

TABLE OF CONTENTS

DISCLAIMER	i
INTRODUCTION	1
CHAPTER 1: TNI Accreditation.....	5
1.0 TNI Standard	5
2.0 What is a Quality Management System?.....	6
3.0 Why Get Accredited? The Big Picture.....	9
4.0 Applying for Initial Accreditation	12
CHAPTER 2: Volume 1 Module 1 – Proficiency Testing.....	25
1.0 - 3.0 Introduction, Normative References, Definitions	25
4.0 Requirements for Accreditation	25
4.1 General Requirements	25
4.2 Sample Handling, Preparation, and Analysis Requirements	26
4.3 Reporting Requirements.....	27
5.0 PT Study Frequency Requirements for Accreditation	31
5.1 Initial Accreditation.....	31
5.2 Continued Accreditation.....	32
6.0 Requirements for Corrective Action	33
7.0 Requirements for Complaint Resolution	34
8.0 Requirements for Reinstatement of Accreditation After Suspension or Revocation ..	34
CHAPTER 3: Volume 1 Module 2 – Quality Systems General Requirements	
1.0 - 3.0 Introduction, Normative References, Definitions	35
4.0 Management Requirements	35
4.1 Organization.....	35
4.2 Management.....	40
4.3 Document Control.....	45
4.4 Review of Requests, Tenders and Contracts	48
4.5 Subcontracting of Environmental Tests.....	49
4.6 Purchasing Services and Supplies	49
4.7 Service to the Client.....	50
4.8 Complaints	50
4.9 Control of Non-Conforming Environmental Testing Work.....	51
4.10 Improvement	52
4.11 Corrective Action	52
4.12 Preventive Action.....	55
4.13 Control of Records	55
4.14 Internal Audits.....	57
4.15 Management Reviews	59
4.16 Data Integrity Investigations.....	60

5.0	Technical Requirements	61
5.1	General.....	61
5.2	Personnel	62
5.3	Accommodation and Environmental Conditions.....	71
5.4	Environmental Methods and Method Validation.....	73
5.5	Calibration Requirements	80
5.6	Measurement of Traceability.....	84
5.7	Sampling.....	86
5.8	Sample Handling	87
5.9	Quality Assurance for Environmental Testing	90
5.10	Reporting of Results.....	91
Attachment 1 – DoD QSM Example Table to Help Laboratories Establish Criteria for Support Equipment		94

CHAPTER 4: Volume 1 Module 4 – Quality Systems for Chemical Testing

1.1 – 1.3	Introduction, Scope, Terms, and Definitions	95
1.4	Method Selection.....	95
1.5	Method Validation	96
1.5.1	Validation of Methods	96
1.5.2	Limit of Detection (LOD) and Limit of Quantitation (LOQ)	97
1.5.3	Evaluation of Precision and Bias	101
1.5.4	Evaluation of Selectivity.....	102
1.6	Demonstration of Capability (DOC)	102
1.6.1	General.....	102
1.6.2	Initial Demonstration of Capability (DOC)	103
1.6.3	Ongoing Demonstration of Capability (DOC).....	103
1.7	Technical Requirements	104
1.7.1	Initial Calibration.....	104
1.7.2	Continuing Calibration Verification (CCV).....	106
1.7.3	Quality Control (QC).....	107
1.7.4	Data Acceptance/Rejection Criteria	109
1.7.5	Sample Handling	111

CHAPTER 5: Volume 1 Module 5 – Quality Systems for Microbiological Testing

1.1 – 1.3	Introduction, Scope and Terms.....	113
1.3.1	Key Terms and Definitions	113
1.4	Method Selection.....	114
1.5	Validation of Methods	114
1.5.1	Evaluation of Accuracy.....	115
1.5.2	Evaluation of Precision.....	115
1.5.3	Evaluation of Selectivity (Sensitivity)	116
1.6	Demonstration of Capability (DOC)	116
1.6.1	General.....	116
1.6.2	Initial DOC	116

1.6.3 Ongoing DOC.....	118
1.7 Technical Requirements	119
1.7.1 Calibration.....	119
1.7.3 Quality Control for Microbiology.....	120
1.7.5 Sample Handling.....	132
Attachment 1 – Demonstration of Capability (DOC)	134

CHAPTER 6: Volume 1 Module 6 – Quality Systems for Radiochemical Testing

1.1 – 1.3 Introduction, Scope and Terms.....	139
1.3.1 Key Terms and Definitions	140
1.3.2 Exclusions and Exceptions	142
1.4 Method Selection.....	142
1.5 Method Validation.....	142
1.5.1 Validation of Methods	142
1.5.2 Detection Capability.....	144
1.5.3 Evaluation of Precision and Bias	145
1.5.4 Measurement Uncertainty	146
1.6 Demonstration of Capability (DOC)	146
1.6.1 General.....	146
1.6.2 Initial DOC	146
1.6.3 Ongoing DOC.....	148
1.7 Technical Requirements	148
1.7.1 Instrument Set-Up, Calibration, Performance Checks, and Background Measurements.....	148
1.7.2 Quality Control (QC) for Radiochemistry.....	158
1.7.3 Data Evaluation and Reporting.....	175
1.7.4 Sample Handling	178
Attachment I – Minimum Detectable Activity and Critical Value.....	180
Attachment 2 – Method Validation Study.....	183
Attachment 3 – Measurement Uncertainty	190
Attachment 4 – Selectivity.....	192
Attachment 5 – Radiation Measurements Batch (RMB)	195

APPENDICES..... 197

Appendix 1: Common Findings	199
Appendix 2: Standard Interpretation Requests (SIRs)	203
Appendix 3: PT Expert Committee Guidance Document – PTRL (<i>Placeholder</i>).....	205
Appendix 4: Chemistry Expert Committee Guidance Document – Quantitation (<i>Placeholder</i>)	207
Appendix 5: Chemistry Expert Committee Guidance Document – Calibration (<i>Placeholder</i>)	209
Appendix 6: Standard Operating Procedure (SOP) Templates.....	211