analysis.
Background	EL-V1M6-2008		VI.3.1,	Neither standard provides	TNI does not state background
measurements	Section 1.7.1.c		VI.3.1.5,	specific procedures to	measurements for every type of
			VI.3.1.6,	determine background	radiation counting instrument.
			VI.3.1.2,	measurements for radiation	
			VI.3.1.1,	counting instruments.	
			VI.3.1.3,		

Subject	TNI Standard	TNI	OW/DWLCP	Similarities	Differences	
, i i i i i i i i i i i i i i i i i i i	Reference	Reference	Reference			
		conform to				
		ISO?				
Radiochemical Analysis Detailed Method Review						
			VI.7.8			
Detection limit	EL-V1M6-2008		VI.3.1,	Yes	The OW CM does not list specific	
	Section 1.5.2.1		VI.3.1.5,		procedures for detection limit	
			VI.3.1.6,		determination or requirements other	
			VI.3.1.2,		than the limits mentioned in the	
			VI.3.1.1,		CFR. TNI describes very specific	
			VI.3.1.3		requirements for detection limits.	
Results with	EL-V1M6-2008		VI.8.4	No	TNI states that uncertain results	
uncertainties reported	Section 1.5.4				should be flagged appropriately.	
					There is no specific mention of this	
					in the OW CM.	
QC program maintain	EL-V1M6-2008		Not Found	No	The OW CM does not mention	
and establish	Section 1.6.2.2				radionuclides in relation to QC	
provisions for					programs. TNI mentions	
radionuclide standards					radionuclides in LCS samples	
					where gamma-ray spectrometry is	
					used.	
Issues of purchase and	EL-V1M6-2008		VI.4.1	Yes	See above "Reagent" discussion for	
labels of standards	Section 1.7.2.5				major differences. In addition, the	
and reagents					OW CM does not mention reagent	
					labeling specifically.	
Cross~contamination	EL-V1M6-2008		VI.3.1.2,	Yes	OW CM does not mention ways to	
and background	Section 1.7.2.7.c		VI.3.1.5,		prevent cross~contamination.	
checks			VI.3.1.6		OW CM does not make clear that	
					background checks for gamma	
					spectrometry are conducted each	
					day of use.	
Laboratory facilities	EL-V1M6-2008		VI.2, VI.4.4,	No	The OW CM is more specific in its	
(general for	Section 1.7.3.7		VI.4.3		expectations of cleanliness,	
radiochemical)					instrument placement, etc. TNI	
					only requires the laboratory	
					facilities to be in such a state as not	
					to attect testing results.	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences
	Ra	diochemical A	nalysis Detai	led Method Review	
Aspects of records and data reporting	EL-V1M6-2008 Section 4.13		VI.8.2, VI8.3, and parts of VI.8.4, VI.8.5, VI.8.6	No	TNI specifies a five-year hold time on all data, while the OW CM requires ten years. 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		VI.7.8	Both discuss control charting.	TNI specifies control charting methods for each type of radiation counting instrument.
Action Response to Noncompliant Laboratory Results	Not Found		VI.9	No	Action taken in response to non- compliant results is discussed only briefly in the TNI standard, however, the OW CM states that the appropriate authorities must be notified when non-compliant results are reported.

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences	
Air Testing Detailed Method Review						
Air Testing			Not Found	No	OW CM only applies to laboratories dealing with water.	
					·	

Subject	TNI Standard Reference	TNI Reference conform to ISO?	OW/DWLCP Reference	Similarities	Differences	
Asbestos Testing						
Asbestos Testing			Not Found	No	OW CM only applies to	
					laboratories dealing with water.	