Electronic Toxic Substances Control Act (eTSCA)/e-PMN Reporting Tool

User's Guide

Version 1.2

December 28, 2009

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Revision Log

Date	Version No.	Description	Author	Reviewer	Review Date
11/20/09	1.0	Updated to reflect Web Start changes	L. Kramer	V. Tran-Lam	11/18/09

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1 Introduction

The eTSCA/e-PMN reporting software is a multi-function desktop application that helps industry comply with TSCA by providing a user-friendly interface for the submission of various TSCA-related forms to the Environmental Protection Agency (EPA).

The eTSCA/e-PMN reporting software is able to perform the following main functionalities:

- Create an electronic version of the Premanufacture Notice Form (PMN)
- Create an electronic version of the Notice of Commencement Form (NOC)
- Create an electronic version of the Biotech form
- Create a supporting/supplemental form to submit information for a previously submitted PMN
- Validate the data in a form
- Sanitize PMN data
- Create PDF versions of a form suitable for printing
- Allow attachments
- Edit form data
- Save incomplete form data
- Open a previously saved form
- Provide integrated help
- Allow forms to be submitted on paper, on CD, or online.
- Be standalone and platform-independent

2 Getting Started

2.1 System Requirements

Systems must meet the following set of minimum requirements to run the eTSCA/e-PMN software:

Machine Specifications

- 200 MB Hard Drive Space
- 1GB RAM
- 500Mhz Pentium PC or equivalent (2.0 Ghz recommended)
- 800 x 600 screen resolution (1280 x 1024 recommended)

Operating System

- Windows XP
- Mac OSX
- Linux Fedora 10

Browser

- Internet Explorer 6 or higher
- Firefox 3.5 or higher
- Safari 4 or higher

Additional Software

- Java Version 6 or greater
- Java Web Start version 1.6 or greater

These requirements reflect those of Java Web Start version 1.6. For questions concerning Java requirements, please refer to the Sun Microsystems website at http://java.sun.com.

For questions concerning the eTSCA/e-PMN software requirements, please contact the CDX Help Desk at helpdesk@epacdx.net or call 1-888-890-1995 between the hours of 8am – 6pm EST.

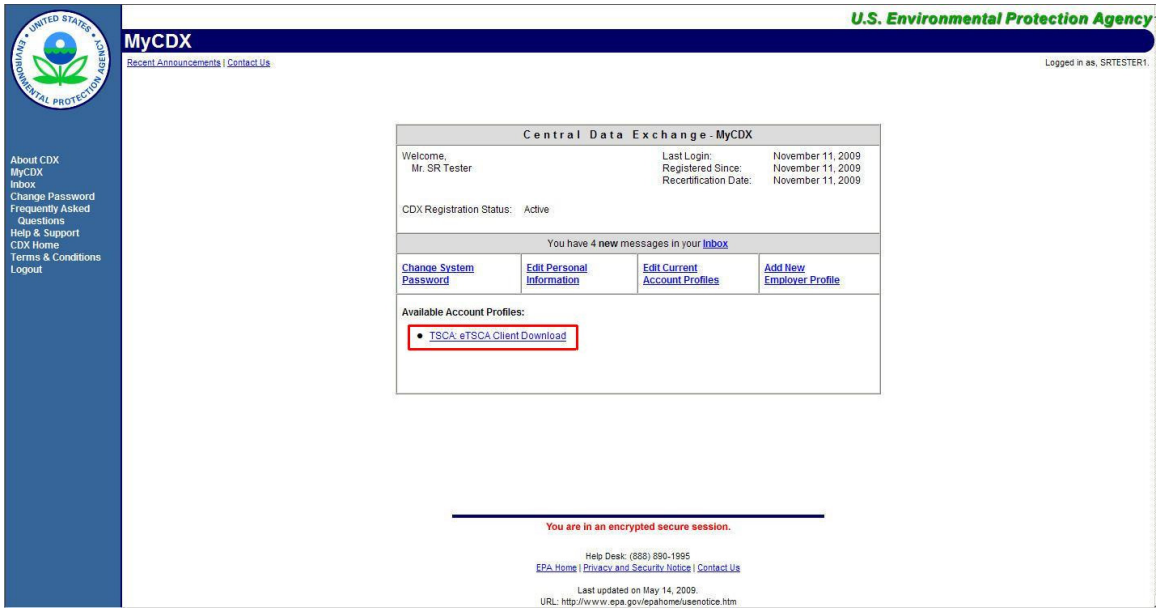
2.2 Installation

There are two methods for installing the eTSCA/e-PMN software. The Web Start installation option can be accessed and downloaded via two CDX internet sites. The version of the eTSCA/e-PMN software with encryption requires a CDX login, whereas the version of the software without encryption can be accessed at https://cdx.epa.gov/ssl/cdx/eTSCA-DownloadLiteClient.asp. The InstallAnywhere version runs off a CD and may be more suitable for users without an internet connection.

2.2.1 Web Start Installation (with encryption)

To download the eTSCA/e-PMN reporting software from the CDX website, log in normally to http://cdx.epa.gov. The installation files can be retrieved from the "TSCA: eTSCA Client Download" link located on the user's MyCDX page [Figure 2-1]. This link will only appear if the user has registered and been approved under the TSCA Program.

Figure 2-1 MyCDX Page / Link to eTSCA/e-PMN software download



The page seen in Figure 2-2 contains a link to the install file for the eTSCA/e-PMN software. There are two (2) versions of the software: a full version and a lite version. The full client includes all of the required encryption libraries to enable online file submission, whereas the lite client does not include the encryption libraries and submissions must be made via CD. Note that only the full client is available for download from this page. To download the lite client, users must visit https://cdx.epa.gov/ssl/cdx/eTSCA-DownloadLiteClient.asp.

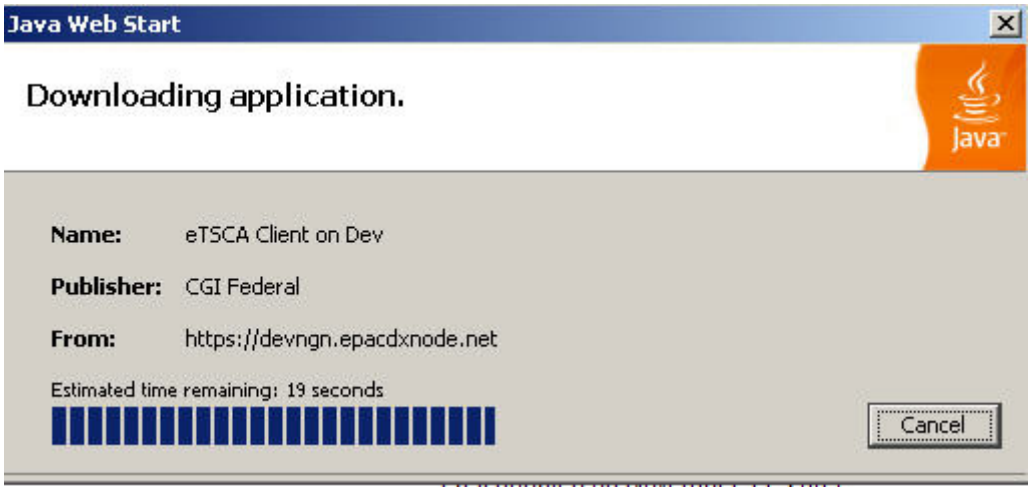
Figure 2-2 eTSCA/e-PMN software download page

To download a file, simply click the “Download Client” button. If browser issues arise with security certificates, the download may be blocked. This can be remedied by allowing blocked content, as seen in Figure 2-3 below.

Figure 2-3 Display Blocked Content option

Users may be prompted to download an updated version of Java before installing the eTSCA/e-PMN Client. When the download starts, the screen will look similar to the image seen below in Figure 2-4.

Figure 2-4 eTSCA/e-PMN Java WebStart software download



Once downloaded, the eTSCA/e-PMN software will automatically launch [Figure 2-5] and load the application [Figure 2-6].

Figure 2-5 eTSCA/e-PMN Client Lite launch

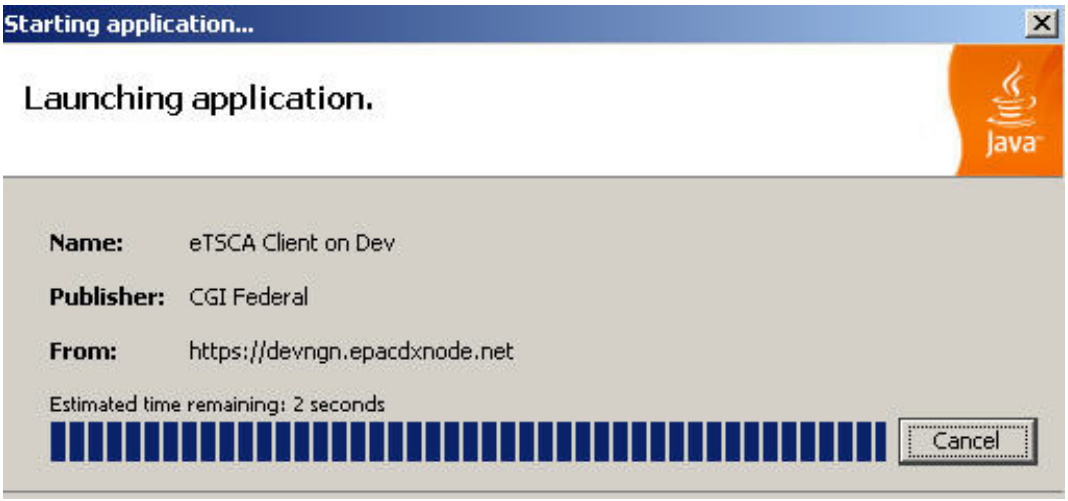


Figure 2-6 eTSCA/e-PMN software load

Once the software has loaded, a shortcut icon will appear on the user's desktop.

2.2.2 InstallAnywhere CD Installation

To install from a CD, navigate to the correct folder corresponding to the operating system and double click the .exe file. Once the file is executed, follow the on-screen directions to install the eTSCA/e-PMN reporting software. Users with a previous version of the program should uninstall first before installing the updated version. A system restart will be required after installation is complete.

Double click on the install file and InstallAnywhere begins the installation process.

Figure 2-7 Install Anywhere Installation

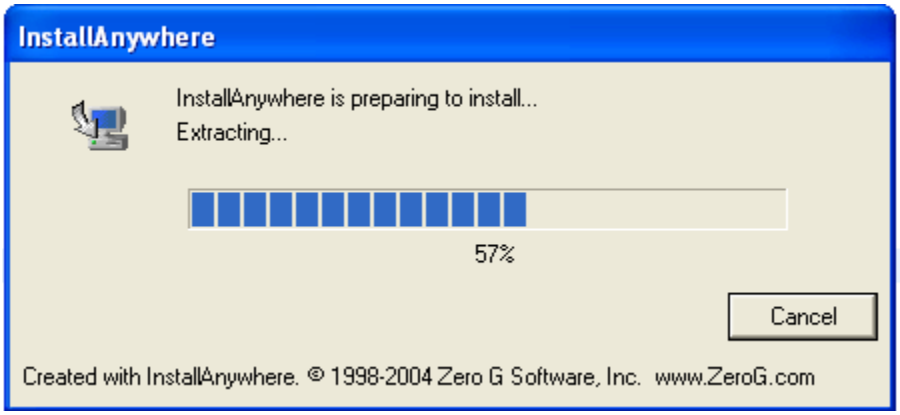


Figure 2-8 Install Anywhere Wizard Introduction

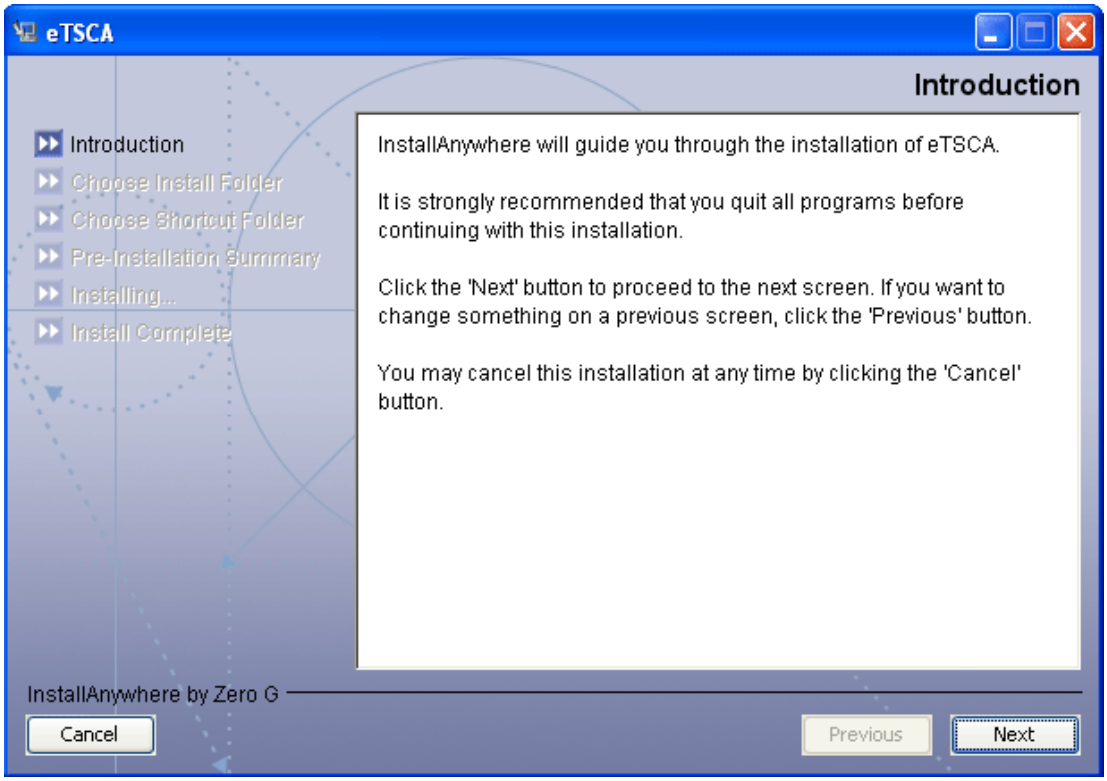


Figure 2-9 Install Anywhere Wizard Installing

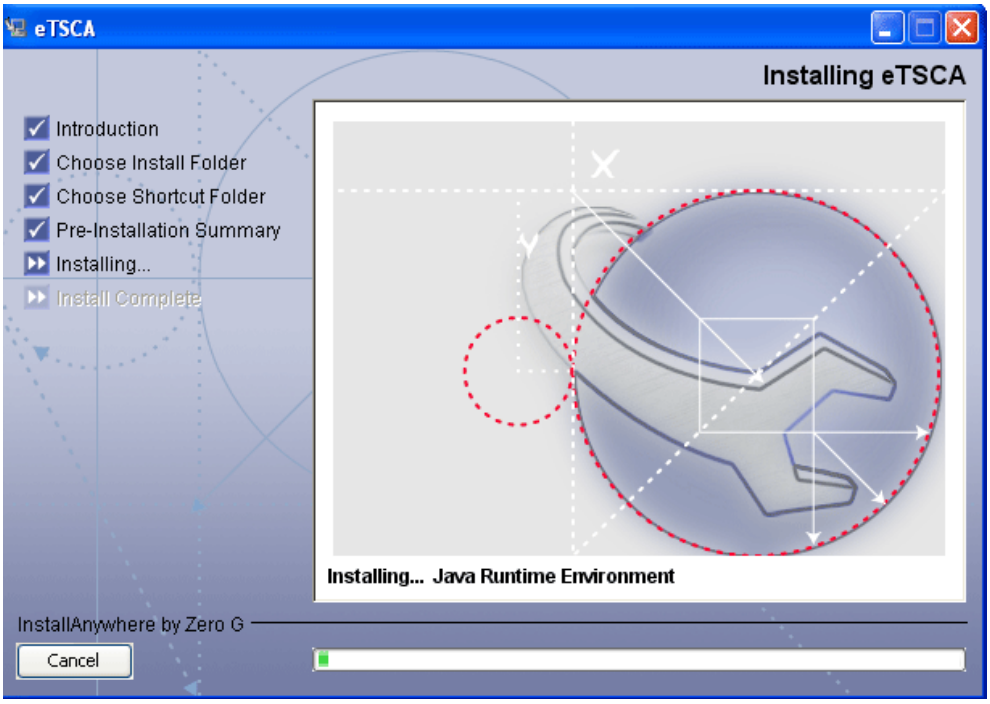
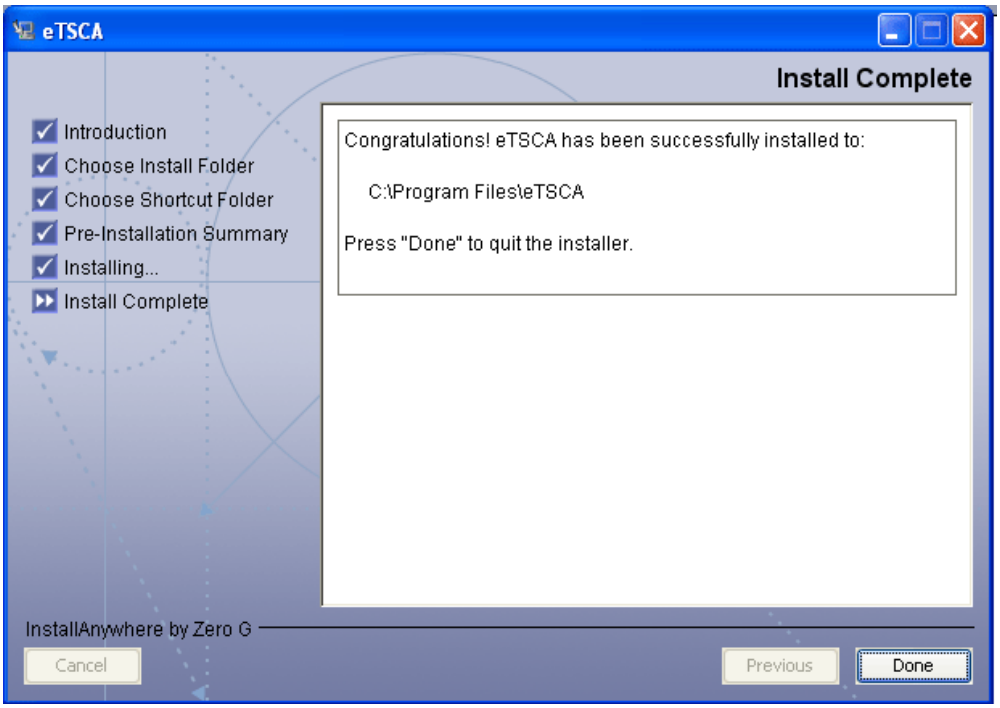


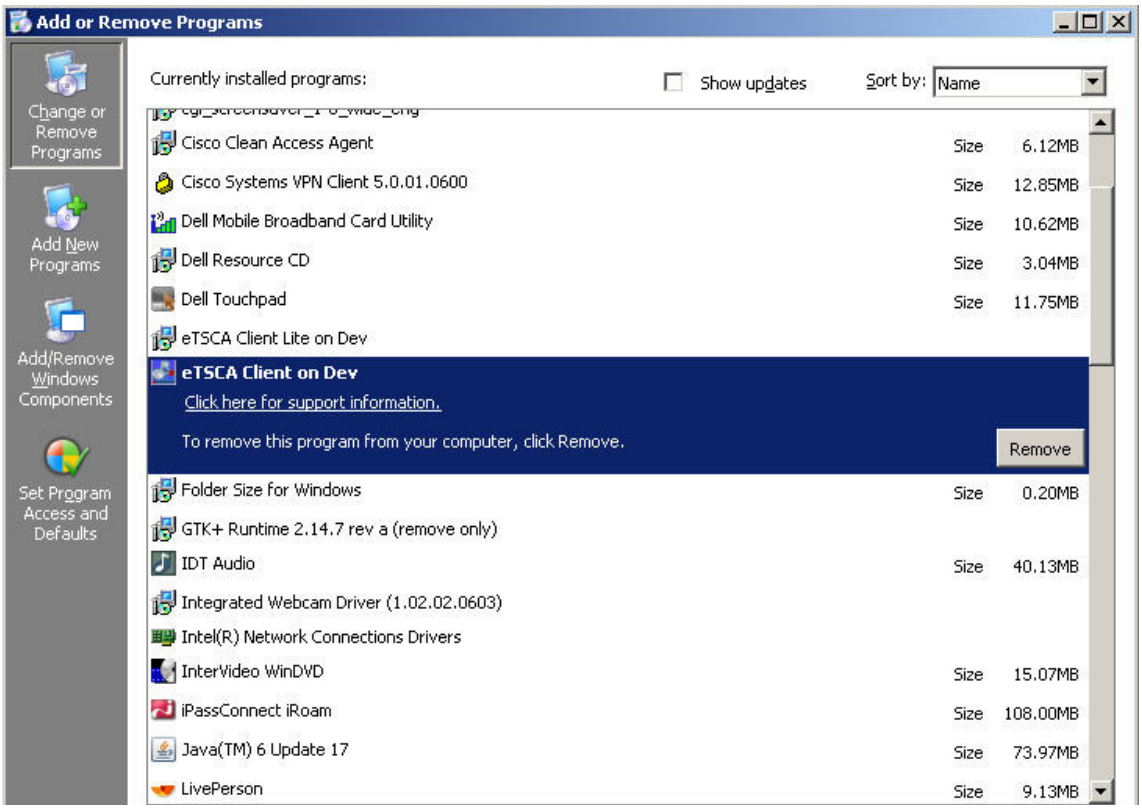
Figure 2-10 Install Anywhere Wizard Install Complete



2.3 Uninstalling the eTSCA/e-PMN software

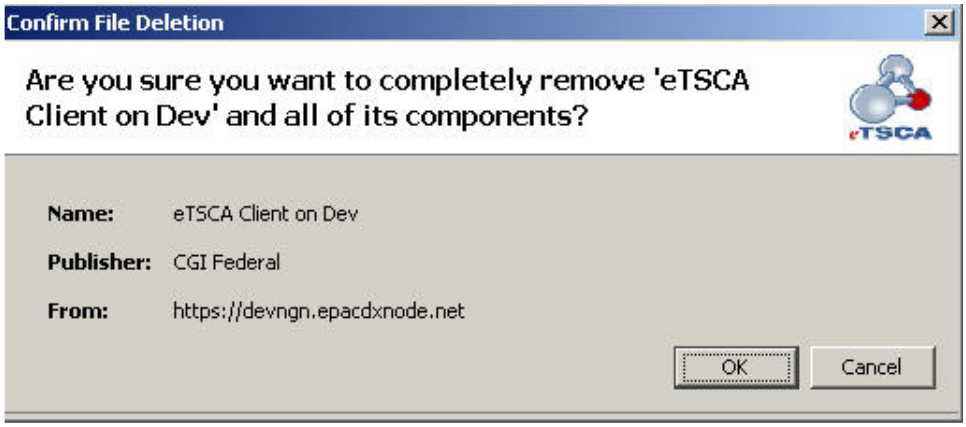
Uninstalling the eTSCA/e-PMN software can be done through the operating system's Control Panel Add or Remove Programs option.

Figure 2-11 Control Panel Add or Remove Programs



Windows will prompt the user to confirm removal of the eTSCA/e-PMN client, as seen in Figure 2-12 below.

Figure 2-12 Confirm eTSCA/e-PMN software removal

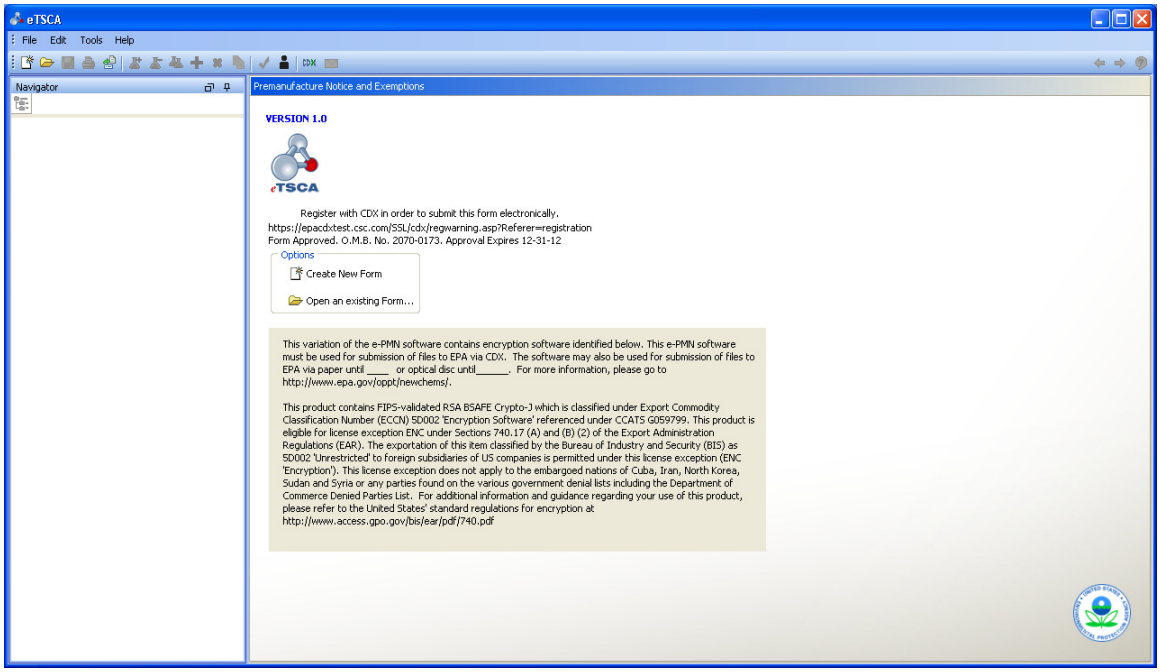


Clicking the "Cancel" button will cancel un-installation. The "OK" button will proceed with software removal. Once complete, the software will no longer be listed amongst the other applications in the Add or Remove Program control panel, and will be absent from the Programs folder of the user's start menu.

2.4 The User Interface

The following welcome screen appears when the eTSCA/e-PMN reporting software is first started.

Figure 2-13 eTSCA/e-PMN software welcome screen

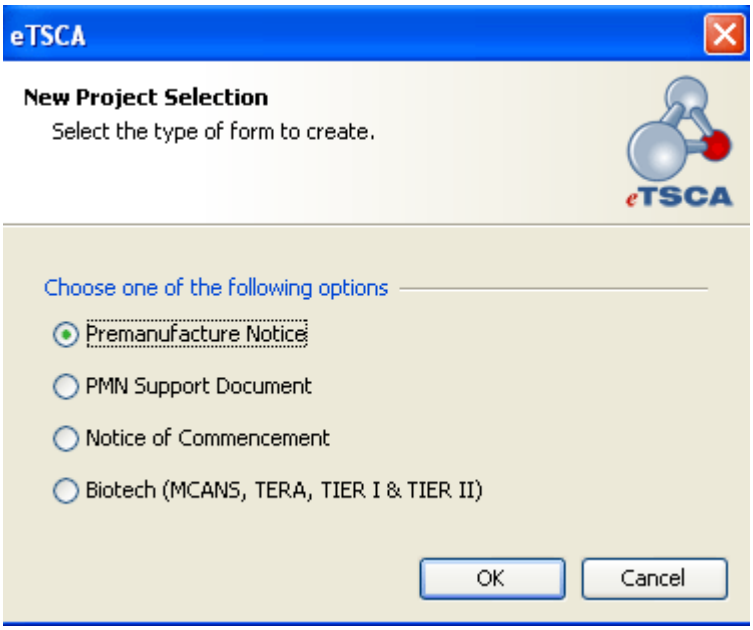


The left side navigation pane allows users to maneuver between forms, while the editor window on the right provides a space for the user to view and complete these forms.

2.5 Creating a new Project

New projects can be created by clicking on the "**Create New Form**" button ( ) or selecting this option from the **File** menu. A new window will appear prompting the user to select a project type.

Figure 2-14 New Project Selection Window



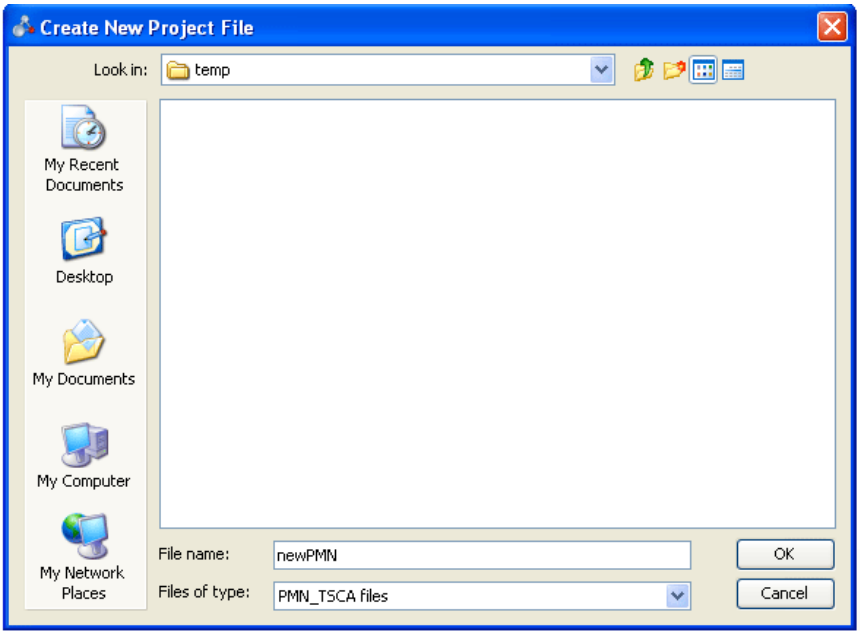
There are four (4) project type options as seen in the figure below.

Figure 2-15 Project Types Tables

Project Types	
Name	**File Extension**
Pre-manufacture Notice (PMN)	.pmn_tsca
PMN Support Document	.sup_tsca
Notice of Commencement (NOC)	.noc_tsca
Biotech (MCANS, TERA, TIER I & TIER II)	.bio_tsca

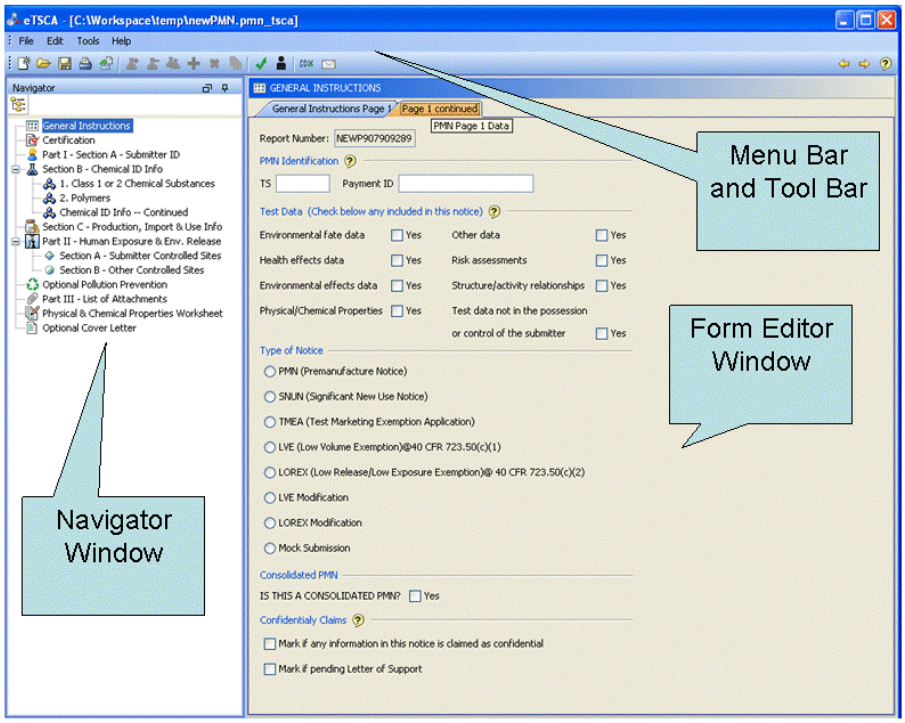
After a selection is made, the user will be asked to name the project.

Figure 2-16 Name File Window



The project is created and the main user interface is displayed.

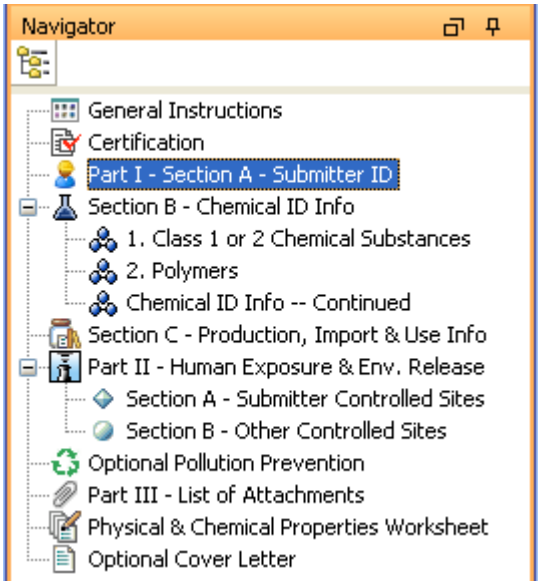
Figure 2-17 eTSCA/e-PMN software user interface



2.6 Navigation

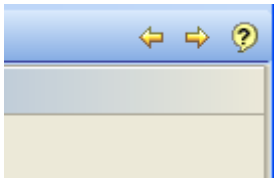
Navigating the eTSCA/e-PMN software is simple and intuitive. Most users will move through the forms in the navigation pane simply by using a mouse. Clicking on a section will highlight the title and open the corresponding form in the form editor window.

Figure 2-18 Navigation Pane



The left-right arrows on the upper-right corner of the toolbar [Figure 2-19] can be used as well.

Figure 2-19 Navigation arrows



2.6.1 Navigating using only the keyboard

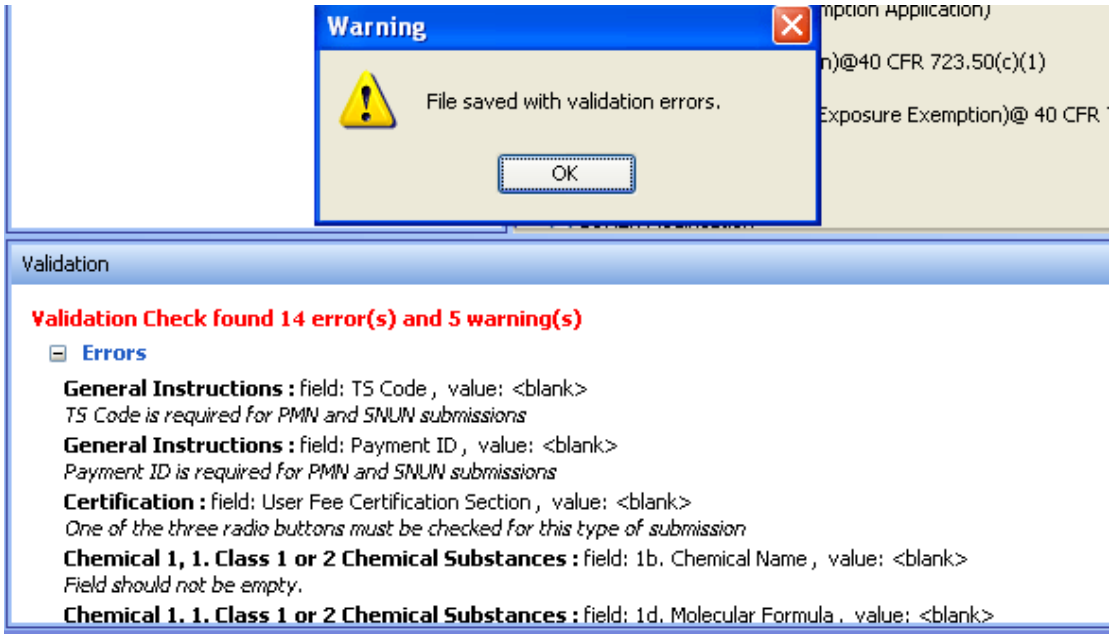
For users who prefer to work without a mouse, there are a number of keyboard shortcuts to navigate the eTSCA/e-PMN software. When the application focus is on the navigator window, the **Up Arrow** and **Down Arrow** will move forward and backward respectively through the forms in the navigation pane. Pressing **Ctrl+F** will manually give focus to the form editor window**.** With the application focus on this window, the **Ctrl + Right Arrow** and **Ctrl + Left Arrow** combinations will work to traverse the forms. Pressing the **Tab** button will toggle between fields within a form. If a table is encountered, tabbing will only move the focus amongst fields within that table. To exit the table and move the focus to the field following the table, press **Ctrl+Tab**.

3 Using the eTSCA/e-PMN Reporting Software

3.1 Saving a project

Projects can be saved in an incomplete state to be finished later. Note that incomplete forms cannot be submitted to EPA. When **Save** or **Save As** is selected from the toolbar or the file menu, eTSCA/e-PMN automatically runs a validation check on the currently open form. If there are validation errors (due to invalid data or incomplete fields), the error message seen in Figure 3-1 will appear, stating that the file was saved with validation errors. A validation window will appear at the bottom of the screen detailing the errors.

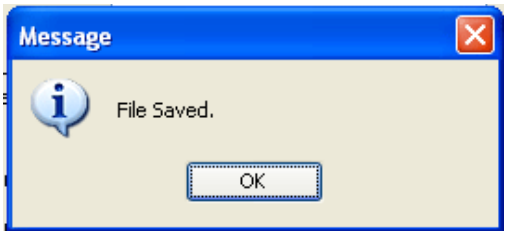
Figure 3-1 File saved with validation errors



Double-clicking one of the listed items in the validation window will allow users to jump to the page of the error for easy correction.

Saving a file without any validation errors produces the following dialog box, seen in Figure 3-2.

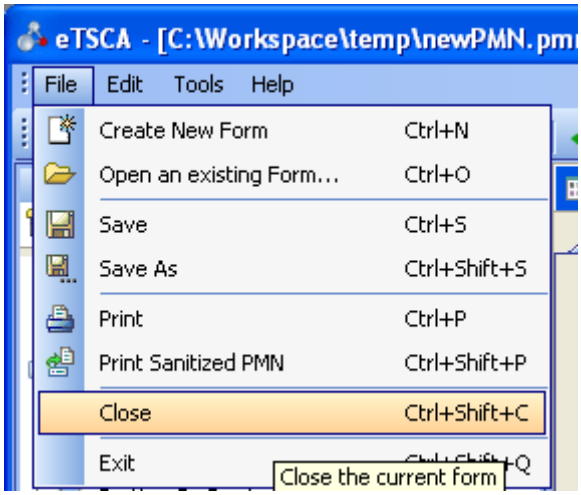
Figure 3-2 File saved without validation errors



3.2 Closing a project

Projects can be closed by selecting the **Close** command from the **File** menu. Selecting the **Exit** command from the **File** menu will close the application completely.

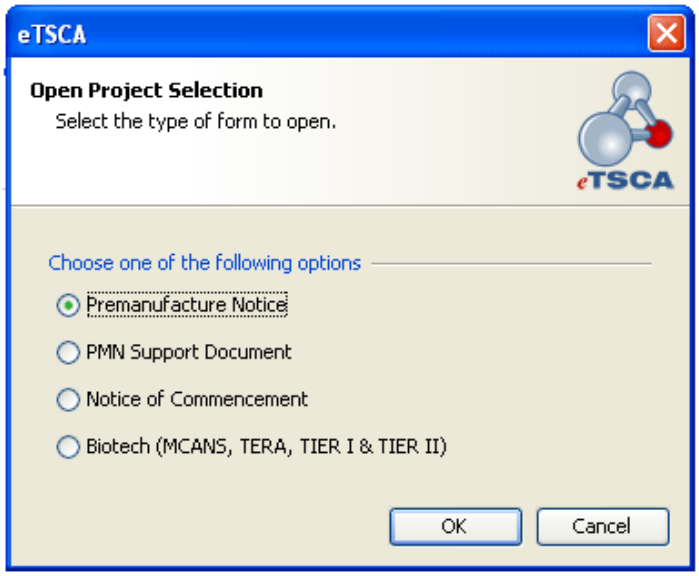
Figure 3-3 Closing a project



3.3 Opening an existing project

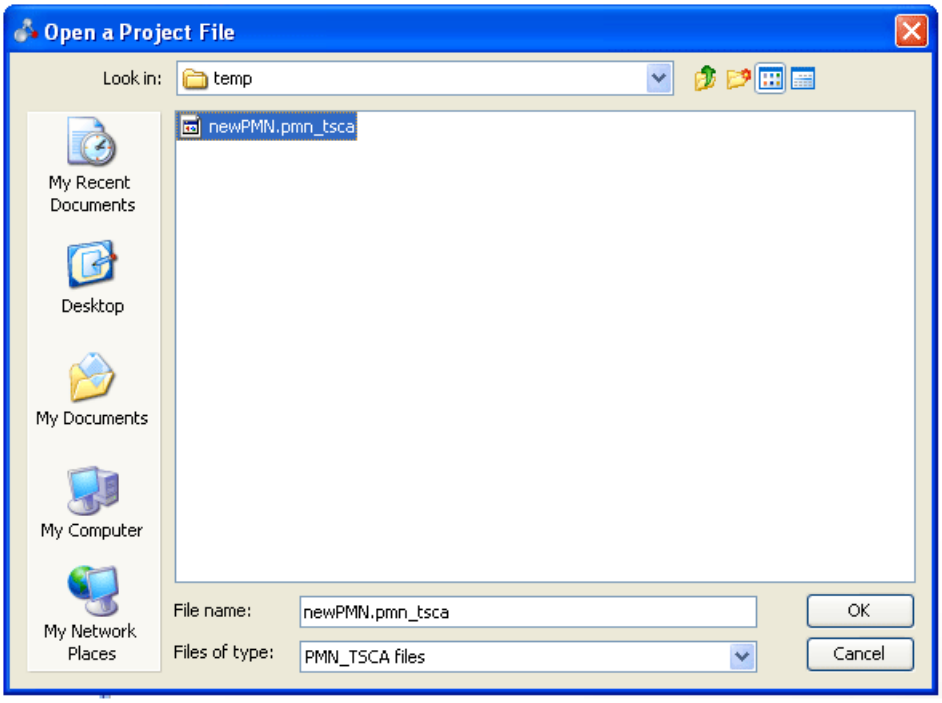
Opening an existing project is similar to creating a new one. Simply select the Open an Existing Form button (📂) or choose **Open an Existing Form** from the **File** menu to pop up the dialog box. Selecting a file type will filter the files that will appear on the following screen for file selection.

Figure 3-4 Opening an existing project



After selecting a form type, a file dialog box will appear prompting the user to select the desired file to be opened. Users will only see projects of the type they have selected in the previous step. Double-clicking or highlighting and clicking the **OK** button will select the file that the eTSCA/e-PMN software will open.

Figure 3-5 Selecting an existing project



3.4 Getting User Help

3.4.1 Page-level Help

Pressing the **Question Mark** button (?) on the top right side of the toolbar [Figure 3-6 below] will activate the dynamic help window, which provides contextual help specifically for the page currently open on the form.

Figure 3-6 Toolbar

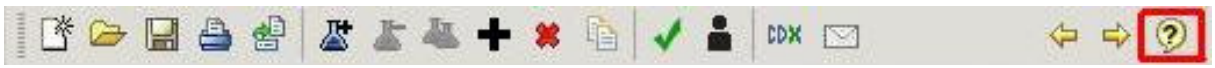
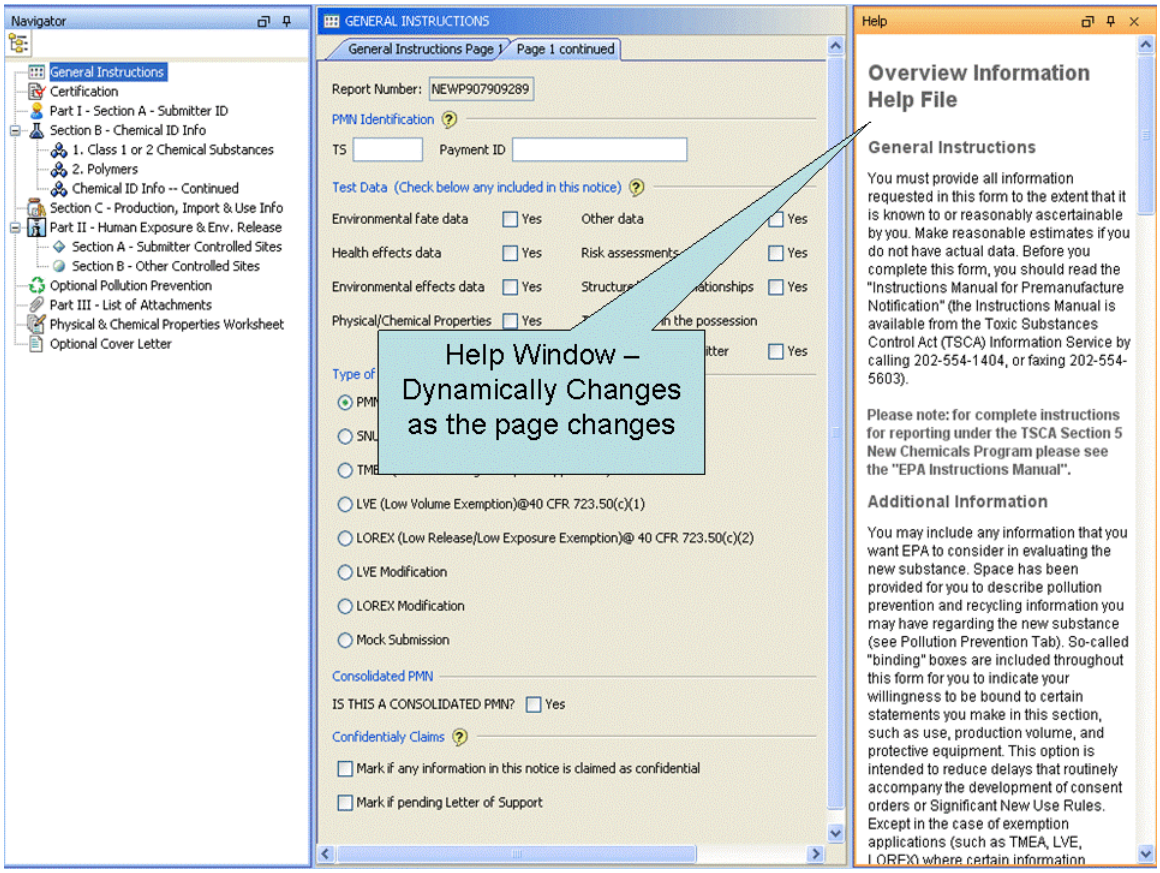


Figure 3-7 Dynamic Help Window



3.4.2 Field-level Help

Specific fields and sections may also contain the **Question Mark** icon [Figure 3-8]. Pressing this icon will launch a pop-up window with information specific to that field or section, as seen in Figure 3-9 below.

Figure 3-8 Field Question Mark Help Icons

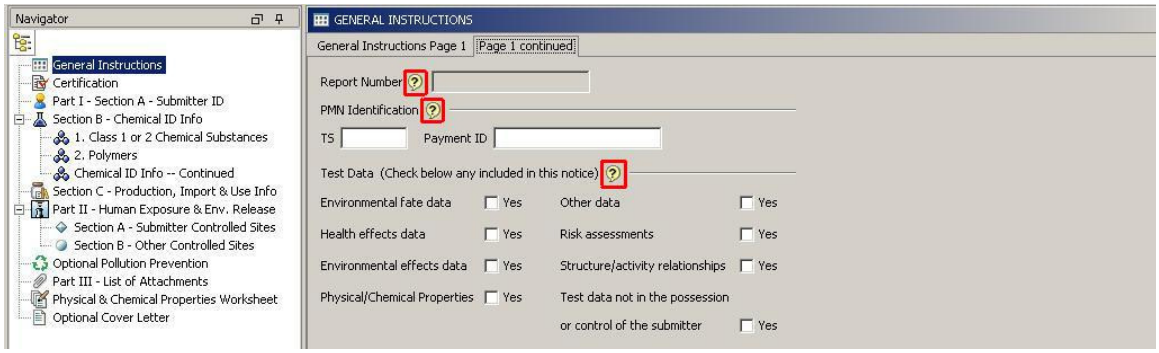
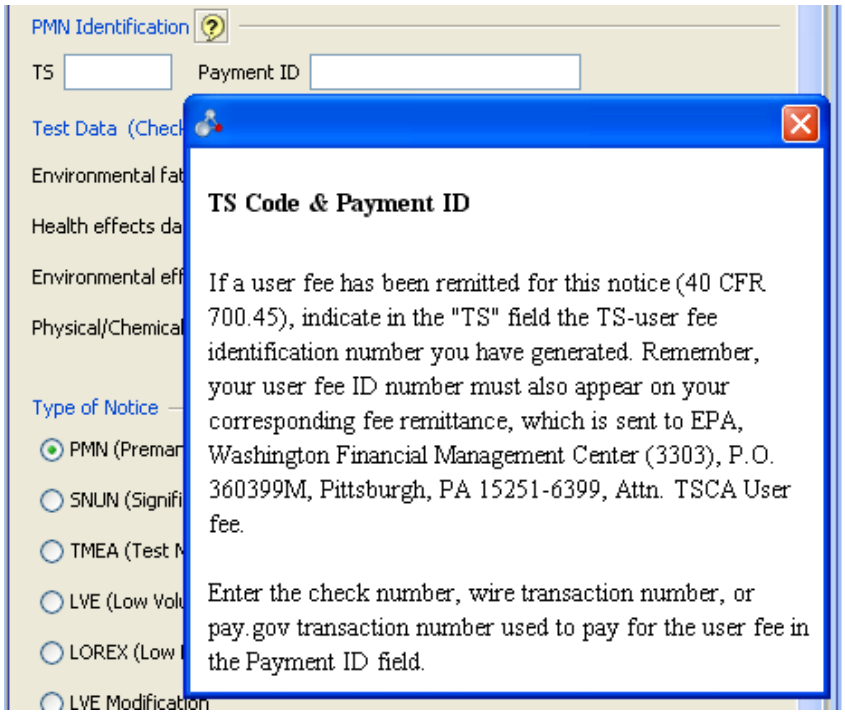


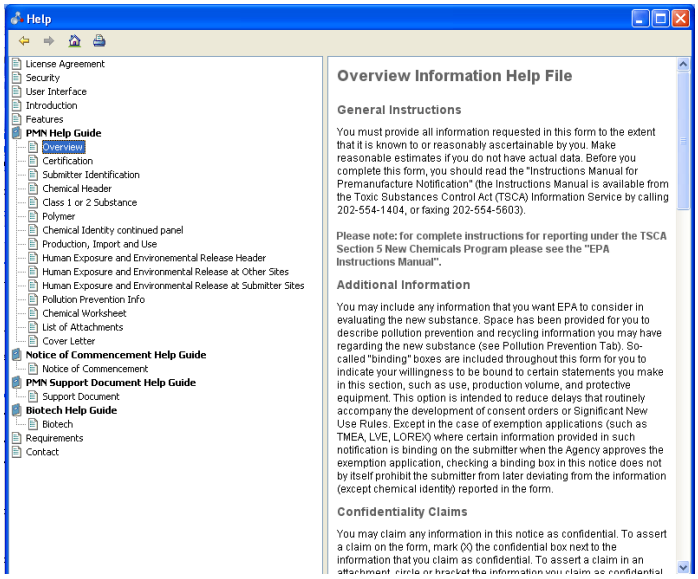
Figure 3-9 Field Specific Help Window



3.4.3 Application-level Help

Application-level help is available by choosing the **Help Contents** menu item in the **Help** menu or by pressing **F1**. A separate help window will appear.

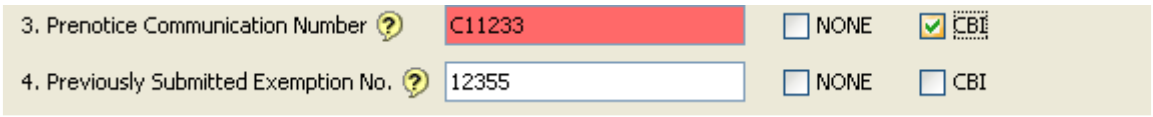
Figure 3-10 Application Help



3.5 Confidential Business Information (CBI)

Fields marked as CBI are highlighted in red for easier identification. These fields will be stripped out when a sanitized version is created. (See section 5.4.1 for details on sanitation). Some fields allow for curvy brackets (e.g., {CBI name}) to designate CBI. Any data between the curvy brackets in these large text fields will be replaced with XXX in the sanitized version.

Figure 3-11 Confidential Business Information



3.6 Contact Profiles

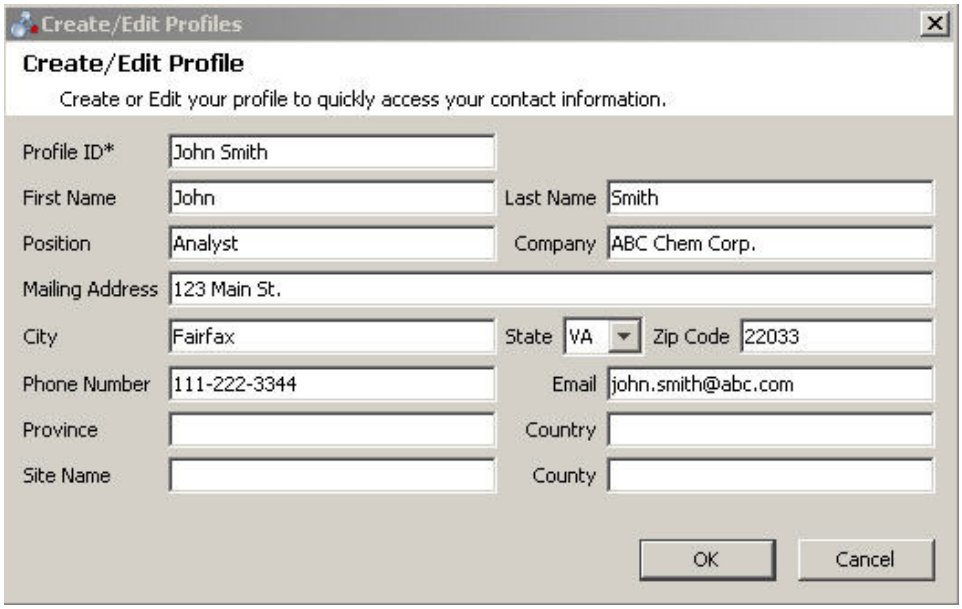
Profiles make form completion more efficient by allowing users to pre-establish and save static information. With the simple click of a button, users can fill in contact information fields such as name, address, phone number, etc. or site information fields such as address and site name. Profiles are not Notice-specific. Once a profile is established for a current Notice, that profile is stored on the user's local machine (as profiles.xml) and can be utilized later for any other eTSCA/e-PMN project. eTSCA/e-PMN has the ability to store multiple profiles.

A profile can be added/modified by choosing **Create/Edit Profile** from the **Tools** menu or by clicking on the Profile button (♟) in the toolbar. The following window will appear.

Figure 3-12 Profiles List Window

The box displays a list of profiles currently stored on the machine. Clicking **Edit** or **New** will bring up the Create/Edit Profile dialog box, as seen in Figure 3-13 below. To edit an existing profile, highlight the profile name and click the **Edit** button.

Figure 3-13 Create/Edit Profile Window



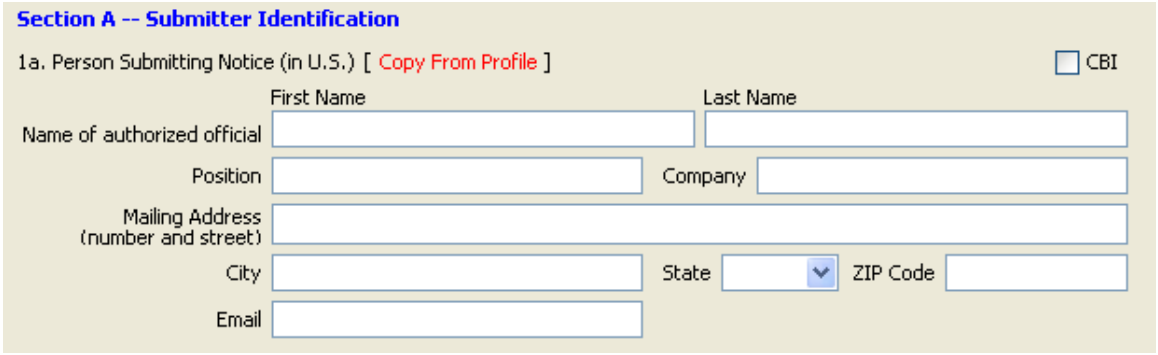
Existing profiles will display all fields currently populated, as well as any blank fields. New profiles will display all blank fields. The **Profile ID** field is used to identify the profile in the Profiles List dialog box—this field is required. All other fields are optional. To save the profile information, click the OK button.

Note: If creating a profile for a user registered with the Central Data Exchange (CDX), it is imperative that the **First Name**, **Last Name**, and **Company** fields remain consistent with the information entered at the point of CDX registration. This information will be used for authentication. Incorrectly entered information will not pass validation upon submission via CDX.

To use a profile within a form or dialog box, look for the "Copy from Profile" or "Profile" link wherever a contact or site information section is located on a form or dialog box.

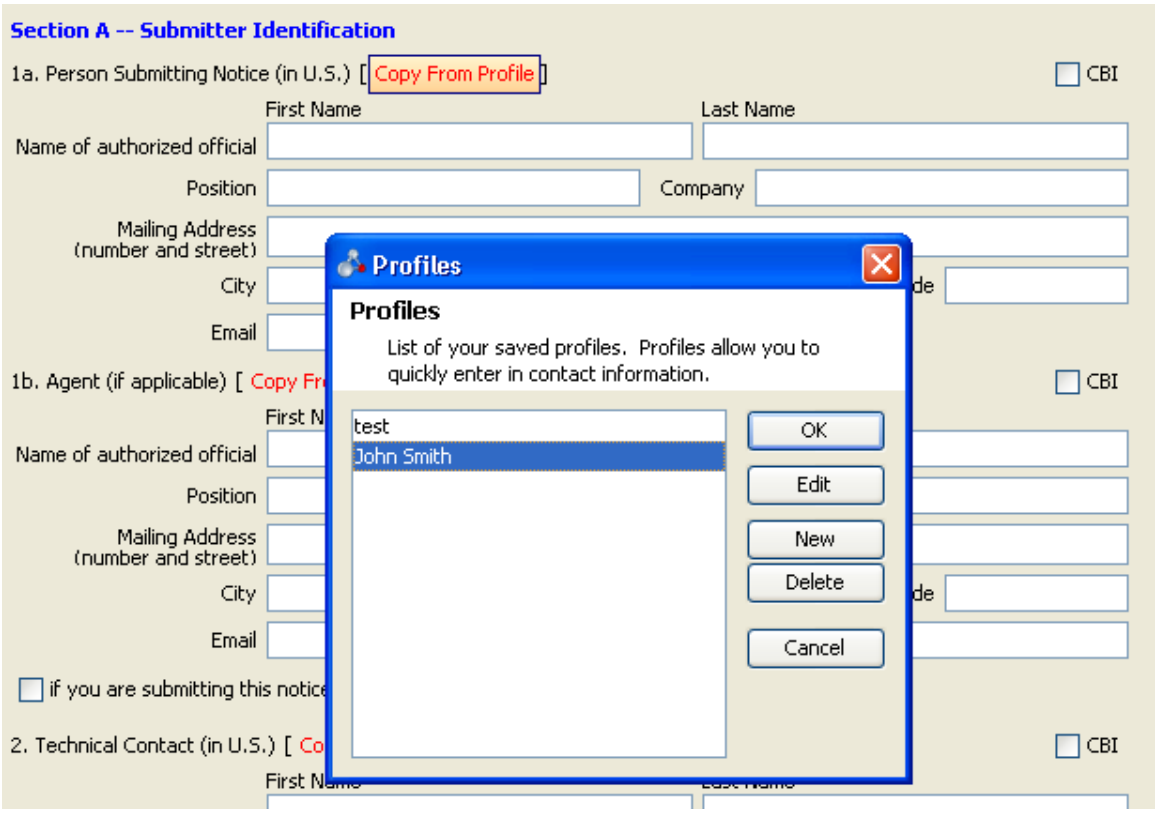
Figure 3-14 below exemplifies a section where a profile may be used.

Figure 3-14 Submitted Identification



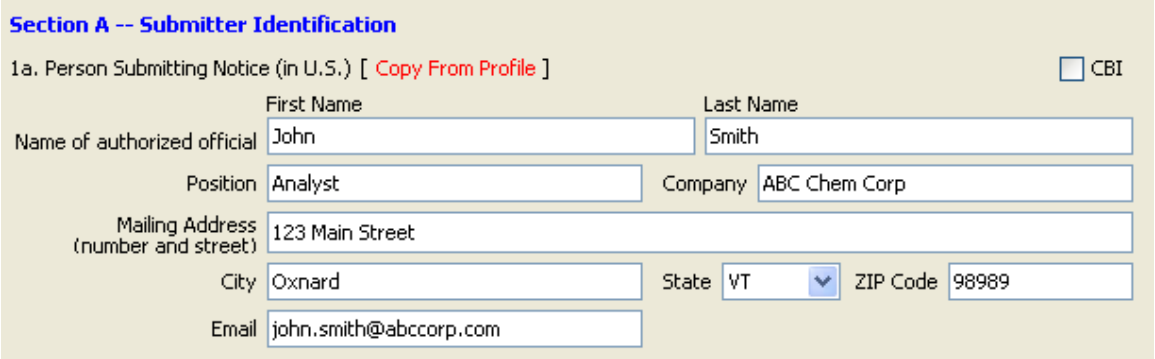
Clicking the "Copy from Profile" section will display the Profiles List dialog box, as seen below.

Figure 3-15 Using a stored profile



Double clicking the John Smith profile (or highlighting and pressing **OK**) will add all of John Smith's profile information into the fields.

Figure 3-16 Profile information transferred



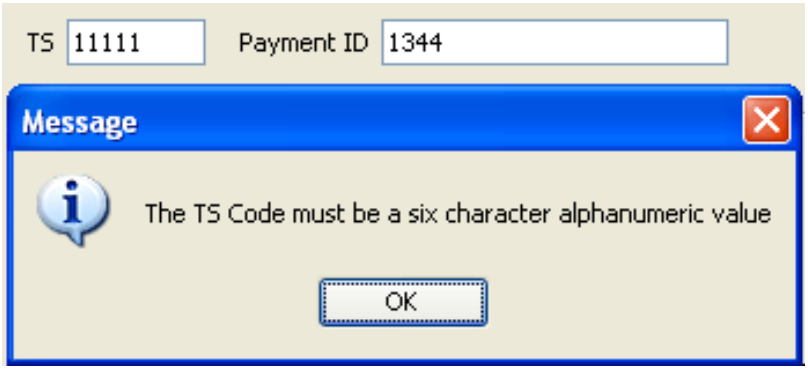
3.7 Validation

eTSCA/e-PMN provides data and business validations on both a field level and an application level.

3.7.1 Field-level Validation

Some fields contain special business rules that require inline validation. In the example seen below, the "TS Code" field requires a six-character alphanumeric string value. eTSCA/e-PMN handles these special validation cases by throwing an error at the point of field exit, preventing an invalid value to be entered. The error will specify the type of input expected for the given field.

Figure 3-17 Field-level validation

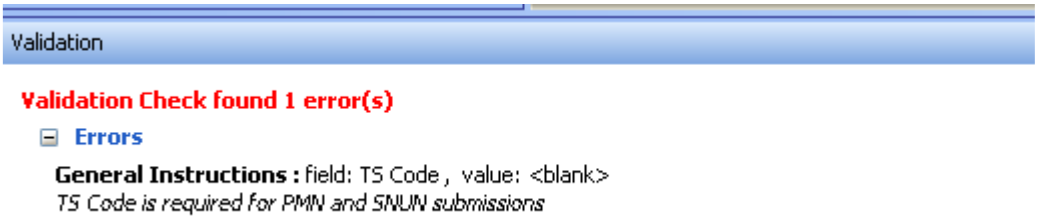


3.7.2 Application-level Validation

eTSCA/e-PMN also performs application-level validation for the entire form. Validation can be activated manually at any time by choosing **Validate** from the **Tools** menu or clicking the validate icon (✔) from the toolbar. This action will start the validation checker, which opens the Validation window at the bottom of the screen and displays any validation errors and warnings.

Figure 3-18 Toolbar Validation icon

Figure 3-19 Application-level validation



Validation errors are critical errors that prevent the form from being submitted. Validation warnings point to potential problems in the form, but are not required to be corrected.

Double-clicking one of the listed items in the validation window will allow users to jump to the page of the error for easy correction.

Validation is automatically performed upon saving an existing project or finalizing a project for EPA submission.

3.8 Printing

Forms are easily printed with eTSCA/e-PMN. The software will create printer-friendly versions of forms in PDF format to facilitate this process. A PDF reader tool, such as Adobe Reader, will be needed to open the PDF files.

A PDF copy can be generated by clicking on the **Print** command from the **File** menu [Figure 3-20] or from the toolbar [Figure 3-21].

Figure 3-20 Printing from the File menu

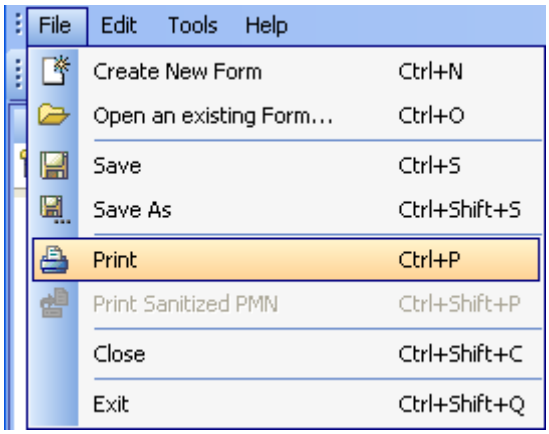
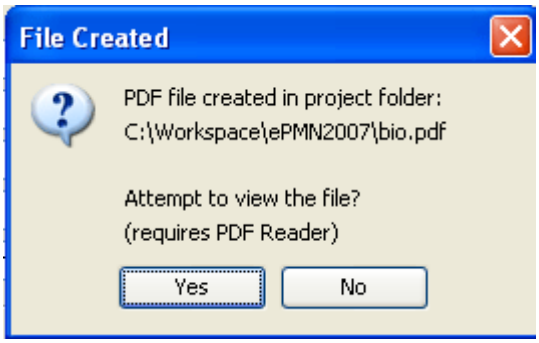


Figure 3-21 Printing from the toolbar icon

A PDF file will be generated with the file name "<Project Name>.pdf" and placed in the current working directory.

Figure 3-22 Saving a PDF



Examples of PDF forms are shown below in Figures 3-23 through 3-26.

Figure 3-23 PMN Sample Output

PMN2008P1

PMN Page 1

U.S. ENVIRONMENTAL PROTECTION AGENCY			AGENCY USE ONLY
EPA	PREMANUFACTURE NOTICE FOR NEW CHEMICAL SUBSTANCES		Date of receipt:
When completed, send this form to:	If sending by Courier: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1201 Constitution Ave NW WASHINGTON, D.C. 20460 Contact Numbers: 202-564-8930/8940	If sending by US Mail: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1200 Pennsylvania Ave NW WASHINGTON, D.C. 20460	Submission Report Number: TEST677689621

Total Number of Pages	User Fee Payment ID Number	TS Number
44	1344	111111

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance, which is sent to EPA, Washington Financial Management Center (3303), P.O. 360399M, Pittsburgh, PA 15251-6399, Attn. TSCA User fee. Indicate the Payment ID number in the box above with the payment source number (e.g., check number, transaction number or wire number).

Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. For all Section 5 Notice submissions (paper or electronic) you must submit an original notice including all test data; if you claimed any information as confidential, an original sanitized copy must also be submitted.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

Part III – LIST OF ATTACHMENTS

For paper submissions, attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance. "Binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . The intention is to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Checking a "binding" box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form; however, in the case of exemption applications (such as TMEA, LVE, LOREX) certain information provided in such notifications is binding on the submitter when the Agency approves the exemption application, especially if the production volume "binding" box is chosen in a LVE.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

- [X] Environmental fate data
- [X] Health effects data
- [X] Environmental effects data
- [X] Physical/Chemical Properties (A physical and chemical properties worksheet is located on the last page of this form.)
- [X] Test data not in the possession or control of the submitter
- [X] Other Data
- [X] Risk Assessments
- [X] Structure/activity relationships

TYPE OF NOTICE (Check Only One)

- [ ] PMN (Premanufacture Notice)
- [X] SNUN (Significant New Use Notice)
- [ ] TMEA (Test Marketing Exemption Application)
- [ ] LVE (Low Volume Exemption) @ 40 CFR 723.50(c)(1)
- [ ] LOREX (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)
- [ ] LVE Modification
- [ ] LOREX Modification
- [ ] Mock Submission
- [X] Mark (X) if pending Letter of Support

IS THIS A CONSOLIDATED PMN (Y/N)?

____ # of chemicals or polymers (Prenotice Communication # required, enter # on p. 3).

- [X] Mark (X) if any information in this notice is claimed as confidential.

EPA FORM 7710-25 (Rev. 5-95) Replaces previous editions of EPA Form 7710-25.

Page 1

Figure 3-24 Notice of Commencement sample output

NOC2008P1

O.M.B. No. 2070-0012 Approval Expires 10/31/96

EPA U.S. Environmental Protection Agency
NOTICE OF COMMENCEMENT OF MANUFACTURE OR IMPORT (40CFR§720.102)

Report Number
XTED548835748

Part I - SUBMITTER IDENTIFICATION Document Control #:

	Name of Authorized Official	Mailing Address (number and street)			CBI*
Manu-facturer/ Importer (In U.S.)	John Smith	123 Main St.			
	Company Name	City	State	Zip	
	ABC Chem Corp.	Oxnard	VT	99999	
Technical Contact (In U.S.)	Name	Telephone Number			
	dsf	sfsf			

Part II - Premanufacture Notice (PMN) "P" Case Number: P081253

Part III - Check the appropriate box and provide the exact date of manufacture or importation:

	First Commercial Manufacture**		First Commercial Importation***
X			
Date:	Apr 4, 2008	Date:	

**Date of commencement is the date of completion of non-exempt manufacture of the first amount (bath, drum, etc.)
***For importees, the date of commencement is the date that the new chemical substance clears U.S. customs.

Part IV - Manufacturing Plant Site(s) or Importing Site(s): (Importers, provide street address of destination)

sfsf

Part V - Specific Chemical Identity: (For Consolidated submissions, each substance must have a separate NOC form with the specific identity of each chemical substance.)

sfdasdf

Part VI - Generic Chemical Name (If chemical identity is claimed CBI*):

Part VII - Substance Identity Confidentiality Status:

	I wish to continue to claim the substance identity confidential and the substantiation to support this claim is attached. Failure to submit the required substantiation in accordance with 40 CFR 720.85(b) will result in a waiver of your claim.
X	I previously claimed the substance identity as confidential and hereby relinquish that claim.
	I did not claim the substance identity as confidential in my original PMN submission.

You must submit your completed notice no later than 30 calendar days after the first date of commercial manufacture/importation to the address shown below:

U.S. Environmental Protection Agency
OPPT Document Control Office (7407M)
1200 Pennsylvania Ave., NW
Washington, D.C. 20460
ATTN: Notice of Commencement

Signature of authorized official		Date	

Note: CBI* - refers to the term "Confidential Business Information". Mark (X) in the box if the information is to be held Confidential.

EPA Form 7710-56 (8-95)

Figure 3-25 PMN Support Document sample output

EPA Support Form							
Support Form Report Number	SUPP648887967			Mark (X) if anything is CBI	X		
I. ORIGINAL NOTICE SUBMISSION IDENTIFICATION							
Report Number	SUPP648887967	TS Number		Case Number			
Original Submission Date	Apr 24, 2008						
Original Submission Media Type	CD						
II. ORIGINAL NOTICE SUBMITTER IDENTIFICATION					CBI		
Authorized Official Name	John Smith		Position	Analyst			
Company Name	ABC Chem Corp.						
Mailing Address (Number & Street)	123 Main St.						
City	Oxnard	State	VT	Postal Code	99999		
e-mail	jsmith@gmail.com		Telephone (include area code)		555-555-5555		
III. CURRENT SUPPORT DOCUMENT IDENTIFICATION INFORMATION					CBI		
Name	John Smith		Position	Analyst			
Company	ABC Chem Corp.						
Mailing Address (Number & Street)	123 Main St.						
City	Oxnard	State	VT	Postal Code	99999		
e-mail	jsmith@gmail.com		Telephone (include area code)		555-555-5555		
IV. TYPE OF SUPPORT (Check One)							
	Letter of Support						
	Withdrawal Request						
	Other Correspondence						
	TEST DATA (Health/Eco/Fate)						
X	Amendment (Changes made to PMN pages 1-13, MSDS or Physical/Chemical properties)						
Check if requested by EPA/ contractor							
EPA person/ contractor							

Figure 3-26 Biotech sample output

EPA Biotech Form

Biotech Form Report Number	XBIO171715277	Mark (X) if anything is CBI ☐

I. SUBMITTER IDENTIFICATION INFORMATION					CBI ☐
Name	John Smith		Position	Analyst	
Company	ABC Chem Corp.				
Mailing Address (Number & Street)	123 Main St.				
City	Oxnard	State	VT	Postal Code	99999
e-mail	jsmith@gmail.com		Telephone (include area code)		555-555-5555

II. TECHNICAL CONTACT IDENTIFICATION INFORMATION					CBI ☐
Name	John Smith		Position	Analyst	
Company	ABC Chem Corp.				
Mailing Address (Number & Street)	123 Main St.				
City	Oxnard	State	VT	Postal Code	99999
e-mail	jsmith@gmail.com		Telephone (include area code)		555-555-5555

III. TYPE OF SUBMISSION (Check One)

- ☒ MCAN (Microbial Commercial Activity Notice)
- ☐ TERA (TSCA Experimental Release Application)
- ☐ Tier I Exemption
- ☐ Tier II Exemption
- ☐ Biotech TME (Test Market Exemption)

IV. TEXT / COMMENTS	CBI ☐
hi there	

Insert Attachment	

3.9 Attachments

Some forms will call for a file attachment for EPA submission. The following is a list of the allowable file types:

- Chemical structure files
  - .mol
  - .skc
  - .pdf or image type

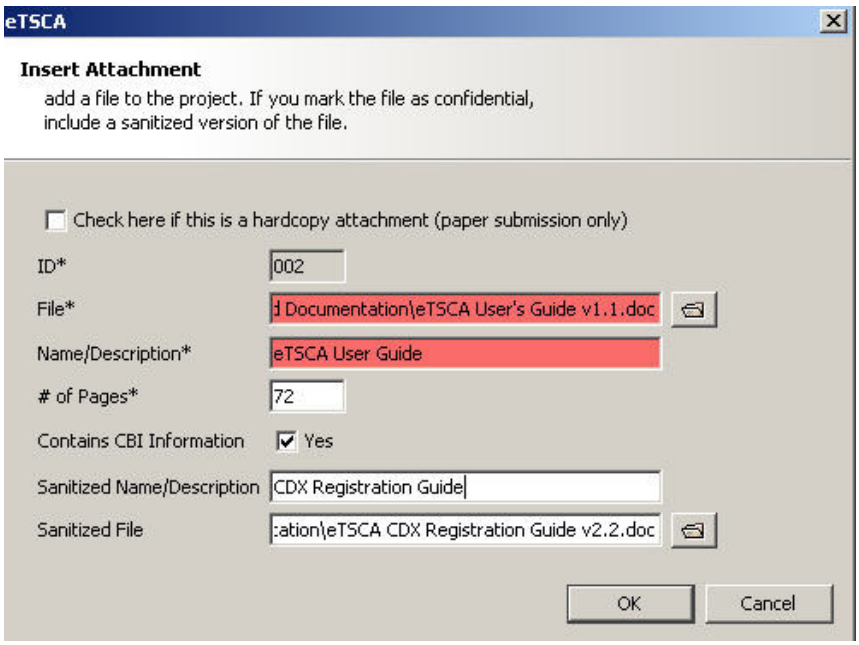
- Image files
  - .gif
  - .jpg
  - .png
  - .bmp

- Document files
  - .pdf
  - .ppt
  - .doc
  - .txt
  - .rtf
  - .xls

- For nucleic acid, amino acid or sequence data submitted for Biotechnology MCANs and TERAs or enzyme related PMNs, the preferred file formats are
  - FASTA files (.fas)
  - GenBank (.gbk)
  - EMBL (.embl)

Attaching a file displays the following dialog box.

Figure 3-27 Attachment Dialog Box



The **ID** field is a unique key to identify the attachment in the project. This ID is automatically generated by the eTSCA/e-PMN reporting software to insure that there are no duplicates.

The **File** field contains path of the file to attach. This field is required for electronic attachments. If the "Check here if this is a hardcopy attachment" field is checked, a paper submission will be expected instead.

The **Name/Description** displays the attachment's title or description.

The **# of Pages** field is for the total number of pages in the attachment.

The **Confidential** checkbox is to indicate whether or not the attachment contains Confidential Business Information (CBI)

The **Sanitized File** field is the path of the sanitized file in the case where the main file contains CBI.

The **Sanitized Name/Description** field displays the sanitized attachment's title or description.

4 Central Data Exchange (CDX)

The EPA Central Data Exchange (CDX) is a service that enables users to electronically submit data to EPA.

Pre-registration with CDX is required to submit online. Please see the CDX Registration Guide for more information on how to register with CDX (https://cdx.epa.gov/TSCA/ eTSCA-CDX_Registration_Guide.pdf)

eTSCA/e-PMN contains a CDX component that performs the following tasks:

- Connecting to the CDX Node
- Validation of the submission information with CDX Registration
- Generation of the cryptographic key pair
- Encryption of the file
- Decryption of the file
- Transmission of the document – ability to electronically submit eTSCA projects to EPA via the CDX Node
- Transaction Search – ability to search the submitted documents by CDX Transaction ID number
- Document Download – ability to download ancillary documents related to submission, e.g., Copy of Record

5 Pre-Manufacture Notice Form

5.1 Usage

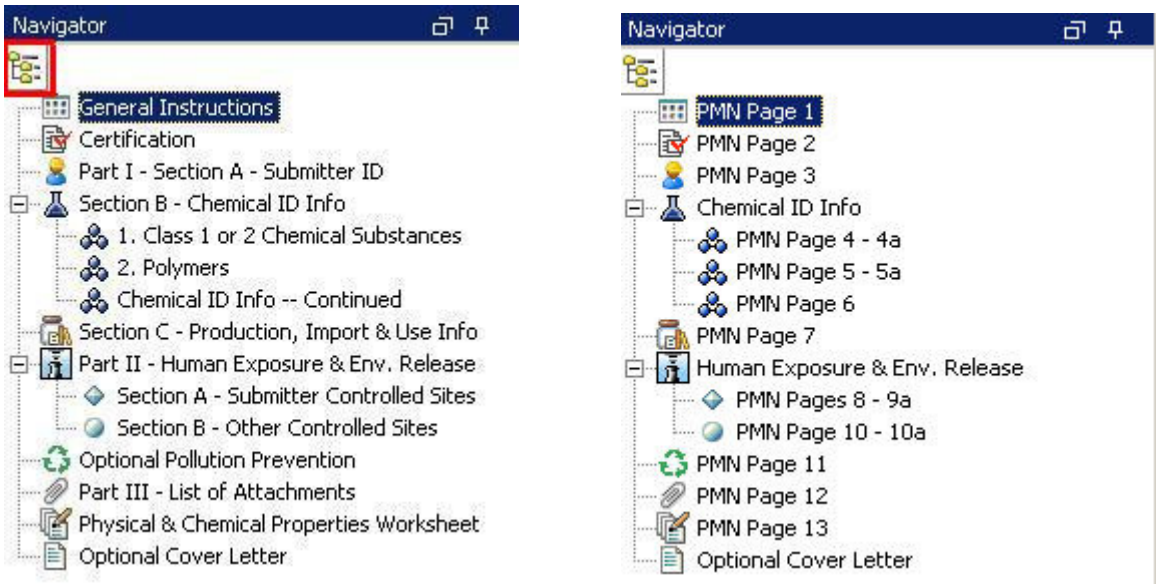
Any organization planning to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by Section 5 of TSCA to provide the Environmental Protection Agency with notice before initiating the activity. This Pre-manufacture notice, or PMN, must be submitted at least 90 days prior to the manufacture or import of the chemical. For more information on the New Chemicals Program, please visit: http://www.epa.gov/oppt/newchems/index.htm.

The PMN form should be used to submit PMNs, SNUNs, LVEs and LoRex Exemptions and Modifications, TMEA exemptions, and Mock PMNs.

5.2 PMN Navigation

The toggle button seen in Figure 5-1 below will switch the view of the navigator window between displaying forms by name and by page number.

Figure 5-1 Navigator Windows with titled by page name and page number

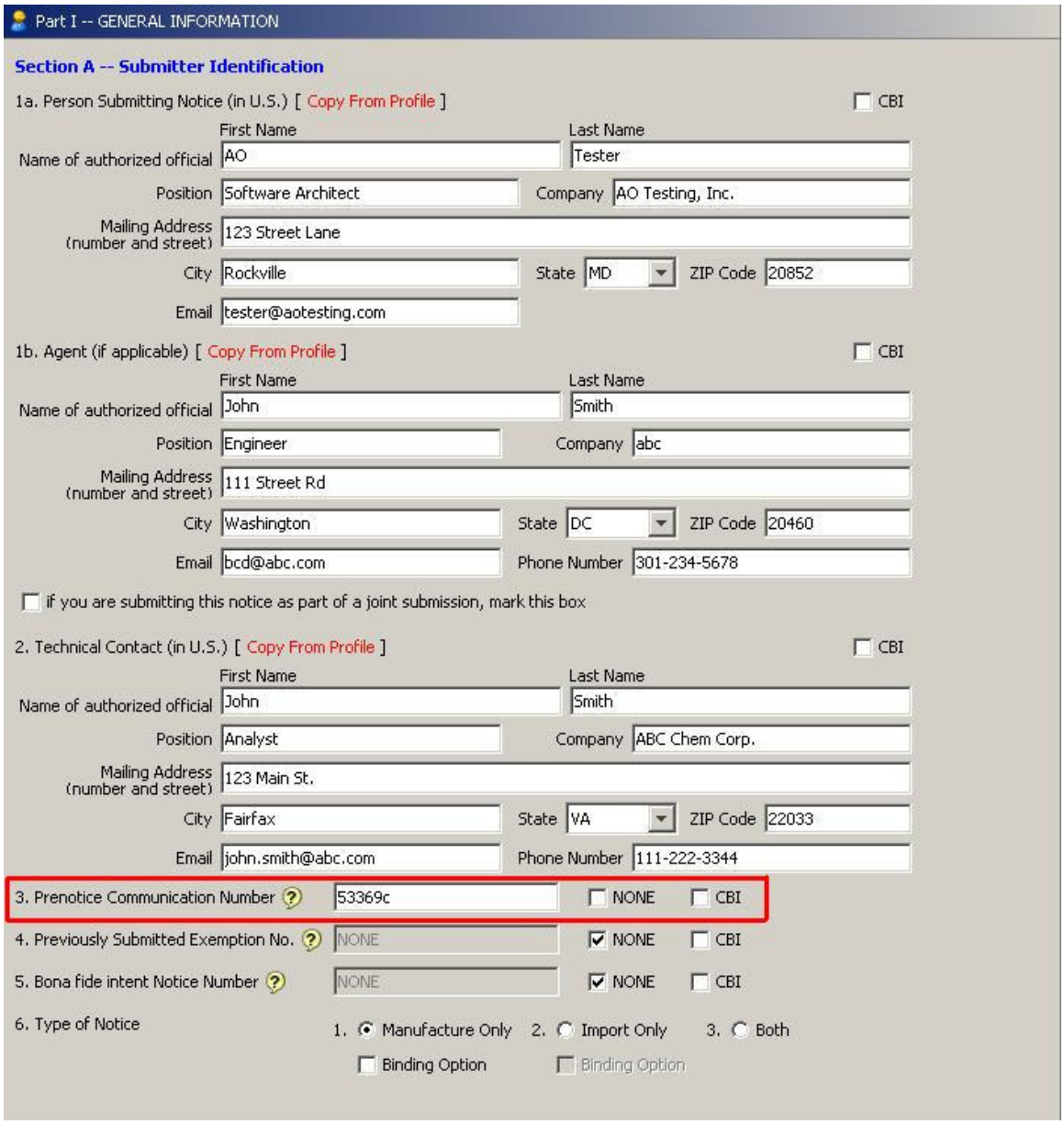


5.3 Consolidated Submissions

Up to six cases may be included in one submission. Any submission containing more than one case is considered a **consolidated submission**.

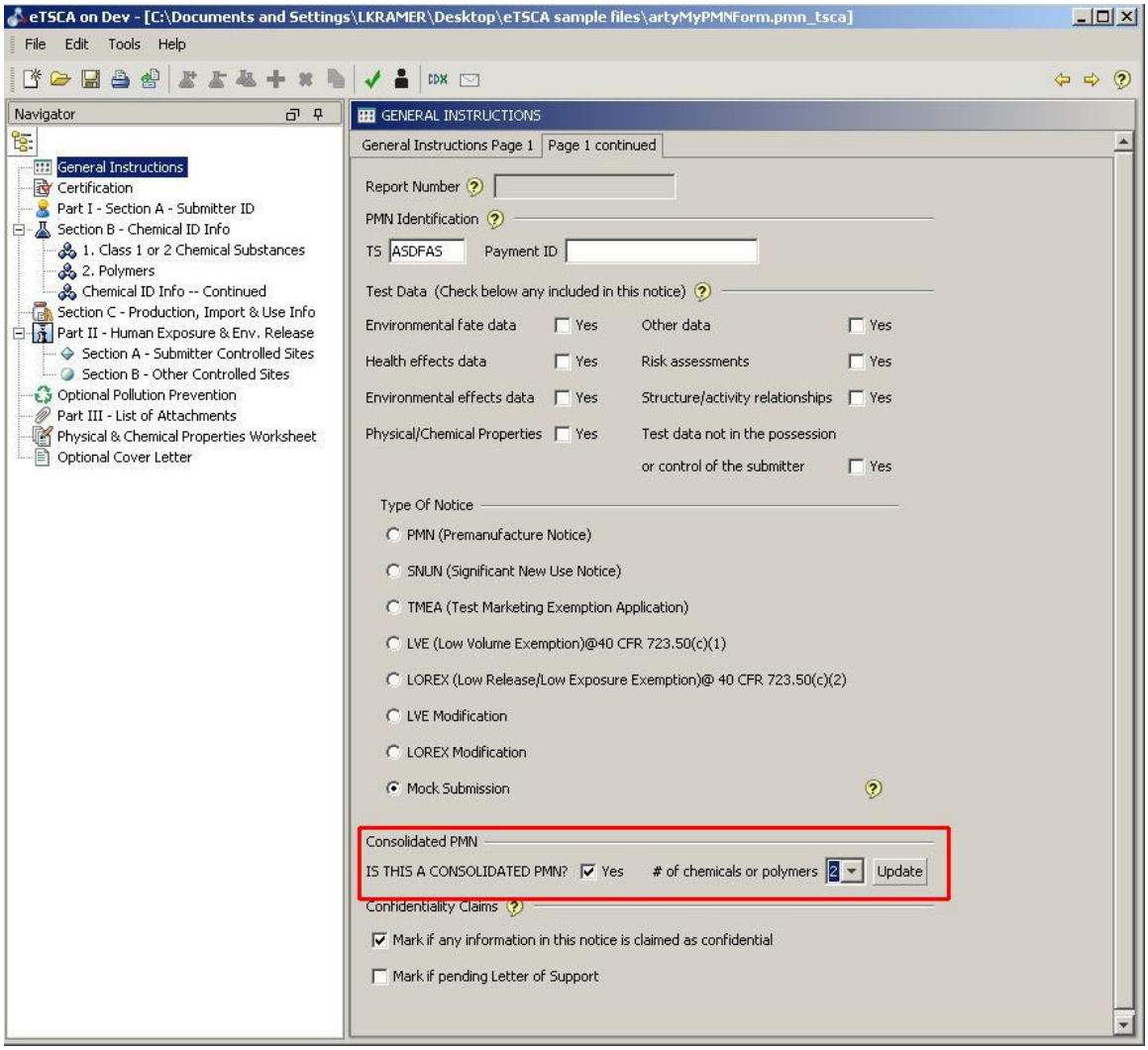
Consolidated submissions require preapproval from the EPA. Contact EPA to receive a Pre-Notice Communication (PNC) number before attempting to submit a consolidated submission.

Figure 5-2 PMN Form: PNC Number



Users submitting a consolidated submission should denote this using the checkbox located on the "General Instructions" page of the PMN.

Figure 5-3 Denoting a consolidated PMN



Consolidated submissions do not need to be specified on the PMN page 1 in advance of adding extra chemicals. See the Adding, Deleting, or Cloning Chemical Data section for information on how to dynamically add or delete a chemical group.

5.4 PMN-specific actions

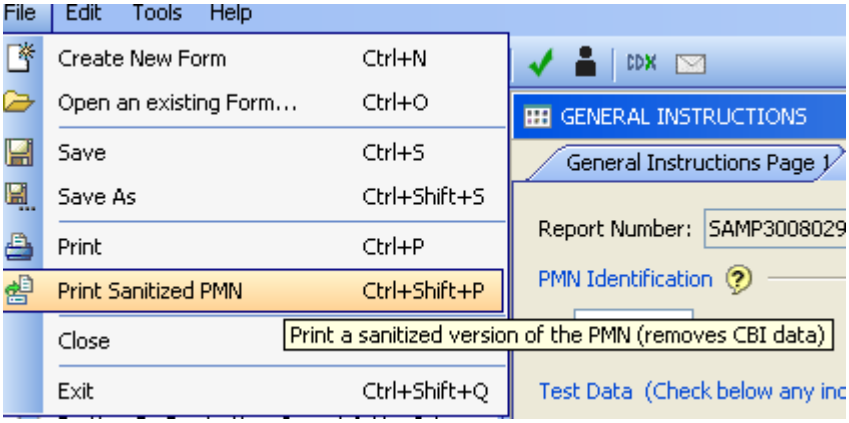
5.4.1 Sanitization

Sanitization removes CBI data from the form so that the data can be shared with the general public.

5.4.1.1 Creating a sanitized version of the PMN form

Submitters should create a sanitized PDF to confirm that all CBI has been properly denoted and removed. A PDF file of a sanitized PMN form can be created by selecting **Print Sanitized PMN** from the **File** menu or by selecting the Sanitize button ( ) from the toolbar.

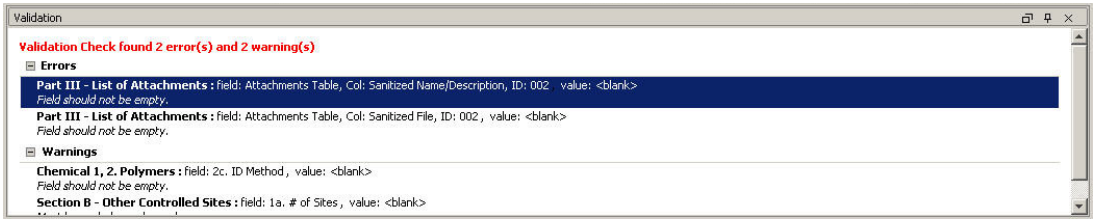
Figure 5-4 Sanitizing a PMN



5.4.1.2 Sanitizing attachment files

File attachments marked as CBI require a sanitized version. The sanitized version must be created by the submitter and attached before submission. The validation checker prevents finalization of the submission until all CBI attachments have corresponding sanitized files attached as well.

Figure 5-5 Sanitized file required



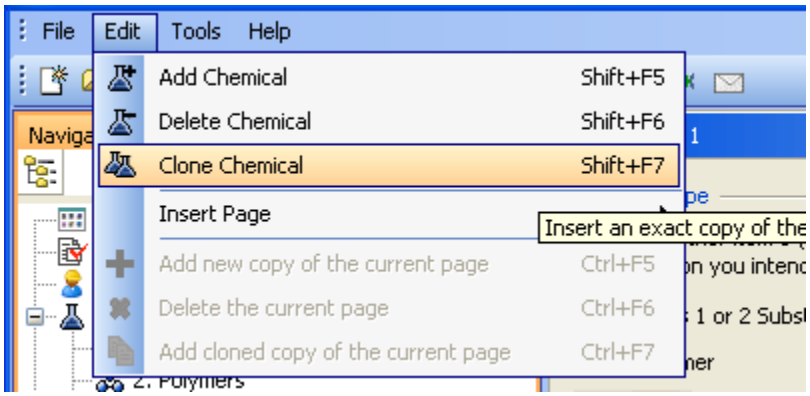
5.4.1.3 Submitting a sanitized version of the PMN form

When a PMN project is finalized for submission, a sanitized copy of the data is automatically generated within the finalized file. A separate submission is not required.

5.4.1.4 Adding, Deleting or Cloning Chemical Data

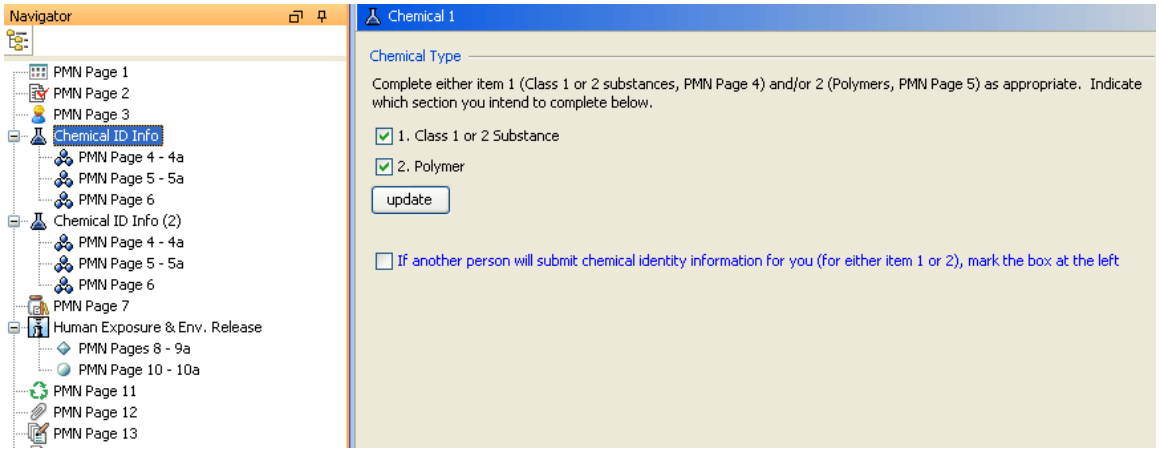
Users can add, delete, or create an exact copy (clone) of a chemical group (PMN Pages 4-6) by clicking on the respective menu items from the **Edit** menu or using the toolbar icons.

Figure 5-6 Cloning a chemical group



Chemical groups may be added at any time, but cloning or deleting a chemical group will require the software focus to be on the header page for that group.

Figure 5-7 Navigation for chemical cloning or deletion



5.4.2 Adding, Deleting or Cloning a PMN page

The eTSCA/e-PMN reporting software allows adding multiple copies of specific PMN pages:

- PMN Page 7 – Part I, Section C., Production, Import and Use Information
- PMN Pages 8-9a – Part II, Section A., Industrial Sites Controlled by the Submitter
- PMN Page 10-10a – Part II, Section B., Industrial Sties Controlled by Others
- PMN Page 13 – Physical & Chemical Properties Worksheet

To add, remove, or clone PMN pages, click on the respective menu items from the **Edit** menu or use the toolbar icons.

Figure 5-8 Adding a PMN page

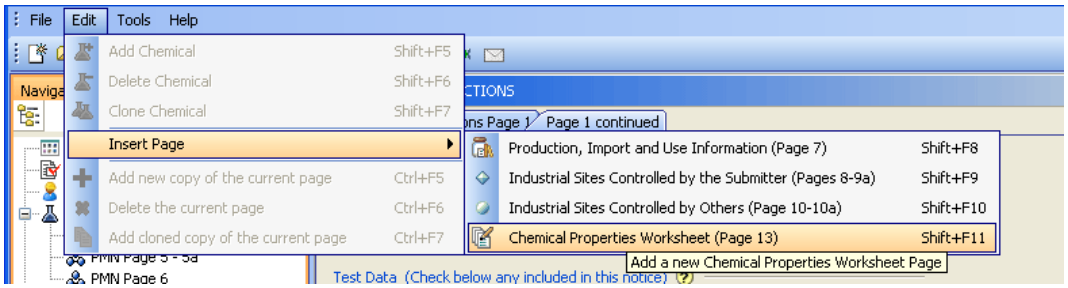
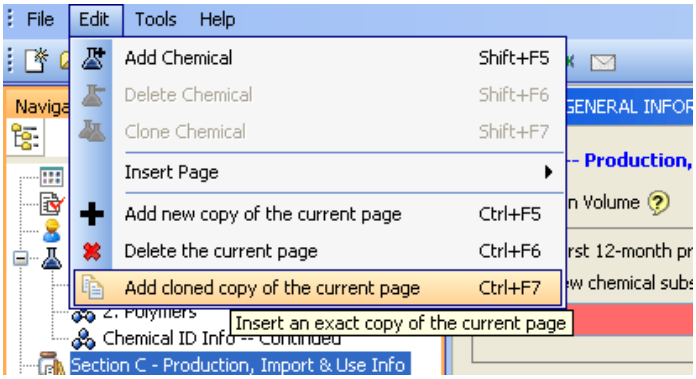


Figure 5-9 Cloning a PMN page



5.5 PMN Pages

The paper PMN form contains 13 PMN pages. eTSCA/e-PMN follows that convention by splitting the eTSCA/e-PMN version of the PMN form as closely as possible into those 13 pages. The PMN pages are as follows:

- PMN Page 1 – General Instructions
- PMN Page 2 – Certification
- PMN Page 3 – Submitter ID
- PMN Page 4—Class 1 or 2 Chemical Substance
- PMN Page 5 – Polymers
- PMN Page 6 – Chemical ID Info—continued
- PMN Page 7 – Production, Import, and Use Information
- PMN Pages 8-9 – Section A—Submitter Controlled Sites
- PMN Page 10 – Other Controlled Sites
- PMN Page 11 – Optional Pollution Prevention
- PMN Page 12 – List of Attachments
- PMN Page 13 – Physical and Chemical Properties Worksheet
- Optional Cover Letter

For specific help with any of these pages, click the dynamic help button on the toolbar. See the Page-level Help section for more information.

6 Notice of Commencement Form

6.1 Usage

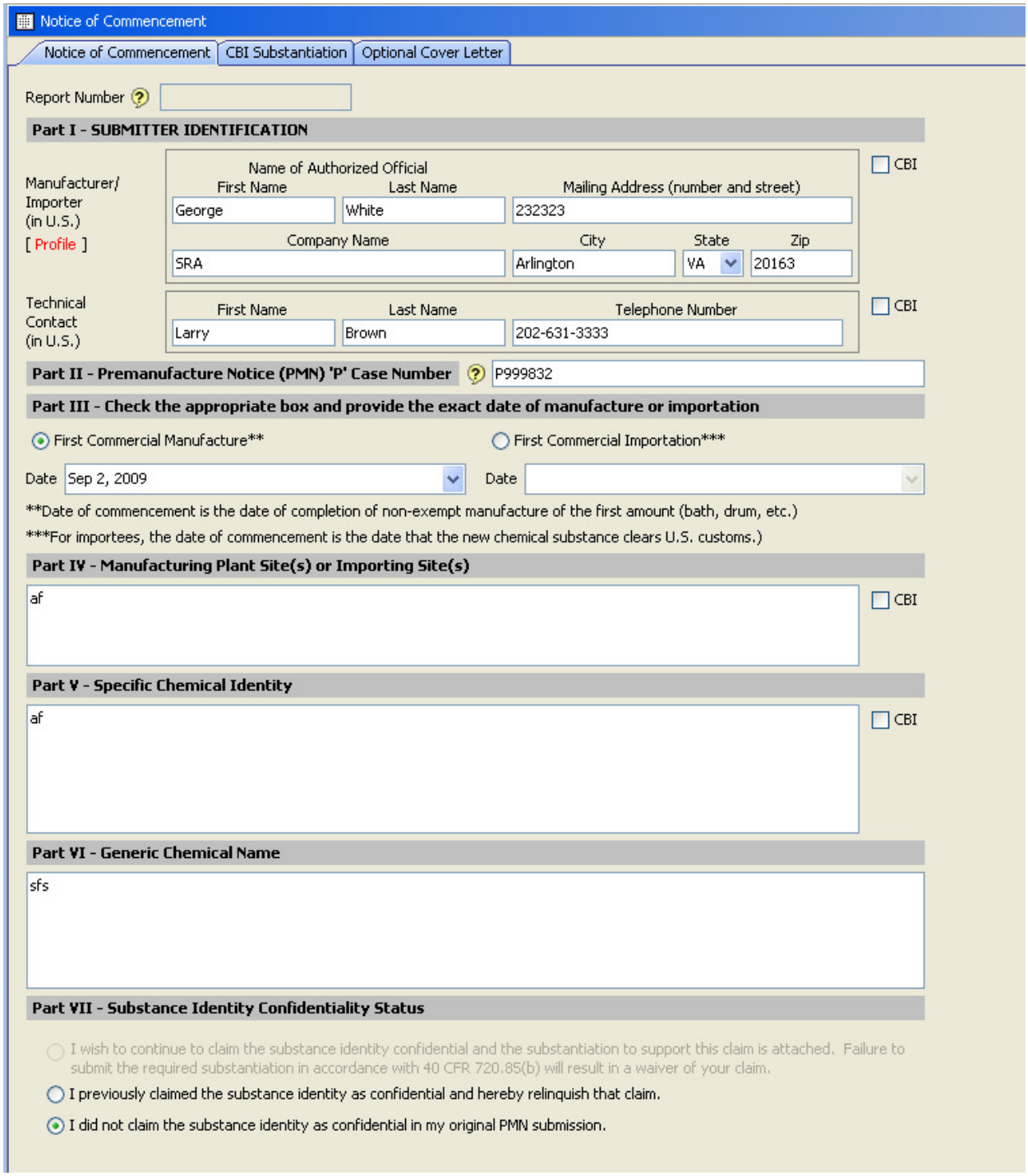
A new chemical is eligible for addition to TSCA Inventory after the PMN review period has expired and the PMN submitter has commenced non-exempt commercial manufacture or import. The submitter of a PMN must provide a Notice of Commencement of Manufacture or Import (EPA Form 7710-56) to EPA within 30 days of the date the substance is first manufactured or imported for nonexempt commercial purposes. It will then be listed on the TSCA Inventory. Once a substance is listed on the TSCA (Toxic Substances Control Act) Inventory, it is considered an "existing" chemical.

For more information on filing a Notice of Commencement, please visit http://www.epa.gov/oppt/newchems/pubs/filenoc.htm.

6.2 Notice of Commencement tab

The main form tab contains all the fields needed to complete a Notice of Commencement form.

Figure 6-1 Notice of Commencement main form tab



6.3 CBI Substantiation tab

Users submitting NOCs with Confidential Business Information (CBI) will be required to substantiate a claim in this section.

6.4 Optional Cover Letter tab

Additional information can be added on the Optional Cover Letter tab. When printed out, this information will appear on the first printed page as the cover letter.

6.5 Printed PDF form sample

Figure 6-2 Sample PDF NOC form

NOC2008P1

O.M.B. No. 2070-0012 Approval Expires 10/31/96

U.S. Environmental Protection Agency
NOTICE OF COMMENCEMENT OF MANUFACTURE OR IMPORT (40CFR§720.102)

EPA

Report Number
XTED548835748

Part I - SUBMITTER IDENTIFICATION Document Control #:

	Name of Authorized Official	Mailing Address (number and street)			CBI*
Manu-facturer/ Importer (In U.S.)	John Smith	123 Main St.			
	Company Name	City	State	Zip	
	ABC Chem Corp.	Oxnard	VT	99999	
Technical Contact (In U.S.)	Name	Telephone Number			
	dsf	sfsf			

Part II - Premanufacture Notice (PMN) "P" Case Number: P081253

Part III - Check the appropriate box and provide the exact date of manufacture or importation:

X	First Commercial Manufacture**		First Commercial Importation***
Date:	Apr 4, 2008	Date:	

**Date of commencement is the date of completion of non-exempt manufacture of the first amount (bath, drum, etc.)
***For importees, the date of commencement is the date that the new chemical substance clears U.S. customs.

Part IV - Manufacturing Plant Site(s) or Importing Site(s): (Importers, provide street address of destination)

sfsf

Part V - Specific Chemical Identity: (For Consolidated submissions, each substance must have a separate NOC form with the specific identity of each chemical substance.)

sfdasdf

Part VI - Generic Chemical Name (If chemical identity is claimed CBI*):

Part VII - Substance Identity Confidentiality Status:

	I wish to continue to claim the substance identity confidential and the substantiation to support this claim is attached. Failure to submit the required substantiation in accordance with 40 CFR 720.85(b) will result in a waiver of your claim.
X	I previously claimed the substance identity as confidential and hereby relinquish that claim.
	I did not claim the substance identity as confidential in my original PMN submission.

You must submit your completed notice no later than 30 calendar days after the first date of commercial manufacture/importation to the address shown below:

U.S. Environmental Protection Agency
OPPT Document Control Office (7407M)
1200 Pennsylvania Ave., NW
Washington, D.C. 20460
ATTN: Notice of Commencement

Signature of authorized official		Date	

Note: CBI* - refers to the term "Confidential Business Information". Mark (X) in the box if the information is to be held Confidential.

EPA Form 7710-56 (8-95)

7 Biotechnology Form (MCAN, TERA, TIER I & TIER 2)

7.1 Regulation

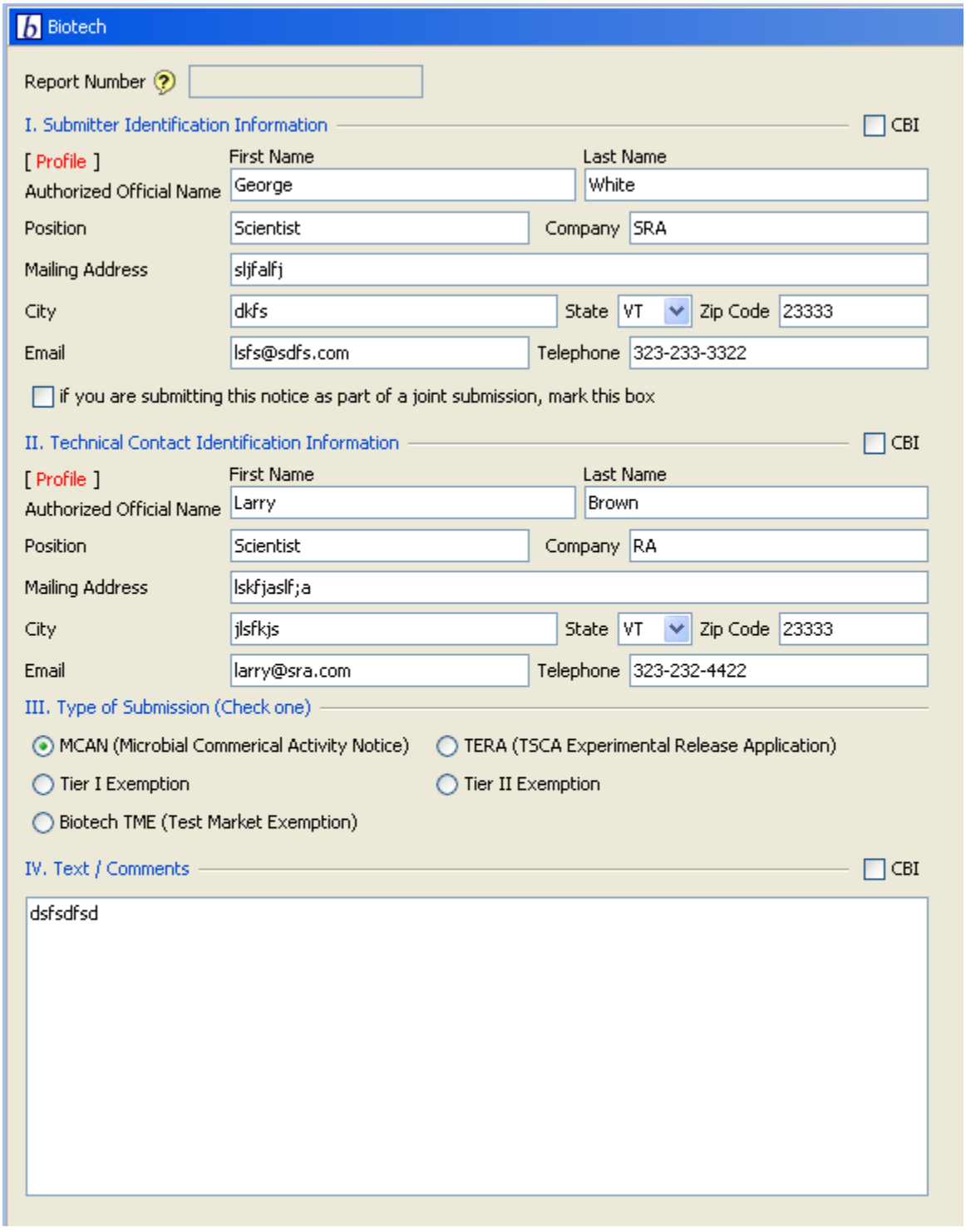
Under a 1986 intergovernmental policy statement and TSCA Section 5, intergeneric microorganisms (microorganisms created to contain genetic material from organisms in more than one taxonomic genera) are considered new chemicals. The Biotechnology rule sets forth the manner in which the Agency will review and regulate the use of intergeneric microorganisms in commerce, or commercial research. For more information, please visit: http://www.epa.gov/oppt/biotech/pubs/biorule.htm.

These regulations create a reporting vehicle specifically designed for microorganisms, the Microbial Commercial Activity Notice (MCAN). Persons intending to use intergeneric microorganisms for commercial purposes in the United States would submit an MCAN to EPA at least 90 days before such use. EPA has 90 days to review the submission in order to determine whether the intergeneric microorganism may present an unreasonable risk to human health or the environment.

The rules also address intergeneric microorganisms used in R&D for commercial purposes and create a vehicle for reporting on testing of new microorganisms in the environment, a TSCA Experimental Release Application (TERA). A TERA would be submitted to EPA at least 60 days prior to initiating such field trials. The TERA is designed, in recognition of the needs of researchers, to provide a high measure of flexibility and a shorter review period of 60 days. Research & Development for commercial purposes are those activities which are funded directly, in whole or in part, by a commercial entity, regardless of who is actually conducting the research; or which will obtain for the researcher an immediate or eventual commercial advantage. For more information on Microbial Products of Biotechnology, please visit: http://www.epa.gov/oppt/biotech/pubs/fs-001.htm.

7.2 Screenshot

Figure 7-1 Biotech Form



7.3 Printed PDF Form Sample

Figure 7-2 PDF Biotech Form sample

EPA Biotech Form

Biotech Form Report Number	XBIO171715277	Mark (X) if anything is CBI ☐

I. SUBMITTER IDENTIFICATION INFORMATION — CBI ☐

Name	John Smith		Position	Analyst	
Company	ABC Chem Corp.				
Mailing Address (Number & Street)	123 Main St.				
City	Oxnard	State	VT	Postal Code	99999
e-mail	jsmith@gmail.com		Telephone (include area code)	555-555-5555	

II. TECHNICAL CONTACT IDENTIFICATION INFORMATION — CBI ☐

Name	John Smith		Position	Analyst	
Company	ABC Chem Corp.				
Mailing Address (Number & Street)	123 Main St.				
City	Oxnard	State	VT	Postal Code	99999
e-mail	jsmith@gmail.com		Telephone (include area code)	555-555-5555	

III. TYPE OF SUBMISSION (Check One)

- ☒ MCAN (Microbial Commercial Activity Notice)
- ☐ TERA (TSCA Experimental Release Application)
- ☐ Tier I Exemption
- ☐ Tier II Exemption
- ☐ Biotech TME (Test Market Exemption)

IV. TEXT / COMMENTS — CBI ☐

hi there

Insert Attachment	

8 PMN Support Document Form

8.1 Usage

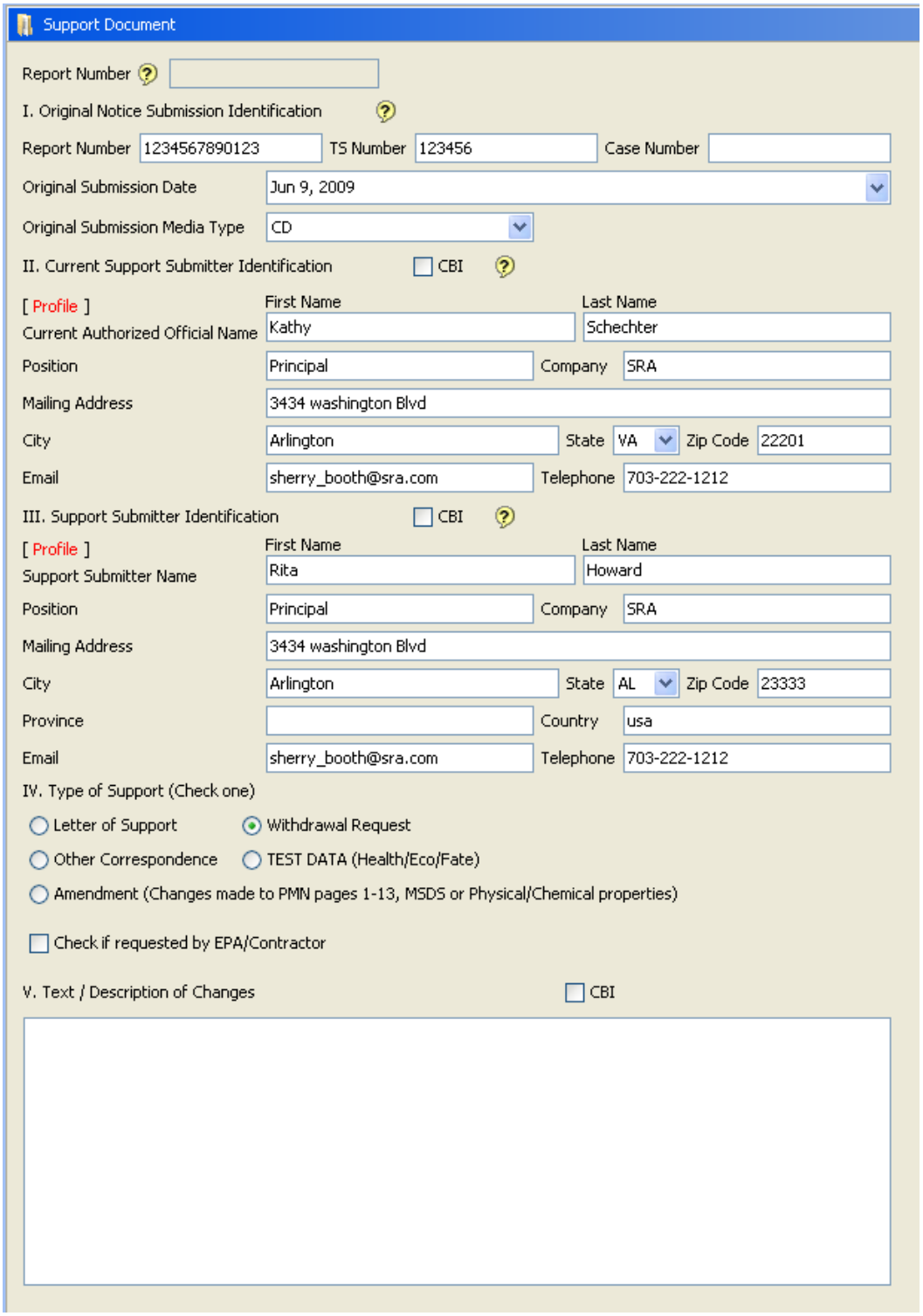
The PMN Support Document provides users with an opportunity to add supporting or supplemental information for an original PMN or Biotechnology submission.

A support document may include the following types of information:

- Letter of Support
- Withdrawal Request
- Test Data (Health/Ecotoxicity/Fate)
- Amendment (changes made to PMN pages 1-13, MSDS or Physical/Chemical properties)
- Other Correspondence

8.2 Screenshot

Figure 8-1 PMN Support Document Form



8.3 Printed PDF Form sample

Figure 8-2 PMN Support Document PDF Sample Form

EPA Support Form					
Support Form Report Number	SUPP648887967			Mark (X) if anything is CBI	X
I. ORIGINAL NOTICE SUBMISSION IDENTIFICATION					
Report Number	SUPP648887967	TS Number		Case Number	
Original Submission Date	Apr 24, 2009				
Original Submission Media Type	CD				
II. ORIGINAL NOTICE SUBMITTER IDENTIFICATION				CBI	
Authorized Official Name	John Smith	Position	Analyst		
Company Name	ABC Chem Corp.				
Mailing Address (Number & Street)	123 Main St.				
City	Oxnard	State	VT	Postal Code	99999
e-mail	jsmith@gmail.com	Telephone (include area code)		555-555-5555	
III. CURRENT SUPPORT DOCUMENT IDENTIFICATION INFORMATION				CBI	
Name	John Smith	Position	Analyst		
Company	ABC Chem Corp.				
Mailing Address (Number & Street)	123 Main St.				
City	Oxnard	State	VT	Postal Code	99999
e-mail	jsmith@gmail.com	Telephone (include area code)		555-555-5555	
IV. TYPE OF SUPPORT (Check One)					
	Letter of Support				
	Withdrawal Request				
	Other Correspondence				
	TEST DATA (Health/Eco/Fate)				
X	Amendment (Changes made to PMN pages 1-13, MSDS or Physical/Chemical properties)				
Check if requested by EPA/ contractor					
EPA person/ contractor					

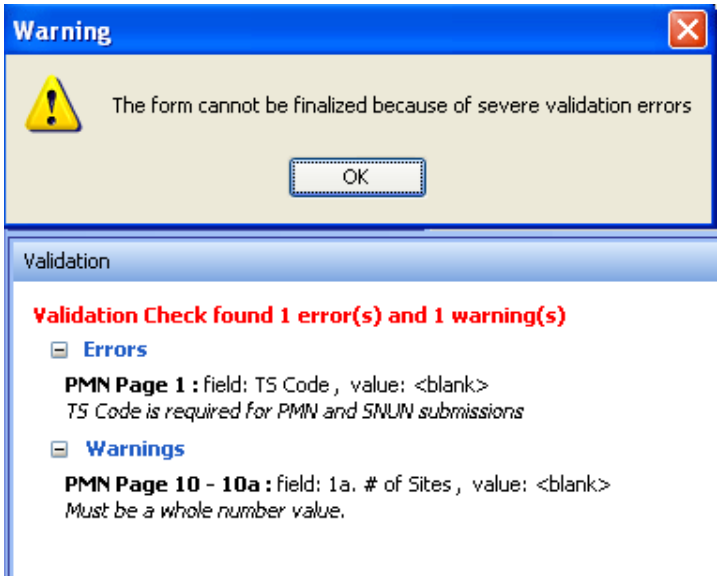
9 Submission Process

9.1 Finalize Command

Projects must be finalized before submission. The finalization process insures that the submitted data is valid and that all preliminary steps have been completed.

Select **Finalize** from the Tools menu, or click the **Finalize** icon ( ) on the toolbar to begin the finalization process. The validation checker will then run. If a project fails validation, the user will not be able to continue until the necessary fixes are made.

Figure 9-1 Cannot finalize due to validation errors



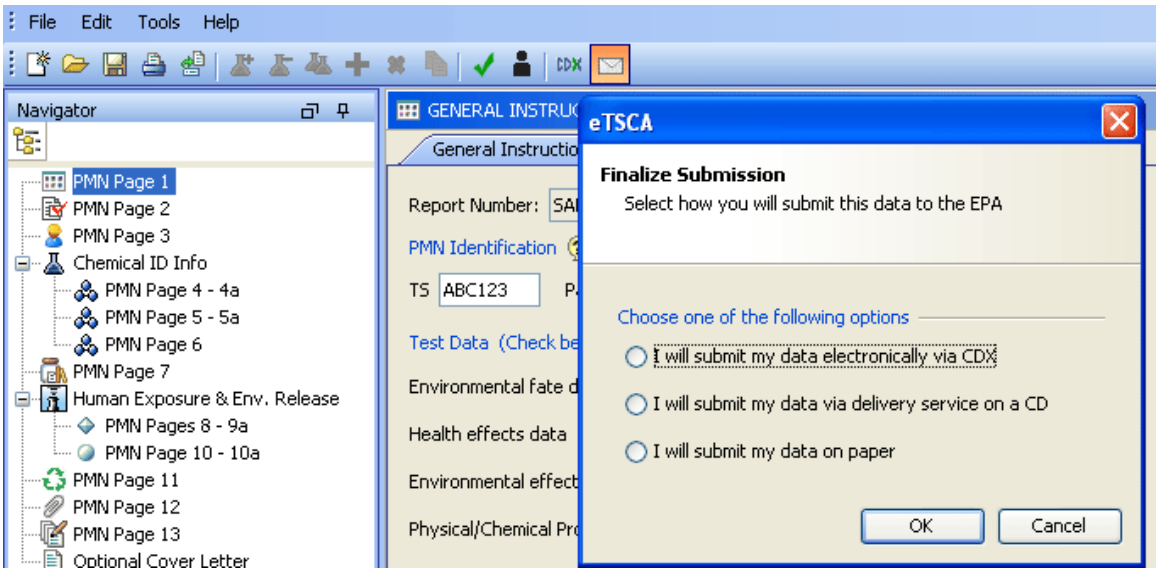
If no critical errors are found, the software will alert the user that a new report number has been generated for the current submission [Figure 9-2], and the **Finalize Submission** dialog box will appear [Figure 9-3].

Figure 9-2 New report number generated

The user will be prompted to select a method of submission to the EPA. Three options will be displayed:

- "I will submit my data electronically via CDX"
- "I will submit my data via delivery service on a CD"
- "I will submit my data on paper"

Figure 9-3 Finalize Submission Dialog Box



9.2 Paper Submission

If the paper submission option is chosen, eTSCA/e-PMN will create a PDF file in your current working directory called **"<Project Name>_finalized.pdf"** and, if necessary, a suitable for submission sanitized PDF file called **"<Project Name>_sanitized_finalized.pdf."** For example, a PMN project called "**proj1.pmn_tsca**" will produce a "**proj1_finalized.pdf**" submission file.

PDF files will contain a barcode on the top-left corner of each page. This is used by EPA for scanning purposes.

If the form contains attachments, the finalized PDF will have a header page for each attachment. Attachments should be printed out (if not already a hardcopy) and placed behind each attachment header page.

9.3 CD Submission

If the CD submission option is chosen, eTSCA/e-PMN will create a "finalized" project file called "**<Project Name>_finalized.<project_type_extension>"** in the current working directory. For example, a PMN project called "**proj1.pmn_tsca**" will produce a **"proj1_finalized.pmn_tsca"** read-only file. The finalized file will contain the sanitized data.

eTSCA/e-PMN will also create a certification PDF print out containing the MD5 checksum value of the file. This checksum number uniquely identifies the content of the finalized file. If the finalized file is changed in any way, the checksum will not be reproducible. In other words, the checksum guarantees that data has not been tampered with after it leaves the user's hands. This file will use the naming convention "**<Project Name>_cert.<project_type_extension>**" (e.g., "**proj1.pmn_tsca**" will produce a "**proj1_cert.pdf**" file).

The certification file will also contain the cover letter, the certification/signature page (PMN page 2) and the contact information page (PMN page 3). Please certify and sign when appropriate and submit the original with the CD to the EPA by courier.

The finalized file must be burned to a CD and submitted along with a copy of the PDF printout containing the checksum. PMN and NOC form printouts must also be signed and dated.

9.4 Online CDX Submission

Only CDX registered users will be able to use the CDX submission option. Please see the CDX Registration Guide for more information on how to register with CDX ((https://cdx.epa.gov/TSCA/ eTSCA-CDX_Registration_Guide.pdf). Users submitting on behalf of another organization must have registered the names of those companies and be authorized to submit for those organizations.

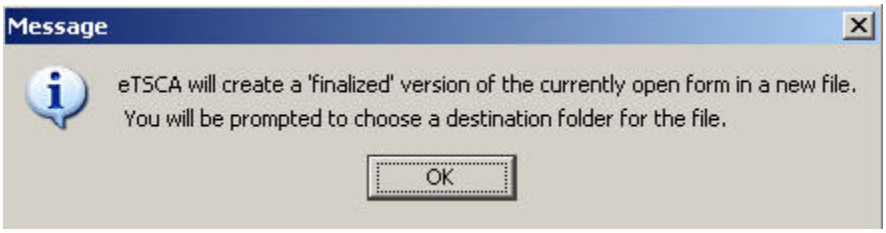
After selecting the Finalize button and after choosing to submit via CDX, eTSCA/e-PMN creates a "finalized" project file called "**<Project Name>_finalized.<project_type_extension>"** in a directory of your choosing. For example, a PMN project called "**proj1.pmn_tsca**" will produce a **"proj1_finalized.pmn_tsca"** read-only file.

Users will be prompted to enter a username and password in order to login before submission [Figure 9-4].

Figure 9-4 Login to CDX from eTSCA/e-PMN software

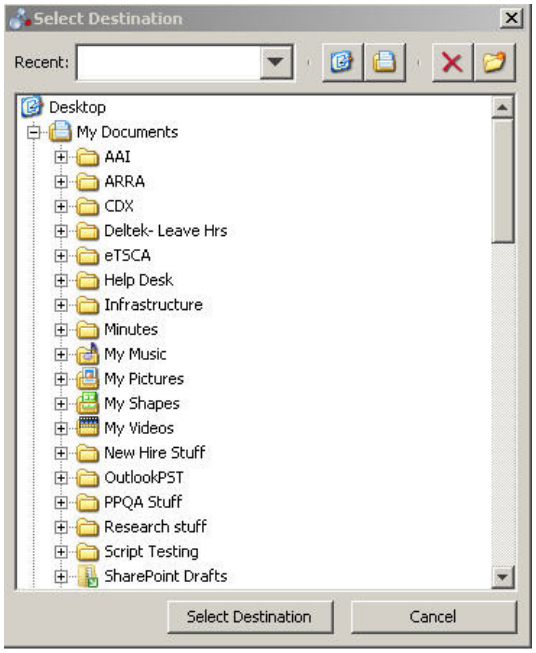
eTSCA/e-PMN software will verify the submission information with CDX registration. If the data agrees, eTSCA/e-PMN will display a message informing the user that a finalized version of the file is being created.

Figure 9-5 Finalization in progress



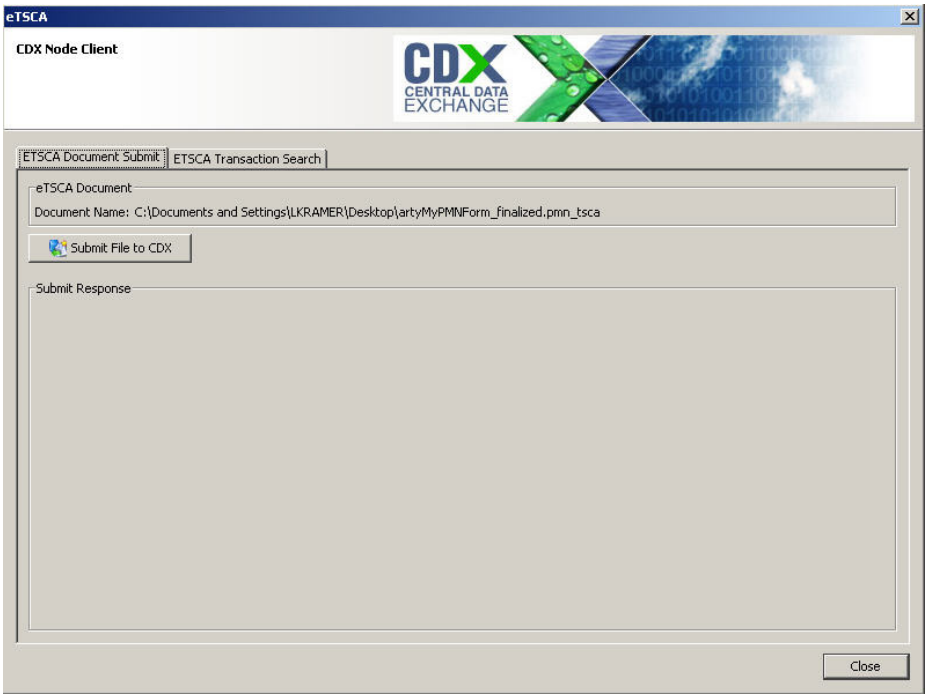
After clicking “OK” the following screen will appear. The user will be asked to select a destination folder to house the finalized version of the file.

Figure 9-6 Select destination for finalized file



Once a location is selected, eTSCA/e-PMN will save the finalized file and open the CDX Node Client, seen in Figure 9-7 below.

Figure 9-7 Node Client



Click the "Submit File to CDX" button to continue the submission process.

9.4.1 User Certificate and Key Pair Generation

A user certificate and Private/Public Key pair is used to digitally sign and encrypt the submitted documents, providing security protection for eTSCA/e-PMN submissions. The certificate and key pair will be automatically obtained by the Node Client after the first login.

The Node Client stores the following data into a keystore under the user home directory:

- user ID
- user private key
- user certificate
- creation time

The following file will be created: \<userHome>\ .<userId>-cromerr-keystore.jks where <userHome> is a local user home directory (C:\Documents and Settings\myuser) and <userId> is an eTSCA/e-PMN user ID registered with CDX Web. Since this file is stored on the user's local drive, the user will only be able to access the submitted documents from this specific machine unless the key file is copied into the same location of another machine. In any case, the user can copy this file to another safe location for backup, if desired.

Upon clicking the "Submit File to CDX" button, the user will need to complete the electronic signature agreement and verify his or her identify. The following screens will be displayed.

Figure 9-8 CROMERR page

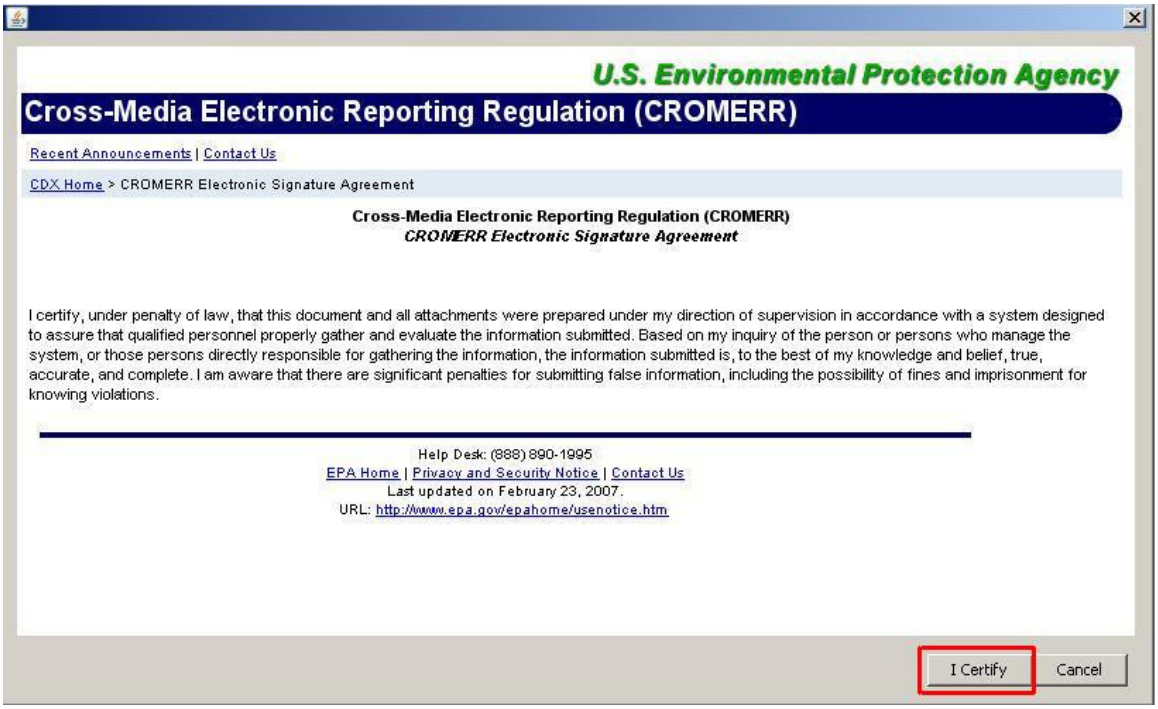


Figure 9-9 20-5-1 Security Question

When the security question is answered correctly, the system will encrypt the document with the public key of the back-end server and transmit the encrypted document with related metadata to CDX. The CDX Transaction ID will act as a unique identifier for the submission and will be presented to the user for reference.

Figure 9-10 Submission in progress

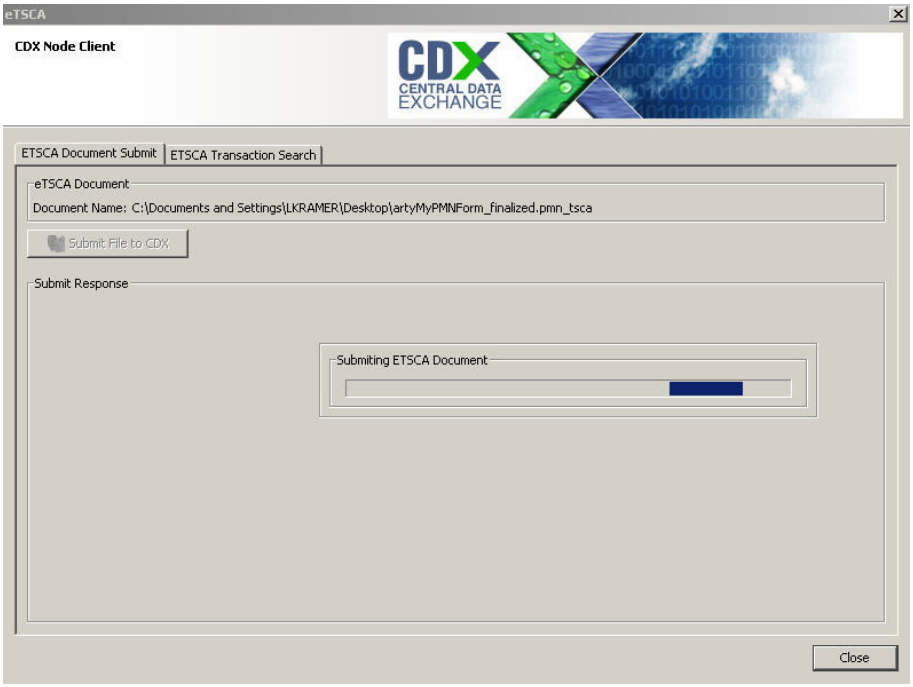
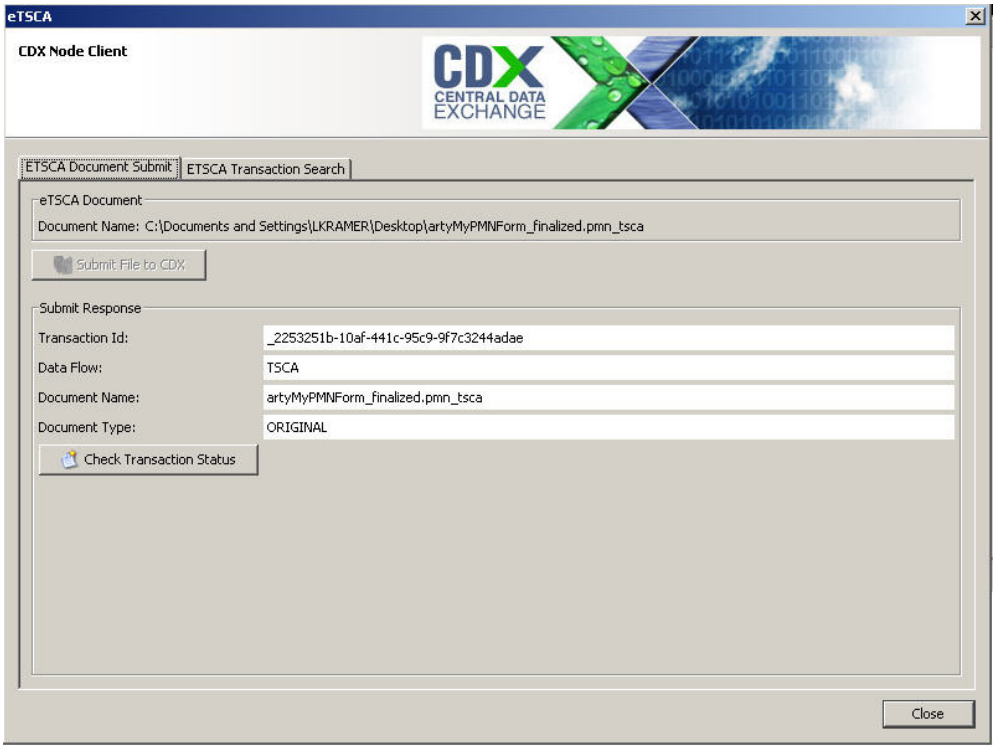


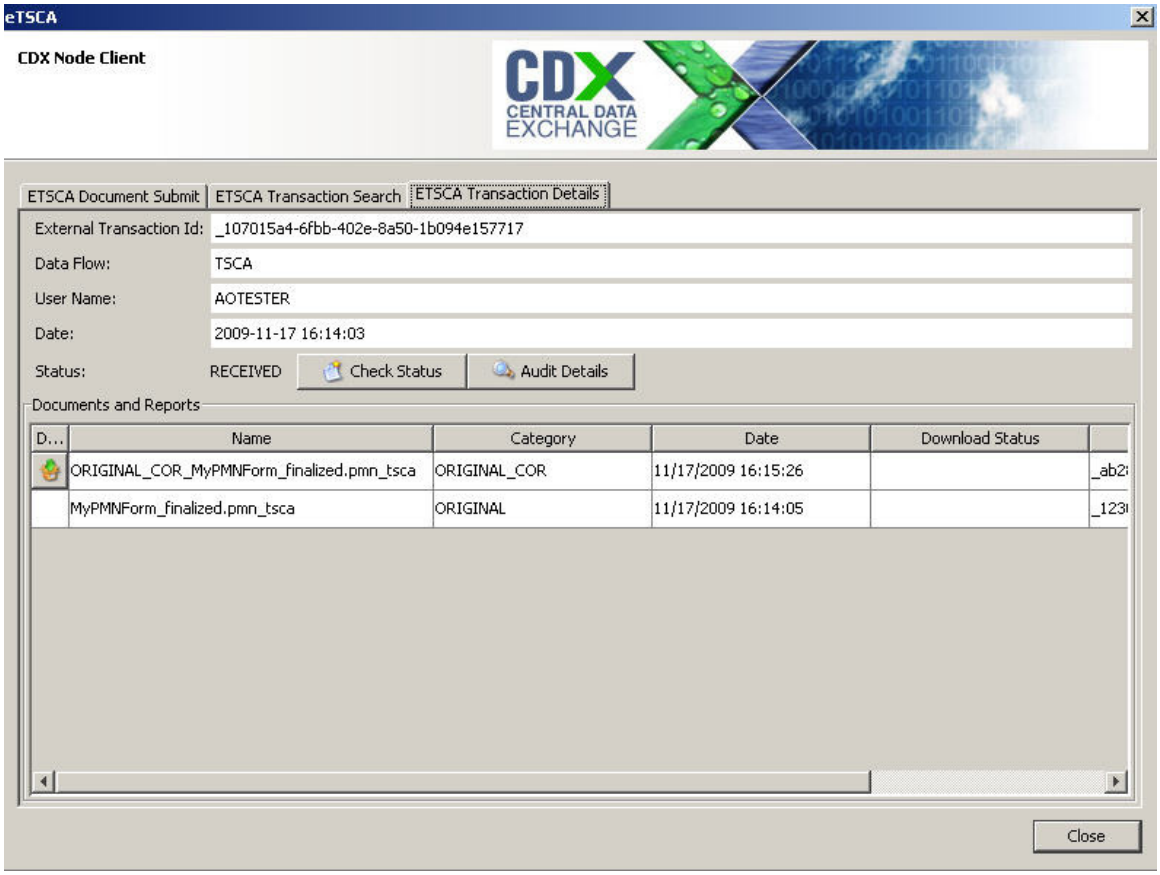
Figure 9-11 Document submitted to CDX



To check submission status, click the "Check Transaction Status" button. The screen below will display the appropriate status. The following is a list of possible statuses and what each status denotes:

- **Processing** – the CDX server has received the document
- **Received** – the backend server has processed the document but the CoR has not been generated yet
- **Completed** –the backend server has processed the document and the CoR is available
- **Failed** –the document failed to transmit or was not received. Please contact the CDX Help Desk.

Figure 9-12 Transaction Details tab



After the file has been successfully submitted and processed, a Copy of Record (CoR) will be available for download to the submitter via the "download" icon ( ) on the "ESTCA Transaction Details" tab of the Node Client. The CoR will be in read-only format—no changes can be made to this document.

The user will receive two automated e-mails from the node after successful submission.

Figure 9-13 E-mail Submission Notification

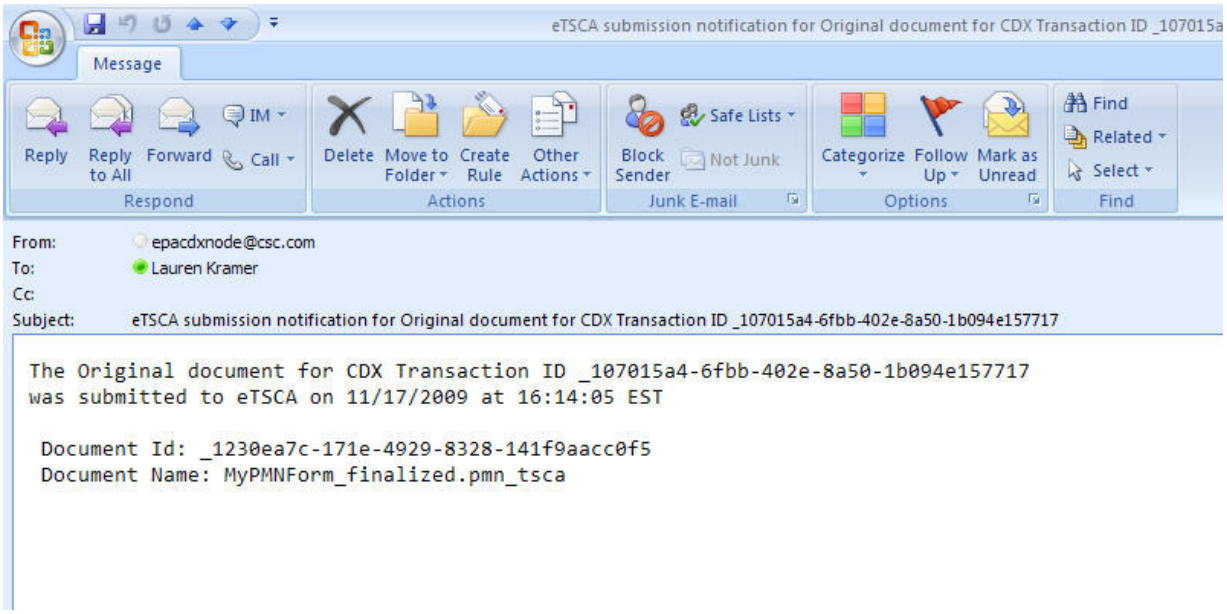
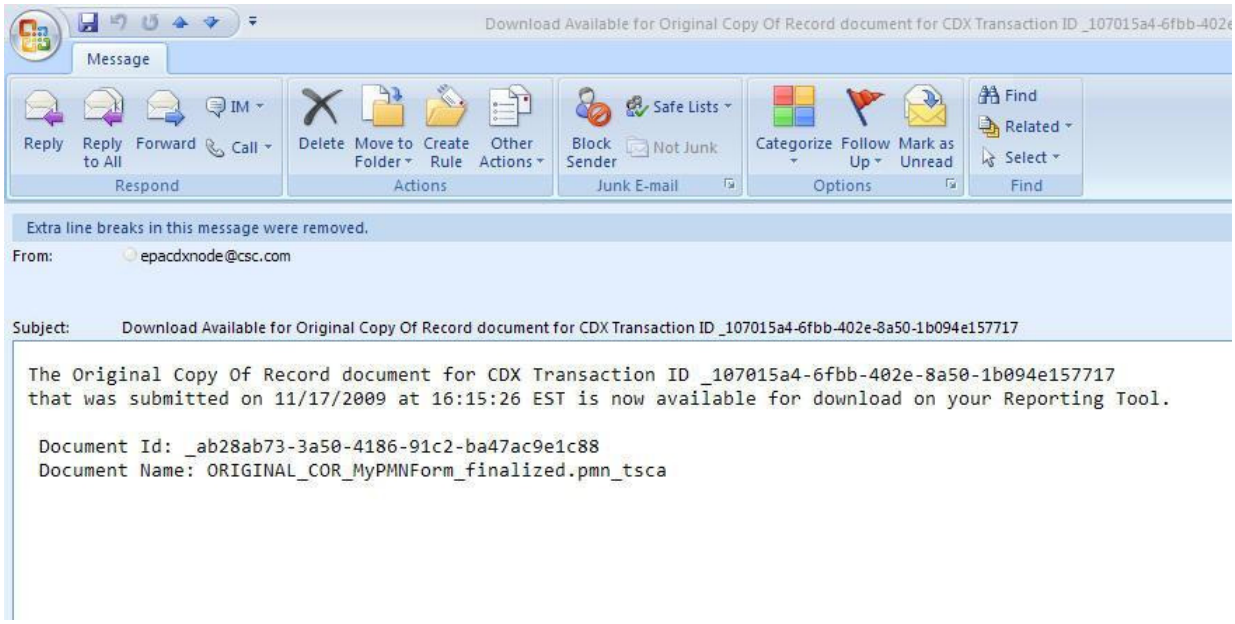


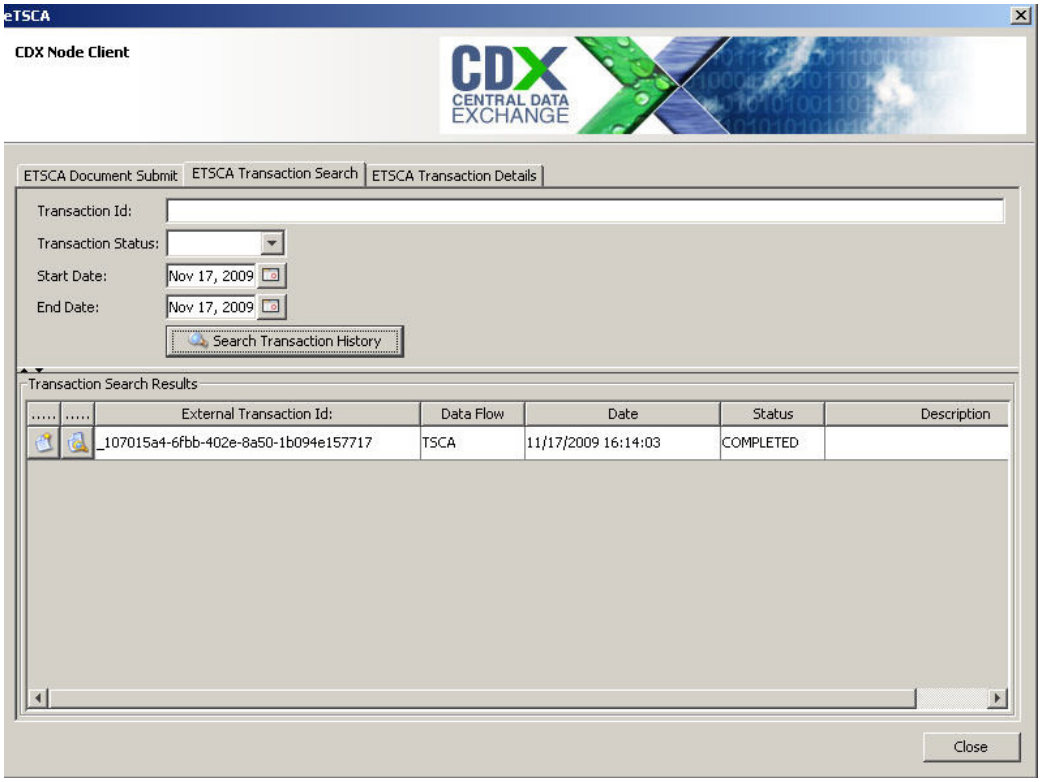
Figure 9-14 Copy of Record Available for Download



9.5 Transaction History

The eTSCA/e-PMN software allows users to search for files they have previously submitted. The "Search Transaction History" button can be found under the "ETSCA Transaction Search" tab of the Node Client as seen in Figure 9-15.

Figure 9-15 Transaction Search and Results



The user can search for a specific transaction using the "Transaction ID" and "Transaction Status" fields, or request a complete list of transactions during a given period by using the "Start Date" and "End Date" fields. Search results will be presented to the user in the "Transaction Search Results" panel.

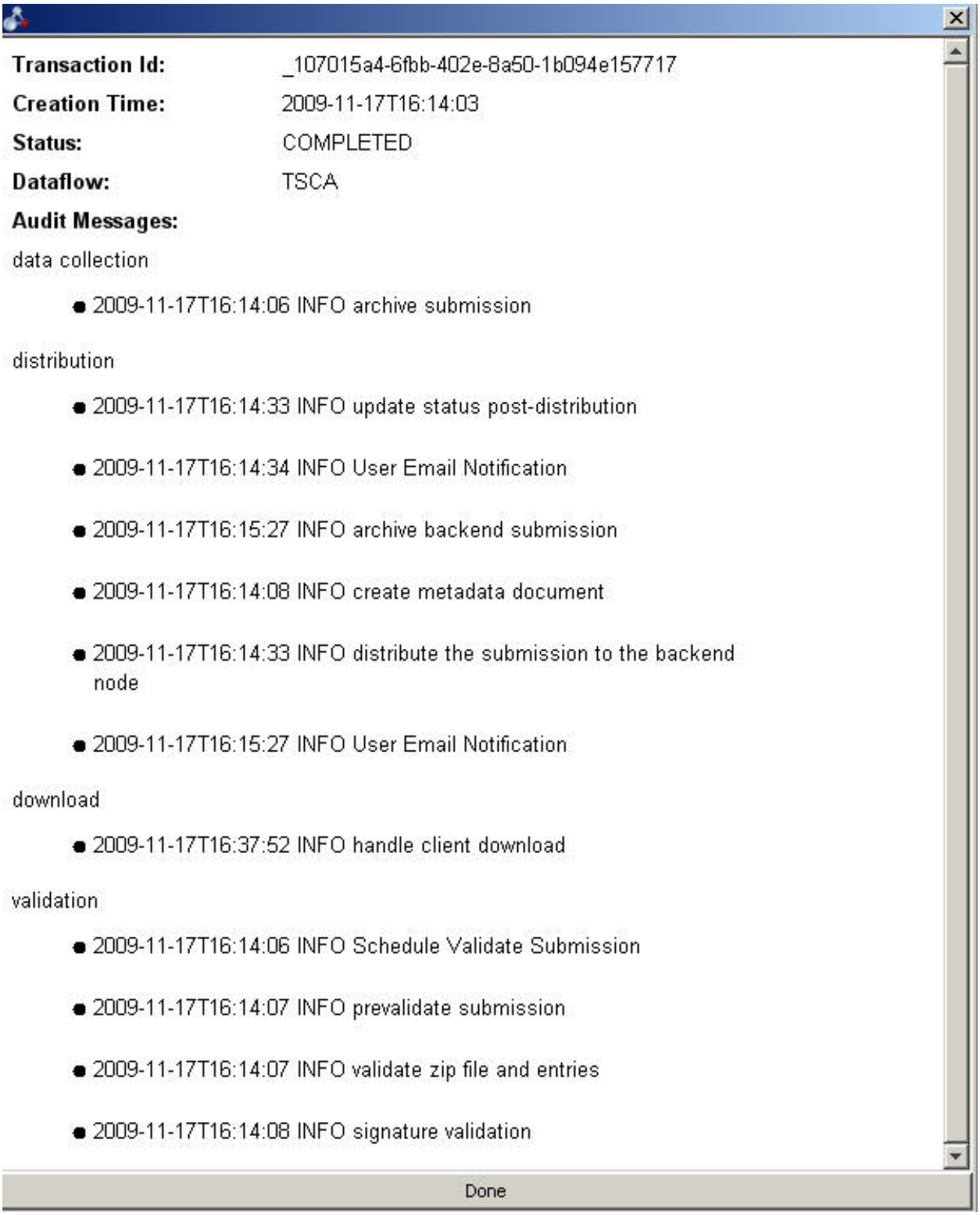
There are two icons located next to each transaction listed in the search result: the "Check Status" button and the "Details" button. The "Check Status" button will refresh the status column of a given transaction with a new CDX status. This provides the user a simple and effective method of monitoring transactions. The "Details" button will open the transaction details dialog.

9.5.1 Transaction Details

The "Transaction Details" tab (pictured in Figure 9-12 above) displays the detailed transaction information, including all of the documents and reports associated with the transaction.

Transaction status can be viewed by clicking the "Check Status" button. The "Audit Details" button will display audit information related to the transaction, as seen in Figure 9-16.

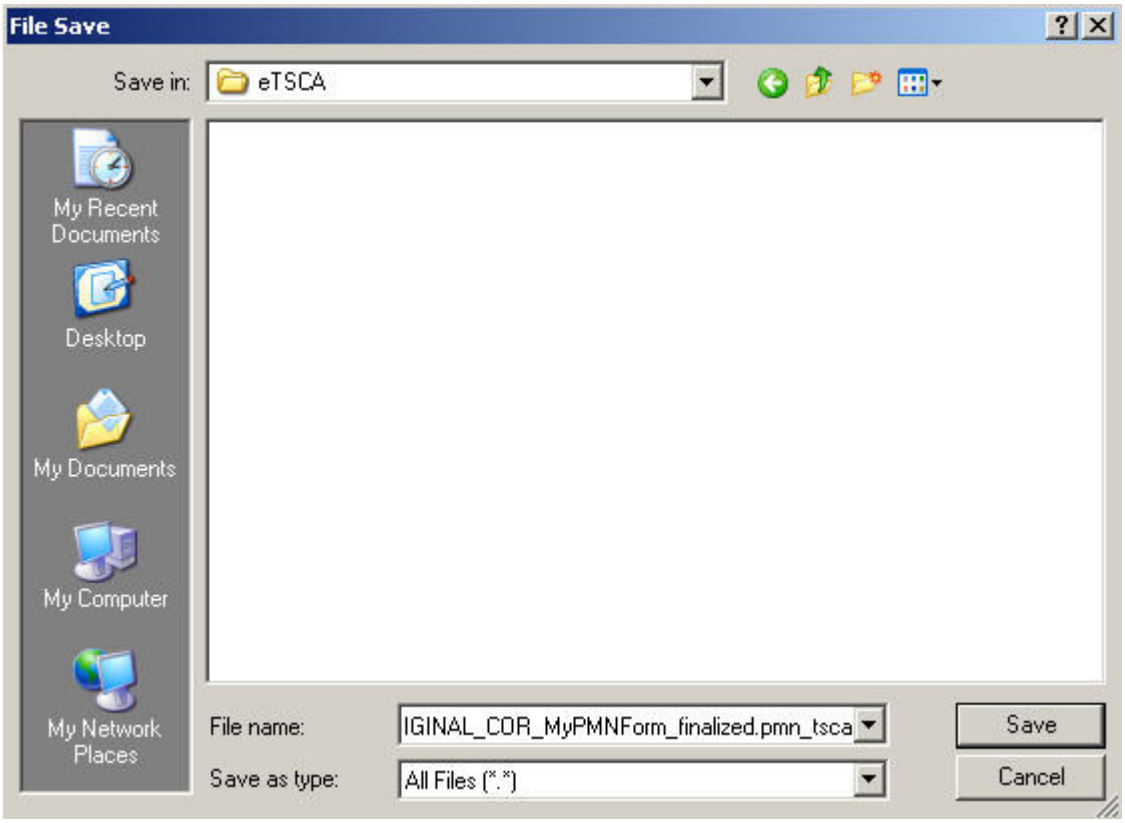
Figure 9-16 Audit Details Dialog



The “Done” button located at the bottom of the window will close the audit details.

The user may also download available reports by clicking the “Download” icon located to the left of the desired report. This will automatically initiate the download process. The document will get decrypted with the current user private key and the “Save File” dialog will be presented to a user [Figure 9-17]. Reports can be saved on a local hard drive and accessed with the appropriate application.

Figure 9-17 Save Downloaded File



10 Administrator's Guide

Windows XP

To setup *.jnlp association for Java Web Start in Windows, please follow the following steps:

1. In Windows, Click Start | Settings| Control Panel| Folder Options | File Types.
2. Check to see if there is already an association for *.jnlp files.
3. If there is no entry for *.jnlp files already then click new | advanced | select "jnlp file"
4. If there is an entry, Select it and click advanced
5. Then edit the open application used to perform action field and make sure it is set to "C:\Program Files\java\jre6\bin\javaws.exe"

Mac OSX 10.5 (Leopard)

JNLP files may lose association with Java Web Start after a Java software update. This will disable Mac OS users from downloading the eTSCA/e-PMN software using the Safari browser. There are two ways to re-associate JNL with the Java Web Start application. Option 1 is recommended for novice users, while option two may be more suitable for Mac OS experts.

Option 1

1. Navigate to the **Core Services** folder located at /System/Library/Core Services
2. Open this folder. Opening the Core Services folder re-associates the .jnlp files with the Java Web Start application
3. Close the window and reattempt to load the eTSCA/e-PMN software

Option 2

1. Navigate to the **Terminal** (/Applications/Utilities/Terminal)
2. Enter the following command:

   /System/Library/Frameworks/CoreServices.framework/Frameworks/LaunchServices.framework/Support/lsregister "/System/Library/CoreServices/Java Web Start.app"

3. Close Terminal and reattempt to load the eTSCA/e-PMN software

11 Contact Information

For further questions or concerns about the eTSCA/e-PMN software not covered in this user guide, please contact the CDX Help Desk at helpdesk@epacdx.net or call 1-888-890-1995 between the hours of 8am – 6pm EST.