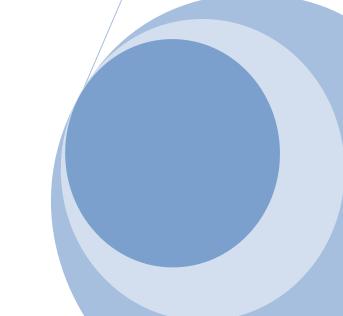


Environmental Laboratory Data-Online (ELDO) 2010

Technical Manual and User Guide for Environmental Laboratories rev. 12/2010

MN-ELAP 601 Robert Street North St. Paul, MN 55155 (651) 201-5200 www.health.state.mn.us/accreditation



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Acknowledgments

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ELDO 2010

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Introduction

Chapter One: Introduction The Minnesota Department of Health's Environmental Laboratory Accreditation Program (MN-ELAP) uses its Environmental Laboratory Data —Online (ELDO) system to do more than just track certifications. The system is comprehensive, enterprise software designed to help regulatory personnel and laboratories track all accreditation information. The system will capture and report current accreditation, accreditation history, assessment information, proficiency testing data, and laboratory documents. The system is designed to help solve the challenges of data entry and document management facing laboratories and accreditation bodies.

WHAT YOU CAN DO WITH ELDO

You can use ELDO to create, view, store, and report data collected from certificate applications, assessments, proficiency testing studies, and documentation for environmental laboratories. The system is divided into five main menu options:

Application: The module used to apply for initial accreditation, renew your current certificate, add or drop fields of testing, change laboratory information, or request to re-instate your accreditation after resolving the reasons for suspension.

Assessments: The module name "Assessments" may be somewhat misleading because MN-ELAP uses this module not only for responses to typical onsite assessments of laboratories but also for receiving and tracking your responses to other errors or missing information in your laboratory file. The module is used anytime MN-ELAP requires a written response from you.

Documents: The module used to upload or update laboratory documents related to obtaining or maintaining accreditation.

Proficiency Testing: The module to view and track proficiency testing data received by MN-ELAP from approved PT Providers.

Reports: The module used to view your laboratory's current scope of accreditation and certificate.

CLIENT REQUIREMENTS

Web browser with JavaScript enabled (Mozilla Firefox[™], Internet Explorer[™], Chrome[™], or others). ELDO requires no special software; it is web-based and completely portable/accessible through any internet connection.

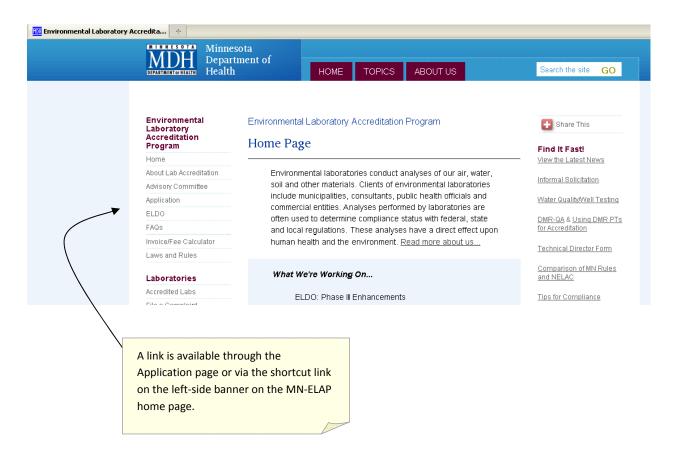
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The Basics/ELDO 101

Chapter Two: The Basics/ELDO 101 ELDO is a versatile application for maintaining accreditation information for environmental laboratories and their accreditation bodies. The system is easy to use and saves time by automating tasks.

USER ACCESS

The ELDO system is maintained on the Minnesota Department of Health's Environmental Laboratory Accreditation Program (MN-ELAP) webpage (www.health.state.mn.us/accreditation).



All system users are approved through MN-ELAP and the MDH Information Systems & Technology Management Division (IS&TM). Four levels of access exist in ELDO: Administrative (MN-ELAP management); Assessor; Program Partner (state and federal agencies); and

Laboratory. Assessor, Program Partner and Administrative users are approved by the MN-ELAP manager with usernames established by the IS&TM development staff. Laboratory users are approved by the MN-ELAP manager based on a Request for User Access form submitted through ELDO.

Login	
Enter	your username and your MDH-authorized password:
User	ID
Pass	word
Remo	ember me
Login	Register New User
	Laboratory users without an approved log-in
	must register with the MN-ELAP for approval
	to use the system.

The Request for User Access form requires data about the user and the laboratory so users may be appropriately matched to the laboratory they represent. MN-ELAP approves each user on a case-by-case basis with the written approval of the laboratory owner, director, or primary contact.

Request New User	
User ID*	
Password*	
Confirm Password*	
First Name*	
Last Name*	
Organization*	
EPA Id*	
Email*	
Phone *	
Fax	
Request Access	Cancel

The description for each of the required items on the form is as follows:

UserID	The suggested username format is 'lastname111' (i.e. the user's last name followed by the last three digits of the MN-ELAP assigned laboratory number). Usernames should not include spaces or special characters. The usernames are case-sensitive.
Password/Password Confirmation	The password is selected by the user and encrypted by the system. The system requires confirmation of user's entry accuracy by re-entering the password on this user access screen. Passwords should include at least eight characters. The selected password must be mixed-case, alphanumeric with at least one special character.
First Name/Last Name	The first name and last name of the individual requesting access.
Organization	The laboratory name for which the user is requesting access.
EPA ID	The USEPA-assigned lab code for which the user is requesting access (e.g. MN00000). This code is NOT the MN-ELAP assigned laboratory number.
Email	The electronic mailing address where confirmation of the user's approval and any ELDO system announcements will be delivered.
Phone	The phone number where the individual may be reached for questions.
Fax (optional)	A fax number, if desired, where communications may be delivered by MN-ELAP concerning this account.

The ELDO system allows multiple Laboratory users for each laboratory. If the laboratory management authorizes more than one person to access the laboratory's information in ELDO, any of the users may perform the tasks allowed in ELDO. For this reason, MN-ELAP requires a username and password combination attributable to one person rather than one log-in associated with a group of persons at the laboratory.

		4	
A Your user request t	for 'susan' has been submitted successfully! You will be notified when yo	ur user request is approved!	
		\	
Lo	ogin		
			A.II
E	inter your username and your MDH-authorized password:		All user requests are manually reviewed
ı	User ID		by the MN-ELAP manager and approved
	Password		
'	Passworu		on a case-by-case basis. Notification of
ı	Remember me 🔲		the approval or denial of the request will
			the approval of defilat of the request will
Lo	ogin Register New User		be delivered via electronic mail.

TERMS OF USE AND ELECTRONIC SIGNATURE

To access the ELDO system, users must review and agree to the Terms of Use. The Terms of Use will appear each time the user accesses the system. Failure to agree to the terms will result in denial of entry to the ELDO system and will return the user to the MN-ELAP webpage.

Printer-Friendly

Terms of Use Agreement

Pursuant to Minnesota Statutes Chapter 325L, I agree submitting information through this application constitutes an electronic signature for all actions and documents requiring signature under Minnesota Statutes 144.98 and Minnesota Rules, Chapter 4740. Where the 2003 NELAC Standard, as adopted in Minn. Stat. 144.98, requires a record or notification to be in writing, submitting the record or notice through this application satisfies the law.

By accessing this application, I agree to restrict the use of my username and password to laboratory representatives authorized to submit documents and make changes to general laboratory information. By agreeing to this provision, I understand that unauthorized use of my account must be reported immediately, in writing, to the Minnesota Department of Health. When notified of unauthorized access, the Minnesota Department of Health will request my verification of the accouracy of recent changes to the account and will issue a new, secure login to me.

I understand and acknowledge that my laboratory is required to be continually in compliance with the 2003 NELAC Standard, as adopted in Minn. Stat 144.98, and with the provisions in Minnesota Rules, Chapter 4740, parts 4740.2010 to 4740.2120, regarding the certification requirements for environmental laboratories.

I understand that the laboratory is subject to the enforcement and penalty provisions of the State of Minnesota

I certify that I have not submitted information through this application that is classified as "trade secret" or "not public" under the Minnesota Data Practices Act. I understand that accreditation program information is public unless designated by me as meeting conditions for trade secret classification.

I certify that I am the designated representative of the applicant/owner and that there are no misrepresentations in my submitted information and any related documentation required for compliance with accreditation requirements.

Except for laboratory identifications, any information saved in this application and not submitted to the Minnesota Department of Health within 60 days of initiating the action will be removed.

Disagree Agree

Agreement with the Terms represents a signature by the user assigned to the usernamepassword combination for all actions, entries and uploaded information contained in the ELDO system for the laboratory of record.

Unauthorized use of the user's account must be reported immediately to the Minnesota Department of Health via the MN-ELAP's email address (health.mnelap@state.mn.us) or mailing address at Minnesota Department of Health, Attn: MN-ELAP, 601 Robert Street North, St. Paul, MN 55155.

PROFILE MAINTENANCE

Passwords should be changed periodically to maintain security. User profiles, including password changes, may be updated by clicking on "My Account" above the Login/Logout prompt on the home screen.



Profile maintenance does NOT include changes to your username or removal of users from access to a particular laboratory account. User accounts may only be de-activated by MDH IS&TM through referral by the MN-ELAP manager.

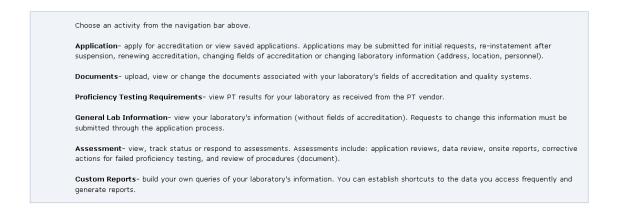


Users should periodically review their profile to maintain updated email addresses and phone numbers. The contact information here is not synchronized with the general laboratory information supplied on the application.

BASIC NAVIGATION

The ELDO home screen for Laboratory users includes a description of activities available to perform in ELDO. The home screen will be updated to include links to the ELDO User Guide as well as provide information regarding the availability of new features, improvements or navigation tools.

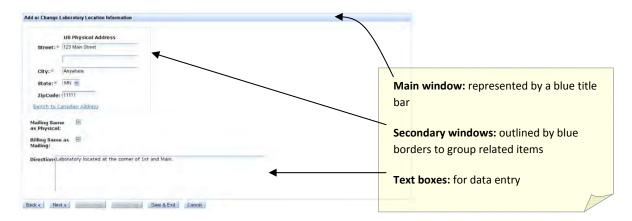
The current system allows laboratories to apply for accreditation, upload or update documents required for accreditation, view proficiency testing results, view general laboratory information, review and respond to assessment reports initiated by MN-ELAP, and review reports.



Similar to MS Word and most internet browsers, all ELDO user screens include a navigation bar across the top. Each menu option in the navigation bar includes specific actions in drop-down boxes beneath the menu title.



Throughout the system, screens are divided into window views, for example:



Pages also include *navigation buttons*. Blue navigation buttons indicate available choices; gray indicates the action cannot be performed. Use the <u>Next</u> button to advance to the next screen as you progress through the system. <u>Save&Exit</u> will saves your work and returns you to the main menu. <u>Cancel</u> will return you immediately to the main menu and will NOT save your work.



Various other buttons or links such as those below will initiate actions in specific screens.



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Applications

Chapter Three: Applications Laboratories may apply for accreditation for the fields of testing (FOT) available in the ELDO system. MN-ELAP posts a list of available fields of testing under the Application link on its webpage (www.health.state.mn.us/accreditation). The list is supplied in CSV format and is available to the general public; no username or access is required.

APPLICATION TYPES

The ELDO system categorizes applications:

Initial – application available to laboratories new to MN-ELAP. Includes laboratories previously accredited by MN-ELAP but not active for more than six years (the retention period for all MN-ELAP laboratory files).

Renewal – application available to laboratories already accredited through MN-ELAP. This application type is available from 120 days prior to the expiration date of the laboratory's current certificate through six years after the expiration date of the last certificate issued. The certificate issued upon acceptance of the application will be December 31st of the following calendar year.

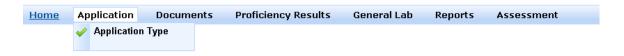
Add/Drop FOTs – application available to laboratories already accredited through MN-ELAP. The application is not available during the renewal period (see Renewal description above). A change fee is required to submit this application. The change fee is equal to the category fee specific to the FOTs selected. The certificate issued upon acceptance of the application will be unchanged from the expiration date on the laboratory's current certificate.

Change Lab Information – application available to all laboratories. A change fee is required to submit this application. The change fee is \$250.00 for each application requesting changes in ownership, location, or personnel (technical directors). For this reason, initial applicants should choose the Initial Application rather than the Change Lab Information option.

Request for Reinstatement – application available to laboratories already accredited, but suspended, through MN-ELAP. The application must be completed prior to submitting an application for renewal. No fee is associated with submitting this application.

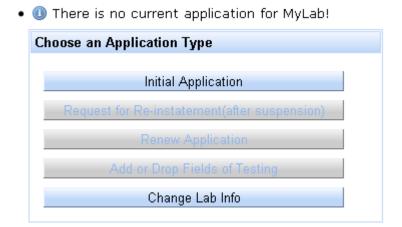
Categorizing allows the system to assign appropriate user access, turnaround times, and fees to each application.

To begin an application, select Application Type from the Application drop-down menu.



In the Application Type menu, the types available to the user are designated by *blue* navigation buttons.

If all buttons are gray, this means an application has already been submitted to MN-ELAP for review. Only one application may be submitted at a time.



After selection of the application type, the ELDO system will notify the user if an application of the same type has already been started (saved) in the system. Saved applications may be edited by any of the laboratory's authorized users. Saved applications are not viewable by MN-ELAP. Select the <u>SAVED</u> link or <u>EDIT</u> button to review the saved work and proceed to the end of the application to select the <u>SUBMIT</u> button and send to MN-ELAP. You may choose to remove the saved application by selecting the <u>Remove</u> link.



If there is no current application, the system will indicate this and ask the user to start a new application.

① There is no current application for MyLab!

Start New Application

ENTERING GENERAL LAB INFORMATION

Applications for initial, renewal, or change laboratory information requests begin with general laboratory information regarding name, location, address, directions, and personnel. Items identified with a red asterisk (*) indicate required entries. Applicants from laboratories already accredited through MN-ELAP will edit pre-populated fields. New applicants are required to fill in all details.

Add or Change General Laboratory Information Laboratory MyLab Name (legal):* Lab -- Select -- Description:* Accepts samples from private home owners: Business Hours:* Next > Instructions Pest Page Save & Exit Cancel

If the **laboratory accepts samples** directly from individuals (e.g. private homes, cabins), click in the checkbox to indicate the laboratory may be included in pamphlets, brochures, webpages, and general publications supplied to organizations and the general public regarding requests to test non-regulatory samples. Typically, the requests received by MN-ELAP are for laboratories available to test drinking water in private residences.

The laboratory-supplied business hours will assist MN-ELAP in scheduling assessments during hours when the majority of the laboratory staff is routinely available.

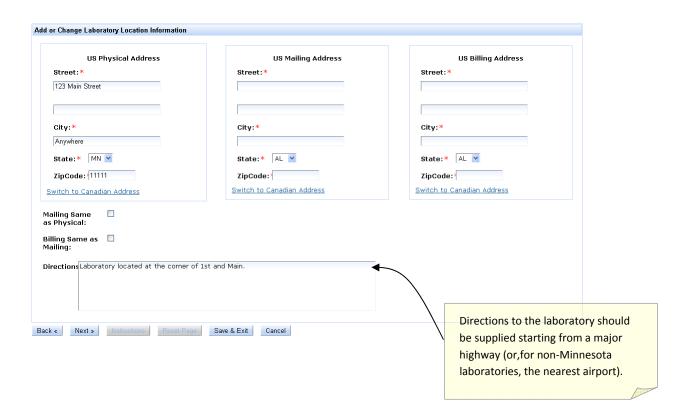
The laboratory description gives the user a drop-down menu of several choices.

Laboratories meeting the description in more than one category should contact MN-ELAP for instruction prior to selection.



There are several screens requiring

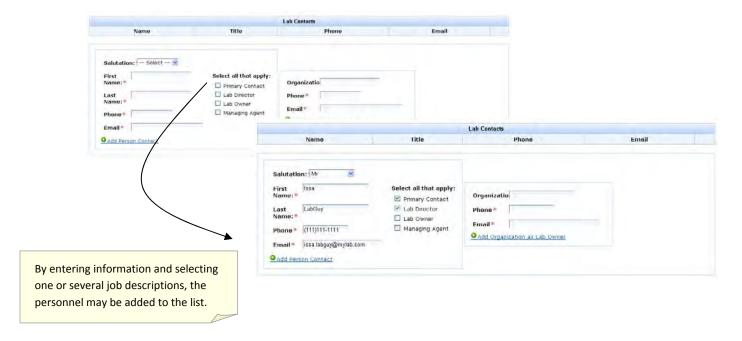
addresses for the laboratory and laboratory personnel. The first address screen requests physical location, mailing address, and billing address. Shortcut checkboxes below the requested addresses can be selected if the laboratory has one address that satisfies the conditions identified (i.e. mailing address same as physical location, or billing address same as mailing address).



Laboratory contact information is included in three parts. The top of the next screen requests contact information for the laboratory, the laboratory owner, and the quality manager.



The bottom of the same page requires the entry of personnel information for four main laboratory positions as required by Minn. Rules, Chapter 4740: the laboratory director, the managing agent, the primary contact person, and the laboratory owner.



Phone numbers should be entered as numbers only. ELDO will standardize the format automatically as you type.

Select the <u>Add Person Contact</u> link to add a person to the list. Personnel information entered into the application will appear in a list above the Lab Contacts window as they are entered.

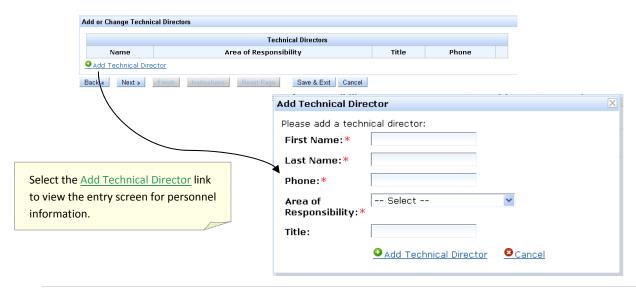
If the laboratory is owned by an organization, you may choose to enter the organization name, phone number, and an email address where a responsible party may be contacted. If you choose to enter an organization as the owner, the Laboratory Owner position will disappear

from the required personnel selection list and the organization name will appear in the Lab Contacts list.

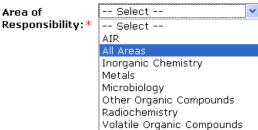


Personnel may be removed from the list by selecting the <u>Remove</u> link at the end of the row displaying the person's contact information. Removing personnel information for one of the required position descriptions will require adding a person to fulfill the role before the system will allow you to proceed to the next screen.

On the next screen, ELDO requires entry of at least one technical director for each laboratory. The technical director must meet the qualifications for accreditation. A worksheet is available on the MN-ELAP webpage under the Application link to assist laboratories in identifying qualified candidates. Documentation of personnel qualifications must be maintained in the personnel files at the laboratory. For laboratories applying for secondary accreditation, the list of technical directors must match the list submitted with the laboratory's primary application. Only technical directors recognized by the primary accreditation body and meeting the qualifications of MN-ELAP will be recognized.



Technical directors must be qualified for the laboratory areas they supervise. The applicant may assign the appropriate areas of supervision to each technical director named. If the technical director supervises all areas (i.e. laboratory director), select "All Areas" from the drop-down menu. If the technical director supervises more than one, but not all areas of the laboratory, add the contact information separately for each responsibility area (i.e. add the person to the list multiple times).



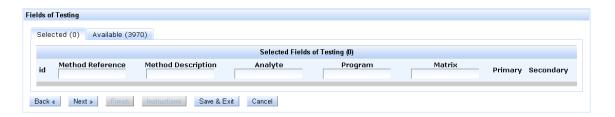
Select the <u>Add Technical Director</u> link to add a person to the list. Personnel information entered into the application will appear in a list above the Technical Directors window as they are entered.



ENTERING FIELDS OF TESTING INFORMATION

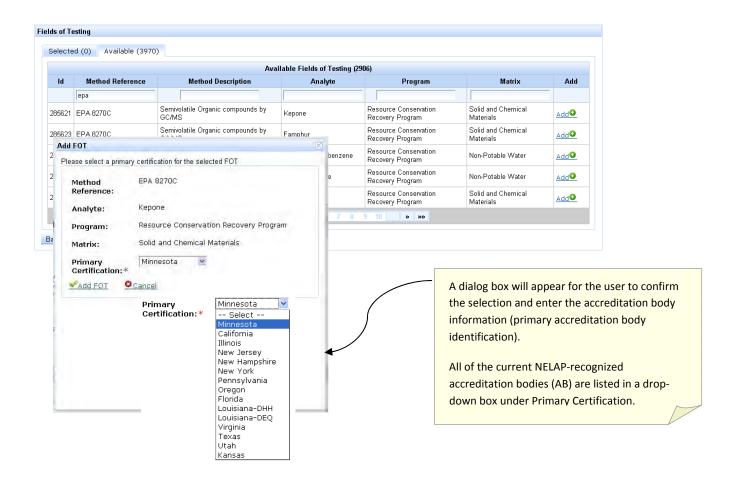
The Fields of Testing main window includes two folder tabs: Selected and Available. If the laboratory is already acccredited by MN-ELAP, the list of FOTs on the laboratory's current scope of accreditation will appear in the Selected folder tab.

ELDO includes a pre-approved list of fields of testing from which laboratories may request accreditation. The available fields of testing not yet selected by the laboratory are listed under the Available tab.



To find fields of testing on the list, the user selects the Available tab filters the list by typing the initial search characters at the head of any of the columns. More than one column may be filtered at once.

To add a field of testing, the user selects the Add link at the end of the corresponding row.



When all required information is entered, select the <u>Add FOT</u> link to add the field of testing to the Selected tab in the Fields of Testing window. The application will jump to the Selected tab after each selection. You may continue to add FOTs to the application by selecting the Available tab and repeating the steps. Choose the <u>Next</u> button when you are finished making selections.

Corrections to the laboratory's selected Primary AB can be made through the Selected tab, if needed. To delete an FOT from the application, select the <u>Remove</u> link.



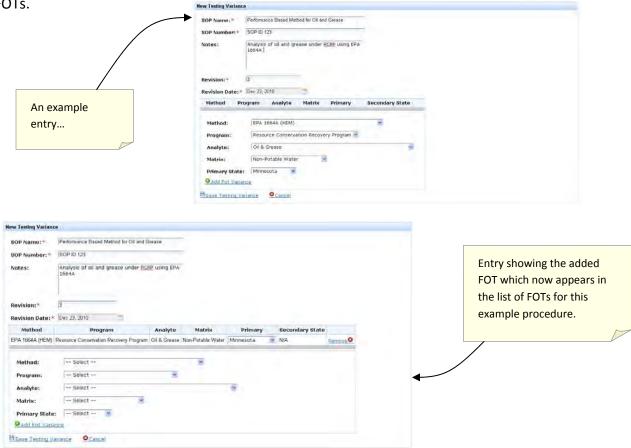
REQUESTING A VARIANCE FROM APPROVED METHODS

The next screen of the application allows the applicant laboratory to request a variance from using/applying for methods on the Available FOTs list. A variance fee is charged for each standard operating procedure entered in lieu of selecting one of the available FOT combinations. Requests for variance are typically used for performance-based, laboratory-developed methods or for the addition of analytes to an existing reference method.

To request a variance, the user must enter the title of the standard operating procedure, the SOP number (i.e. The number assigned by the lab to identify the document.), a revision number, revision date, and each individual FOT for which the procedure is used and for which a variance is requested.

ew Testing Variance				
SOP Name:*				
SOP Number:*				
Notes:	'			
1100031				
Revision:*				
Revision Date:*				
Method Pro	gram Analyte	Matrix	Primary	Secondary State
Method Pro	gram Analyte	Matrix	Primary	Secondary State
Method Pro	gram Analyte	Matrix	Primary	Secondary State
		Matrix	Primary	Secondary State
Method:	Select	Matrix		Secondary State
Method: Program:	Select	Matrix		<u>v</u>
Method: Program: Analyte:	Select Select Select	Matrix		<u>v</u>
Method: Program: Analyte: Matrix:	Select Select Select Select Select	Matrix		<u>v</u>

Upon entry of each FOT covered by the procedure, the user must select the <u>Add FOT variance</u> link to enter the selected FOT on the list. After all FOTs are added to the list, the user must choose to <u>Save Testing Variance</u> to save the overall procedure information and all selected FOTs.



The saved Testing Variance appears in a summary list. Additional testing variances (i.e. additional standard operating procedures) may be added to the list by selecting the Add Testing Variance link and repeating the steps above.

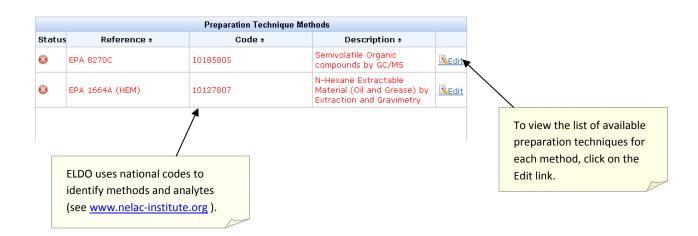


SELECTING PREPARATION TECHNIQUES

The ELDO system associates required preparation techniques with the applicable methods. As with the fields of testing available in ELDO, the preparation-method associations only cover preparation techniques entered into the ELDO system by MN-ELAP, not ALL preparation-method combinations are available for accreditation.

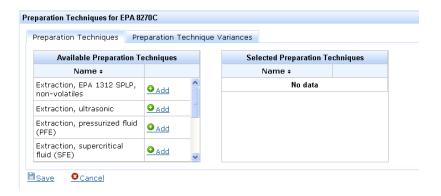
If a preparation technique is required to perform the method but not listed as an option in the ELDO preparation-method combinations, the laboratory must continue to comply with the preparation requirements of the method.

Methods with preparation techniques associated are designated in the next screen by appearing in a list. The methods represented in red are methods for which a preparation-method association exists but the laboratory has not yet selected the preparation performed. To view the list of potential preparation techniques, click on the Edit link at the end of the corresponding row.

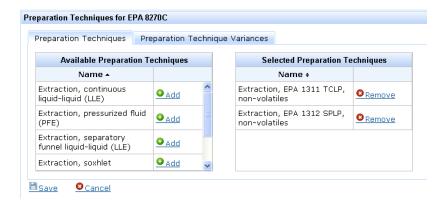


A list of available preparation techniques will appear. The method reference is highlighted in the navigation bar of the main window. A secondary window shows two folder tabs: Preparation Techniques and Preparation Technique Variances.

To add a preparation technique to your application, click the Add link.



The selected preparation technique will move to the Selected Preparation Techniques window. To remove a selected preparation technique, select the <u>Remove</u> link. The removed preparation technique will move back into the Available Preparation Techniques window.

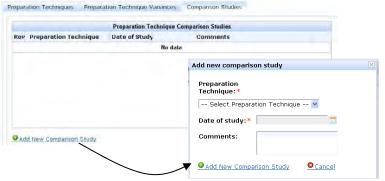


ELDO allows a second option for selecting preparation techniques. Laboratories may create a custom Preparation Technique Variance. When the Preparation Technique Variance file folder tab is selected, a window appears allowing entry of the name and description of the preparation technique used.



You should NOT enter Preparation Technique Variances without first contacting MN-ELAP for instruction. Variances entered here are used for temporary requests from a laboratory and may be used by MN-ELAP to expand the list of available preparation techniques. Permanent requests for variance are assessed an application fee of \$500.00 per request and are reviewed by MN-ELAP on a case-by-case basis.

For some methods, a third option is available and appears as a third folder tab in the Preparation Techniques window. Methods which allow a comparison study in lieu of the preparation (e.g. ammonia or fluoride distillations) will trigger a Comparison Study tab to appear. Select Add New Comparison Study link, select the replaced preparation technique, and enter the study information.



When you have completed your selections, click on the <u>Save</u> link below the Preparation Technique windows to save your selections and associate the preparation techniques with the method on your application.

You will need to repeat this process until you complete the association of all methods requiring a preparation technique. A status screen shows your progress toward completing the required associations. Items in red text mean that a required association has not been completed.

	Preparation Technique Methods				
Status	Reference +	Code +	Description +		
V	EPA 8270C	10185805	Semivolatile Organic compounds by GC/MS	<u>REdit</u>	
&	EPA 1664A (HEM)	10127807	N-Hexane Extractable Material (Oil and Grease) by Extraction and Gravimetry	<u>REdit</u>	

When you see a green checkmark in the status column, this means that a preparation technique has been assigned. When all associations are complete, ELDO will allow you to move to the next page.

REVIEWING AND SUBMITTING THE APPLICATION

At the end of the selection process, you must view a summary of the entered information. The summary page may be printed for your records using your web browser's print option (File/Print, or Ctrl+P). This is the official record of your application for accreditation.



When you are finished reviewing the accuracy of the application, you must select Finish & Submit to send the application to MN-ELAP for review. If you are not ready to send the application to MN-ELAP, you may select Save & Exit to return to the application.

Saved applications can be edited by selecting the <u>SAVED</u> link and progressing through the application steps outlined in this guide.

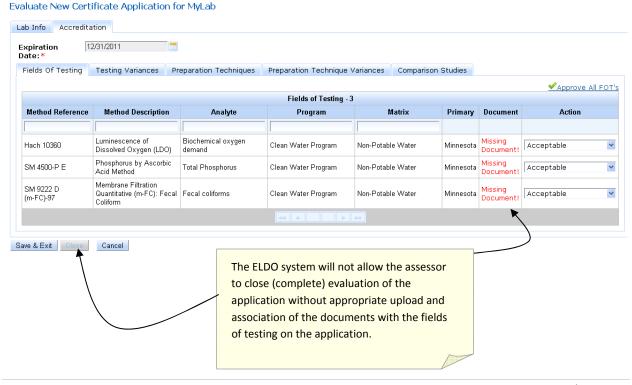


Saved applications will be accessible in the ELDO system for 30 days from the date of last activity or up to 120 days prior to the expiration date of the laboratory's current certificate, whichever is sooner.

When a laboratory submits the application, a message appears to indicate that the application is in the evaluation process by MN-ELAP. Until the evaluation is complete, no other applications may be submitted by the laboratory. The options will all be grayed out indicating they are not accessible.



After submitting the application, proceed to the Documents module and view the list of required documents. See Chapter 5 of this User Guide for instruction on the Documents module.



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Assessments

Chapter Four: Assessments Assessors will initiate a request for a corrective action response using the following assessments types: Onsite, Follow-up, Document Review, Application Review, and Proficiency Testing (PT) Review. Assessments are identified by a numerical code; categorized by type; and assigned a status for tracking turnaround times and actions required.

SEARCHING AND VIEWING ASSESSMENT REPORTS

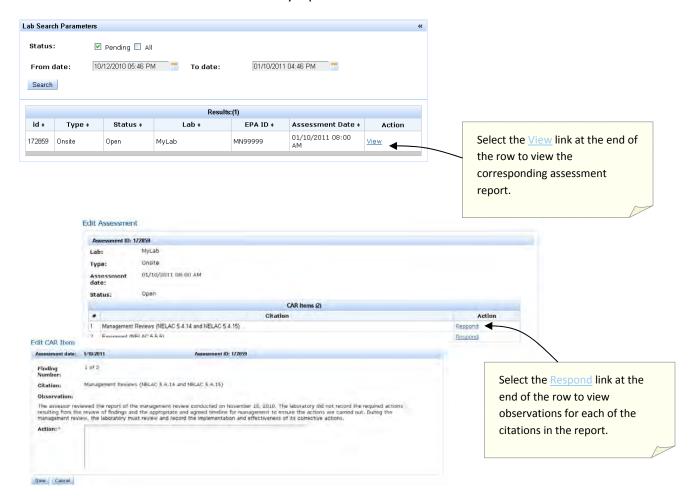
The assessment reports and findings are assigned a status. Each status indicates a particular action required and responsible party who must perform the action. The table below lists the various status designations, the responsible party, and the expected action. Table rows with yellow highlights indicate a status associated with a required <u>laboratory</u> action.

Assessment Report Status	Indicator/Use
Draft	Requires Action by: Assessor The initial status assigned to assessment records for scheduled or completed assessments with findings not fully documented or released to the MN-ELAP Admin for peer-review.
Review Open	Requires Action by: MN-ELAP Admin The assessment activities are completed and findings have been documented. The report is now ready for peer-review before release to the laboratory.
Open	Requires Action by: Laboratory The assessment report has been reviewed for conformance to the standard, clarity, and consistency. The report is now ready for the laboratory's corrective action response entry.
Pending Review1	Requires Action by: Assessor The laboratory has entered responses to all findings and submitted the responses through ELDO. The responses are ready for review by the assessor.
Additional Info Required (if needed)	Requires Action by: Laboratory The laboratory's first corrective action response has been rejected by the assessor and requires additional detail before the report can be closed. The findings with rejected responses will be labeled as Additional Info Required. Acceptable responses will be labeled with a status of 'Closed' (see below). The assessor will enter a comment for clarification of expectations or clarification of the finding. The laboratory must enter a second, final response.
Pending Review2 (if needed)	Requires Action by: Assessor The laboratory's second response is ready for review by the assessor.
Closed	No further action required unless findings are unresolved. The assessment will be closed and any unresolved findings will be forwarded to the program manager. The program manager will open a new assessment recommending enforcement action by the commissioner.

Choose the Assessment module menu option and enter search criteria (data range) and status. 'Pending' means the assessment requires a response from you. Choose ALL to find all assessments entered into the ELDO system. The columns may be sorted by clicking on the column title.

RESPONDING TO AN ASSESSMENT

When you are notified that an assessment is available for your corrective action response, enter the Assessment module and search for any Open assessments.

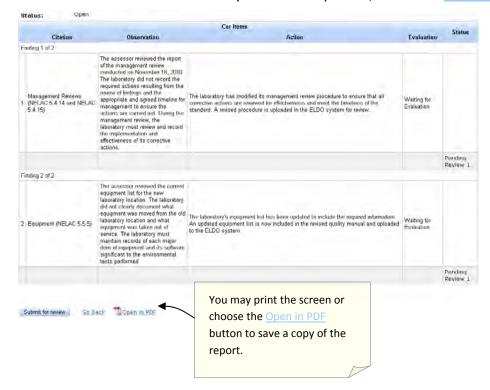


Enter your response in the Action text box and select the Save button to return to the Edit Assessment screen (i.e. the main page with the list of citations).

The Edit Assessment screen will help track your progress in responding to all assessment findings in the report. Continue selecting each finding and entering your responses. When there are no more findings with Respond in the Action column, you have completed your draft response to the report.



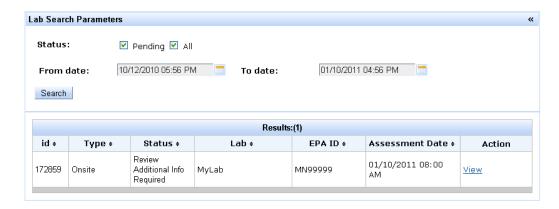
To view all assessor observations and your draft responses, select the View Summary button.



To edit responses, select Go Back to return to the list of citations. Select the Submit for Review button when you are ready to send your responses to MN-ELAP.

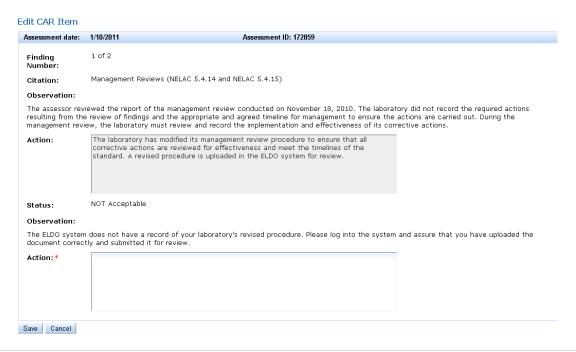
SENDING A SECOND CORRECTIVE ACTION RESPONSE

If the laboratory's response is not acceptable to MN-ELAP, the assessor will reject the plan for corrective action and request a second response from the laboratory. Assessments requiring a second attempt at corrective action are assigned a status of Additional Info Required.



The laboratory will enter the second corrective action response in the same manner as the first. The view will show the original observation, the laboratory's initial response, the status/assessor evaluation, and the assessor's new entry clarifying the observation or reason for rejection of the first corrective action response.

The laboratory will enter its second (and FINAL) response in the text box provided. After two failed attempts to correct the reason for the finding, the assessor will close the assessment report and direct the program manager to recommend enforcement action.



If you are unsure about how to respond or what the requirements are, please contact your assessor before submitting a second response. The assessor or program manager may be able to help clarify the finding for you.

When you are finished responding to the findings, continue to the View Summary page and select the Submit for Review button to send the responses to MN-ELAP.

ENFORCEMENT ACTIONS

Once you submit responses, you will not be able to change them. The system will not allow assessors to release the report back to you for editing. MN-ELAP staff only have the option to reject your response and send the assessment back to you to enter a second attempt for correction or to close the report and forward the findings for enforcement action.

The system will continue to save your responses and will show all responses in the official record. For this reason, the Submit for Review button is located at the bottom of the Summary page so that you may have an opportunity to review your responses in their entirety prior to submitting them.

RETRIEVING AND REVIEWING PAST ASSESSMENT REPORTS

Assessment records are retained for six years from the date the assessment was closed. You may retrieve records of past assessments by expanding your search dates and looking for assessment reports with a status of "closed".

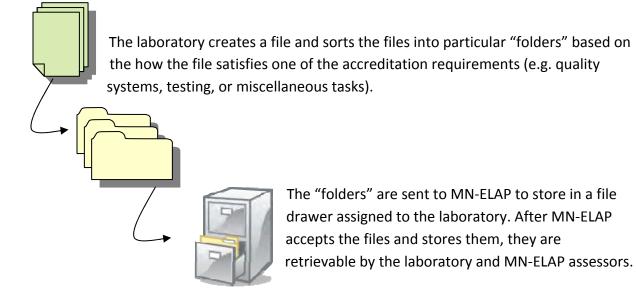
Note: The first assessments were entered into the ELDO system in August 2010. Assessment reports issued prior to this date are maintained on the MN-ELAP file server (not accessible through ELDO).

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Documents

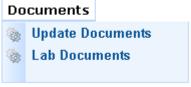
Chapter Five: Documents The ELDO system requires uploading and maintaining current documents for laboratory activities related to accreditation. The required documents include the laboratory's quality system documentation as well as the laboratory's written test procedures used to perform analysis of samples.

In the simplest terms, the ELDO Document module is a document management system; therefore, the system functions similar to storing papers in a filing cabinet.



VIEWING YOUR DOCUMENTS

To view documents already stored in the system, choose the Lab Documents option from the Documents menu on the ELDO home page.



If no current documents are stored, the Lab Documents screen will return empty folders (tabs only) and a message that no documents are uploaded.



If you have already sent a request to upload your documents and they do not appear in the ELDO folders, then MN-ELAP may not have reviewed the files and accepted them into the system. MN-ELAP reviews document upload requests chronologically in the order received. Depending on the volume of the request or requests preceding yours in the queue, the documents may not appear for a few days.

Note: Only one document upload request may be entered at a time so you should avoid trying to do daily or weekly updates to your documents. If you plan to edit several documents within a short timeframe upload the entire batch of edited documents at one time.

PREPARING DOCUMENTS

Completing document uploads requires preparation time on the part of the laboratory. Take a close look at the required documents and prepare your information and your documents ahead of time. The ELDO system will time-out if there is more than 45 minutes of inactivity (i.e. no changes in screen views). We suggest that you gather your laboratory documents into one folder on your computer so that you can find them all easily when you need to upload them.

Your documents must meet the following formatting rules:

- 1. File type: portable document format (PDF)
- 2. File size: 5 MB or less

You will need to upload the following documents:

- 1. Procedures for quality system items (i.e. Quality Manual)
- 2. Procedures for laboratory tests (i.e. SOPs)
- 3. Additional documents needed to satisfy accreditation requirements

STARTING AN UPLOAD REQUEST

To send documents to MN-ELAP, select the Upload Documents option under the Documents menu. The screen will indicate whether an upload request has already been saved. If there is no saved upload request in the system, you may choose to start a new request.

There is no current documents upload request for MyLab!

Start Documents Upload Request

Saved applications may be edited by selecting <u>SAVED</u> or <u>Edit</u>. Saved upload requests may be removed by selecting <u>Remove</u>.



There are four sections to the Document module: **Quality Manual, Standard Operating Procedures, Additional Documents, and Summary.** All four sections must be completed before you may submit the documents to MN-ELAP.

Note: You cannot toggle between screens in the Document module. You must complete all sections in the order they are presented before you may move to the next section.

THE QUALITY MANUAL

The ELDO system will ask you whether your quality system documentation is in one document or several separate procedures.

Documents Upload Request for MyLab

QAM Documents

Quality Assurance Manuals Documents

My documents one Document
are in: * Several Separate Documents

Next > Cancel

If you have one manual with all 25 required items (see below), you may select "One Document" to upload the single file. If you have one document that you call the Quality Manual but have separate procedures providing detail on how you comply with the specific requirements in the accreditation standard, then you must select "Several Separate Documents".

The next screen shows the current list of required items to be addressed in an acceptable quality system. If you selected "One Document" you will enter the page numbers where each

of the items can be located. If you selected "Several Separate Documents", you will upload a document and enter the basic document information (title, revision, revision dates) for each item.

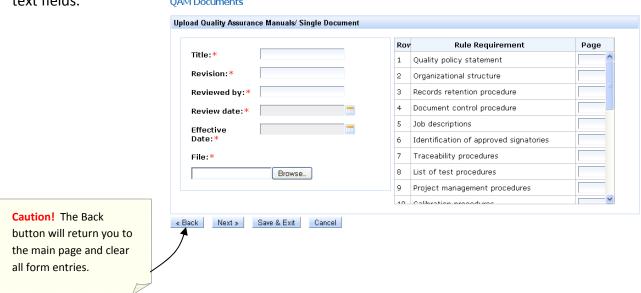
You may need to enter the same document multiple times. For example, a laboratory that has one document containing job descriptions and the table of organization should upload the document under both requirements.

When you are finished reviewing the list of items, select <u>Next</u> to proceed to the next screen and begin entry and upload. Select <u>Cancel</u> to return to the Main menu page.

QAM Documents Required Rule Rule Requirement + Requirements: Quality policy statement Organizational structure Records retention procedure Document control procedure Job descriptions Identification of approved signatories Traceability procedures List of test procedures Project management procedures Calibration procedures Calibration verification procedures Sample handling/receiving procedures Equipment list procedures Maintenance and repair procedures for equipment Proficiency testing procedures Quality control procedures Corrective action procedure Preventive action procedure Procedures to handle nonconforming work Complaint procedure Procedures to protect trade secret data Data review procedures Internal audit procedures Training procedures Procedures for reporting results Next » Cancel

If you selected a single document for your quality manual, then you will enter the revision information once and cite the page number where the 25 items may be found. This should be very similar to your document's Table of Contents. The page column contains alphanumeric text fields.

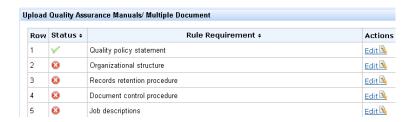
QAM Documents



If you selected to upload your documents as several separate documents, then you will enter the document title and revision history for each of the 25 documents individually. Select the

edit button to view each entry screen. Upload Quality Assurance Manuals/ Multiple Document Row Status # Rule Requirement + Actions 0 Quality policy statement Edit 🛚 **3** Edit 🛭 63 Records retention procedure Edit 🛚 • Edit 🖹 Document control procedure 5 • Job descriptions Edit 🖹 Identification of approved signatories Edit 🛝 **3** Traceability procedures Edit 🛝 8 **a** List of test procedures Edit 🛝 0 Project management procedures Edit 10 0 Calibration procedures Edit 💫 11 • Calibration verification procedures Edit 🕓 12 **3** Sample handling/receiving procedures Edit 🛝 13 • Equipment list procedures Edit 🛝 14 Maintenance and repair procedures for equipment Edit 🛝 **QAM Documents** 15 • Proficiency testing procedures <u>Edit 🔼</u> Document details for 'Quality policy stateme 16 (3) Quality control procedures Edit 🛝 17 • Corrective action procedure Edit A Title:* 18 **3** Preventive action procedure Edit 🛝 Revision:* 19 **3** Procedures to handle nonconforming work <u>Edit 🔼</u> 20 0 Complaint procedure Edit 🛝 Reviewed by:* 21 0 Procedures to protect trade secret data Edit A Review date:* 22 **3** Edit 🛝 Data review procedures Effective Date:* 23 <u>Edit 🕓</u> 24 **3** Training procedures Edit 🛝 File:* Browse... Procedures for reporting results Edit 🕓 Save <u>Cancel</u> « Back Next » Save & Exit Cancel

The upload screen will show your progress toward completing the upload of all required documents. A green checkmark indicates a document has been uploaded. A red plus sign indicates that no document is currently attached to your request.



When all procedures are uploaded (i.e. green checkmarks next to each item), select the <u>Next</u> button to advance to the next screen to upload your testing procedures. You may save your work and continue the upload by selecting the <u>Save & Exit</u> button.



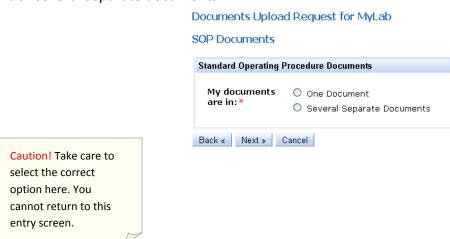
A saved document request may be accessed through the Document menu by selecting the Update Documents option and selecting <u>SAVED</u> or <u>Edit</u> on the Existing Documents Request window.

STANDARD OPERATING PROCEDURES

STOP!! If you are in the process of filling out an application in the Application module, you should complete the application process and submit the application request before beginning the document uploads. The ELDO system will query your current scope of accreditation and any submitted applications to determine the list of required documents to upload in this section of the module.

If you do not apply first and upload your documents second, then the system will require you to upload procedures for tests you may wish to drop and will not have a place for you to upload the documents for tests you wish to add.

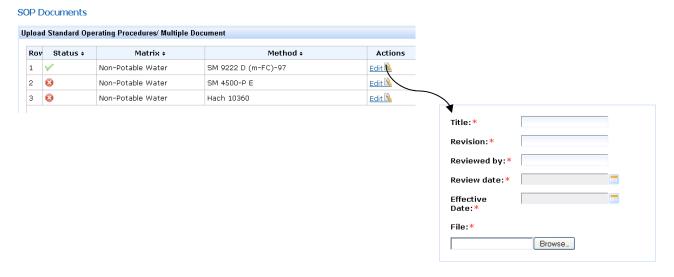
As with the Quality Manual upload, the ELDO system wants to know if your testing procedures are in one document or several separate documents.



The system will give you an opportunity to upload documents to support your existing accreditation, any applications you have submitted to MN-ELAP, and for any suspended tests for which you are requesting re-instatement of accreditation.



Like the Quality Manual entry, the SOP Documents window tracks your progress toward completing the required uploads. A green checkmark indicates a document has been uploaded. A red plus sign indicates that no document is currently attached to your request.



Each document (or single manual) requires the entry of the same detail: Title, Revision, Reviewed by, Review date, Effective date, and the attachment of the file.

When all procedures are uploaded (i.e. green checkmarks next to each item), select the <u>Next</u> button to advance to the next screen to upload additional documents, if needed.

Additional Documents

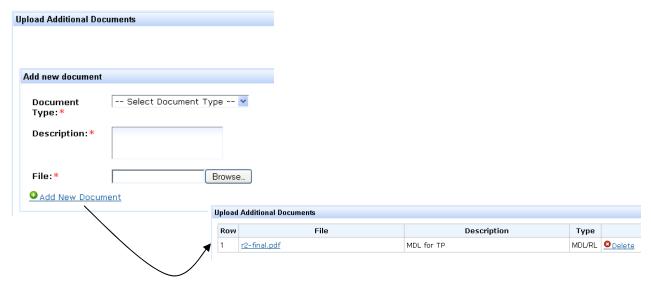
When you have completed the Quality Manual and Standard Operating Procedure uploads, you will have an opportunity to upload additional documents into the system.

There are a few options in the drop down menu to identify the document type. If none of the suggested types fit the description of your document, choose Other. MN-ELAP will expand the list of document types periodically based on the most common uploads applied by laboratories.

You should choose to upload additional documents if:

- 1. Your laboratory has more documents in your quality system and not enough spaces to attach them to the required items under the Quality Manual section (e.g. sample receiving and sample handling procedures in two separate documents but only one entry line in ELDO).
- 2. You are attaching appendices or manufacturer instructions referenced in the quality manual or SOP which are not part of the main document.
- 3. You have corrective action forms, benchsheets, logbooks, work instructions, or other items, which provide objective evidence of corrective action in response to a failed proficiency test or assessment.
- 4. You are applying for secondary accreditation and must supply the most recent certificate, scope and assessment report from your primary accreditation body.

When you have filled in the required information and selected the file, select the <u>Add New Document</u> link to add the document to the list.



You may add as many documents as you wish. The documents will be saved in the Additional Documents section of the ELDO system until they are replaced by you or deleted by MN-ELAP.

SUBMITTING THE DOCUMENTS

When you have uploaded all documents, the final window will show you a summary of your work. Review the summary for accuracy and select either the Save&Exit button to come back later and make changes or select the Submit button to send your documents to MN-ELAP.

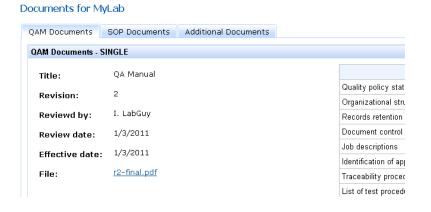


VIEWING YOUR DOCUMENTS

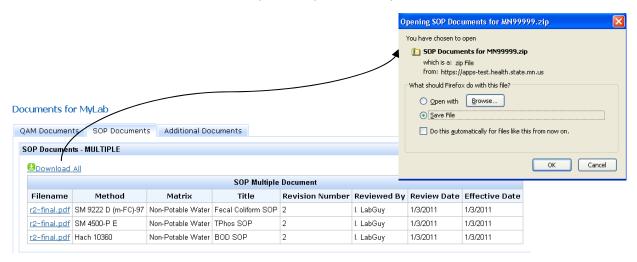
Now that you have uploaded documents, you must wait for MN-ELAP to accept them into the system. By submitting the documents, you have taken the files and placed them into 'folders'. MN-ELAP is now responsible for reviewing your work and placing the folders into the filing system.

You may only have one active request with MN-ELAP at one time. If you have more documents to upload and the Start Document Request button is grayed out, you must wait for MN-ELAP to process your first upload request before submitting another.

You can monitor the acceptance of your documents into the system by viewing your uploaded documents in the Document menu under the Lab Documents option. The file folders will be updated with your most recent documents if your request was processed.



If you need to send a set of documents to a regulatory agency, client, or laboratory staff, you may select the <u>Download All</u> link to send a ZIP file to your computer desktop.



The ELDO system is designed to provide you with the list of procedures with effective dates as required by the accreditation standards. You may print this page for your records to satisfy this requirement.