Development Plan

for

TNI National Environmental Laboratory Accreditation Management System (LAMS)

TNI National Database Committee

August 2007

1. INTRODUCTION

1.1 Objective

This document describes the structure and data requirements for a national environmental laboratory accreditation database and, in conjunction with the ITQA Plan, will be used for the development of a request for proposal. Successful deployment entails achieving buy-in and subsequent compliance from the system users.

1.2 Statement of Need

This database is needed to provide a system for tracking environmental laboratory and approved PT provider accreditation status, Field Sampling and Measurement Organizations, provide data to assist with secondary recognition by Accreditation Bodies (ABs) and provide easily accessible data repository using web-based technology for global access by all stakeholders. The system is also needed to provide a central location for method codes, analyte codes, and technology codes.

1.3 History

The NELAC Institute (TNI) National Database Committee was originally formed in 2005, as an Institute for National Environmental Laboratory Accreditation (INELA) committee, and reformed in 2006 under TNI in order to provide the impetus to create a national central repository for information regarding the accreditation status of environmental laboratories. This database system (DBS) will be available to all accreditation bodies, environmental laboratories as well as the general public. NELAC developed a national database, but due to technical difficulties it was never implemented. This development plan has been based on the groundwork provided from the original NELAC national database development plan.

1.4 Stakeholders

1.4.1 NELAP Recognized Accreditation Bodies

1.4.2 State and Federal Accreditation Bodies

1.4.3 Other Accreditation Bodies

1.4.4 Laboratories

1.4.5 Field Sampling and Measurement Organizations (FSMOs)

1.4.6 Engineering and consulting firms

1.4.7 PT Providers

1.4.8 Assessors

1.4.9 General public

1.5 Background

A NELAP Accreditation Body (AB) is a state recognized to accredit Laboratories or Field Sampling and Measurement Organizations for operation within one or more fields of accreditation. The agency requesting recognition as an Accrediting Body must submit an application and supporting material to initiate a request for recognition. TNI is responsible for reviewing the application and the operations of the submitting agency according to the procedures outlined in the TNI standards, policies and procedures. After the application is accepted and agency completes a successful onsite evaluation, the agency is recognized as an Accreditation Body.

Other Accreditation Bodies may wish to use the national database to track accreditation status of those organization to which they offer accreditation. These could be states, federal agencies or other organizations offering accreditation.

An AB is evaluated and recognized for combinations of Matrix-Technology which are known as “areas of recognition.” Specific matrix-method-analyte combinations do not need to be applied for, because the AB is approved to accredit organizations in all of its areas of recognition. The data base will track recognized Matrix-Technology fields of recognition for each AB.

NELAC standards define both primary and secondary ABs. The Primary AB is the AB that actually performs a laboratory onsite assessment and grants accreditation in accordance with applicable NELAC standards. A Secondary AB is an Accreditation Body that grants approval to an organization based on accreditation by its Primary Accreditation Body. This approval is known as reciprocity and is granted on an organization by organization basis. NELAC standards define duties and responsibilities of both Primary and Secondary ABs in implementing reciprocity. Primary ABs will use the TNI database to record any changes in the accreditation status of a laboratory. Secondary ABs will base their reciprocal accreditation on the Primary Accreditation. The primary AA retains responsibility for ensuring that the laboratory complies with applicable NELAC standards, and must notify all secondary AAs of any changes in the accreditation status of a laboratory. Because not all ABs offer the same Fields of Accreditation, it is possible for an organization to have multiple Primary ABs. It is common for organizations to have multiple Secondary ABs.

The NELAC standards specify the steps that an Accreditation Body must take to assess an organization and determine whether to grant NELAP accreditation for one or more fields of accreditation. The Accreditation Body may conduct all necessary reviews and on-site assessments itself, or it may contract with an assessor body to carry out these functions on its behalf. These assessor bodies are also known as third party assessors. In all cases, the Accreditation Body retains responsibility for deciding whether or not to grant NELAP accreditation to the laboratory.

An environmental laboratory seeks NELAP accreditation to conduct tests for specific environmental programs. Different fields of accreditation may be approved by different Accreditation Bodies. Accreditations expire, and they can be revoked or temporarily suspended or withdrawn. Laboratories seeking NELAP accreditation must apply to the AB in their home state of operations. In instances when a state is not participating in TNI and does not have a NELAP AB, the organization may apply to any NELAP AB. Because NELAP accreditation is granted on a matrix-method-analyte basis, it is also possible that an AB has elected not to be recognized for specific fields of accreditation. In these cases as well, laboratories would apply to an AB different than their home state AB.

NELAC standards specify a tiered structure for laboratory accreditation. Accreditation is granted for matrix--method-analyte combinations. The national database will track the primary Accreditation Body that awarded the accreditation for each matrix-method-analyte

along with the effective date of the accreditation status. Dates are needed in order to track the change in accreditation status and provide subsequent notification of any Secondary AB that has accredited that laboratory.

The NELAC standards require that the TNI database track the status of proficiency testing (PT) providers. For purposes of a functional model, recognition of a PT provider by TNI requires the input of detailed contact information and a summary status into the database.

1.6 Product Overview

1.6.1 The TNI national database will incorporate the graphical user interface of today's standard web browser. This user interface is well known by most users, and it is intuitive and easy to learn and navigate for new users. The system will provide Windows-style functionality, including point and click, pull-down menus, tool bars, a status bar, on-screen prompts, dialog boxes, check boxes, and on-line help and documentation. The interface will facilitate data entry as well as reporting and data retrieval. The system will provide on-line data entry screens with immediate error detection and correction, as well as a streamlined batch data submission process. Additional edit checks and validations will be in place, improving the quality of the data. Edit/Update reports will be available to ensure that the data loaded into the database is of the highest quality.

1.6.2 Flexible data retrieval will be supported in the TNI national database, with a choice of standard outputs and reports. Users will be able to choose from categories of selection criteria, with the option of multiple choices in each category. Display pages will allow users to drill down through successive layers of information. Users will be able to generate reports interactively, and may choose to print the report on a local printer or write the output to a file Appropriate levels of security, restricting access, will be provided for each stakeholder group.

1.6.3 Bulk data loads from data files submitted by Accreditation Bodies from their own laboratory accreditation program systems will be accepted.

1.6.4 The system will maintain the most recent 5 years of accreditation status history.

1.7 Product Ownership

All aspects of the product including database schema and structure, queries, forms, reports, modules, web interface and associated coding shall become the property of the database owner.

2.0 DOCUMENT SCOPE

2.1 In Scope

2.1.1 This document defines the data, functions and information technology architecture for the TNI national database. Part of this analysis will define what business functions of the accreditation program will be modeled in the TNI database. This report will address database content and size, logical design, levels of access, security, data entry and display, and on-going maintenance and data administration. The requirements presented in this report were gathered from a review of pertinent standards and technical references, and interviews with key NELAC personnel and members of the NELAC ad hoc national database committee. The requirements are comprehensive as far as the objective stated above. Issues yet to be decided that may impact the stated requirements are presented at the end of the report.

2.1.2 The TNI national database will maintain information about the accreditation status of laboratories, Field Sampling and Measurement Organizations, and approved PT providers. It is designed to maintain method codes, analyte codes, technology codes, and facilitate the sharing of information regarding laboratory accreditations and 3rd party Assessors across government agencies, laboratories, partners, and the general public.

2.1.3 This document defines a data model and functional specification that will meet the objectives for the TNI national database. The functional specification includes attributes of web pages to allow user query, reports, and data entry. These pages will exist in the context of a TNI Web site. While the TNI home page may provide links to individual state Web sites, it is not intended that the proposed national database contain any such general purpose links. The early decision to implement a centralized rather than a distributed database precludes such links.

2.2 Out of Scope

All items out of scope will not be included in this phase of the project. These items may be addressed at a later date as a separate project or upgrade to the system. Items in this section will be considered as they apply to an upgrade path of this product.

2.2.1 PT performance data will not be included in this project. The current charge of the national database ad hoc committee does not include proficiency testing, even though this requirement is spelled out in the NELAC standards. This document does not address data and functional requirements needed to include proficiency testing in the national database. However, with the selection of a relational database, it is likely that these requirements can be accommodated by adding to the design and will not necessitate any major restructuring. The proficiency testing database may, at some future time, be targeted for inclusion in the national database

2.2.2 Advertising for services.

2.2.3 The TNI national database specified in this document is not designed to be used to manage and operate an accreditation program. The individual requirements and existing systems that different primary Accreditation Bodies have for managing laboratory accreditations are beyond the scope of the TNI national database.

3.0 DOCUMENT DELIVERABLES

3.1 Order of Deliverables

3.1.1 Project Plan

3.1.2 Functional Process Analysis

3.1.3 Database Design

3.1.4 System Model

3.1.5 Graphical User Interface Mock Up

3.1.6 Support and Maintenance Plan

3.1.7 Hardware Requirements

The complete document deliverables package must be submitted to, reviewed, and approved by the TNI Database Committee (TNIDBC) prior to development of physical deliverables.

3.2 Acceptance Criteria

The final documents from each of the following tasks will be accepted when it is judged to reflect a system design that is optimized for the TNI requirements. The judgment will be made by the TNIDBC and other experts identified by the TNIDBC. The contractor shall deliver an electronic copy of the draft and final documents to the TNIDBC in Microsoft Word. The briefing shall be scheduled within 10 working days after the document is delivered by consultation with the TNIDBC. Acceptable forms of the briefing may be either a meeting or a conference call or the combination. The appropriate form and scheduling for the briefing shall be worked out in consultation between the TNIDBC and the contractor. If the briefing is done totally or partially by teleconference, at least 5 days prior to the teleconference, the contractor shall provide electronic copies of any slides or other handout material in Microsoft Word or PowerPoint. The TNIDBC and others identified by the TNIDBC shall provide feedback on the draft documents to the contractor at of the briefing and within 10 working days thereafter.

3.3 Project Plan

3.3.1 Overview

Upon issuance of the Delivery Order, the Contractor shall develop a technical proposal (Project Plan) including technical approach, database performance and capability, estimated resources, staffing, deliverables, schedule and cost estimate addressing the requirements of the contract, and the requirements in this Development Plan.

3.3.2 The Project Plan shall address all the requirements established in this Development Plan. The technical approach shall clearly define the proposed methodology for accomplishing the goals of this plan.

3.3.3 Components that must be addressed in the Project Plan

3.3.3.1 Scope

3.3.3.2 Deliverables

3.3.3.3 Work Breakdown

3.3.3.4 Communication Plan

3.3.3.5 Risk Management Plan

3.3.3.6 Comprehensive Test Plan

3.4 Functional Process Analysis

3.4.1 Overview

The contractor shall produce the Functional Process Analysis Document including the design, structure, and flowcharts. The national database will need a subsystem for dealing with fields of testing (FOT), i.e., matrix/method/analyte combinations. This subsystem will include tables for analytical methods, method references, analytes, technologies, and a linking table which defines fields of testing. The TNIDBC will work with the contractor to arrange any needed meetings or conference calls.

3.4.2 Deliverables

3.4.2.1 Draft Functional Process Analysis Document

3.4.2.2 Briefing of TNIDBC and others identified by the TNIDBC

3.4.2.3 Final Functional Process Analysis Document

3.5 Database Design

3.5.1 Overview

The contractor shall develop a logical database design optimized for TNI business processes. The design shall include a description of system's schema, including tables, fields, data flow, input/output, linkages and relationships.

3.5.2 Deliverables

3.5.2.1 Draft Database Design Document

3.5.2.2 Briefing of TNIDBC and others identified by the TNIDBC

3.5.2.3 Final Database Design Document

3.6 System Model

3.6.1 Overview

The contractor shall develop a model for the complete system including the interface

between the database and the web. The system will include provisions for upload of data by the various authorized groups and for download of reports by users. The contractor shall develop draft data standards for uploading all categories of data including: populating the method table, analyte table, technology table, and tracking any changes in recognitions and accreditations. The contractor shall coordinate with the TNIDBC on any questions or unresolved issues.

3.6.2 Deliverables

3.6.2.1 Draft System Model Document.

3.6.2.2 Briefing of TNIDBC and others identified by the TNIDBC

3.6.2.3 Final System Model Document

3.7 Graphical User Interface (GUI) Mock Up

3.7.1 Overview

The contractor shall develop a mock up of the graphical user interface. This mock up will include each page the user will see when navigating the TNI National Database. The mock up will be in enough detail such that the TNIDBC and others can accurately visualize what the final product will look like to the user.

3.7.2 Deliverables

3.7.2.1 Draft GUI Mockup

3.7.2.2 Briefing of THIDBC and others identified by the TNIDBC

3.7.2.3 Final GUI Mockup

3.8 Support and Maintenance Plan

3.8.1 Overview

The contractor shall develop a maintenance and support plan that includes provisions for data archival, backup and restoration, updates to software, hardware and user interface, and response to user questions.

3.8.2 Support Plan Required Elements

3.8.2.1 Data Archival, Backup, Restoration

3.8.2.2 User Interface

3.8.2.3 User Questions

3.8.2.4 Hardware updates

3.8.2.5 Software updates

3.8.3 Deliverables

3.8.3.1 Draft Support and Maintenance Document.

3.8.3.2 Briefing of TNIDBC and others identified by the TNIDBC

3.8.3.3 Final Support and Maintenance Document

3.9 Hardware Requirements

3.9.1 Overview

The contractor shall provide a hardware requirements document that includes provisions for hardware needed to support a system design that is optimized for the TNI requirements.

3.9.2 The plan must address the following elements:

3.9.2.1 Compatibility, including communication protocol and supported devices

3.9.2.2 Performance Specifications

3.9.2.3 Standards

3.9.2.4 Security, including recommended location and access

4.0 PHYSICAL DELIVERABLES

4.1 Software Application

4.1.1 Overview

The database shall be a optimized relational database developed utilizing the current version of either the Oracle or Microsoft SQL Server platform. The web-enabled user interface must be developed utilizing non-proprietary coding with an industry standard application such as Java.

4.1.2 Components

4.1.2.1 Data Architecture

The architecture of the database application and server will be flexible enough to allow future enhancements and will allow data elements to be added or combined without compromising existing functionality. The architecture must also allow for easy data backup, archival, purge and restoration.

4.1.2.2 Data Contents

The data subjects below represent the chief classes of information that must be maintained in order to fulfill the objective of the TNI database. The data subjects represent either a player who acts in the business model, or an object that is acted upon by one or more business functions. These data subjects are broken down into one or more detailed entities in the data model presented in Appendix D.

4.1.2.2.1 Accreditation Bodies

4.1.2.2.2 AB Fields of Recognition

4.1.2.2.3 Accredited Organizations

4.1.2.2.4 Laboratory/FSMO Fields of Accreditation

4.1.2.2.5 PT Providers

4.1.2.2.6 3rd Party Assessors

4.1.2.2.7 Matrix

4.1.2.2.8 Technology

4.1.2.2.9 Method

4.1.2.2.10 Analyte

4.1.2.2.11 Audit Information

4.1.2.3 Custom Queries and Reports

4.1.2.4 Functional Maintenance

4.1.2.5 User Interface

The national database application will be Web-enabled, and all access will be through a current version Web browser installed on the user's workstation. No additional client software will be required. This choice yields maximum ease of use because most users will be familiar with using a browser and navigating through pages via links, browser buttons, etc. Queries, data drill down, and preformatted reports will be provided using pages built with standard Web constructs.

4.1.2.5.1 Manual Data Entry/Manual Data Edit

The data entry portion of the application will be available to authorized users who have a valid user ID and password. Data entry pages will utilize standard Web input features such as selection lists, radio buttons, and command buttons to guide the user through the input process and offer help on entering valid data and provide error checking to ensure all required fields have been entered.

The following forms must be created:

- Create/Change Accreditation Body
- Update Accreditation Body recognitions
- Create/Change Accredited Entity (Laboratory, FSMO)
- Create/Change laboratory's primary field of accreditation
- Create/Change laboratory's secondary field of accreditation
- Create/Change third party assessor
- Create/Change PT Provider
- Create/Change PT Provider fields of proficiency testing

4.1.2.5.2 Bulk Data Upload

Some states already have automated systems to manage their accreditation programs. Typically, these systems are tailored to specific requirements of the state and often have more functionality than is envisioned for the national database. However, these systems do contain information that must be entered into the national database. Periodic automated loading of updated information from existing databases maintained by NELAP Accreditation Bodies is a functional requirement of the national database.

Several different approaches can be considered for bulk data uploading. Because Internet access is a requirement for users of the TNI national database, an electronic method of file transfer will be required. Data will not be accepted on physical media. Automated data transferal requires clearly defined data standards that specify the content, format, and order of the data fields being transferred. For purposes of minimizing processing errors, only new or changed records will be accepted at the server. The system must import an industry standard data transmission file, such as a delimited ASCII text file, XML file, or Microsoft Excel Spreadsheet that is easily produced by the AB and can be readily loaded into the national database using standard data loading tools. These tools must provide mechanisms for data validation and verification. Data loading summary reports will be created to record the results of the data loading, and include any problems or errors that need to be resolved by the

submitter. Files must not import until all errors have been eliminated.

4.1.2.6 Administrative Maintenance Interface

Data administration tasks, which will be the responsibility of the TNI data librarian, will be performed via a Web-enabled interface. No direct database access is anticipated for routine data administration tasks. A TNI data librarian will be required to maintain the login and password table and the Matrix, Technology, Method, and Analyte tables using an interactive Web-based interface. Security criteria and procedures for approving a user for password protected access is defined in the security section of this document. At this time, none of the other reference tables in the database are expected to require routine updating. Any data administration on these tables will be performed through direct database access by the DBA.

The following forms must be supported for manual table maintenance:

- Create/Change Matrix information
- Create/Change Method information
- Create/Change Analyte information
- Create/Change Method-Analyte linkage
- Create/Change Technology information

4.1.2.7 Standard Queries and Reports

Any information displayed or reported must carry the following disclaimer:

"**All information obtained through the TNI National Database is accurate to the best of our knowledge. The quality and accuracy of the data is the responsibility of the appropriate Accreditation Body."**

Standard Queries are intended to answer quick, one-time questions. Query pages will be implemented so that text boxes and selection lists present a structured set of standard fields and offer help on specifying the selection criteria. Multiple criteria can be combined to narrow the expected result set, and wild cards will be allowed where appropriate. For example, one standard query might answer the question "What laboratory is located in a geographic/regional area?" The query would include all laboratories if no selection criteria were specified. Alternatively, the user could enter a selection criteria to create a shorter query that includes just the laboratories in one state or region.

It may be desirable to create different standard query pages for the different user access levels assigned to TNI, Accreditation Bodies, Assessors and Laboratories, and public users.

Results of queries will be presented using dynamic web pages that display the result set in tabular form, with drill down to successive layers of detail. Users must be able to select download or printable report option.

The following standard queries and reports will be supported depending on user security level:

4.1.2.7.1 Accreditation Body List by Type

4.1.2.7.2 3rd Party Assessor List

4.1.2.7.3 Search by Organization Name or Location

4.1.2.7.4 Search by Matrix, Method, and/or Analyte

4.1.2.7.5 Show all FOAs for a specific Organization

4.1.2.7.6 Show Accreditation History of Specific Organization FOA

4.1.2.7.7 Show Organization FOAs on Specific Date

4.1.2.8 Ad Hoc Queries

Based on security access rights, all fields in the TNI database will be accessible for ad hoc queries. Queries will be implemented so that text boxes and selection lists present a structured set of fields and offer help on specifying the selection criteria. Data must be displayed in a table format an allow option for download.

4.1.3 Compatibility

4.1.3.1 The system must support the 3 most popular web browsers, versions spanning from 5 years ago to 6 months ago.

4.1.3.2 System must provide ASCII delimited file output/download for reports.

4.1.4 Performance Specifications

Estimate of database size:

A realistic estimate of the average number of laboratories that will seek accreditation in a state is 500. The NELAC standards require that organizations are accredited on a matrix-method-analyte basis. A unique combination of matrix, analyte and method is known as a field of accreditation (FOA). An organization will need a separate accreditation for each FOA and status change so the number of specific accreditations is potentially large. A realistic estimate for the average number of accreditations that a laboratory will seek is 300. The database will need to hold information on each accreditation and status. A rough estimate of the eventual number of accreditation records can be calculated: 300 accreditations/organization x 500 organizations/state x 50 states = 7.5 M records. It is estimated that 10 percent of the FOA status changes 4 times per year and the system will hold 5 years history so the total expected estimated records = (7.5 M + (7.5 M x 10%)) x 5 years = 52.5 M records. The database will also need to contain several other types of records as discussed.

4.1.4.1 Maximum downtime must be no more than 24 hours.

4.1.4.2 Maximum time to perform searches must be less than 10 seconds for all searches.

4.1.4.3 Data upload and download must take no more than 30 seconds for all uploads and downloads, pending that client system does not slow the process.

4.1.5 Standards

4.1.5.1 Appearance

4.1.5.1.1 Ease of navigation and quick download are a top priority of the GUI design.

4.1.5.1.2 Layout and design of each page must be consistent throughout the application and corresponding web pages.

4.1.5.1.3 The application must look similar in the three required internet browsers. It is not required that the application looks identical.

4.1.5.1.4 One standard font such as Arial or Verdana must be used. No more than 5 different typefaces may be used to the entire system. An example of a typeface would be Arial size 12 bold.

4.1.5.1.5 Standard web colors must be used. A light colored background with a high contrast dark text must be used. No more than 6 distinct colors may be used in the entire interface, excluding images. Images should be used sparingly.

4.1.5.1.6 Links should be text based. Featured items such as buttons, links etc. must be a different color than the informational text. Links should have text descriptors integrated into the link if it is a graphic (image only links to features such as an image of a gear are not acceptable, but an image that contains the word “home” is acceptable).

4.1.5.2 Features

4.1.5.2.1 Ease of navigation is a top priority of the feature design. Features must comply with the above appearance requirements.

4.1.5.2.2 Features should have standard appearance and placement on each page.

4.1.5.2.3 Help menus should be easy to find on each page.

4.1.5.2.4 Features that present the user with data must be easy to read and be available in a printer friendly format, either through separate styles applied to the information when it is printed or via a “printer friendly” link.

4.1.6 Security

4.1.6.1 Access permissions define what operations a user can perform on the database. User access levels define who is authorized to update different portions of the database. TNI, as the oversight body for the accreditation program, defines the criteria by which a user is to be assigned one of the available access levels.

4.1.6.2 TNI

TNI owns the National Database and is responsible for housing information submitted by authorized users. User access levels will be controlled by a login and password that is assigned by TNI. TNI staff also acts as the data librarian and will be responsible for maintaining the login, password, and reference tables.

Authorized TNI users will have access to data input forms and a specially tailored set of reports.

4.1.6.3 Database Administrator

The database administrator (DBA) sets permissions for user access to the database, performs backup and recovery functions, adds or drops tables, and handles other unscheduled activities that may be required for database maintenance.

This level of user access is controlled by TNI and requires direct access to the database. Generally, one database administrator will be selected.

Additional application-level security for specific user functions will be implemented using a login and password table maintained in the TNI national database. Detailed requirements of the application security model are described in Appendix A entitled User Access Control List.

4.1.6.4 Primary Accreditation Bodies

Primary Accreditation Bodies own and are responsible for information about laboratories that they accredit, and the current status and expiration date of all accreditations that they issue in various fields of accreditation.

This level of user access will be controlled by a login and password that is assigned by TNI. A designated user in each primary Accreditation Body will have responsibility for the data for their program. Additional login and password access can be granted at the discretion of TNI. Authorized primary Accreditation Body users will have access to data input forms and a specially tailored set of reports.

4.1.6.5 Secondary Accreditation Bodies

Primary Accreditation Bodies own and are responsible for information about laboratories that they accredit, and the current status and expiration date of all accreditations that they issue in various fields of accreditation.

This level of user access will be controlled by a login and password that is assigned by TNI. A designated user in each primary Accreditation Body will have responsibility for the data for their program. Additional login and password access can be granted at the discretion of TNI. Authorized primary Accreditation Body users will have Third Party Assessors and Laboratories

4.1.6.6 Laboratories/FSMOs

Laboratories and FSMOs are allowed to maintain their own contact and general description of operation information. They do not have authority to update any of the information about their status in the accreditation process. This level of user access will be controlled by a login and password that is assigned by TNI at the request of the AB. One user in each organization will have responsibility for the general data for their organization. Additional login and password access can be granted at the discretion of TNI and the AB. Authorized users will have access to data input forms for their own organization.

4.1.6.7 3rd Party Assessors

Third party assessors are allowed to maintain their own contact and general description of operation information. This level of user access will be controlled by a login and password that is assigned by TNI. One user in each organization will have responsibility for the general data for their agency. Additional login and

password access can be granted at the discretion of TNI. Authorized users will have access to data input forms for their own organization.

4.1.6.8 External Users/ General Public

The TNI national database contains publicly available information. External users are any users other than those described above. This level of user access includes local government, regulated industry, environmental interest or public health groups, academia, and the general public.
External users do not own any data and are not allowed to perform any data input. These users view the contents of the database through standard queries and reports accessible without any login and password control.

4.2 Software

4.2.1 Components

4.2.1.1 User interface software (plugins) required for the application to run on the client computer must be free and easy to download.

4.2.1.2 Development software must comply with the requirements in section 4.1 of this document.

4.2.1.3 The Hardware/Server Operating System must compatible with the application software and the version must be supported by the software vendor.

4.2.1.4 Maintenance Software must compatible with the application software and the version must be supported by the software vendor.

4.2.1.5 All software including development software, maintenance software, client and server software and server operating system software will be compatible with itself and the version must be supported by the software vendor.

4.3 License

4.3.1 The software licenses required to run, maintain and allow users to access the system shall be sufficient to allow The software license should be flexible enough to be able to allow purchasing of additional licenses if the user load is heavier than anticipated. The license shall be maintained as a part of he application maintenance plan.

4.4 User Support

4.4.1 Customer support requirements will be handled through email and on-line documentation. Public access Web sites are generally self-explanatory, and the TNI national database is expected to follow this model. Minimal support may be necessary to assign login and passwords to authorized users at each Accreditation Body. Online help documentation will be comprehensive enough to contain instructions on how to use each feature in the user interface.

4.4.2 The question and complaint form will be available to all users and the contents of the form will be emailed to the person(s) designated to perform those tasks. Questions and complaints submitted will be stored in a historical table in the database and kept for

future reference.

4.5 Documentation

4.5.1 User

All end user documentation will be provided via on-line help that is accessed through the Web browser. Hard copy manuals will not be provided.
Browser features such as selection lists and tool tips will offer a first level of user assistance. An on-line manual with a table of contents and index will be provided for more extensive help. If desired, links to applicable NELAC standards can be set up. A Comments or Help link will be provided for users to email any questions about the national database to designated TNI staff.

4.5.2 Technical

Technical documentation regarding maintenance and common troubleshooting will be provided as an electronic document as part of the software package. This document may or may not be posted on the web. The documentation shall provide sufficient detail to provide instruction for all required maintenance tasks for the hardware, software, data and licenses. It will also provide information to perform common troubleshooting tasks.

5.0 BUSINESS RULES

5.1 Data Update Frequency

5.1.1 Accreditation data must be uploaded to the national database by the Accreditation Bodies at least every two weeks. They may be uploaded more frequently. Upload shall be automated in conformance with a specified data format.

5.2 Change Control

5.2.1 Any changes made to the final development plan and any changes made to the system after it is released shall be made in a controlled manner. Changes shall be documented to include, but not be limited to the following items:

What change will be made
Why the change is being made
Possible consequences of the change being made
Approval of the change
Version of the GUI that the change is contained in
Who made the change
Date the change was made
Who tested the results of the change
Date of the test

5.3 User Profiles and Rights

5.3.1 Different levels of access will be granted to groups of users who share a common profile. TNI and other administrative level users will be permitted full access to all data and functions. Administrative users will be responsible for maintaining the lookup tables for programs, analytes, etc. Accreditation Bodies will be able to update data for laboratories they accredit and have read access to the entire database. Laboratories, third party assessors, and the general public will be able to view the database through the standard query, browsing, and reporting options of the application. See appendices for user groups and rights.

6.0 APPENDICES

6.1 User Classes and Rights

The following table shows allowable access permissions for the classes of users that will use the TNI database. The DBA has direct access to the database and can perform any operation. For all other users, the table indicates what level of access will be provided.

The available operations are: Create, Delete, Update, or Read.

Data Entity	TNI	Primary AB	Secondary AB	Assessors Labs/FSMOs	External Users
AB Description	CRU	RU	RU	R	R
AB Recognition Status	CRU	R	R	R	R
3rd Party Assessors	CRU	R	R	R	R
Organization Description	CRU	CDRU	CDRU	RU	R
Laboratory/FSMO Primary FOA	R	CDRU	R	R	R
Laboratory/FSMO Secondary FOA	R	R	CDRU	R	R
Valid Fields of Accreditation	CDRU	R	R	R	R
Other Reference Tables	R	R	R	R	R

6.2 Data Specifications

{tc \l1 "Appendix C. Sizing Estimates}

The following size estimates will be used to estimate the resource demand the TNI national data base will make on the National Computing Center hardware.

Data Entity	Minimum Rows	Maximum Rows	Update Frequency
Accreditation Bodies	20	75	2/yr.
Third Party Assessors	10	100	5/yr.
Laboratories	1,200	50,000	10/mo.
PT Providers	8	20	2/yr.
Passwords	1,500	100,000	10/mo.
Fields of Accreditation Status	5,000,000	50,000,000	5-200/day
Matrices	5	5	none
Methods	1,200	5,000	10/mo.
Analytes	1,500	5,000	10/mo.

At this time, it is not possible to quantify the expected usage level (or “number of hits” per day) of the TNI database. No comparable system exists on a national level.

6.3 Database Data Elements

Common Location and Contact Information

- Street address 1
- Street address 2
- City
- State/ Province
- Country
- Postal Code
- PO Box
- PO Box zip
- Contact Person (First and Last)
- General contact phone
- General contact fax
- General contact email
- Website

Accreditation Body (AB)

- Primary unique identifier (AB ID)
- Common Location and Contact Information
- Accreditation Body Code (state abbreviation or two-letter AB code)
- EPA region (1-10)
- AB time zone
- Hours of operation
- Environmental Laboratory Accreditation Program Manager
- Quality System Officer
- Overall recognition status for AB
- Effective date for status (null allowed if recognition not yet approved)
- Fields of Recognition (Matrix-Technology)
- Performs Out-of-State Accreditation (Y/N)
- In-State Fee (Y/N)
- Out-of-State Fee (Y/N/NA)
- URL to AB home page

Proficiency Testing (PT) Providers

- PT provider organization ID
- Common Location and Contact Information
- Approved Fields of Proficiency Testing
  - Program
  - Matrix
  - Technology
  - Method
  - Analyte
- PT provider status
- Effective date of status
- Primary unique identifier
- Program

Laboratories/FSMO

- Laboratory/FSMO ID
- EPA ID Code
- Common Location and Contact Information
- Active (Y/N)
- Effective date of overall accreditation
- Owner
- Technical Director
  - Name (First and Last)
  - Disipline
- Type
  - Federal
  - State
  - Municipal
  - Industrial
  - Commercial
- Hours of operation
- GIS Location
- Fields of Accreditation
  - Program
    - Matrix
    - Method
    - Analyte
    - FOA Type
      - NELAP Primary
      - NELAP Secondary
      - State
        - Other
    - Status
    - Effective Status Date

Third Party Assessor Organization

- Assessor organization ID
- Common Location and Contact Information
- Contact person
- URL to assessor organization home page

User

- Person unique identifier (login ID)
- Person name (First and Last)
- Person organization
- Person phone
- Person fax
- Person email
- Security Level

Reference Use

Status

- Applied
- Denied
- Expired
- Revoked
- Suspended
- Withdrawn

Analytes – each record contains:

- Analyte Code
- Analyte name (allowable set of names to be determined)
- Analyte Type (VOC, Metals, etc)

Laboratory Certificate Status – allowable values are:

- Approved
- Interim
- Suspended
- Revoked
- Expired

Programs – allowable values are:

- CAA
- CWA
- SDWA
- CERCLA
- RCRA
- FIFRA
- TSCA
- State

Matrix Description – allowable values are:

- Air
- Drinking Water
- Non-potable Water
- Solids & Chemical waste
- Biological Tissue

Methods – each row contains:

- Method Code
- Method Name
- Method short name
- Method description
- Method Revision/Edition
- Method Revision/Edition Date
- Citation
- Technology
    - Technology Name
    - Technology Description
    - Scientific Disciplines
        - Organic Chemistry
        - Inorganic Chemistry
        - Microbiology
        - Microscopy
        - Radiation Chemistry
        - Whole Effluent Toxicology (W.E.T.)