



Section 4 User Guide – Primary Support

Environmental Protection Agency

Office of Pollution Prevention and Toxics

Manage Toxic Substances

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1 Introduction

This document presents the user guide for the Office of Pollution Prevention and Toxics (OPPT) Section 4 application submission process. This document is the user guide for the Primary Support user of the Section 4 tool.

As a Primary Support, you can edit a submission created by the Primary AO. You are only able to access submissions to which the Primary AO has granted you access.

General information on Section 4 is available at <http://www.epa.gov/oppt/chemtest/ereporting/index.html>. Information on CDX registration, including user roles that apply to completing a Section 4 is available at <http://cdx.epa.gov/About/UserGuide>

Toxic Substances Control Act (TSCA) regulations require industry to provide the Environmental Protection Agency (EPA) with documentation regarding chemical production, manufacture, distribution, use, disposal, import, and export. As a result, the implementation of TSCA has generated a large volume of documents submitted to the Agency by the regulated community.

The Section 4 application is the electronic, web-based tool provided by the Environmental Protection Agency (EPA) for the submission of Section 4 data. As a Primary Support, you can edit a submission created by the Primary AO. You are only able to access submissions to which the Primary AO has granted you access.

For questions concerning the Toxic Substances Control Act (TSCA) Section 4 software requirements, please contact the CDX Help Desk at helpdesk@epacdx.net or call 1-888-890-1995 between the hours of 8am – 6pm Eastern Standard Time (EST). For TSCA Section 4 requirements, please contact the TSCA Hotline at TSCA-Hotline@epamail.epa.gov or call 202-554-1404.

Please note: Any person who submits a positive test result for a specific chemical substance listed under section 766.25 must submit to EPA, no later than 90 days after the date of submission, a completed 7710-51 form. The form can be downloaded from the following link: <http://www.epa.gov/oppt/chemtest/pubs/7710-51.pdf>.

1.1 Labeling Confidential Information

This user guide presents instructions and screenshots for the ‘Section 4 Test Rules, ECA, MOU, and 40 CFR 766 submission’ electronic application as if you were logged in as the Primary Support. As the Primary Support you are able to modify a Section 4 submission. The user may claim certain information as Confidential Business Information (CBI). If the data is claimed as CBI, it will be treated in accordance with Agency confidentiality regulations at 40 CFR part 2, subpart B.

This TSCA Section 4 Test Rules, ECA, MOU, and 40 CFR 766 submission electronic application is optional for the production and submission of these filings. The paper option for filing will continue to be allowed.

Potential users may find that the use of this application saves time, burden and, because it is in an electronic format, provides easy access to reporting forms. Potential users are reminded to carefully read and follow application instructions. Persons who wish to use this application must

address all provisions in the application, including those relating to indexing information (i.e., company name, address, chemical name etc.) and those related to CBI submissions, including the requirement for the submission of sanitized or redacted filings.

Please note that certain CBI claims will not be accepted if you choose to use this electronic application for TSCA Section 4 Test Rules, ECA, MOU, and 40 CFR 766 submission. For example, chemical name and/or chemical identity, if the chemical is listed on the public portion of the TSCA Inventory, may not be claimed as CBI in a submission using this application.

If the user believes that these or other data elements should be treated as CBI, then the user may use the paper option to file the Section 4 submission form and assert CBI claims.

If the user claims an uploaded document as CBI, a sanitized document must be provided.

The following fields can be claimed as CBI within the ‘Section 4 Test Rules, ECA, MOU, and 40 CFR 766 submission’ application:

- Test Rules:
 - Technical Contact Information
 - Submitting on Behalf of Consortium information
 - Submitting on Behalf of Company information
 - A single chemical substance and associated chemical test(s)
 - Sponsoring Firm information
 - Study Plan document(s)
 - Submission of Equivalence Data document(s)
 - Result document(s)
- ECA:
 - Technical Contact Information
 - Submitting on Behalf of Company information
 - Principal Test Sponsor information
 - Principal Sponsor Organization information
 - Testing facility’s contact role information
 - Study Professional information
 - Results document(s)
- MOU:
 - Technical Contact Information
 - Submitting on Behalf of Company information
 - Principal Test Sponsor information
 - Principal Sponsor Organization information
 - Testing facility’s contact role information

- Study Professional information
- Results document(s)
- 40 CFR 766:
 - Technical Contact Information
 - Submitting on Behalf of Consortium information
 - Submitting on Behalf of Company information
 - A single chemical substance
 - Sponsoring Firm
 - Protocol document(s)
 - Results document(s)
 - Waiver document(s)
 - Exclusion document(s)
 - Exemption document(s)

2 System Requirements

To use the Section 4 application the following are required:

- An e-mail account
- A supported web browser (see Section 2.1 below) with Java Script enabled
- Internet access
- Adobe Acrobat Reader 5.0 or higher
- CDX username and password

2.1 Supported Browsers

One of the following supported browsers is required to access the Section 4 application:

- Internet Explorer 7 or above
 - Go to the following link to download:
<http://windows.microsoft.com/en-US/internet-explorer/downloads/ie>
- Mozilla Firefox 3.5 or above
 - Go to the following link to download:
<http://www.mozilla.com/en-US/firefox/all-older.html>
- Safari 4 or above
 - Go to the following link to download:
<http://support.apple.com/kb/dl877>
- Google Chrome
 - Go to the following link to download:
<http://www.google.com/chrome>

2.2 Screen Resolution

- Screen resolution should be set to 1024 x 768 or higher.

3 Primary Support Functions

This section describes how to:

- Access the application
- Navigate the Section 4 ‘Home’ screen
- Complete a Section 4 submission
- Complete an amendment

As a Primary Support, you can edit a submission created by the Primary AO. You are only able to access submissions to which the Primary AO has granted you access.

You can save a submission at any point during the data entry process. The save functionality will allow you to return to that same submission at any point in the future. You can print the submission document at any point; however, the ‘Not for Submission’ watermark will be placed on the portable document format (PDF) each time the submission is printed.

3.1 Log into Section 4 Application

After you create an account in CDX and click the ‘Primary Support’ link under the Chemical Safety and Pesticide Programs (CSPP) workflow, you will be taken to the ‘Chemical Information Submission System’ screen.

Note: Information on CDX registration, including user roles that apply to completing a Section 4 is available at <http://cdx.epa.gov/About/UserGuide>.

Exhibit 3-1 shows a screen capture of the ‘Chemical Information Submission System’ screen:

Exhibit 3-1: Chemical Information Submission System Screen

Logged in as: John Doe, Primary Support
Log Out

CHEMICAL INFORMATION SUBMISSION SYSTEM

TSCA Section 4

OK

The software includes embedded help files and a downloadable user manual to guide you through the Section 4 submission process.

The Toxic Substances Control Act gives EPA authority to issue data development regulations that require manufacturers and processors of existing chemicals to test their chemicals for health and environmental effects. EPA has the broad authority under the law to issue:

Information collection regulations that require the submission of health and safety studies which are known or available to those who manufacture, process, or distribute in commerce specified chemicals; and regulations designed to gather information from manufacturers and processor about production/import volumes, chemical uses and methods of disposal, and the extent to which people and the environment are exposed.

TSCA also requires EPA to develop regulations that establish import/export requirements for chemicals which are subject to certain requirements under TSCA.

Paperwork Reduction Act Notice

The information collection requirements contained in this final rule have been submitted for OMB approval under PRA, 44 U.S.C. 3501 et seq. The ICR document prepared by EPA, identified under EPA ICR No. 2412.01 and OMB control number 2070-0004, is available in the docket for the final rule. The ICR addresses the incremental changes to the currently approved ICR documents that cover the existing reporting and record keeping programs that are approved under OMB control numbers 2070-0004, 2070-0033, and 2070-0054. An agency may not conduct or sponsor, and a person is not required to, respond to a collection of information unless it displays a currently valid OMB control number. The amended information collection activities contained in this final rule are designed to assist the Agency in meeting its responsibility under TSCA to receive, process, and review reports, data, and other information. As such, responses to the collection of information covered by this ICR would still be mandatory, but with the final rule, respondents would be required to use the CISS reporting tool.

Authority

The Government Paperwork Elimination Act (GPEA) (44 U.S.C. 3504) provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3) (Ref. 2), provides that any requirement in title 40 of the CFR to submit a report directly to EPA can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form. For more information about CROMERR, go to <http://www.epa.gov/cromerr>.

Navigation: Select 'TSCA Section 4' from the drop-down menu and click the 'OK' button to navigate to the Section 4 'Home' screen.

3.2 Home Screen Navigation

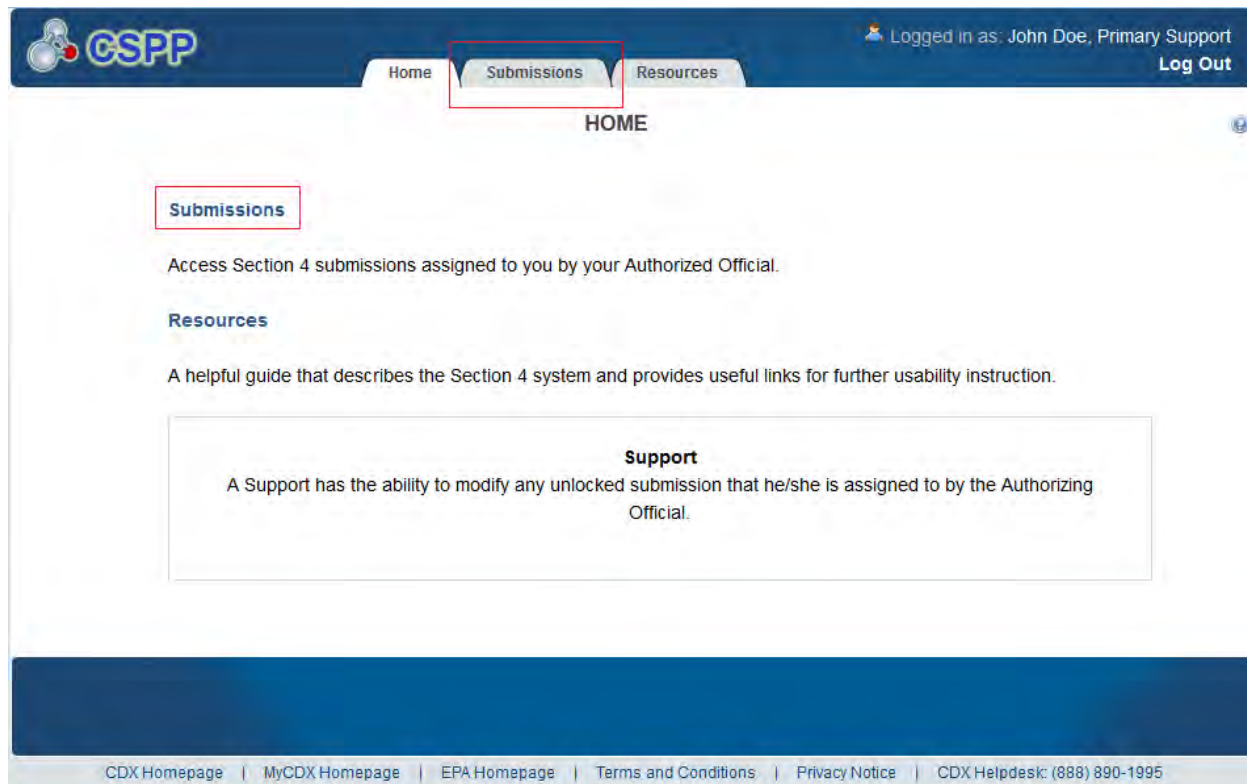
You can access the Section 4 'Home' screen by selecting 'TSCA Section 4' submission type from the drop-down menu on the 'Chemical Information Submission System' screen and clicking the 'OK' button.

The Section 4 ‘Home’ screen is the first screen within the Section 4 application. It provides you with links and tabs to access the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions and ‘Resources’ screens. To navigate to these screens, click the screen link (in blue text), or click the screen tab (located within the application header). The links and tabs provide the same functionality.

- **Submissions:** Click the ‘Submissions’ link or tab to navigate to the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen. You are able to modify Section 4 test rules, enforceable consent agreement (ECA), memorandum of understanding (MOU), and/or 40 code of federal regulation (CFR) 766 submissions using the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen. For additional details about the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen, please refer to **Section 3.3.1**.
- **Resources:** Click the ‘Resources’ link or tab to navigate to the ‘Resources’ screen. You can find the Section 4 user guides, as well as useful links for further usability instruction on the ‘Resources’ screen. For additional details about the ‘Resources’ screen, please refer to **Section 9**.

Exhibit 3-2 shows a screen capture for the Section 4 ‘Home’ screen:

Exhibit 3-2: Home Screen



Navigation: Click the ‘Submissions’ link or tab on the ‘Home’ screen to access the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen.

3.3 Edit a Section 4 Submission

As a Primary Support, you can edit a Section 4 submission. You will be able to access only those submissions for which the Primary AO has assigned to you.

3.3.1 Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766 Submissions

You can access the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen by clicking the ‘Submissions’ link from the Section 4 ‘Home’ screen or by clicking the tab located within the application header.

You are only able to edit Section 4 submissions for which the Primary AO has granted you access. Each column of the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ table can be sorted by clicking the column headers.

Edit a Submission: Submissions will not be available on this screen until one has been created by the Primary AO and you have been assigned to it. To modify an existing Section 4 submission, click the submission alias link for a submission that has a status of ‘In Progress.’ You will be required to enter the passphrase associated with that particular submission, which is obtained from your AO, to access and continue editing the submission.

In addition to ‘Status’ column, the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen displays the following columns:

- **Submission Alias:** Displays the submission alias that generates from the ‘Submission Information Type’ screen. The ‘Submission Alias’ column will display as a time stamp unless the user has provided a unique alias on the ‘Submission Information Type’ screen. The purpose of the submission alias is to help identify each Section 4 submission when there is more than one.
- **CFR/FRN:** Displays the CFR/federal register notice of the Section 4 submission.
- **Status:** Displays the status of the Section 4 submission.
- **Modify Date:** Displays the date the submission was last modified.
- **Submission Date:** Displays the date your AO submitted to EPA. This date populates only after your AO submits.
- **Export Options:** Displays ‘CSV,’ ‘Excel,’ ‘XML,’ and ‘PDF’ links for you to export the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen in one of the specified formats as an Excel spreadsheet, Comma-Separated Values (CSV), Extensible Markup Language (XML), or PDF.

Exhibit 3-3 shows a screen capture of the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen:

Exhibit 3-3: Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766 Submissions Screen

The screenshot shows the GSPP web application interface. At the top, there is a navigation bar with 'Home', 'Submissions', and 'Resources' tabs. The user is logged in as 'John Doe, Primary Support'. The main heading is 'SECTION 4 TEST RULES, ECAS, MOUS, AND 40 CFR 766'. Below the heading, there is a message: 'To edit an In Progress submission, click the submission link in the Submission Alias column in the table below.' The table shows 7 items found, and the user is on page 1 of 1. The table has the following data:

Submission Alias	CFR/FRN	Status	Modify Date	Submission Date
CFR766-20130711-14:48:50 EDT	40 CFR 766 Dibenzodioxins / Dibenzofurans	In Progress	07/15/2013	
ECA-20130709-09:20:05 EDT	70 FR 39630	In Progress	07/09/2013	
ECA-20130711-13:14:59 EDT	68 FR 33125	In Progress	07/15/2013	
MOU-20130709-09:29:33 EDT	MOUForm	In Progress	07/09/2013	
MOU-20130711-14:11:31 EDT	MOUForm	In Progress	07/15/2013	

Export options: [CSV](#) | [Excel](#) | [XML](#) | [PDF](#)

At the bottom of the page, there are links for 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Navigation: Click the submission alias link with a status of ‘In Progress’ to navigate to the ‘Enter Passphrase’ screen.

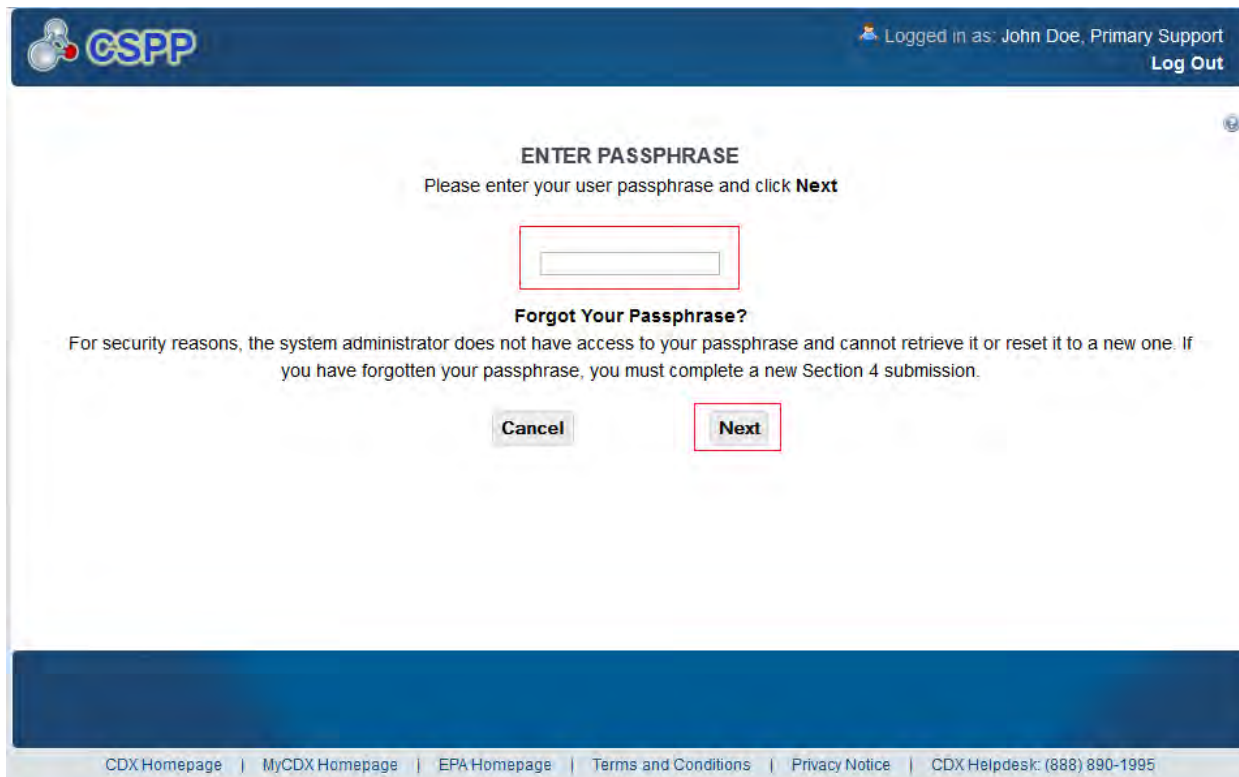
3.3.2 Enter Passphrase Screen

To edit a submission, click the submission alias link for a submission with a status of ‘In Progress’ on the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen. The ‘Enter Passphrase’ screen allows you to enter the passphrase that your AO has associated with the submission.

- **Enter Passphrase:** Enter the passphrase that your AO originally created and associated with the submission.

Exhibit 3-4 shows a screen capture of the ‘Enter Passphrase’ screen:

Exhibit 3-4: Enter Passphrase Screen



Navigation: Enter the passphrase that the AO originally created and associated with the submission and click the ‘Next’ button to navigate to the ‘Submission Information Type’ screen.

3.3.3 Navigation Tree

The navigation tree is located on the left hand side of each screen. You can perform the following functions using the navigation tree:

- **Collapse and Expand folders:** Each section of the submission falls under a collapsible folder within the navigation tree, which allows you to save space or easily view items in the navigation tree. When a folder is expanded, you can click the minus sign (-), the folder icon (📁), or the folder title link to collapse that section of the navigation tree. When a folder is collapsed, you can click the plus sign (+), the folder icon (📁), or the folder title link to expand that section of the navigation tree. When you place your cursor over a folder title link, it will highlight in red.
- **Open and Close the Navigation Tree:** To provide more visual form space, a navigation arrow (↔) that opens and closes the navigation tree is located to the right of the navigation tree. Click the arrow (↔) to close the navigation tree and increase the space of the form content. Likewise, click the arrow (↔) on the closed navigation tree to open the navigation tree.
- **Navigate between screens:** You can use the navigation tree to navigate between the various screens within the application. Each screen of the submission is denoted with a



form icon (). You can click the form icon () or the screen title link to navigate to the selected screen. You are required to save all information entered on a particular screen before navigating to the next screen or all entered information will be lost. A prompt will appear after you click a link in the navigation tree indicating, 'Are you sure you want to leave the current page? Any unsaved changes will be lost.' If you click the 'OK' button, you will be taken to the requested screen without saving any of the data in the previous screen. If you click the 'Cancel' button, the prompt will close and you will not be taken to the requested screen.

Exhibit 3-5 shows a screen capture of the navigation prompt window:

Exhibit 3-5: Navigation Prompt

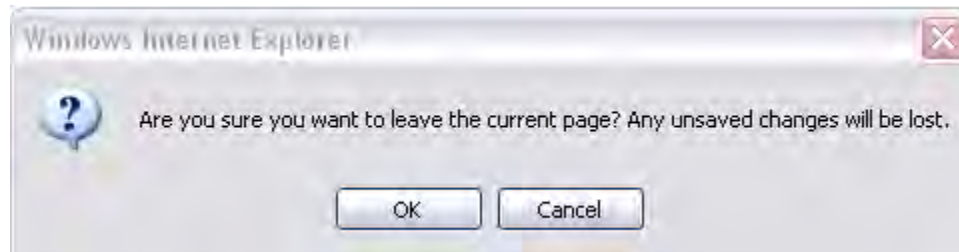


Exhibit 3-6, Exhibit 3-7, Exhibit 3-8, and Exhibit 3-9 show the screen captures of the navigation tree for the Test Rules, ECA, MOU and 40 CFR 766 submissions:

Exhibit 3-6: Section 4 Test Rules Navigation Tree

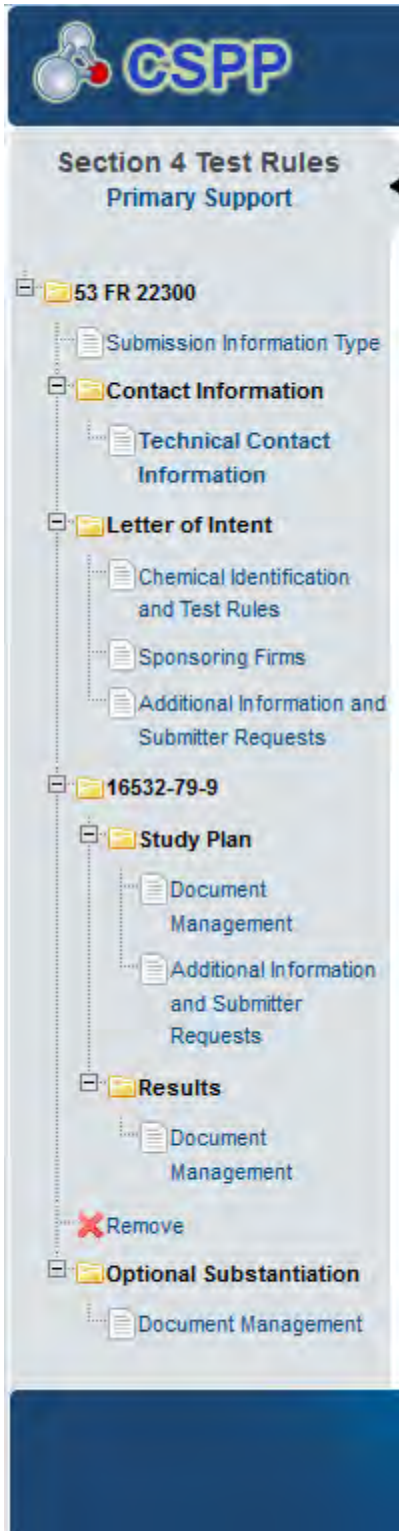


Exhibit 3-7: Section 4 ECA Navigation Tree

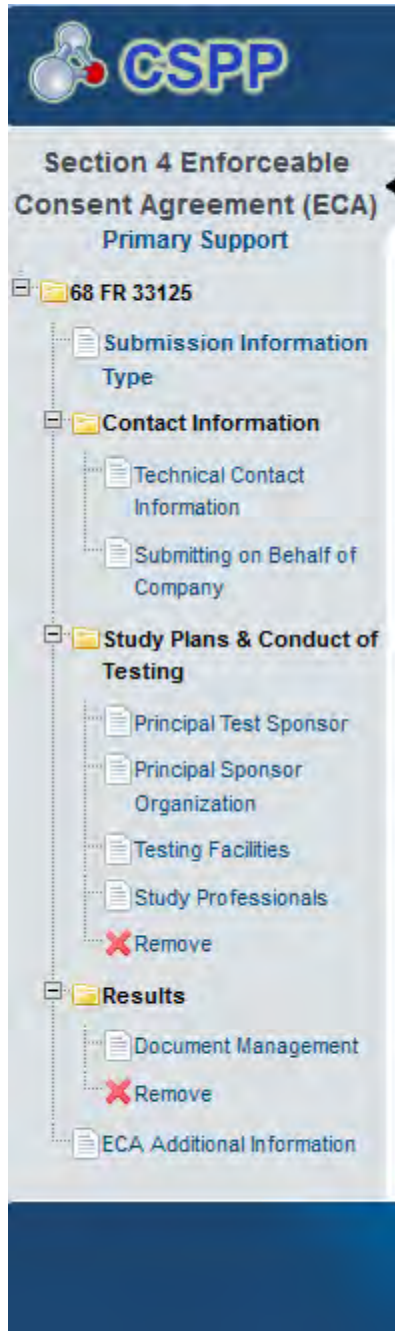
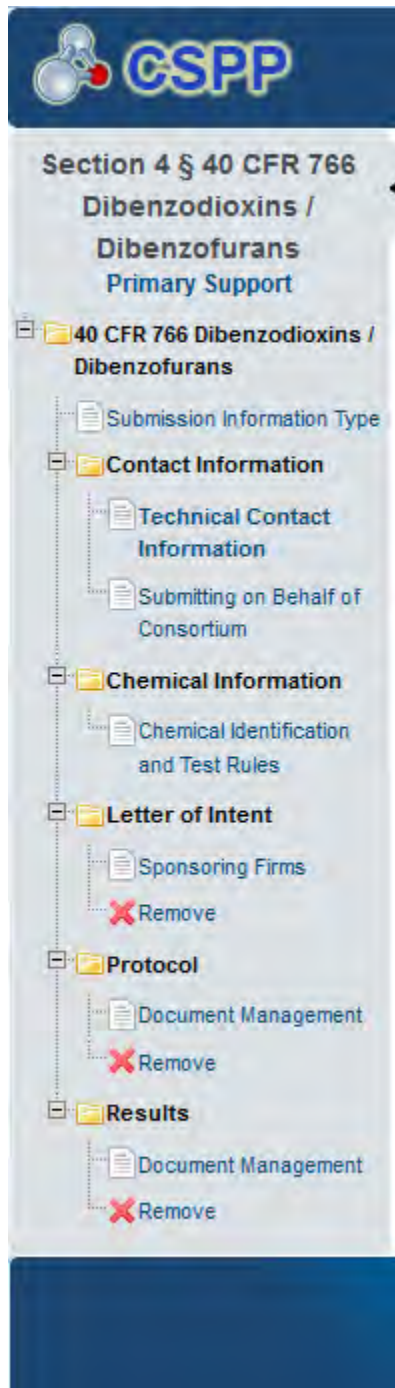


Exhibit 3-8: Section 4 MOU Navigation Tree



Exhibit 3-9: Section 4 40 CFR 766 Navigation Tree



3.3.4 Action Bar

The action bar is located at the bottom of each screen. You can perform the following functions using the action bar:

- Validate:** You can click the ‘Validate’ icon (✓) at any stage of completing a Section 4 submission to check for certain types of errors in a submission. A ‘Section 4 Validation’ pop-up window generates when you click the ‘Validate’ icon (✓). The ‘Section 4

Validation' pop-up window displays a report of all validation errors relating to a failed validation. Refer to **Section 8** for more information on validating a submission.

Exhibit 3-10, Exhibit 3-11 and Exhibit 3-12 show the screen captures for the action bar:

Exhibit 3-10: Action Bar – Validate





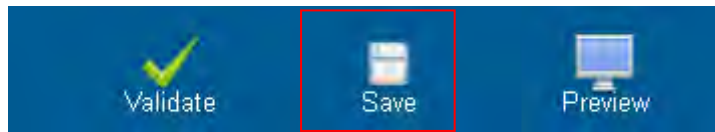
- **Save:** You can click the 'Save' icon () at any stage of completing a Section 4 submission. After you click the 'Save' icon (), the data entered on the screen will save. The 'Save' function does not validate any data entered.

Exhibit 3-11: Action Bar – Save





- **Preview:** You can click the 'Preview' icon () at any stage of completing a Section 4 submission to preview the submission. After you click the 'Preview' icon (), you will be taken to the 'Preview Section 4 Submission' screen. This screen allows you to view the regular or sanitized PDF. Clicking the 'Regular' or 'Sanitized' button will generate the 'Not for Submission' watermarked PDF version of the submission.

Exhibit 3-12: Action Bar – Preview



- **Help Links:** You can click any of the Help links, located at the bottom of each screen, at any stage of completing a Section 4 submission.
 - If you click the 'CDX Homepage' link, you will be taken to the CDX Homepage.
 - If you click the 'MyCDX Homepage' link, you will be taken to the CDX Login.
 - If you click the 'EPA Homepage' link, you will be taken to the EPA Homepage.
 - If you click the 'Terms and Conditions' link, you will be taken to the CDX Terms and Conditions screen.
 - If you click the 'Privacy Notice' link, you will be taken to the CDX Privacy and Security Notice screen.

Exhibit 3-13 shows the screen capture of the action bar 'Help' links:

Exhibit 3-13: Action Bar – Help Links

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk: \(888\) 890-1995](#)

4 Test Rules

4.1 Submission Information Type Screen

You can access the ‘Submission Information Type’ screen by clicking the ‘Next’ button from the ‘Enter Passphrase’ screen. Once you are in the ‘Test Rules’ flow of the Section 4 application, the ‘Submission Information Type’ screen is displayed.

The ‘Submission Information Type’ screen allows you to select the submission information type that you will be submitting to EPA. This screen consists of the following fields:

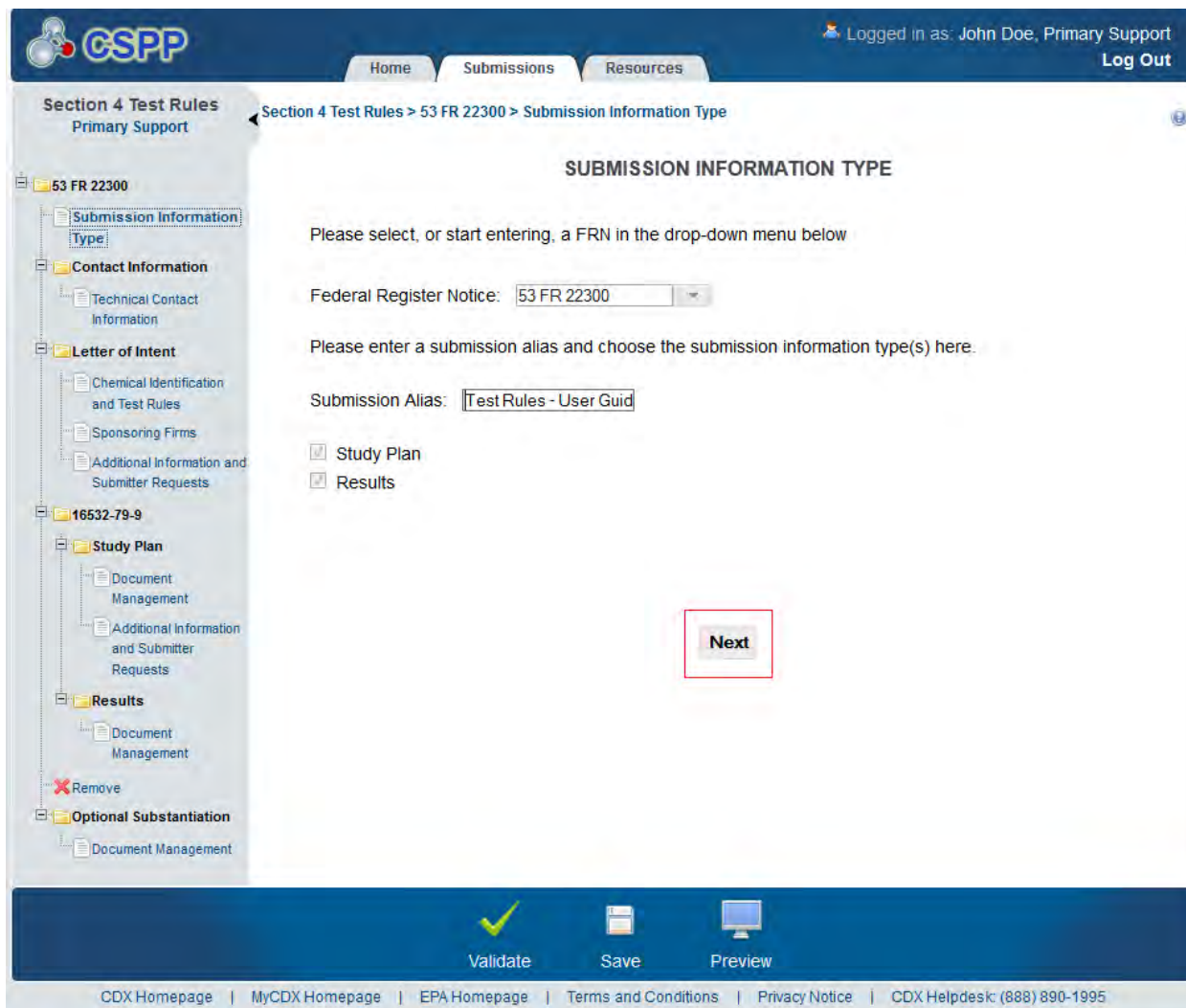
- **Federal Register Notice:** Select an FRN from the drop-down menu. The selected FRN will dictate which chemicals the user will be able to report on. If you change the FRN at any point while completing the submission, a warning message will display indicating that all data associated with the current FRN will be deleted. This field is required.
- **Submission Alias:** This field is auto-populated with a date and time stamp and is displayed on the ‘Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766’ submissions screen within the ‘Submission Alias’ column. This field is editable should you choose to provide your own submission alias. This field is required.
- **Study Plan:** The ‘Study Plan’ checkbox will only be available after the Letter of Intent has been submitted. Checking the ‘Study Plan’ checkbox indicates that you are fulfilling the requirements to submit a study plan to EPA. Once you have checked the ‘Study Plan’ checkbox and either saved the information on this screen by clicking the ‘Save’ icon or by clicking the ‘Next’ button, the ‘Study Plan’ folder is generated within the navigation tree allowing you to access the study plans screens required to be completed.
- **Results:** The ‘Results’ checkbox will only be available after the study plan has been submitted. Checking the ‘Results’ checkbox indicates that you are fulfilling the requirements to submit results to EPA. Once you have checked the ‘Results’ checkbox and either saved the information on this screen by clicking the ‘Save’ icon or by clicking the ‘Next’ button, the ‘Results’ folder is generated within the navigation tree allowing you to access the results screens required to be completed.

If you previously identified a submission type, accessed the submission type screens, and unchecked the previously checked submission information type (i.e. Study Plan), you will receive a prompt indicating that all associated information will be lost. Clicking the ‘OK’ button within the prompt will delete all data associated with that submission information type. To close the prompt without losing associated information, click the ‘Cancel’ button.

Once you have identified the type(s) of information you will submit to EPA, you are able to access the screen required for completion.

Exhibit 4-1 shows the screen capture of the ‘Submission Information Type’ screen:

Exhibit 4-1: Submission Information Type Screen



Navigation: If this is the first submission, select a federal register notice from the ‘Federal Register Notice’ drop-down menu and click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. If you have previously submitted a letter of intent, check the ‘Study Plan’ checkbox and click the ‘Save’ or ‘Next’ button to generate the study plan screens and links within the navigation tree. If you have previously submitted a study plan, check the ‘Results’ checkbox and click the ‘Save’ or ‘Next’ button to generate the results screens and links within the navigation tree.

4.2 Technical Contact Information Screen

You can access the ‘Technical Contact Information’ screen by clicking the ‘Next’ button from the ‘Submission Information Type’ screen, or by clicking the ‘Technical Contact Information’ link located within the navigation tree.

The ‘Technical Contact Information’ screen allows you to submit on behalf of another company or submit on behalf of a consortium. To identify that you are submitting on behalf of another

entity, the system provides radio buttons for ‘This is a submission on behalf of a consortium’ and ‘This is a submission on behalf of another company.’ The system will not allow you to submit on behalf of a single company and on behalf of a consortium per submission.

If you are submitting on behalf of another company, select the ‘This is a submission on behalf of another company’ radio button. This functionality has been implemented to accommodate a company that may use an agent or another individual. If this radio button is selected, you can enter the contact information for the manufacturing or processing establishment on whose behalf the submission is being made into the ‘Submitting on Behalf Of Company’ screen upon clicking the ‘Next’ button. If you select the radio button for ‘This is a submission on behalf of a consortium,’ you are taken to the ‘Submitting on Behalf of Consortium’ screen upon clicking the ‘Next’ button.

If you are not submitting on behalf of another company or on behalf of a consortium, you must select the ‘N/A’ radio button.

The following fields are displayed on the ‘Technical Contact Information’ screen:

- **CBI:** Checking this checkbox will claim the technical contact information as Confidential Business Information (CBI).
- **N/A:** Selecting the ‘N/A’ radio button allows you to signify that you are neither making a submission on behalf of a consortium nor making a submission on behalf of another company.
- **This is a submission on behalf of a consortium:** Selecting the ‘This is a submission on behalf of a consortium’ radio button allows you to identify yourself as an individual submitting on behalf of a consortium.
- **This is a submission on behalf of another company:** Selecting the ‘This is a submission on behalf of another company’ radio button allows you to identify yourself as an individual submitting on behalf of another company.
- **Copy CDX Registration:** Clicking the ‘Copy CDX Registration’ button will automatically populate the fields with your contact information provided during CDX registration.
- **Prefix:** Displays all optional prefixes. If applicable, select the appropriate prefix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **First Name:** Enter the technical contact’s first name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Middle Initial:** Enter the technical contact’s middle initial. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **Last Name:** Enter the technical contact’s last name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.

- **Suffix:** Displays all optional suffixes. If applicable, select the appropriate suffix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **Company Name:** Enter the technical contact’s company name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Phone Number:** Enter the technical contact’s daytime phone number; U.S. or international. This field does not accept dashes. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Ext:** Enter the extension to the technical contact’s daytime phone number.
- **Email Address:** Enter the technical contact’s email address. The email address must follow the standard email address format: john.doe@abc.com. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 1:** Enter the first line of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 2:** Enter the second line of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **City:** Enter the city of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **State:** Enter the state of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This is a required field if the ‘Country’ field is ‘United States.’
- **Postal Code:** Enter the postal code of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Country:** Displays all available countries. Select the country of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This is a required field.

Exhibit 4-2 shows the screen capture of the ‘Technical Contact Information’ screen:

Exhibit 4-2: Technical Contact Information Screen

Section 4 Test Rules
Primary Support

Section 4 Test Rules > 53 FR 22300 > Contact Information > Technical Contact Information

TECHNICAL CONTACT INFORMATION

Identify the technical contact who is capable of answering questions related to the chemical(s) submitted to EPA within this submission. Identify if this submission is being submitted on behalf of another company or consortium by selecting the appropriate radio button. If submitting on behalf of is not applicable, select the N/A radio button. Click the 'Copy CDX Registration' button to copy your information from CDX Registration.

N/A
 This is a submission on behalf of a consortium
 This is a submission on behalf of another company

Click here to copy your information from CDX Registration: [Copy CDX Registration](#)

CBI:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

[Previous](#) [Next](#)

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Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Identification and Test Rules’ screen if you are not submitting on behalf of a consortium or another company. You can also access this screen by clicking the ‘Chemical Identification and Test Rules’ link within the navigation tree. If you are submitting on behalf of a consortium, you are taken to the ‘Submitting on Behalf of Consortium’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Consortium’ link within the navigation tree. If you are submitting on behalf of another

company, you are taken to the ‘Submitting on Behalf of Company’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree.

4.3 Submitting on Behalf of Consortium Screen

You can access the ‘Submitting on Behalf of Consortium’ screen by selecting the ‘This is a submission on behalf of a consortium’ radio button and by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Consortium’ link within the navigation tree.

The ‘Submitting on Behalf of Consortium’ screen allows you to enter contact information for each consortium member. The system provides you with the ability to identify the consortium name. The contact information of the logged in user will pre-populate the first consortium field set; this information is editable. To add a consortium member, click the ‘Add’ button to display fields that can be populated and saved. You can click the ‘Save’ button for each consortium member added to capture all information entered on the screen. A minimum of two consortium members must be added to pass validation.

The following fields are displayed on the ‘Submitting on Behalf of Consortium’ screen:

- **Consortium Name:** Enter the name of the consortium.
- **CBI:** Checking this checkbox will claim the consortium information as CBI.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes and captures the consortium member contact’s prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the consortium member contact’s first name. This field is required.
- **Middle Initial:** Enter the consortium member contact’s middle initial.
- **Last Name:** Enter the consortium member contact’s last name. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the consortium member contact’s suffix. If applicable, select the appropriate suffix.
- **Company Name:** Enter the consortium member contact’s company name. This field is required.
- **Phone Number:** Enter the consortium member contact’s daytime phone number, U.S. or international. This field does not accept dashes. This field is required.
- **Ext:** Enter the extension to the contact’s daytime phone number.
- **Email Address:** Enter the consortium member contact’s email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the consortium member contact’s mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the consortium member contact’s mailing address.
- **City:** Enter the city of the consortium member contact’s mailing address. This is a required field.

- **State:** Enter the state of the consortium member contact's mailing address. This field is required if the 'Country' field is set to 'United States.'
- **Postal Code:** Enter the postal code of the consortium member contact's mailing address. This field is required.
- **Country:** Enter the country of the consortium member contact's mailing address. This field is required.

Exhibit 4-3 shows the screen capture for the ‘Submitting on Behalf of Consortium’ screen:

Exhibit 4-3: Submitting on Behalf of Consortium Screen

The screenshot displays the 'Submitting on Behalf of Consortium' screen. At the top, the user is logged in as 'John Doe, Primary Support'. The navigation tree on the left shows the current path: Section 4 Test Rules > 53 FR 22300 > Contact Information > Submitting on Behalf of Consortium. The main form area contains the following elements:

- Instruction: "Provide the consortium name and click the Add button to enter member contact information."
- Fields: Consortium Name (text input), Consortium CBI (checkbox).
- Modal Form: "Test Company (John Doe)" with fields for:
 - Prefix (dropdown)
 - First Name (text input)
 - Middle Initial (text input)
 - Last Name (text input)
 - Suffix (dropdown)
 - Company Name (text input)
 - Phone Number (text input) and Ext. (text input)
 - Email Address (text input)
 - Mailing Address 1 (text input)
 - Mailing Address 2 (text input)
 - City (text input)
 - State (dropdown)
 - Postal Code (text input)
 - Country (dropdown)
- Buttons: "Save" (at the bottom of the modal), "Add" (below the modal), "Previous" and "Next" (at the bottom of the page).

Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Identification and Test Rules’ screen. You can also access this screen by clicking the ‘Chemical Identification and Test Rules’ link within the navigation tree.

4.4 Submitting on Behalf of Company Screen

You can access the ‘Submitting on Behalf of Company’ screen by selecting the ‘This is a submission on behalf of another company’ radio button and clicking the ‘Next’ button from the

‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree.

The ‘Submitting on Behalf of Company’ screen presents you with a list of fields that allows you to input the contact information for the manufacturing or processing establishment for which the submission is being made.

The following fields are displayed on the ‘Submitting on Behalf of Company’ screen:

- **CBI:** Checking this checkbox will claim the manufacturing or processing establishment contact for which the submission is being made as CBI.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes and captures the prefix of the manufacturing or processing establishment contact for which the submission is being made. If applicable, select the appropriate prefix.
- **First Name:** Enter the first name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Middle Initial:** Enter the middle initial of the manufacturing or processing establishment contact for which the submission is being made.
- **Last Name:** Enter the last name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the suffix of the manufacturing or processing establishment contact for which the submission is being made. If applicable, select the appropriate suffix.
- **Company Name:** Enter the company name of the manufacturing or processing establishment. This field is required.
- **Phone Number:** Enter the daytime phone number of the manufacturing or processing establishment contact for whom the submission is being made, U.S. or international. This field is required.
- **Ext:** Enter the extension to the contact’s daytime phone number.
- **Email Address:** Enter the email address of the manufacturing or processing establishment contact for which the submission is being made. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the manufacturing or processing establishment contact.
- **City:** Enter the city of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **State:** Enter the state of the mailing address of the manufacturing or processing establishment contact. This is a required field if the ‘Country’ field is defined as ‘United States.’
- **Postal Code:** Enter the postal code of the mailing address of the manufacturing or processing establishment contact. This field is required.

- **Country:** Enter the country of the mailing address of the manufacturing or processing establishment contact. This field is required.

Exhibit 4-4 shows the screen capture of the ‘Submitting on Behalf of Company’ screen:

Exhibit 4-4: Submitting on Behalf of Company Screen

Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Identification and Test Rules’ screen. You can also access this screen by clicking the ‘Chemical Identification and Test Rules’ link within the navigation tree.

4.5 Letter of Intent

The ‘Letter of Intent’ section within the navigation tree must be submitted to EPA before you can complete the ‘Study Plan’ and ‘Results’ screens.

4.5.1 Chemical Identification and Test Rules Screen




You can access the 'Chemical Identification and Test Rules' screen by clicking the 'Next' button from the 'Technical Contact Information,' 'Submitting on Behalf of Company,' or the 'Submitting on Behalf of Consortium' screen. You can also navigate to this screen by clicking the 'Chemical Identification and Test Rules' link located within the navigation tree under the 'Letter of Intent' folder.

The 'Chemical Identification and Test Rules' screen requires you to identify the chemical substance(s) the sponsor(s) intends to use in each of their tests. To identify the chemical substances click the 'Assign Chemicals' button. Clicking the 'Assign Chemicals' button will generate the 'Chemical Management' pop-up window.

The 'Chemical Management' pop-up window displays all chemical substances you are able to select. You can select each chemical by checking the checkbox that is located to the left of the chemical. Once the chemical(s) has been checked, click the 'Save' button to close the 'Chemical Management' pop-up window and display the data on the 'Chemical Identification and Test Rules' screen. The chemicals displayed in the 'Chemical Management' pop-up window are specific to the FRN selected.

The system allows you to edit previous chemical assignments. To delete a chemical, click the 'Assign Chemical' button and uncheck the chemical's associated checkbox. Click the 'Save' button to close the 'Chemical Management' pop-up window and save all changes.

Each chemical substance assigned using the 'Chemical Management' pop-up window will be displayed on the 'Chemical Identification and Test Rules' screen within a field set. Each chemical substance field set requires you to identify a minimum of one test per substance. The system provides a 'CBI' checkbox allowing you to claim those tests as CBI.

The system provides a 'Chemical Test' drop-down menu for each identified substance. The 'Actions' column provides buttons that allow you to save, delete, and add the data entered within the 'Chemical Test' drop-down menu. To save entered data click the 'Save' icon (). To delete entered data click the 'Delete' icon (). To add chemical tests click the 'Add' icon ().

- **CBI:** Check the 'CBI' checkbox you to claim information as confidential.
- **Assign Chemicals:** Click the 'Assign Chemicals' button to generate the 'Chemical Management' window.
- **Chemical Test:** Select the test to be performed using the assign chemical substance. At least one chemical test must be selected.
- **Actions:** The 'Actions' column provides you with 'Save,' 'Delete,' and 'Add' icons that allow you to perform desired functions to the entered chemical test.

Exhibit 4-5 shows the screen capture of the 'Chemical Identification and Test Rules' screen:

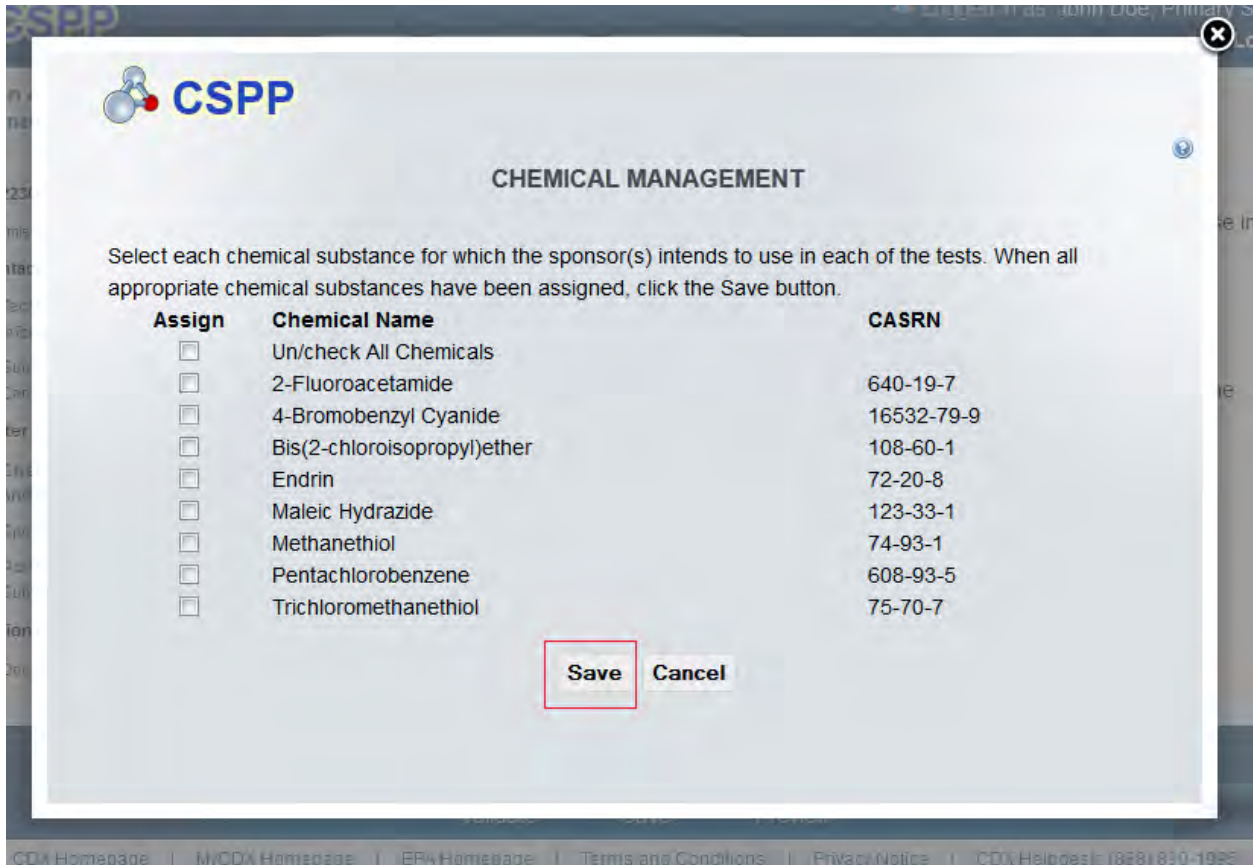
Exhibit 4-5: Chemical Identification and Test Rules Screen

Navigation: Click the ‘Assign Chemicals’ button to identify the chemical substance that the sponsor intends to use in each of the tests.

- **Save:** Clicking the ‘Save’ button will save all delegated assignments to the ‘Chemical Identification and Test Rules’ screen.
- **Cancel:** Clicking the ‘Cancel’ button will close the ‘Chemical Management’ pop-up window and will not save any changes.

Exhibit 4-6 shows the screen capture for the ‘Chemical Management’ pop-up window:

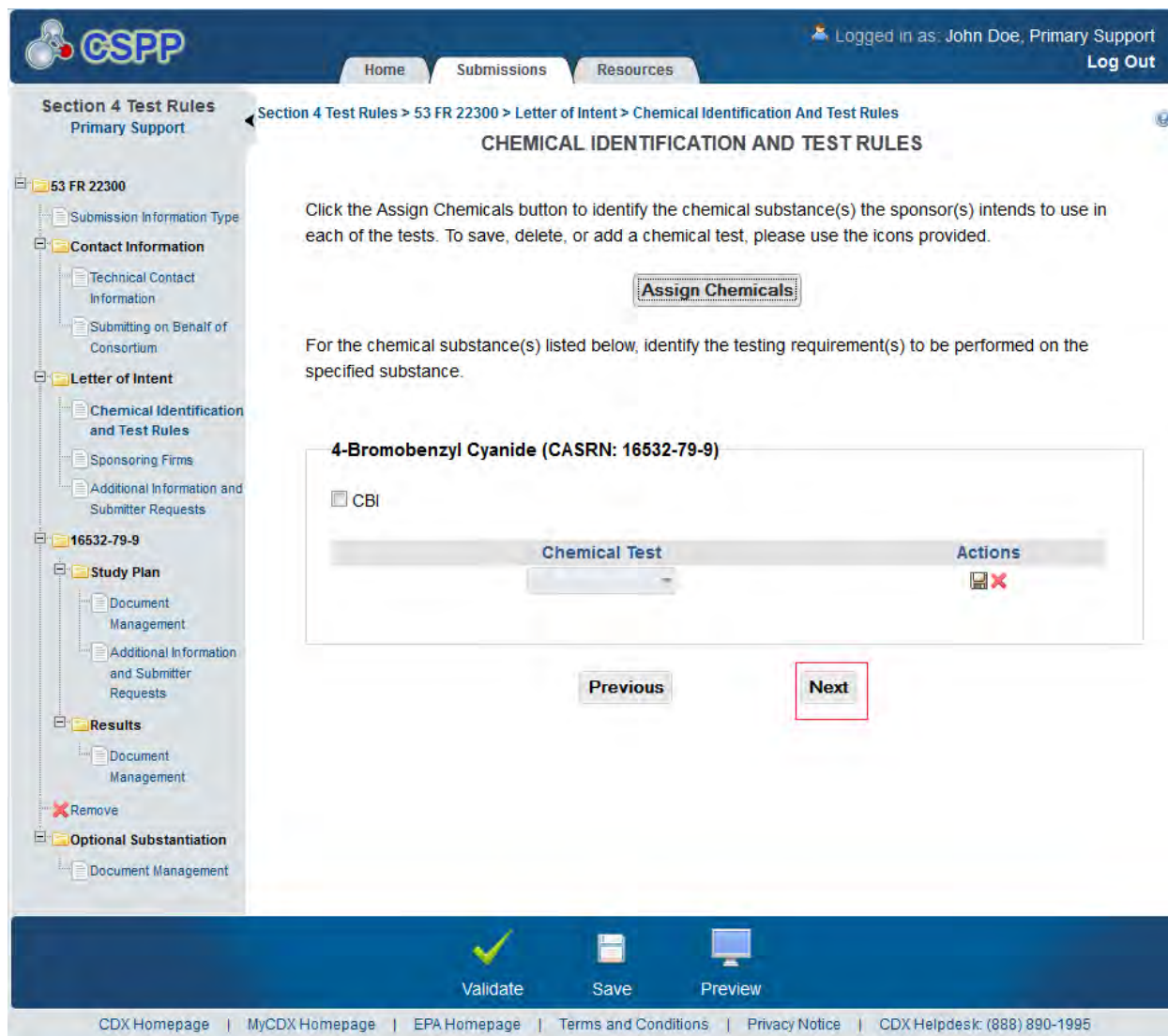
Exhibit 4-6: Chemical Management Pop-up Window



Navigation: Click the ‘Save’ button to return to the ‘Chemical Identification and Test Rules’ screen.

Exhibit 4-7 shows the screen capture for the populated ‘Chemical Identification and Test Rules’ screen:

Exhibit 4-7: Chemical Identification and Test Rules Screen (Populated)



Navigation: Click the ‘Next’ button to navigate to the ‘Sponsoring Firms’ screen. You can also access this screen by clicking the ‘Sponsoring Firms’ link within the navigation tree.

4.5.2 Sponsoring Firms Screen

To access the ‘Sponsoring Firms’ screen click the ‘Next’ button from the ‘Chemical Identification and Test Rules’ screen. You can also access this screen by clicking the ‘Sponsoring Firms’ link located within the navigation tree under the ‘Letter of Intent’ folder.

The ‘Sponsoring Firms’ screen requires you to identify each sponsoring firm involved in the testing of the identified chemical substances. To identify a sponsoring firm click the ‘Add Sponsoring Firm’ button. Clicking the ‘Add Sponsoring Firm’ button generates a sponsoring firm field set. Once you have entered data into a sponsoring firm field set, you must click the ‘Save’ button located within that field set prior to adding another firm. If the data previously

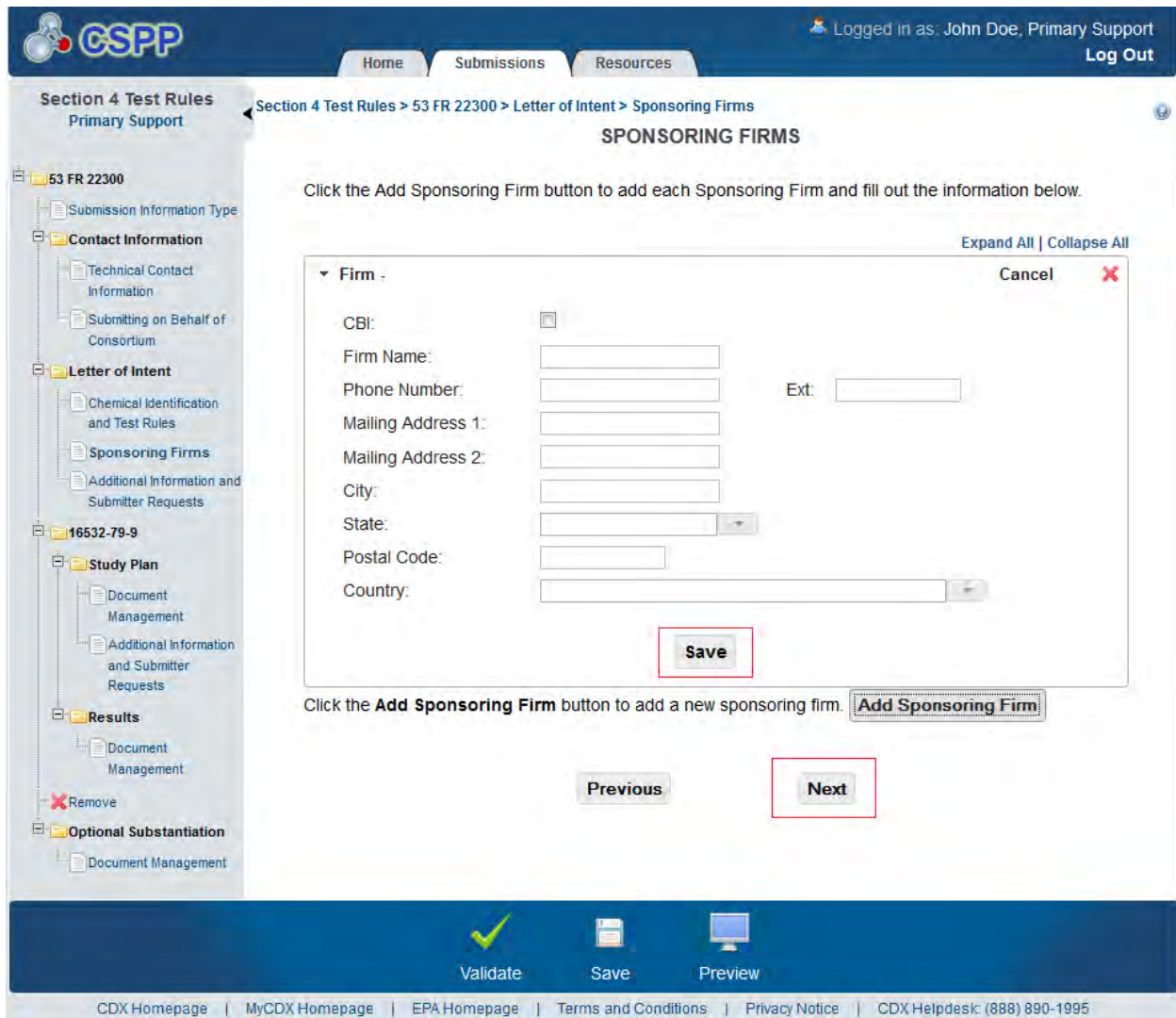
entered and saved within a field set needs to be edited, you can click the ‘Edit’ button located in the upper right corner of that field set. If a sponsoring firm needs to be deleted, you can click the ‘Delete’ icon that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the sponsoring firm field set header. If you wish to expand/collapse all field sets simultaneously, click the ‘Expand All’ or ‘Collapse All’ links located at the top right of all consortium field sets.

- **CBI:** Check the ‘CBI’ checkbox to claim the sponsoring firm as CBI. If you claim information as CBI, you are required to complete substantiation.
- **Firm Name:** Enter the sponsoring firm’s company name. This field is required.
- **Phone Number:** Enter the sponsoring firm’s daytime phone number; U.S. or international. This field does not accept dashes. This field is required.
- **Ext:** Enter the extension to the contact’s daytime phone number.
- **Mailing Address 1:** Enter the first line of the sponsoring firm’s mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the sponsoring firm’s mailing address.
- **City:** Enter the city of the sponsoring firm’s mailing address. This field is required.
- **State:** Enter the state of the sponsoring firm’s mailing address. This field is required when ‘United States’ is identified as the country.
- **Postal Code:** Enter the postal code of the sponsoring firm’s mailing address. This field is required.
- **Country:** Enter the country of the sponsoring firm’s mailing address. This field is required.

Exhibit 4-8 shows the screen capture of the ‘Sponsoring Firms’ screen:

Exhibit 4-8: Sponsoring Firms Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Additional Information and Submitter Requests’ screen. You can also access this screen by clicking the ‘Additional Information and Submitter Requests’ link within the navigation tree.

4.5.3 Additional Information and Submitter Requests Screen

The ‘Additional Information and Submitter Requests’ screen allows you to submit additional information or special requests. This is not a required screen and does not need to be completed prior to submitting information to EPA.

The system provides you with an ‘Information/Request Type’ drop-down menu that contains the following values:

- Amendment to the Study Plan
- Exemption Application

- Extension of Time to Submit a Study Plan
- Modification of Test Standards or Schedules during Conduct of Test
- Submission of Equivalence Data
- Appeal of Denial of Exemption Application

To submit additional information or a special request select the desired value from the ‘Information/Request Type’ drop-down menu and click the ‘Add Information’ button. Depending on your information or request selection, this choice dictates the pop-up window that generates upon clicking the ‘Add Information’ button.

Amendment to the Study Plan: If you select ‘Amendment to the Study Plan’ from the ‘Information/Request Type’ drop-down menu and click the ‘Add Information’ button, the ‘Amendment to the Study Plan’ pop-up window generates. The ‘Amendment to the Study Plan’ pop-up window allows you to attach documentation. To attach documentation, click the ‘Browse’ button. Clicking the ‘Browse’ button will generate the ‘File Upload’ window on your hard drive. Search for your desired document and click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and populate the ‘Browse’ field with the attached document. Click the ‘OK’ button within the ‘Amendment to the Study Plan’ pop-up window to return to the ‘Additional Information and Submitter Requests’ screen. The attached document will be displayed within the table.

Exemption Application: If you select ‘Exemption Application’ from the ‘Information/Request Type’ drop-down menu and click the ‘Add Information’ button, the ‘Exemption Application’ pop-up window generates. The ‘Exemption Application’ pop-up window allows you to identify the testing requirement(s) from which you seek exemption. The ‘Exemption Application’ pop-up window also allows you to provide the basis for the exemption request within a text box. Click the ‘OK’ button within the ‘Exemption Application’ pop-up window to return to the ‘Additional Information and Submitter Requests’ screen. The previously entered data will be displayed within the table.

Extension of Time to Submit Study Plan: If you select ‘Extension of Time to Submit Study Plan’ from the ‘Information/Request Type’ drop-down menu and click the ‘Add Information’ button, the ‘Extension of Time to Submit Study Plan’ pop-up window is generated. The ‘Extension of Time to Submit Study Plan’ pop-up window provides a text box that allows you to identify why EPA should grant the extension. Click the ‘OK’ button within the ‘Extension of Time to Submit Study Plan’ pop-up window to return to the ‘Additional Information and Submitter Requests’ screen. The previously entered data will be displayed within the table.

Modification of Test Standards or Schedules During Conduct of Test: If you select ‘Modification of Test Standards or Schedules During Conduct of Test’ from the ‘Information/Request Type’ drop-down menu and click the ‘Add Information’ button, the ‘Modification of Test Standards or Schedules During Conduct of Test’ pop-up window generates. The ‘Modification of Test Standards or Schedules During Conduct of Test’ pop-up window provides a text box that allows you to enter an explanation and rationale for the modification. Click the ‘OK’ button within the ‘Modification of Test Standards or Schedules During Conduct of Test’ pop-up window to return to the ‘Additional Information and Submitter Requests’ screen. The previously entered data will be displayed within the table.

Submission of Equivalence Data: If you select ‘Submission of Equivalence Data’ from the ‘Information/Request Type’ drop-down menu and click the ‘Add Information’ button, the

‘Submission of Equivalence Data’ pop-up window generates. The ‘Submission of Equivalence Data’ pop-up window allows you to attach documentation. To attach documentation click the ‘Browse’ button. Clicking the ‘Browse’ button will generate the ‘File Upload’ window on your hard drive. Search for your desired document and click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and populate the ‘Browse’ field with the attached document. The system allows you to claim the attached documentation as CBI. When information is claimed as CBI, substantiation of that information is optional. Click the ‘OK’ button within the ‘Amendment to the Study Plan’ pop-up window to return to the ‘Additional Information and Submitter Requests’ screen. The previously attached document will be displayed within the table.

Appeal of Denial of Exemption Application: If you select ‘Appeal of Denial of Exemption Application’ from the ‘Information/Request Type’ drop-down menu and click the ‘Add Information’ button, the ‘Appeal of Denial of Exemption Application’ pop-up window generates. The ‘Appeal of Denial of Exemption Application’ pop-up window provides a text box that allows you to identify the basis for the reconsideration. The system also allows you to claim a hearing by checking the ‘Check here if you wish to request a hearing’ checkbox. If you request a hearing, a second text box generates and requires you to explain why a hearing is necessary. Click the ‘OK’ button within the ‘Appeal of Denial of Exemption Application’ pop-up window to return to the ‘Additional Information and Submitter Requests’ screen. The previously entered data will be displayed within the table.

The table on the ‘Additional Information and Submitter Requests’ screen displays the following columns:


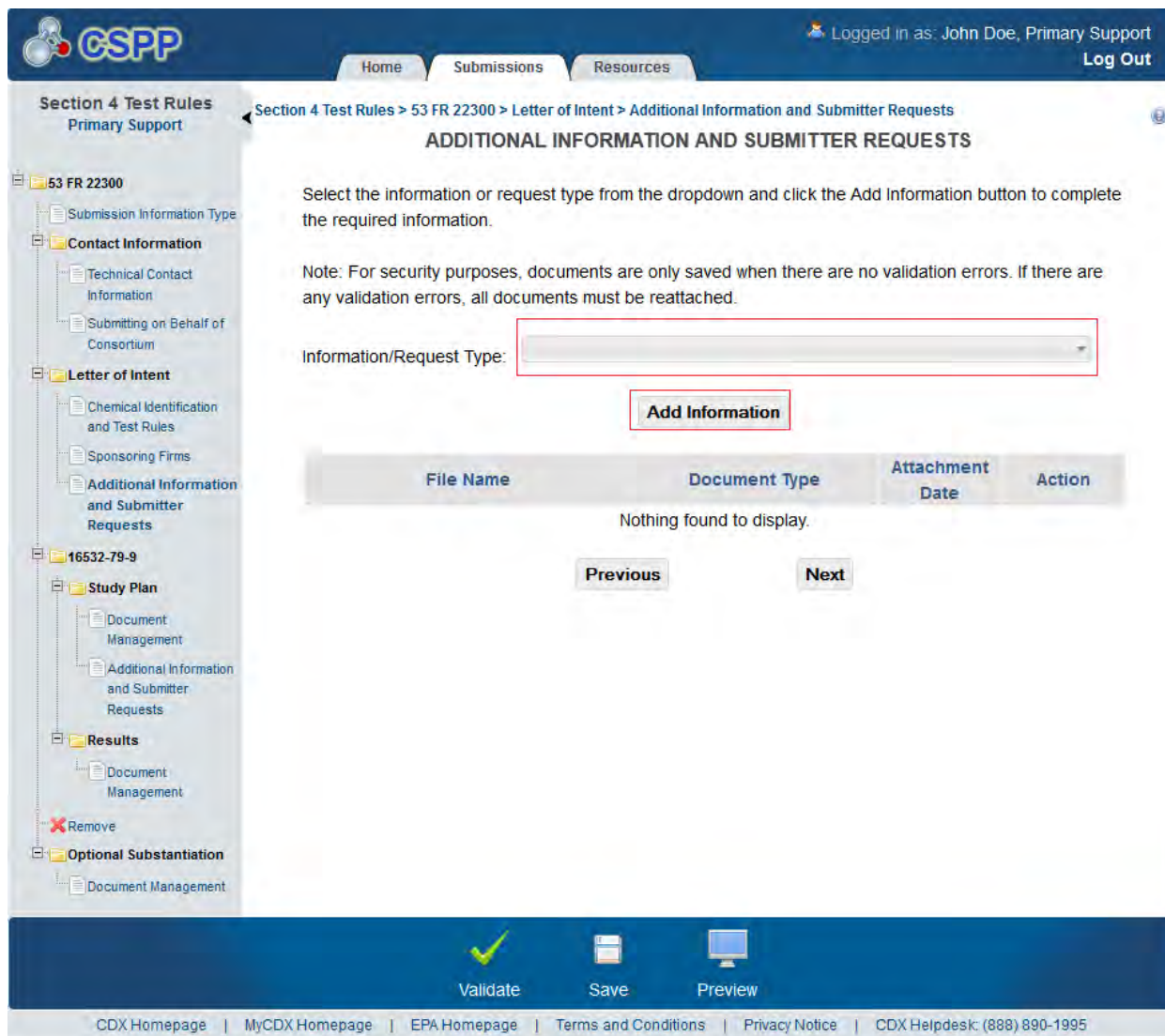
- **File Name:** Displays the file name of the attached document if applicable. If text was entered within the information/request type pop-up window the ‘File Name’ column will display as ‘N/A.’ The system allows you to click the file name link for each information/request type to edit previously attached documentation or text.
- **Information/Request Type:** Displays the information/request type selected from the ‘Information/Request Type’ drop-down menu.
- **Attachment Date:** Displays the date the information/request type was attached.
- **Action:** Displays the ‘Delete’ icon (), which allows you to delete a desired row within the table and all associated information that pertained to the information/request type.

Exhibit 4-9 shows the screen capture for the ‘Additional Information and Submitter Requests’ screen:

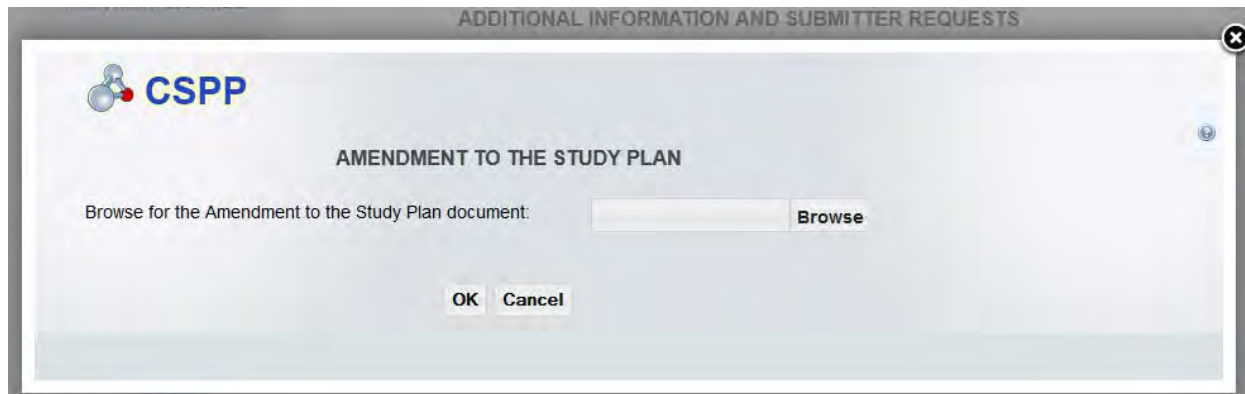
Exhibit 4-9: Additional Information and Submitter Requests Screen



Navigation: If you are completing a letter of intent, click the ‘Submit’ icon located in the bottom action bar to begin the submission process. If you have previously submitted a letter of intent and checked the ‘Study Plan’ checkbox, click the ‘Next’ button to navigate to the ‘Document Management’ screen located under the ‘Study Plan’ folder within the navigation tree. You can also access this screen by clicking the ‘Document Management’ link under the ‘Study Plan’ folder within the navigation tree.

Exhibit 4-10 shows the screen capture of the ‘Amendment to the Study Plan’ pop-up window:

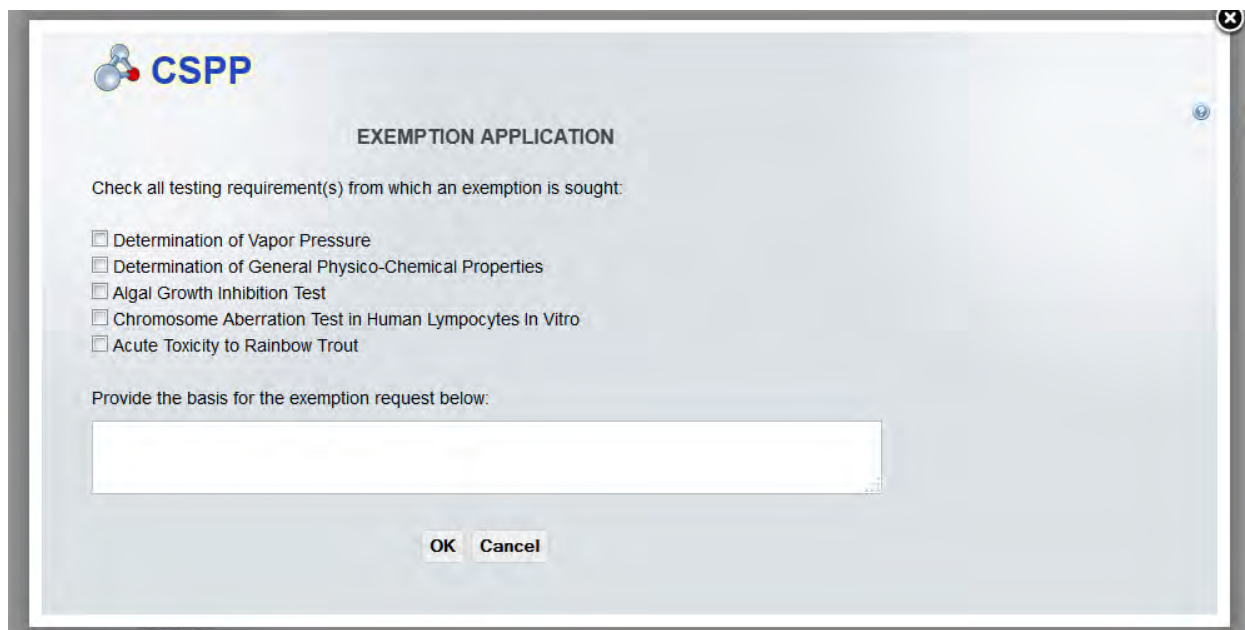
Exhibit 4-10: Amendment to the Study Plan Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-11 shows the screen capture of the ‘Exemption Application’ pop-up window:

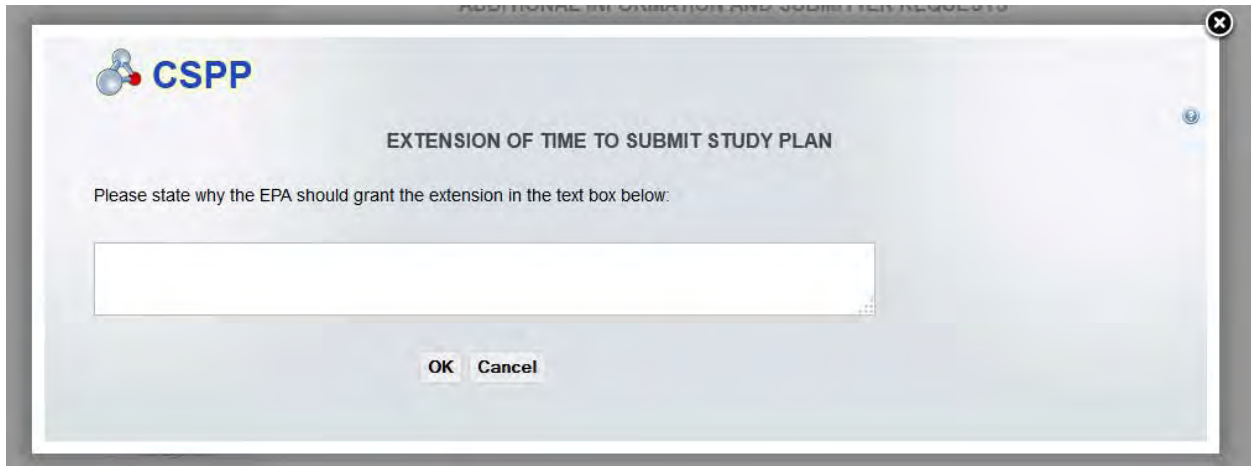
Exhibit 4-11: Exemption Application Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-12 shows the screen capture of the ‘Extension of Time to Submit Study Plan’ pop-up window:

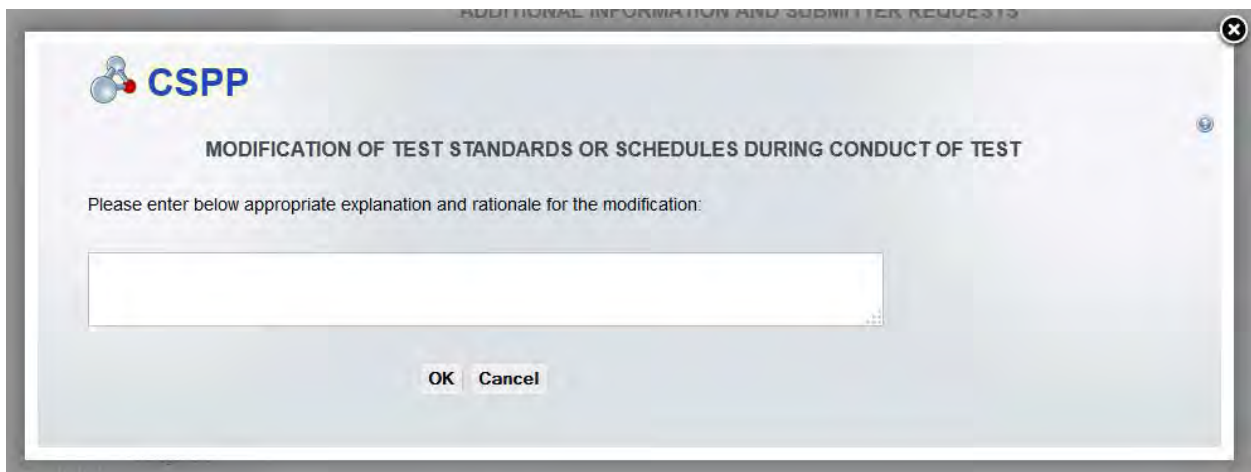
Exhibit 4-12: Extension of Time to Submit Study Plan Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-13 shows the screen capture of the ‘Modification of Test Standards or Schedules during Conduct of Test’ pop-up window:

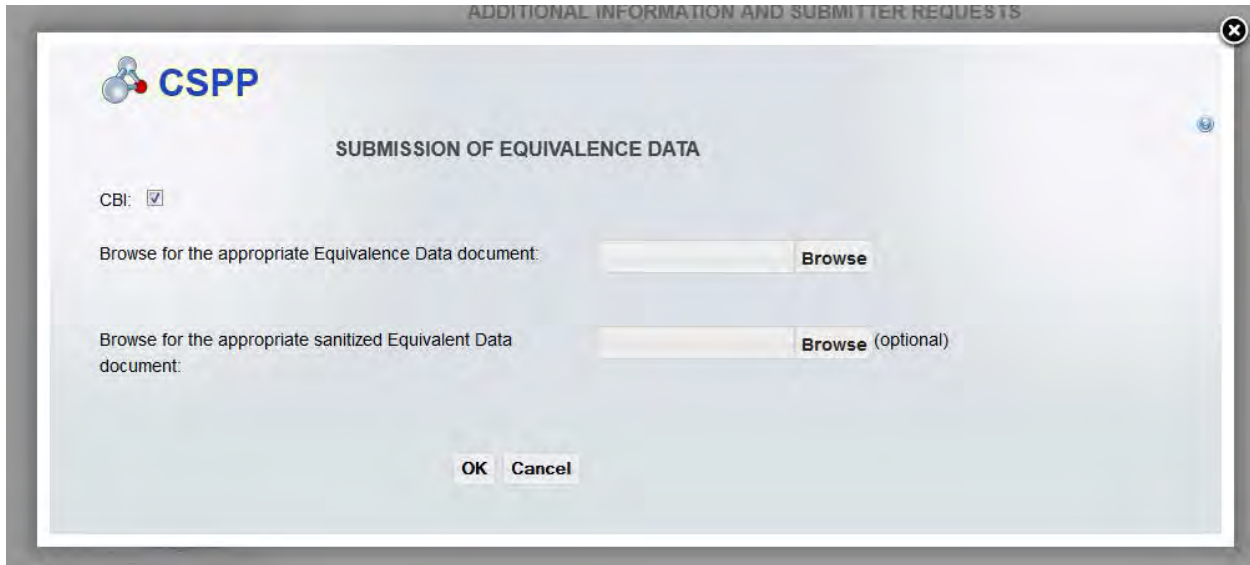
Exhibit 4-13: Modification of Test Standards or Schedules during Conduct of Test Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-14 shows the screen capture of the ‘Submission of Equivalence Data’ pop-up window:

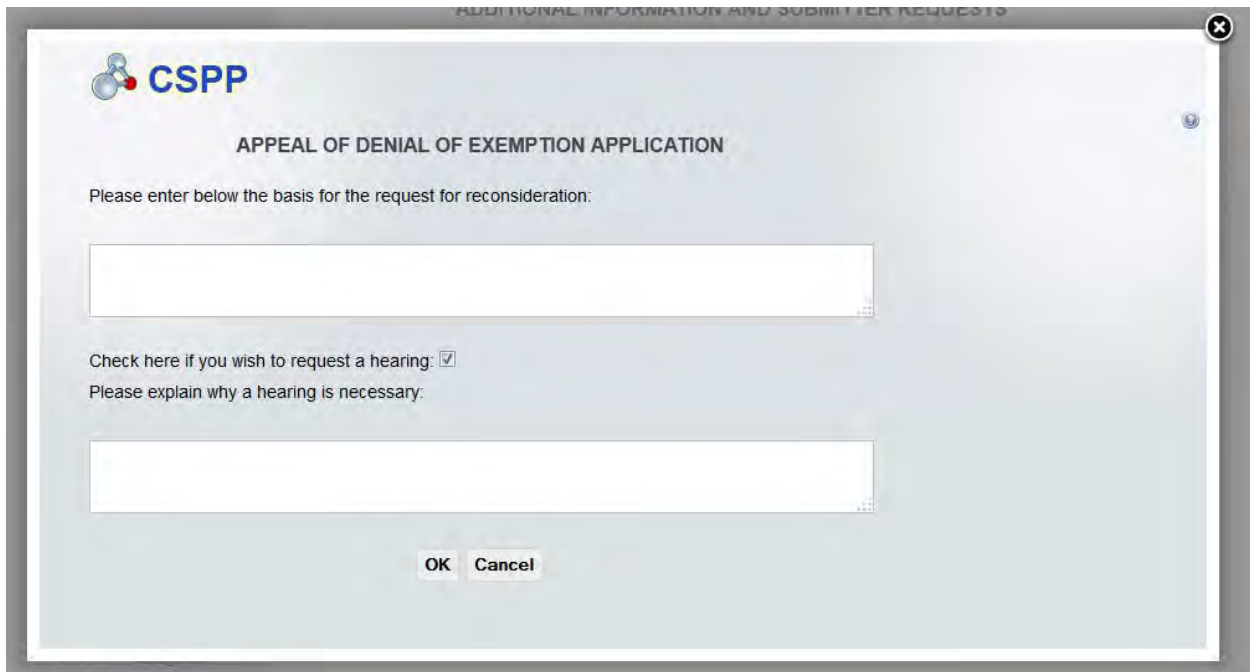
Exhibit 4-14: Submission of Equivalence Data Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-15 shows the screen capture of the ‘Appeal of Denial of Exemption Application’ pop-up window:

Exhibit 4-15: Appeal of Denial of Exemption Application Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

4.6 Study Plan

If you have identified you are completing a study plan, you are required to complete the following screens to satisfy the reporting requirements.

4.6.1 Document Management Screen

You can access the ‘Document Management’ screen by clicking the ‘Next’ button from the ‘Additional Information and Test Rules’ screen or by clicking the ‘Document Management’ link within the navigation tree under the ‘Study Plan’ folder. This screen is only available once your AO has submitted the letter of intent and you have checked the ‘Study Plan’ checkbox on the ‘Submission Information Type’ screen.

The ‘Document Management’ screen allows you to upload documents related to Section 4 reporting requirements. To add Section 4 study plan documentation, click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘Document Management’ pop-up window.

The ‘Document Management’ pop-up window requires you to identify the document type by selecting ‘Phase I’ or ‘Phase II’ from the ‘Document Type’ drop-down menu. Once you have identified the document type to be attached, click the ‘Browse’ button. Clicking the ‘Browse’ button will generate the ‘File Upload’ window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. To claim attached documentation as CBI, check the ‘CBI’ checkbox. If you claim the attached documentation as CBI you are required to attach the sanitized version of the attached document. To do so, follow the steps outlined above. Once you have attached all desired documentation, click the ‘OK’ button to return to the ‘Document Management’ screen.

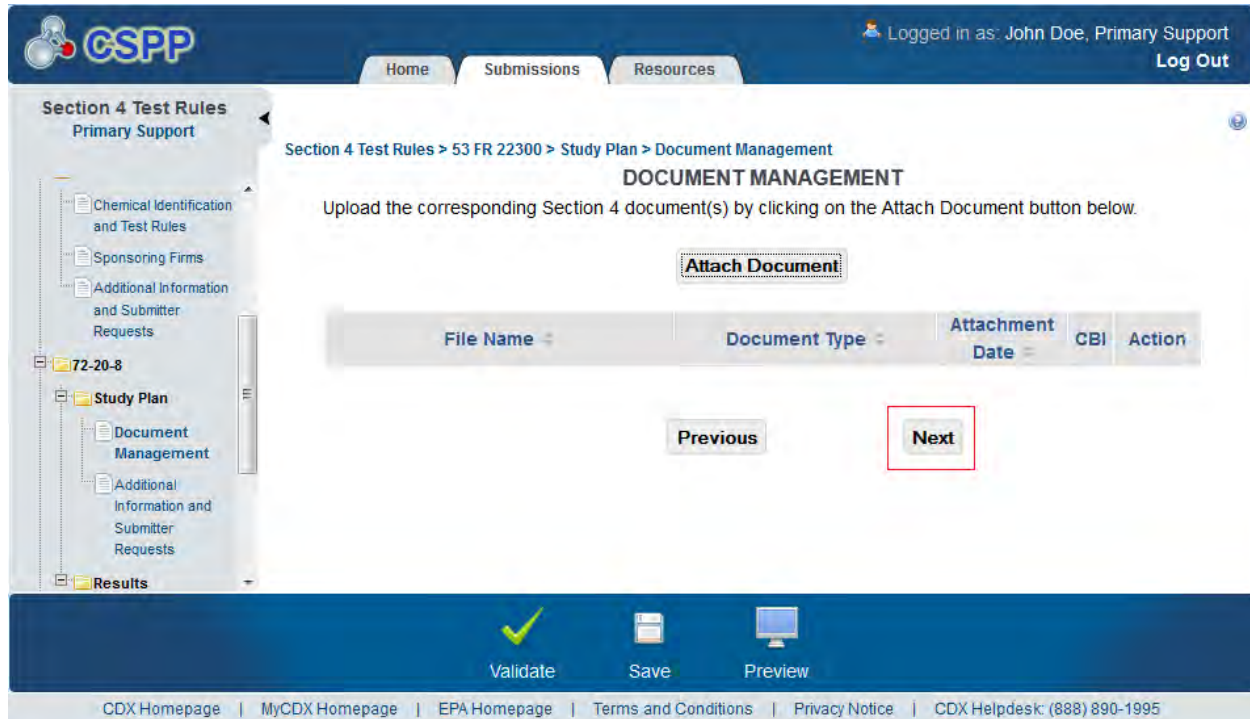
The ‘Document Management’ table displays the file name of the document, the document type, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon located under the ‘Action’ column for a given row. Clicking the file name links within the ‘File Name’ column generates the ‘Document Management’ pop-up window. This allows you to view and edit previously attached documents.

- **Attach Document:** Clicking the ‘Attach Document’ button displays the ‘Document Management’ pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the ‘Document Management’ pop-up window and allows you to view and edit the attached document.
- **Document Type:** Displays the document type of the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed CBI.

- **Action:** Clicking the ‘Delete’ icon () will generate a prompt confirming the command. If you click the ‘OK’ button within the prompt, this will delete the specified row and all contents within.

Exhibit 4-16 shows the screen capture of the ‘Document Management’ screen:

Exhibit 4-16: Document Management Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Additional Information and Submitter Requests’ screen.

The ‘Document Management’ pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach at least one document. Clicking the ‘Browse’ button will generate the ‘File Upload’ window on your hard drive. Select the document you wish to attach and click the ‘Open’ button. If a document is marked as ‘CBI’ then a sanitized copy of the document can be attached. To save the attached document to the ‘Document Management’ screen, click the ‘OK’ button within the ‘Document Management’ pop-up window.

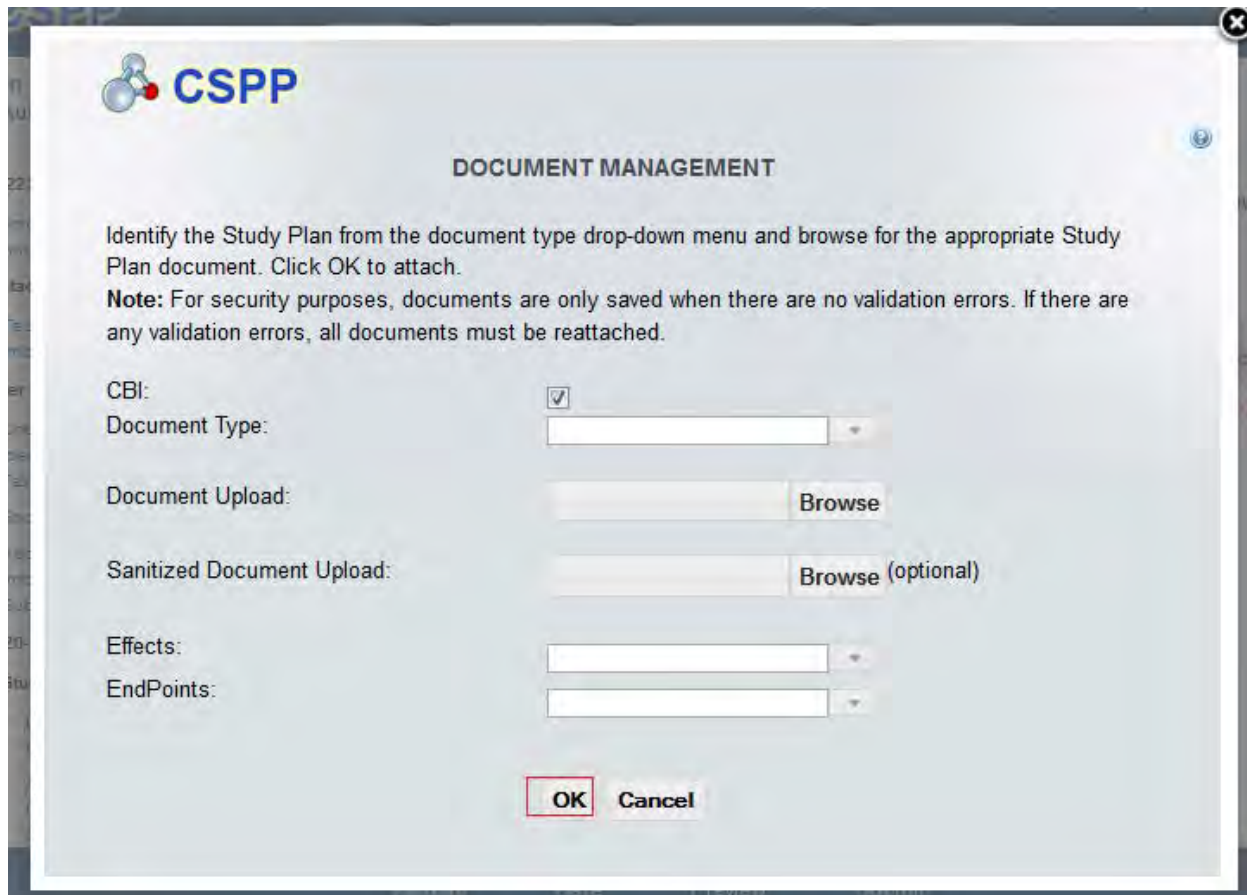
- **Document Type:** Select the document type specific to the uploaded document. Displays the following options: ‘Phase I’ and ‘Phase II.’
- **CBI:** Checking the ‘CBI’ checkbox will claim the uploaded document as CBI and generate a sanitized document upload field.
- **Document Upload:** Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Sanitized Document Upload:** This field will only be displayed when the ‘CBI’ checkbox is checked. Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.

- **Effects:** Select the effect specific to the chemical report. Displays the following options: ‘Health Effects,’ ‘Environmental Fate,’ ‘Ecotoxicity,’ and ‘Physical Chemical Properties.’
- **Endpoints:** Select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the ‘Effects’ drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Appendix B for a complete list of values that are found within each of the drop-down menus on the ‘Document Management’ pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 4-17 shows the screen capture of the ‘Document Management’ pop-up window:

Exhibit 4-17: Document Management Pop-Up Window



Navigation: Click the ‘OK’ button to return to the ‘Document Management’ screen.

4.6.2 Additional Information and Submitter Requests Screen

You can access the ‘Additional Information and Submitter Requests’ screen by clicking the ‘Next’ button from the ‘Document Management’ screen. You can also access this screen by clicking the ‘Additional Information and Submitter Requests’ link within the navigation tree under the ‘Study Plan’ folder.

The ‘Additional Information and Submitter Requests’ screen allows you to submit additional information or special requests. This screen does not need to be completed prior to submitting information to EPA.

The system provides you with an ‘Information/Request Type’ drop-down menu that contains the following values:

- Amendment to the Study Plan
- Exemption Application
- Extension of Time to Submit a Study Plan
- Modification of Test Standards or Schedules During Conduct of Test

- Submission of Equivalence Data
- Appeal of Denial of Exemption Application

To submit additional information or a special request select the desired value from the 'Information/Request Type' drop-down menu and click the 'Add Information' button. Depending on your information or request selection this dictates the pop-up window that will be generated upon clicking the 'Add Information' button.

If you select 'Amendment to the Study Plan' from the 'Information/Request Type' drop-down menu and click the 'Add Information' button, the 'Amendment to the Study Plan' pop-up window generates. The 'Amendment to the Study Plan' pop-up window allows you to attach documentation. To attach documentation click the 'Browse' button. Clicking the 'Browse' button will generate the 'File Upload' window. Search for your desired document on your hard drive and click the 'Open' button. Clicking the 'Open' button will close the 'File Upload' window and populate the 'Browse' field with the attached document. Click the 'OK' button within the 'Amendment to the Study Plan' pop-up window to return to the 'Additional Information and Submitter Requests' screen. The previously attached document will be displayed within the table.

If you select 'Exemption Application' from the 'Information/Request Type' drop-down menu and click the 'Add Information' button, the 'Exemption Application' pop-up window generates. The 'Exemption Application' pop-up window allows you to identify the testing requirement(s) from which you seek exemption. The 'Exemption Application' pop-up window also allows you to provide the basis for the exemption request within a text box. Click the 'OK' button within the 'Exemption Application' pop-up window to return to the 'Additional Information and Submitter Requests' screen. The previously entered data will be displayed within the table.

If you select 'Extension of Time to Submit Study Plan' from the 'Information/Request Type' drop-down menu and click the 'Add Information' button, the 'Extension of Time to Submit a Study Plan' pop-up window is generated. The 'Extension of Time to Submit Study Plan' pop-up window provides a text box that allows you to identify why EPA should grant the extension. Click the 'OK' button within the 'Extension of Time to Submit Study Plan' pop-up window to return to the 'Additional Information and Submitter Requests' screen. The previously entered data will be displayed within the table.

If you select 'Modification of Test Standards or Schedules During Conduct of Test' from the 'Information/Request Type' drop-down menu and click the 'Add Information' button, the 'Modification of Test Standards or Schedules During Conduct of Test' pop-up window generates. The 'Modification of Test Standards or Schedules During Conduct of Test' pop-up window provides a text box that allows you to enter an explanation and rationale for the modification. Click the 'OK' button within the 'Modification of Test Standards or Schedules During Conduct of Test' pop-up window to return to the 'Additional Information and Submitter Requests' screen. The previously entered data will be displayed within the table.

If you select 'Submission of Equivalence Data' from the 'Information/Request Type' drop-down menu and click the 'Add Information' button, the 'Submission of Equivalence Data' pop-up window generates. The 'Submission of Equivalence Data' pop-up window allows you to attach documentation. To attach documentation click the 'Browse' button. Clicking the 'Browse' button will generate the 'File Upload' window. Search for your desired document on your hard drive and click the 'Open' button. Clicking the 'Open' button will close the 'File Upload'

window and populate the 'Browse' field with the attached document. The system allows you to claim the attached documentation as CBI. When information is claimed as CBI, substantiation of that information is then required. Click the 'OK' button within the 'Amendment to the Study Plan' pop-up window to return to the 'Additional Information and Submitter Requests' screen. The previously attached document will be displayed within the table.

If you select 'Appeal of Denial of Exemption Application' from the 'Information/Request Type' drop-down menu and click the 'Add Information' button, the 'Appeal of Denial of Exemption Application' pop-up window generates. The 'Appeal of Denial of Exemption Application' pop-up window provides a text box that allows you to identify the basis for the reconsideration. The system also allows you to claim a hearing by checking the 'Check here if you wish to request a hearing' checkbox. If you request a hearing, a second text box generates and requires you to explain why a hearing is necessary. Click the 'OK' button within the 'Appeal of Denial of Exemption Application' pop-up window to return to the 'Additional Information and Submitter Requests' screen. The previously entered data will be displayed within the table.

The table on the 'Additional Information and Submitter Requests' screen displays the following columns:



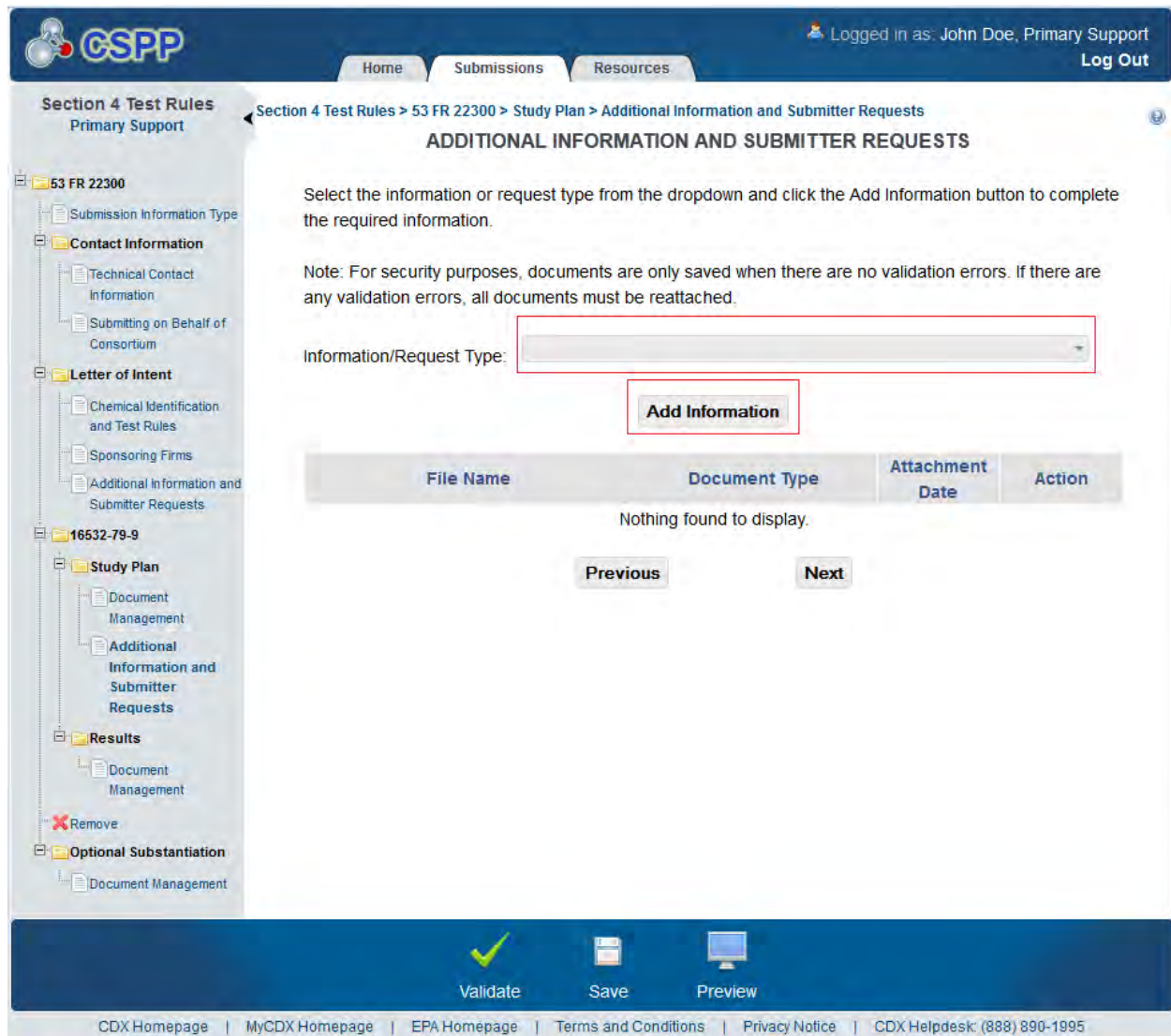
- **File Name:** Displays the file name of the attached document if applicable. If text was entered within the information/request type pop-up window the 'File Name' column will display as 'N/A.' The system allows you to click the file name link for each information/request type to edit previously attached documentation or text.
- **Document Type:** Displays the information/request type selected from the 'Information/Request Type' drop-down menu.
- **Attachment Date:** Displays the date the information/request type was attached.
- **Action:** Displays the 'Delete' icon () which allows you to delete a desired row within the table and all associated information that pertained to the information/request type. Clicking the 'Delete' icon () will generate a prompt confirming the command. Clicking the 'OK' button within the prompt will delete the desired row and all contents within.

Exhibit 4-18 shows the screen capture for the ‘Additional Information and Submitter Requests’ screen:

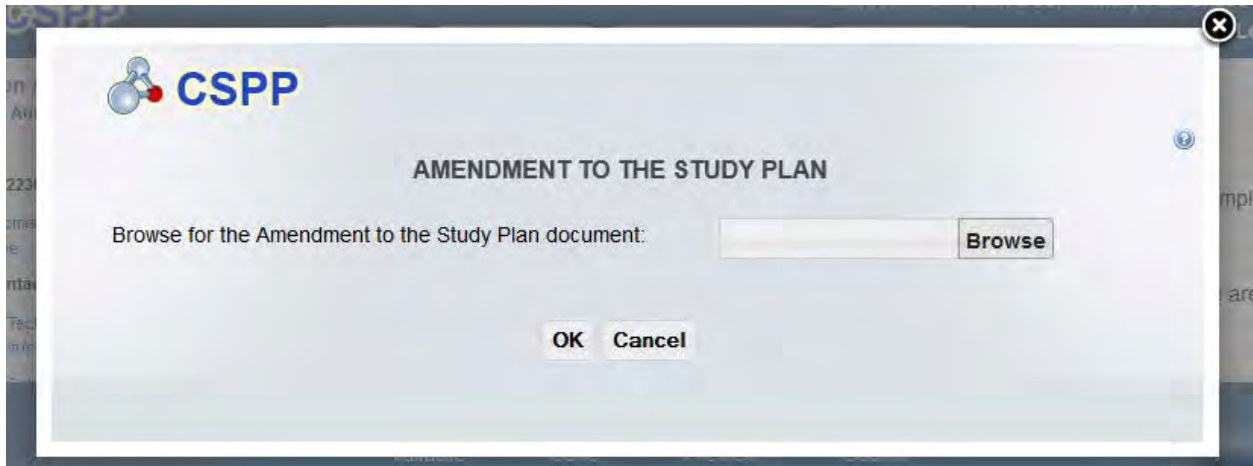
Exhibit 4-18: Additional Information and Submitter Requests Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Test Rules Substantiation Part 1’ screen if information has been claimed CBI. If information has not been claimed CBI and you have not identified other submission information types on the ‘Submission Information Type’ screen, you are ready to submit the Section 4 test rules submission to EPA. If you have identified you are submitting results, you will be taken to the ‘Document Management’ screen under the ‘Results’ folder within the navigation tree.

Exhibit 4-19 shows the screen capture of the ‘Amendment to the Study Plan’ pop-up window:

Exhibit 4-19: Amendment to the Study Plan Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-20 shows the screen capture of the ‘Exemption Application’ pop-up window:

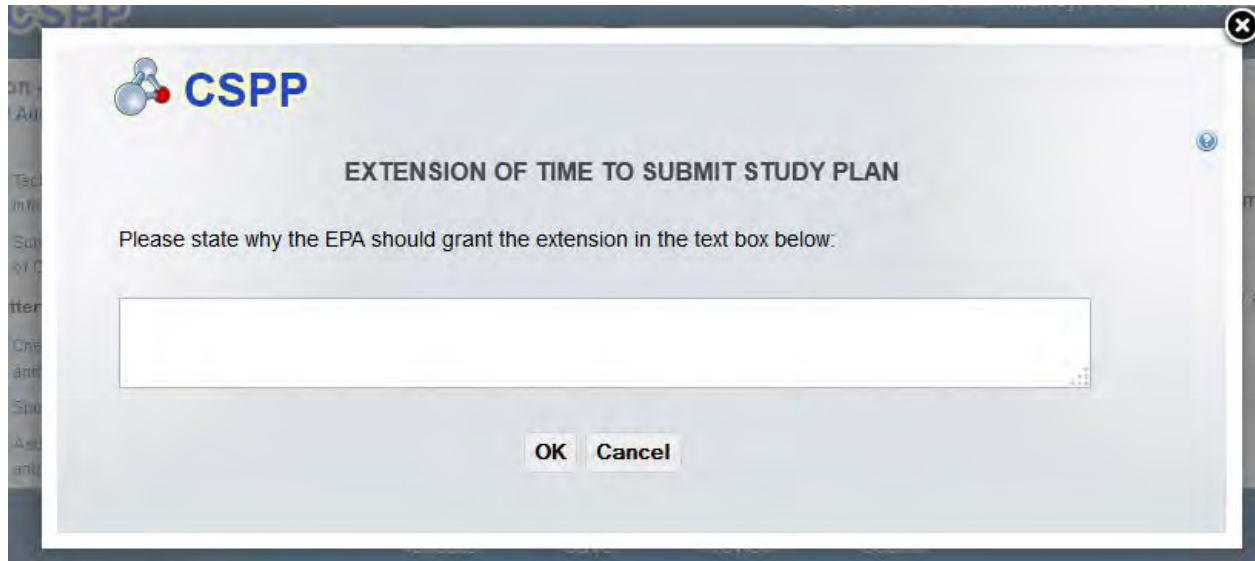
Exhibit 4-20: Exemption Application Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-21 shows the screen capture of the ‘Extension of Time to Submit Study Plan’ pop-up window:

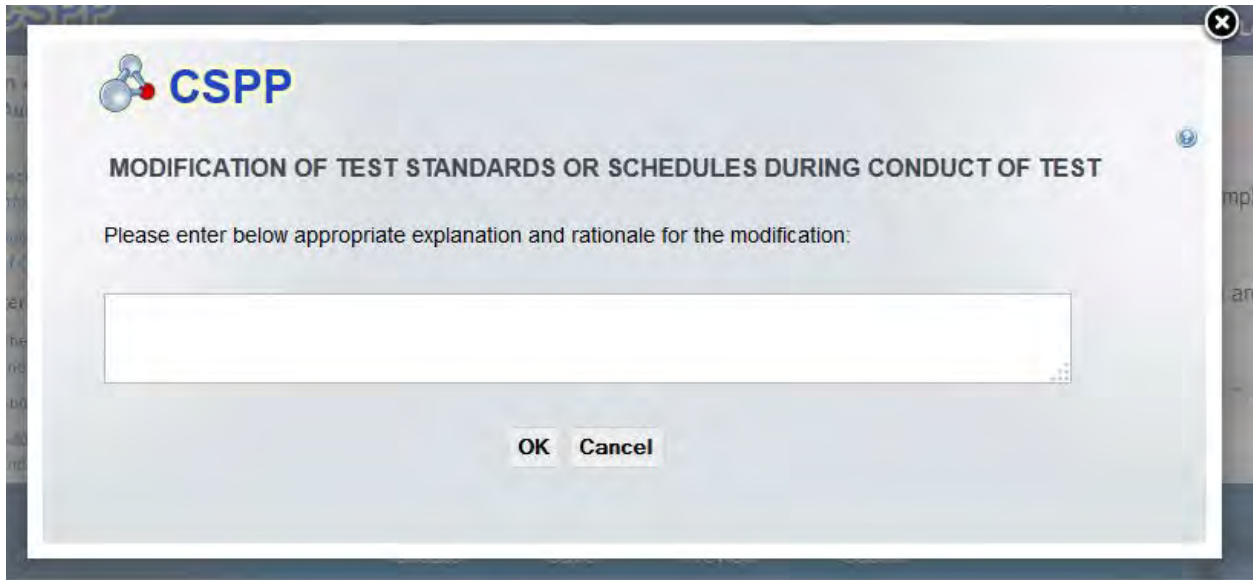
Exhibit 4-21: Extension of Time to Submit Study Plan Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-22 shows the screen capture of the ‘Modification of Test Standards or Schedules during Conduct of Test’ pop-up window:

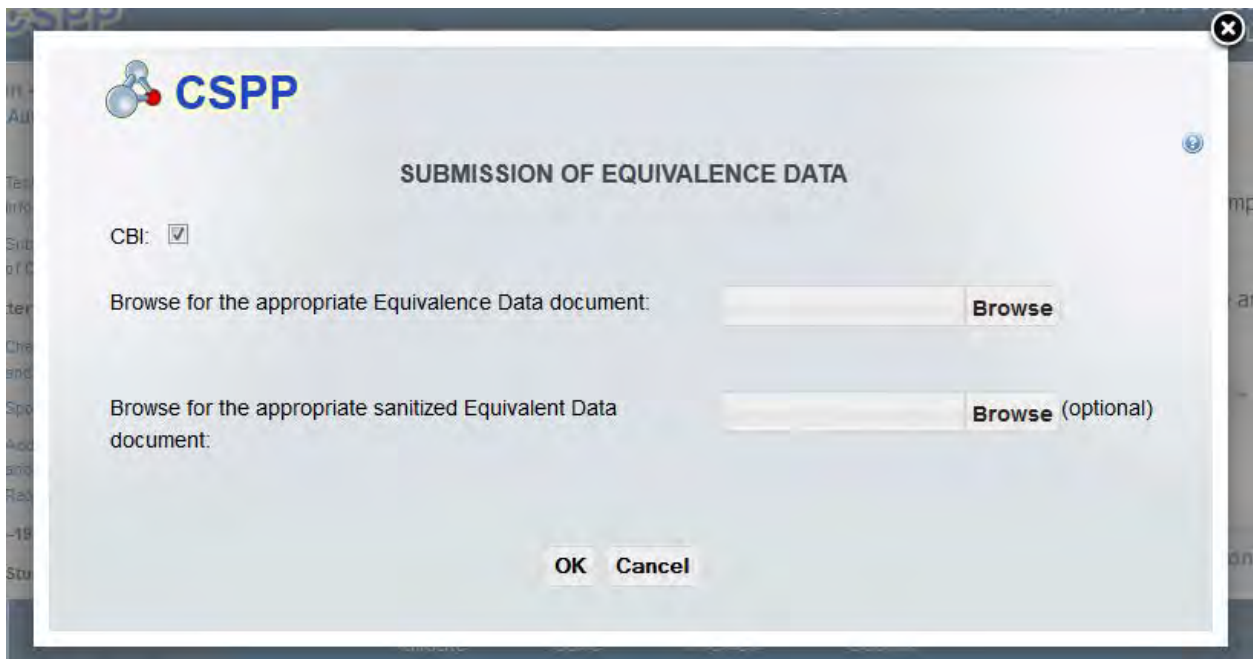
Exhibit 4-22: Modification of Test Standards or Schedules during Conduct of Test Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-23 shows the screen capture of the ‘Submission of Equivalence Data’ pop-up window:

Exhibit 4-23: Submission of Equivalence Data Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

Exhibit 4-24 shows the screen capture of the ‘Appeal of Denial of Exemption Application’ pop-up window:

Exhibit 4-24: Appeal of Denial of Exemption Application Pop-up Window



Navigation: Click the ‘OK’ button to return to the ‘Additional Information and Submitter Requests’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Additional Information and Submitter Requests’ screen without saving the entered information.

4.7 Test Rules Substantiation

If you claim items within study plan as CBI that require substantiation, you must complete the ‘Test Rules Substantiation Part 1 and Part 2’ screens prior to submission.

4.7.1 Test Rules Substantiation Part 1 Screen

You can access the ‘Test Rules Substantiation Part 1’ screen by clicking the ‘Next’ button from the ‘Document Management’ or the ‘Additional Information and Submitter Requests’ screens. You can also navigate to the ‘Test Rules Substantiation Part 1’ screen by clicking the ‘Test Rules Substantiation Part 1’ link within the navigation tree.

- **Substantiation Question 1:** Question 1 requires you to identify whether the information has been disclosed in a patent. To complete substantiation for question 1, the system provides ‘Yes’ and ‘No’ radio buttons.
 - Question 1 of the ‘Test Rules Substantiation Part 1’ screen states as follows:
 - Has the information been disclosed in a patent?

- **Substantiation Question 2:** Question 2 requires you to identify whether the disclosure of the study plan information would disclose processes used in the manufacture of a chemical. To complete substantiation for question 2 the system provides ‘Yes’ and ‘No’ radio buttons. If you select the ‘Yes’ radio button, you are required to identify how the process would occur.
 - Question 2 of the ‘Test Rules Substantiation Part 1’ screen states as follows:
 - Would disclosure of the study plan information disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur.
- **Substantiation Question 3:** Question 3 requires you to identify whether disclosure of the study plan information would disclose the portion of a mixture. To complete substantiation for question 3 the system provides ‘Yes’ and ‘No’ radio buttons. If you select the ‘Yes’ radio button, you are required to identify how the disclosure would occur.
 - Question 3 of the ‘Test Rules Substantiation Part 1’ screen states as follows:
 - Would disclosure of the study plan information disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur.
- **Substantiation Question 4:** Question 4 of the ‘Test Rules Substantiation Part 1’ screen requires you to identify if the information claimed as CBI has been disclosed to the public. To complete substantiation for question 4 the system provides ‘Yes’ and ‘No’ radio buttons. If you select the ‘Yes’ radio button, you are required to identify the circumstances in which the information has been disclosed to the public.
 - Question 4 of the ‘Test Rules Substantiation Part 1’ screen states as follows:
 - Has this information been disclosed to the public in any form? Describe the circumstances.

Exhibit 4-25 shows the screen capture for the ‘Test Rules Substantiation Part 1’ screen:

Exhibit 4-25: Test Rules Substantiation Part 1 Screen

The screenshot displays the 'TEST RULES SUBSTANTIATION PART 1' screen. The navigation tree on the left includes sections for '53 FR 22300' (Submission Information Type, Contact Information, Letter of Intent) and '16532-79-9' (Study Plan, Results, Optional Substantiation). The main content area contains the following questions:

- Has the information been disclosed in a patent?
Yes No
- Would disclosure of the study plan information disclose processes used in the manufacture or processing of a chemical substance or mixture?
Yes No
Describe how this would occur.
- Would disclosure of the study plan information disclose the portion of a mixture comprised by any of the substances in the mixture?
Yes No
Describe how this would occur.
- Has this information been disclosed to the public in any form?
Yes No
Describe the circumstances.

At the bottom of the screen, there are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red box. Below these buttons are 'Validate', 'Save', and 'Preview' icons. The footer contains links to CDX Homepage, MyCDX Homepage, EPA Homepage, Terms and Conditions, Privacy Notice, and CDX Helpdesk: (888) 890-1995.

Navigation: Click the ‘Next’ button to navigate to the ‘Test Rules Substantiation Part 2’ screen. You can also access this screen by clicking the ‘Test Rules Substantiation Part 2’ link within the navigation tree.

4.7.2 Test Rules Substantiation Part 2 Screen

You can access the ‘Test Rules Substantiation Part 2’ screen by clicking the ‘Next’ button from the ‘Test Rules Substantiation Part 1’ screen. You can also navigate to this screen by clicking the ‘Test Rules Substantiation Part 2’ link within the navigation tree.

- **Substantiation Question 5:** The system provides a text box to enter information pertaining to question 5. The system also provides a calendar widget to identify the date to which the claim of confidentiality should extend and a text box to provide an explanation as to why confidential treatment should be given. At least one radio button must be selected.
 - Question 5 of the ‘Test Rules Substantiation Part 2’ screen states as follows:
 - For what period of time should confidentiality treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why should confidential treatment be given?
- **Substantiation Question 6:** The system provides a text box to enter information pertaining to question 6.
 - Question 6 of the ‘Test Rules Substantiation Part 2’ screen states as follows:
 - What harmful effects to your competitive position, if any, do you think would result from disclosure of this information? How would a competitor use such information? How substantial would the harmful effects be? What is the causal relationship between disclosure and the harmful effects?
- **Substantiation Question 7:** Question 7 requires you to identify what measure you have taken to guard against disclosure of the information and provides a text box to enter information pertaining to the question.
 - Question 7 of the ‘Test Rules Substantiation Part 2’ screen states as follows:
 - What measures have you taken to guard against disclosure of this information to others?
- **Substantiation Question 8:** Question 8 requires you to identify the extent to which the information has been disclosed and the precautions that have been taken to safeguard it. Question 8 provides a text box to enter information pertaining to the question.
 - Question 8 of the ‘Test Rules Substantiation Part 2’ screen states as follows:
 - To what extent has this information been disclosed to others? What precautions have been taken in connection with such disclosures?
- **Substantiation Question 9:** Question 9 requires you to identify if EPA or another Federal Agency or any Federal court has made any confidentiality determinations. If you select the ‘Yes’ radio button, the system requires you to attach such documentation. If you select the ‘No’ radio button, you are not required to provide documentation.
 - Question 9 of the ‘Test Rules Substantiation Part 2’ screen states as follows:
 - Has EPA, another Federal Agency, or any Federal court made any pertinent confidentiality determination regarding this information? Click the Browse button and search the appropriate document(s). Click the Upload button to attach copies of such determinations.

Exhibit 4-26 and Exhibit 4-27 show the screen captures for ‘Test Rules Substantiation Part 2’ screen:

Exhibit 4-26: Test Rules Substantiation Part 2 Screen (Scroll 1)

Section 4 Test Rules
Primary Support

Section 4 Test Rules > 53 FR 22300 > Study Plan > Test Rules Substantiation Part 2

TEST RULES SUBSTANTIATION PART 2

5. For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently?

Event
 Date
 Permanently

Why should confidential treatment be given?

6. What harmful effects to your competitive position, if any, do you think would result from disclosure of this information? How would a competitor use such information? How substantial would the harmful effects be? What is the causal relationship between disclosure and the harmful effects?

7. What measures have you taken to guard against disclosure of this information to others?

8. To what extent has this information been disclosed to others? What precautions have been taken in connection with such disclosures?

Validate Save Preview

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Exhibit 4-27: Test Rules Substantiation Part 2 Screen (Scroll 2)

Section 4 Test Rules
Primary Support

53 FR 22300

- Submission Information Type
- Contact Information
 - Technical Contact Information
 - Submitting on Behalf of Consortium
- Letter of Intent
 - Chemical Identification and Test Rules
 - Sponsoring Firms
 - Additional Information and Submitter Requests
- 16532-79-9
 - Study Plan
 - Document Management
 - Additional Information and Submitter Requests
 - Test Rules Substantiation Part 1
 - Test Rules Substantiation Part 2
 - Results
 - Document Management

Remove

Logged in as: John Doe, Primary Support
Log Out

Home Submissions Resources

7. What measures have you taken to guard against disclosure of this information to others?

8. To what extent has this information been disclosed to others? What precautions have been taken in connection with such disclosures?

9. Has EPA, another Federal Agency, or any Federal court made any pertinent confidentiality determination regarding this information?
Yes No

Click the Browse button and search for the appropriate document(s). Click the Upload button to attach copies of such determinations.

Browse Upload

File Name	Attachment Date	Action
Nothing found to display.		

Previous Next

Validate Save Preview

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Navigation: If you are completing the study plan submission, click the ‘Submit’ icon to begin the submission process. If you have checked the ‘Results’ checkbox on the ‘Submission Information Type’ screen, click the ‘Next’ button to navigate to the ‘Document Management’ screen under the ‘Results’ folder within the navigation tree.

4.8 Results

If you have identified you are completing results, you are required to complete the following screens to satisfy the reporting requirements.

4.8.1 Document Management Screen

The 'Document Management' screen allows you to upload documents related to Section 4 reporting requirements. To add Section 4 results documentation, click the 'Attach Document' button. Clicking the 'Attach Document' button initiates the 'Document Management' pop-up window.

The 'Document Management' pop-up window allows you to attach documentation by clicking the 'Browse' button. This will generate the 'File Upload' window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the 'Open' button. Clicking the 'Open' button will close the 'File Upload' window and display the attached document within the 'Browse' field. To claim attached documentation as CBI, check the 'CBI' checkbox. If you claim the attached documentation as CBI, you are required to attach the sanitized version of the attached document. To do so, follow the steps outlined above. Once you have attached all desired documentation, click the 'OK' button to return to the 'Document Management' screen.

The 'Document Management' table displays the file name of the document, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the 'Delete' icon located under the 'Action' column for a given row. Clicking the file name links within the 'File Name' column generates the 'Document Management' pop-up window. This allows you to view and edit previously attached documents.


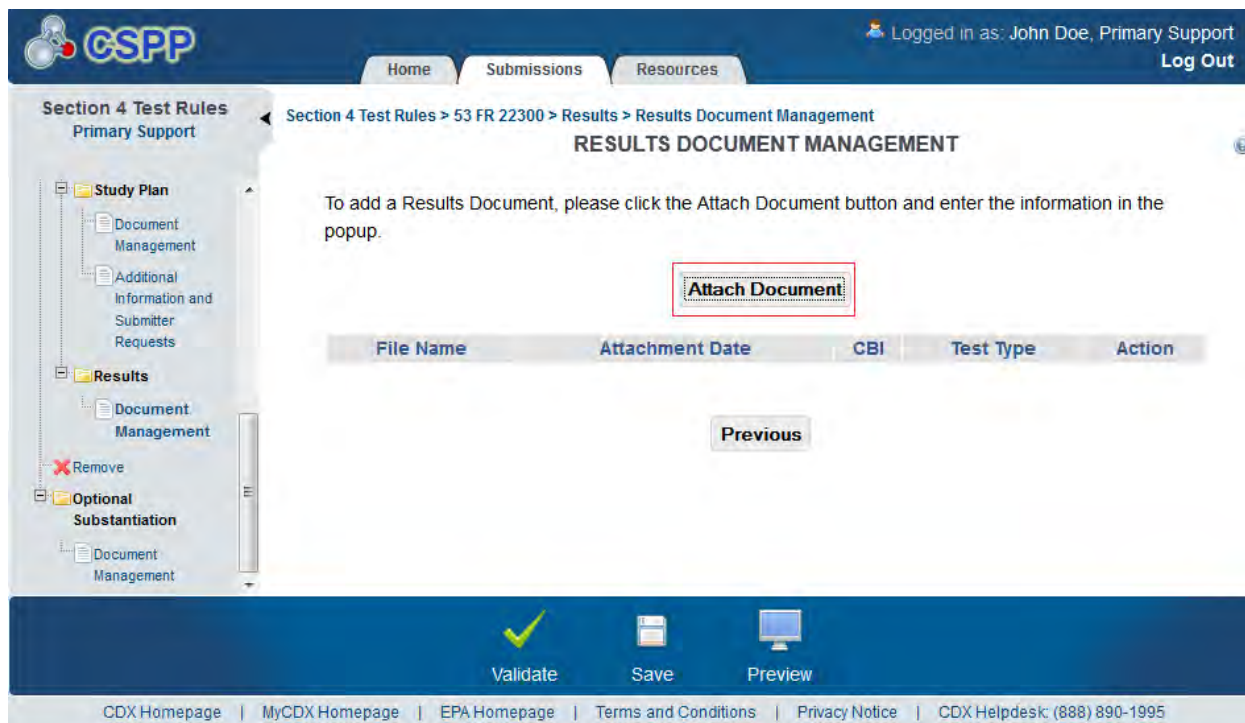
- **Attach Document:** Clicking the 'Attach Document' button displays the 'Document Management' pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the 'Document Management' pop-up window and allows you to view the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed as CBI.
- **Test Type:** Displays the test that is associated with the chemical and the result's document.
- **Action:** Clicking the 'Delete' icon () will generate a prompt confirming the command. To delete the specified row and all contents within click the 'OK' button within the prompt.

Exhibit 4-28 shows the screen capture of the ‘Document Management’ screen:

Exhibit 4-28: Document Management Screen



Navigation: Once all documentation has been uploaded, click the ‘Save’ button to save all entered information. If multiple chemicals have been selected on the ‘Chemical Identification and Test Rules’ screen, complete all required fields prior to submitting.

The ‘Document Management’ pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach at least one document. Clicking the ‘Browse’ button will generate the ‘File Upload’ window on your hard drive. Select the document you wish to attach and click the ‘Open’ button. If a document is marked as ‘CBI’ then a sanitized copy of the document can be attached. To save the attached document to the ‘Document Management’ screen, click the ‘OK’ button within the ‘Document Management’ pop-up window.

- **CBI:** Checking the ‘CBI’ checkbox will claim the uploaded document as CBI and generate a sanitized document upload field.
- **Test Type:** Displays the tests that are specific to the chemical that was selected on the ‘Chemical Identification and Test Rules’ screen.
- **Original Document:** Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Sanitized Document:** This field will only be displayed when the ‘CBI’ checkbox is checked. Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Effects:** Select the effect specific to the chemical report. Displays the following options: ‘Health Effects,’ ‘Environmental Fate,’ ‘Ecotoxicity,’ and ‘Physical Chemical Properties.’

- **Endpoints:** Select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the 'Effects' drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Appendix B for a complete list of values that are found within each of the drop-down menus on the 'Document Management' pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 4-29 shows the screen capture of the ‘Results Document Management’ pop-up window:

Exhibit 4-29: Results Document Management Pop-Up Window

CSPP

RESULTS DOCUMENT MANAGEMENT

Identify the Chemical Test from the drop-down menu and browse for the appropriate Results document. Click OK to attach.

Note: For security purposes, documents are only saved when there are no validation errors. If there are any validation errors, all documents must be reattached.

CBI:

Test Type:

Document Upload: **Browse**

Sanitized Document Upload: **Browse (optional)**

Effects:

EndPoints:

OK **Cancel**

Navigation: Click the ‘OK’ button to return to the ‘Results Document Management’ screen. Click the ‘Cancel’ or ‘X’ button to close the window and return to the ‘Results Document Management’ screen without saving the information.

4.9 Optional Substantiation

If you have claimed any information other than a chemical or a document as CBI, and wish to upload a substantiation document, you can click on the ‘Document Management’ link within the navigation tree.

4.9.1 Optional Document Management Screen

You can access this screen by clicking the ‘Document Management’ link under the ‘Optional Substantiation’ folder.

You can upload substantiation documentation by clicking the ‘Attach Document’ button.

The ‘Document Management’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. Once you have attached all desired documentation, click the ‘OK’ button to return to the ‘Optional Document Management’ screen.

The optional document management table displays the file name of the document and the date the document was attached. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon located under the ‘Action’ column for a given row. Clicking the file name links within the ‘File Name’ column generates the ‘Document Management’ pop-up window. This allows you to view and edit previously attached documents.


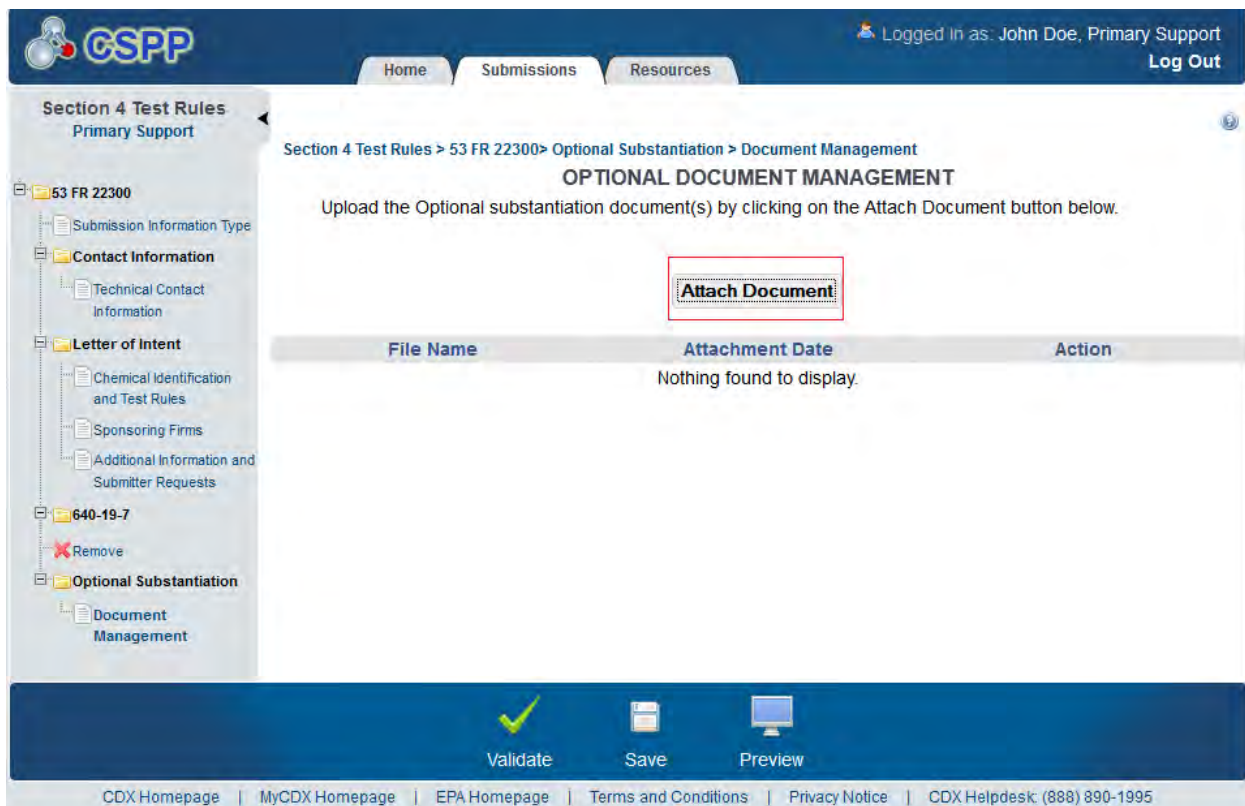
- **Attach Document:** Clicking the ‘Attach Document’ button displays the ‘Optional Substantiation Document Management’ pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the ‘Optional Substantiation Document Management’ pop-up window and allows you to view the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **Action:** Clicking the ‘Delete’ icon () will generate a prompt confirming the command. To delete the specified row and all contents within click the ‘OK’ button within the prompt.

Exhibit 4-30 shows the screen capture for the ‘Optional Document Management’ screen:

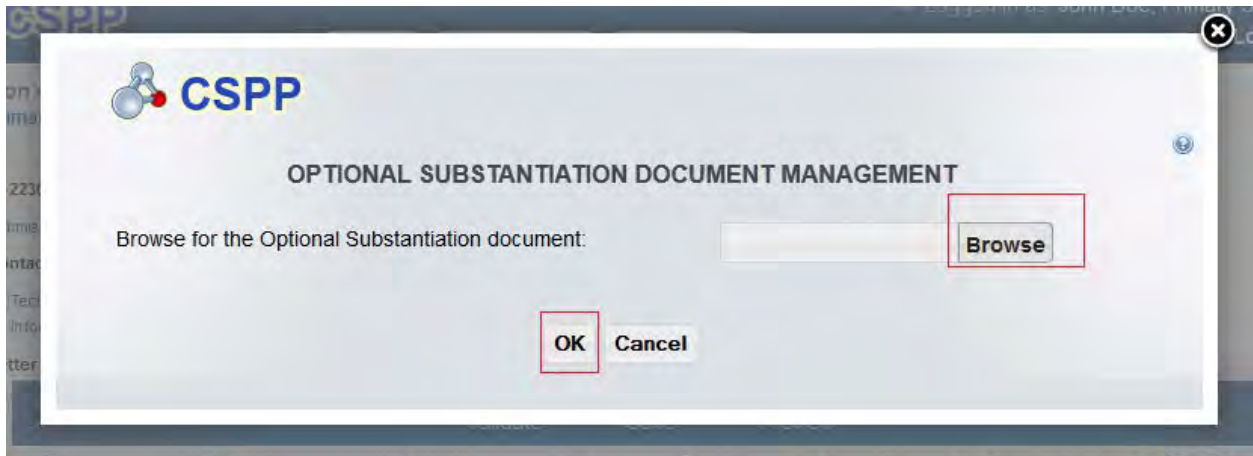
Exhibit 4-30: Optional Document Management Screen



Navigation: Click the ‘Attach Document’ button to generate the ‘Optional Substantiation Document Management’ pop-up window. Once all documents have been uploaded and you have completed all required screens you may click the ‘Save’ to save all previously entered information.

Exhibit 4-31 shows the screen capture for the ‘Optional Substantiation Document Management’ pop-up window:

Exhibit 4-31: Optional Substantiation Document Management Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ button to return to the ‘Optional Document Management’ screen.

5 Enforceable Consent Agreements (ECAs)

5.1 Submission Information Type Screen

You can access the 'Submission Information Type' screen by clicking the 'Next' button from the 'Enter Passphrase' screen. Once you are within the 'Enforceable Consent Agreement' flow of the Section 4 application, the 'Submission Information Type' screen can also be accessed by clicking the 'Submission Information Type' link located within the navigation tree.

The 'Submission Information Type' screen allows you to select the submission information type that you will be submitting to EPA. This screen consists of the following fields:

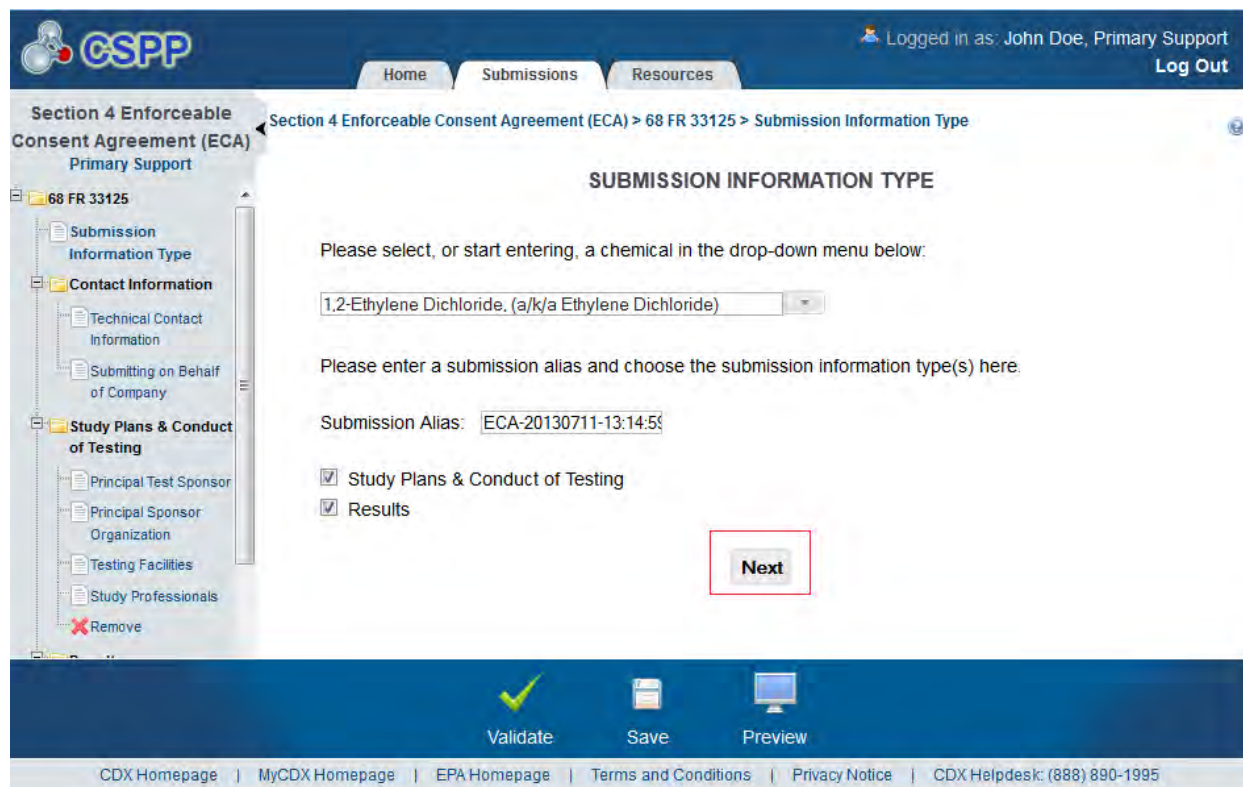
- **Please select, or start entering, a chemical in the drop-down menu below:** Displays all chemicals associated with an ECA. This field is required.
- **Submission Alias:** This field is auto-populated with a date and time stamp and is displayed on the 'Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766' submissions screen within the 'Submission Alias' column. This field is editable should you choose to provide your own submission alias.
- **Study Plans and Conduct Testing:** Checking the 'Study Plans & Conduct of Testing' checkbox identifies that you are fulfilling the requirements to submit a study plan to EPA. Once you have checked the 'Study Plans & Conduct of Testing' checkbox and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'Study Plans & Conduct of Testing' folder is generated within the navigation tree allowing you to access the study plan screen required to be completed.
- **Results:** Checking the 'Results' checkbox indicates that you are fulfilling the requirements to submit results to EPA. Once you have checked the 'Results' checkbox and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'Results' folder is generated within the navigation tree allowing you to access the results screens required to be completed.

If you previously identified a submission type, accessed the submission type screens, and unchecked the previously checked submission information type (i.e. Study Plans & Conduct Testing), you will receive a prompt indicating that all associated information will be lost. Clicking the 'OK' button within the prompt will delete all data associated with that submission information type.

Once you have identified the type(s) of information you will submit to EPA, you are able to access the screens required to be completed.

Exhibit 5-1 it shows the screen capture of the ‘Submission Information Type’ screen:

Exhibit 5-1 Submission Information Type Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

5.2 Technical Contact Information Screen

The ‘Technical Contact Information’ screen allows you to submit on behalf of another company. To identify if you are submitting on behalf of another company, the system provides the radio button ‘This is a submission on behalf of another company.’ The system will not allow you to select more than one radio button per submission.

If you are submitting on behalf of another company, select the ‘This is a submission on behalf of another company’ radio button. This functionality has been implemented to accommodate a company that may use an agent or another individual. If this radio button is selected, the information of the contractor/consultant’s company is to be entered into the ‘Submitting on Behalf Of Company’ screen. If you are not submitting on behalf of another company and have selected the ‘N/A’ radio button, you are taken to the ‘Principal Test Sponsor’ screen.

- **N/A:** Selecting the ‘N/A’ radio button allows you to signify that you are not making a submission on behalf of a company.
- **This is a submission on behalf of another company:** Selecting the ‘This is a submission on behalf of another company’ radio button allows you to identify yourself as an individual submitting on behalf of another company.

- **Copy CDX Registration:** Clicking the ‘Copy CDX Registration’ button will automatically populate the fields with your contact information provided during CDX registration.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **First Name:** Enter the technical contact’s first name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Middle Initial:** Enter the technical contact’s middle initial. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **Last Name:** Enter the technical contact’s last name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes. If applicable, select the appropriate suffix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **Company Name:** Enter the technical contact’s company name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Phone Number:** Enter the daytime phone number of the manufacturing or processing establishment contact for whom the submission is being made, U.S. or international. This field does not accept dashes. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Ext:** Enter the extension to the daytime phone number of the manufacturing or processing establishment contact for whom the submission is being made.
- **Email Address:** Enter the technical contact’s email address. The email address must follow the standard email address format: john.doe@abc.com. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 1:** Enter the first line of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 2:** Enter the second line of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **City:** Enter the city of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **State:** Enter the state of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during

CDX registration. This is a required field if the ‘Country’ field is defined as ‘United States.’

- **Postal Code:** Enter the postal code of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Country:** Displays all available countries. Enter the country of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This is a required field.

Exhibit 5-2 shows the screen capture of the ‘Technical Contact Information’ screen:

Exhibit 5-2 Technical Contact Information Screen

Navigation: If you are submitting on behalf of another company, select the ‘This is a submission on behalf of another company’ radio button and click the ‘Next’ button to navigate to the ‘Submitting on Behalf of Company’ screen. If you are submitting study plan information and are not submitting on behalf of another entity, you are taken to the ‘Principal Test Sponsor’ screen. If you are not submitting either study plan information or results information and are not

submitting on behalf of another entity, the application navigates to the ‘ECA Additional Information’ screen.

5.3 Submitting on Behalf of Company Screen

You can access the ‘Submitting on Behalf of Company’ screen by selecting the ‘This is a submission on behalf of another company’ radio button and by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree.

The ‘Submitting on Behalf of Company’ screen presents a list of fields that allow you to input the contact information for the manufacturing or processing establishment for which the submission is being made.

- **CBI:** Checking this checkbox will claim the information as CBI.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix.
- **First Name:** Enter the first name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Middle Initial:** Enter the middle initial of the manufacturing or processing establishment contact for which the submission is being made.
- **Last Name:** Enter the last name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the suffix of the manufacturing or processing establishment contact for which the submission is being made. If applicable, select the appropriate suffix.
- **Company Name:** Enter the company name of the manufacturing or processing establishment. This field is required.
- **Phone Number:** Enter the daytime phone number of the manufacturing or processing establishment contact for whom the submission is being made; U.S. or international. This is a required field.
- **Ext:** Enter the extension to the daytime phone number of the manufacturing or processing establishment contact for whom the submission is being made.
- **Email Address:** Enter the email address of the manufacturing or processing establishment contact for which the submission is being made. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the manufacturing or processing establishment contact.
- **City:** Enter the city of the mailing address of the manufacturing or processing establishment contact. This field is required.

- **State:** Enter the state of the mailing address of the manufacturing or processing establishment contact. This is a required field if the ‘Country’ field is defined as ‘United States.’
- **Postal Code:** Enter the postal code of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **Country:** Enter the country of the mailing address of the manufacturing or processing establishment contact. This field is required.

Exhibit 5-3 shows the screen capture of the ‘Submitting on Behalf of Company’ screen:

Exhibit 5-3 Submitting on Behalf of Company Screen

Section 4 Enforceable Consent Agreement (ECA) > 68 FR 33125 > Contact Information > Submitting on Behalf of Company

SUBMITTING ON BEHALF OF COMPANY

Fill out the fields below for the manufacturing or processing establishment on whose behalf this submission is being made.

CBI:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

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Navigation: If you are submitting study plans click the ‘Next’ button to navigate to the ‘Principal Test Sponsor’ screen. If you only checked the ‘Results’ checkbox, click the ‘Next’

button to navigate to the ‘Document Management’ screen under the ‘Results’ folder within the navigation tree. If you are only completing the letter of intent, click the ‘Submit’ icon located in the action bar to begin the submission process.

5.4 Study Plans & Conduct of Testing

If you have identified you are submitting information for study plans and conduct of testing, you are required to complete the following screens to satisfy the reporting requirements.

5.4.1 Principal Test Sponsor Screen

The ‘Principal Test Sponsor’ screen presents a list of fields that allow you to input the contact information for the principal test sponsor.

- **CBI:** Check the ‘CBI’ checkbox to claim the principal test sponsor information as CBI.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix.
- **First Name:** Enter the first name of the principal test sponsor contact. This field is required.
- **Middle Initial:** Enter the middle initial of the principal test sponsor contact.
- **Last Name:** Enter the last name of the principal test sponsor contact. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the suffix of the principal test sponsor contact. If applicable, select the appropriate suffix.
- **Company Name:** Enter the company name of the principal test sponsor contact. This field is required.
- **Phone Number:** Enter the daytime phone number of the principal test sponsor contact; U.S. or international. This field is required.
- **Ext:** Enter the extension to the daytime phone number of the principal test sponsor contact.
- **Email Address:** Enter the email address of principal test sponsor contact. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the mailing address of the principal test sponsor’s company. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the principal test sponsor’s company.
- **City:** Enter the city of the mailing address of the principal test sponsor’s company. This field is required.
- **State:** Enter the state of the mailing address of the principal test sponsor contact’s company. This is a required field if the ‘Country’ field is defined as ‘United States.’
- **Postal Code:** Enter the postal code of the principal test sponsor contact’s company. This field is required.

- **Country:** Enter the country of the mailing address of principal test sponsor contact's company. This field is required.

Exhibit 5-4 shows the screen capture of the ‘Principal Test Sponsor’ screen:

Exhibit 5-4 Principal Test Sponsor Screen

The screenshot shows the 'Principal Test Sponsor' screen in the GSPPP system. The page title is 'PRINCIPAL TEST SPONSOR'. The user is logged in as 'John Doe, Primary Support'. The breadcrumb trail is: Section 4 Enforceable Consent Agreement (ECA) > 68 FR 33125 > Study Plans & Conduct of Testing > Principal Test Sponsor. The form contains the following fields:

- CBI:
- Prefix:
- First Name:
- Middle Initial:
- Last Name:
- Suffix:
- Company Name:
- Phone Number: Ext:
- (Do not enter any dashes (-) in Phone Number field above)
- Email Address:
- Mailing Address 1:
- Street address, P.O. box, company name, etc.
- Mailing Address 2:
- Apartment, suite, etc.
- City:
- State:
- Postal Code:
- Country:

At the bottom of the form, there are 'Previous' and 'Next' buttons. The 'Next' button is highlighted with a red box. Below the form, there are three icons: a green checkmark for 'Validate', a floppy disk for 'Save', and a computer monitor for 'Preview'. The footer contains the following text: CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Navigation: Click the ‘Next’ button to navigate to the ‘Principal Sponsor Organization’ screen. You can also access this screen by clicking the ‘Principal Sponsor Organization’ link within the navigation tree.

5.4.2 Principal Sponsor Organization Screen

The ‘Principal Sponsor Organization’ screen allows you to enter the contact information for each administrative official and project manager within the principal test sponsor’s organization. To add each professional click the ‘Add Sponsor Organization’ button. This will generate a new set of text fields. Once you have entered data into one field set, you must click the ‘Save’ button located within that field set prior to adding another member. If the data previously entered and saved within a field set needs to be edited, you can click the ‘Edit’ button located in the upper right corner of that field set. If a field set needs to be deleted, you can click the ‘Delete’ icon () that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the field set header. If you wish to expand/collapse all field sets simultaneously, click the ‘Expand All’ or ‘Collapse All’ links located at the top right of all field sets.

- **CBI:** Check the ‘CBI’ checkbox to claim the member contact information as CBI.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes and captures the member contact’s prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the member contact’s first name. This field is required.
- **Middle Initial:** Enter the member contact’s middle initial.
- **Last Name:** Enter the member contact’s last name. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the member contact’s suffix. If applicable, select the appropriate suffix.
- **Company Name:** Enter the member contact’s company name. This field is required.
- **Job Title:** Enter the member contact’s job title. This field is required.
- **Phone Number:** Enter the member contact’s daytime phone number; U.S. or international. This field is required.
- **Ext:** Enter the extension to the contact’s daytime phone number.
- **Email Address:** Enter the member contact’s email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the member contact’s mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the member contact’s mailing address.
- **City:** Enter the city of the member contact’s mailing address. This is a required field.
- **State:** Enter the state of the member contact’s mailing address. This field is required when ‘United States’ is identified as the country.
- **Postal Code:** Enter the postal code of the member contact’s mailing address. This field is required.
- **Country:** Enter the country of the mailing address of the contact. This is a required field.

Exhibit 5-5 shows the screen capture of the ‘Principal Sponsor Organization’ screen:

Exhibit 5-5 Principal Sponsor Organization Screen

Navigation: Click the ‘Next’ button to navigate to the ‘Testing Facilities’ screen. You can also access this screen by clicking the ‘Testing Facilities’ link within the navigation tree.

5.4.3 Testing Facilities Screen

The ‘Testing Facilities’ screen allows you to enter contact information for each facility responsible for testing as well as a contact for each facility. To add a facility and contact, click

the 'Add Testing Facility' button to generate a new field set. Once you have entered data into one field set, you must click the 'Save' button located within that field set prior to adding another facility and contact. If the data previously entered and saved within a field set needs to be edited, you can click the 'Edit' button located in the upper right corner of that field set. If a facility needs to be deleted, you can click the 'Delete' icon (✖) that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the field set header. If you wish to expand/collapse all field sets simultaneously, click the 'Expand All' or 'Collapse All' links located at the top right of all field sets.

- **Testing Facility:** Enter the name of the testing facility. This field is required.
- **Phone Number:** Enter the phone number of the testing facility. This field is required.
- **Ext:** Enter the extension to the phone number of the testing facility.
- **Mailing Address 1:** Enter the first line of the mailing address of the testing facility. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the testing facility.
- **City:** Enter the city of the testing facility's mailing address. This is a required field.
- **State:** Enter the state of the testing facility's mailing address. This field is required when 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the testing facility's mailing address. This field is required.
- **Country:** Enter the country of the mailing address of the testing facility. This is a required field.
- **Select the testing facility contact role:** Select the job title of the contact of the testing facility from the drop-down menu. This drop-down menu contains the following values: 'Administrative Official' and 'Project Manager.' This field is required.
- **CBI:** Check the checkbox to claim the contact information of the testing facility as CBI.
- **Prefix:** The 'Prefix' drop-down menu displays all optional prefixes and captures the testing facility's contact's prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the testing facility contact's first name. This field is required.
- **Middle Initial:** Enter the testing facility contact's middle initial.
- **Last Name:** Enter the testing facility contact's last name. This field is required.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes and captures the testing facility contact's suffix. If applicable, select the appropriate suffix.
- **Phone Number:** Enter the testing facility contact's daytime phone number; U.S. or international. This field is required.
- **Ext:** Enter the extension to the testing facility contact's daytime phone number.
- **Email Address:** Enter the testing facility contact's email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.

- **Mailing Address 1:** Enter the first line of the testing facility contact's mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the testing facility contact's mailing address.
- **City:** Enter the city of the testing facility contact's mailing address. This is a required field.
- **State:** Enter the state of the testing facility contact's mailing address. This field is required when 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the testing facility contact's mailing address. This field is required.
- **Country:** Enter the country of the mailing address of the testing facility's contact. This is a required field.

Exhibit 5-6 and Exhibit 5-7 show the screen captures of the ‘Testing Facilities’ screen:

Exhibit 5-6 Testing Facilities Screen (Scroll 2)

Section 4 Enforceable Consent Agreement (ECA) > 68 FR 33125 > Study Plans & Conduct of Testing > Testing Facilities

TESTING FACILITIES

Fill out the information below for the responsible testing facilities.

Expand All | Collapse All

Cancel X

▼ Facility -

Testing Facility:

Phone Number: Ext:
(Do not enter any dashes (-) in Phone Number field above.)

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Select the testing facility contact role:

CBI:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Phone Number: Ext:
(Do not enter any dashes (-) in Phone Number field above)

Validate Save Preview

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Exhibit 5-7: Testing Facilities Screen (Scroll 2)

Section 4 Enforceable Consent Agreement (ECA) Primary Support

68 FR 33125

- Submission Information Type
- Contact Information
 - Technical Contact Information
 - Submitting on Behalf of Company
- Study Plans & Conduct of Testing
 - Principal Test Sponsor
 - Principal Sponsor Organization
 - Testing Facilities
 - Study Professionals
 - Remove
- Results
 - Document Management
 - Remove
 - ECA Additional Information

Postal Code:

Country:

Select the testing facility contact role:

CBI:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Save

Click the **Add Testing Facility** button to add a new testing facility. **Add Testing Facility**

Previous **Next**

Validate Save Preview

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Navigation: Click the ‘Next’ button to navigate to the ‘Study Professionals’ screen. You can also access this screen by clicking the ‘Study Professionals’ link within the navigation tree.

5.4.4 Study Professionals Screen

The ‘Study Professionals’ screen allows you to provide the contact information and a summary of the training and experience of each professional involved in the study. To add each professional click the ‘Add Study Professional’ button. This will generate a new set of text fields. Once you have entered data into one field set, you must click the ‘Save’ button located within that field set prior to adding another professional. If the data previously entered and saved within a field set needs to be edited, you can click the ‘Edit’ button located in the upper right

corner of that field set. If a professional needs to be deleted, you can click the 'Delete' icon (✖) that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the field set header. If you wish to expand/collapse all field sets simultaneously, click the 'Expand All' or 'Collapse All' links located at the top right of all field sets.

- **Select the Study Professional Role:** Select the study professional's role from the drop-down menu. This drop-down menu contains the following values: 'Chemist,' 'Laboratory Assistant,' 'Microbiologist,' 'Pathologist,' 'Study Director,' 'Toxicologist,' 'Veterinarian,' and 'Other.' This field is required.
- **CBI:** Check the checkbox to claim the professional's contact information as CBI.
- **Prefix:** The 'Prefix' drop-down menu displays all optional prefixes and captures the professional's prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the professional's first name. This field is required.
- **Middle Initial:** Enter the professional's middle initial.
- **Last Name:** Enter the professional's last name. This field is required.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes and captures the professional's suffix. If applicable, select the appropriate suffix.
- **Company Name:** Enter the professional's company name. This field is required.
- **Phone Number:** Enter the professional's daytime phone number; U.S. or international. This field is required.
- **Ext:** Enter the extension to the professional's daytime phone number.
- **Email Address:** Enter the professional's email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the professional's mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the professional's mailing address.
- **City:** Enter the city of the professional's mailing address. This is a required field.
- **State:** Enter the state of the professional's mailing address. This field is required when 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the professional's mailing address. This field is required.
- **Country:** Enter the country of the professional's mailing address. This is a required field.
- **Experience Summary:** Enter the summary of the study professional's experience. This field is required.

Exhibit 5-8 and Exhibit 5-9 show the screen captures of the ‘Study Professionals’ screen:

Exhibit 5-8: Study Professionals Screen (Scroll 1)

CDX GSPSP Logged in as: John Doe, Primary Support [Log Out](#)

Home Submissions Resources

Section 4 Enforceable Consent Agreement (ECA) > 68 FR 33125 > Study Plans & Conduct of Testing > Study Professionals

STUDY PROFESSIONALS

Provide a brief summary of the training and experience of each professional involved in the study below.

Expand All | Collapse All

Study Professional - Cancel ✖

Select the Study Professional Role:

CBI:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above.)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Experience Summary:

Validate
 Save
 Preview

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Exhibit 5-9: Study Professionals Screen (Scroll 2)

Section 4 Enforceable Consent Agreement (ECA) Primary Support

68 FR 33125

- Submission Information Type
- Contact Information
 - Technical Contact Information
 - Submitting on Behalf of Company
- Study Plans & Conduct of Testing
 - Principal Test Sponsor
 - Principal Sponsor Organization
 - Testing Facilities
 - Study Professionals
 - Remove
- Results
 - Document Management
 - Remove
 - ECA Additional Information

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above.)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Experience Summary:

Save

Click the **Add Study Professional** button to add a new study professional. **Add Study Professional**

Previous **Next**

Validate Save Preview

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Navigation: If you did not check the 'Results' checkbox on the 'Submission Information Type' screen, click the 'Next' button to navigate to the 'ECA Additional Information' screen. If you checked the 'Results' checkbox on the 'Submission Information Type' screen, click the 'Next' button to navigate to the 'Document Management' screen.

5.5 Results

If you have identified you are submitting results, you are required to complete the following screens to satisfy the reporting requirements.

5.5.1 Document Management Screen

The 'Document Management' screen allows you to upload documents related to Section 4 reporting requirements. To add Section 4 results documentation, click the 'Attach Document' button. Clicking the 'Attach Document' button displays the 'Document Management' pop-up window.

The 'Document Management' pop-up window allows you to attach documentation by clicking the 'Browse' button. This will generate the 'File Upload' window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the 'Open' button. Clicking the 'Open' button will close the 'File Upload' window and display the attached document within the 'Browse' field. To claim attached documentation as CBI, check the 'CBI' checkbox. If you claim the attached documentation as CBI you are required to attach the sanitized version of the attached document. To do so, follow the steps outlined above. Once you have attached all desired documentation, click the 'OK' button to return to the 'Document Management' screen.

The document management table displays the file name of the document, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the 'Delete' icon located under the 'Action' column for a given row. Clicking the file name links within the 'File Name' column generates the 'Document Management' pop-up window. This allows you to view and edit previously attached documents.


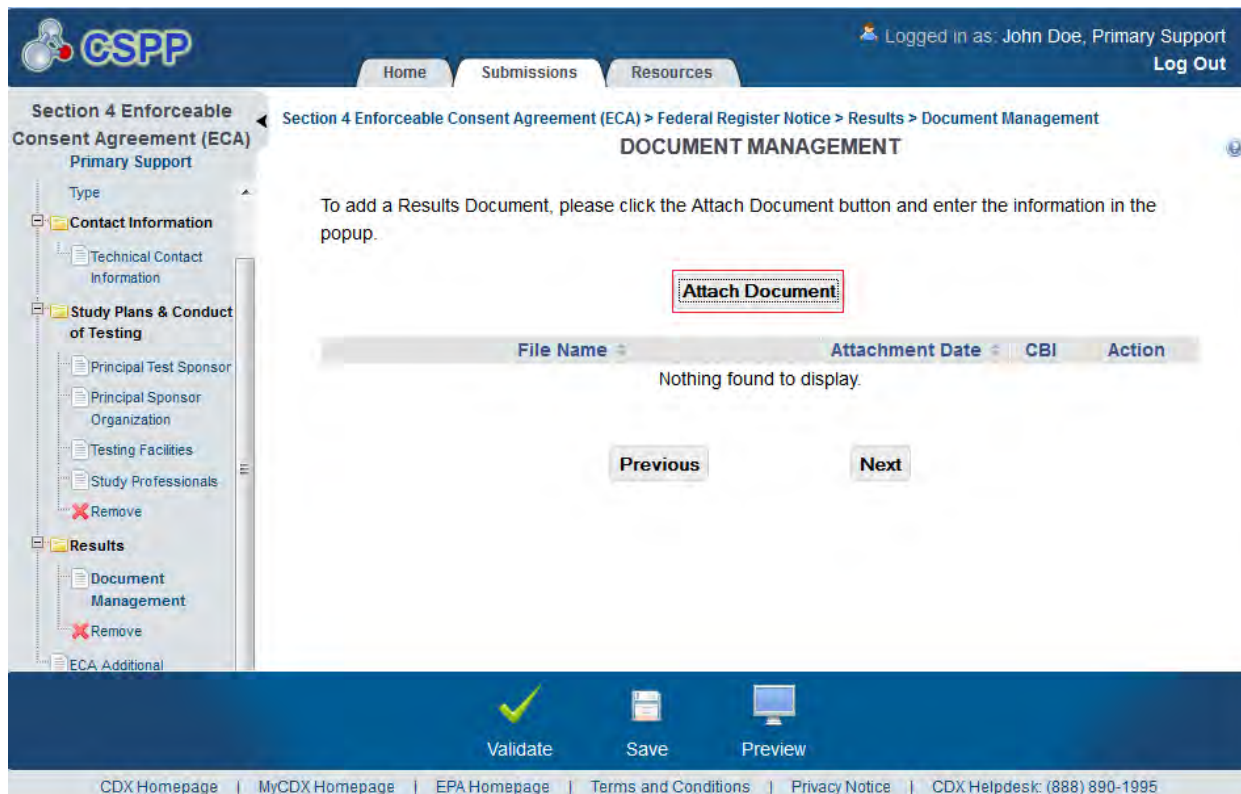
- **Add Document:** Clicking the 'Add Document' button displays the 'Document Management' pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the 'Document Management' pop-up window and allows you to view the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed CBI.
- **Action:** Clicking the 'Delete' icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the 'OK' button within the prompt.

Exhibit 5-10 shows the screen capture of the ‘Document Management’ screen:

Exhibit 5-10 Document Management Screen



Navigation: Click the ‘Next’ button to navigate to the ‘ECA Additional Information’ screen. You can also access this screen by clicking the ‘ECA Additional Information’ link within the navigation tree.

The ‘Document Management’ pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach at least one document. Clicking the ‘Browse’ button will generate the ‘File Upload’ window on your hard drive. Select the document you wish to attach and click the ‘Open’ button. If a document is marked as ‘CBI’ then a sanitized copy of the document must be attached. To save the attached document to the ‘Document Management’ screen, click the ‘OK’ button within the ‘Document Management’ pop-up window.

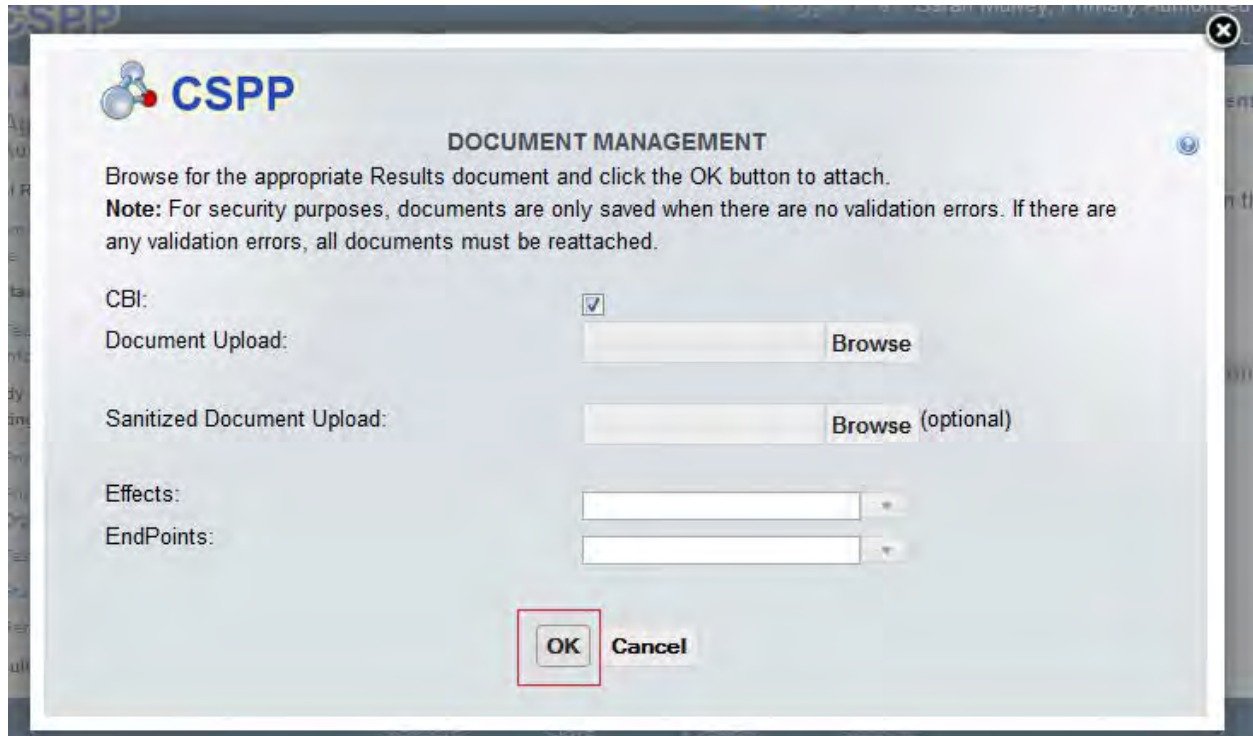
- **CBI:** Checking the ‘CBI’ checkbox will claim the uploaded document as CBI and generate a sanitized document upload field.
- **Document Upload:** Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Sanitized Document Upload:** This field will only be displayed when the ‘CBI’ checkbox is checked. Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Effects:** Select the effect specific to the chemical report. Displays the following options: ‘Health Effects,’ ‘Environmental Fate,’ ‘Ecotoxicity,’ and ‘Physical Chemical Properties.’

- **Endpoints:** Select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the 'Effects' drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Appendix B for a complete list of values that are found within each of the drop-down menus on the 'Document Management' pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 5-11 shows the screen capture of the ‘Document Management’ pop-up window:

Exhibit 5-11 Document Management Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ buttons to return to the ‘Document Management’ screen.

5.5.2 ECA Additional Information Screen

You can access the ‘ECA Additional Information’ screen by clicking the ‘Next’ button from the ‘Document Management’ screen within the ‘Results’ folder of the navigation tree. If you did not check the ‘Results’ checkbox on the ‘Submission Information Type’ screen, click the ‘Next’ button from the ‘Study Professionals’ screen. You can also access the ‘ECA Additional Information’ screen by clicking the ‘ECA Additional Information’ link within the navigation tree.

The ‘ECA Additional Information’ screen allows you to upload documents related to Section 4 reporting requirements. To add additional information select the appropriate additional information type and click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘ECA Additional Information’ pop-up window. If you select the ‘Amendments to the Study Plan’ radio button and click the ‘Attach Document’ button, the ‘Amendments to the Study Plan’ pop-up window generates. If you select the ‘Modification of ECAs’ radio button and click the ‘Attach Document’ button, the ‘Modification of ECAs’ pop-up window generates.

The ‘Amendment to the Study Plan’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. Once you have attached all

desired documentation, click the 'OK' button to return to the 'ECA Additional Information' screen.

The 'Modification of ECAs' pop-up window allows you to provide an explanation and rationale for the modification of the ECA within a text box. Once you have provided an explanation click the 'OK' button to return to the 'ECA Additional Information' screen.

The 'ECA Additional Information' table displays the file name of the document, the document type, and the date the document was attached. The system allows you to delete unwanted documents by clicking the 'Delete' icon located under the 'Action' column for a given row. Clicking the file name links within the 'File Name' column generates the pop-up window. This allows you to view and edit previously attached documents or information.


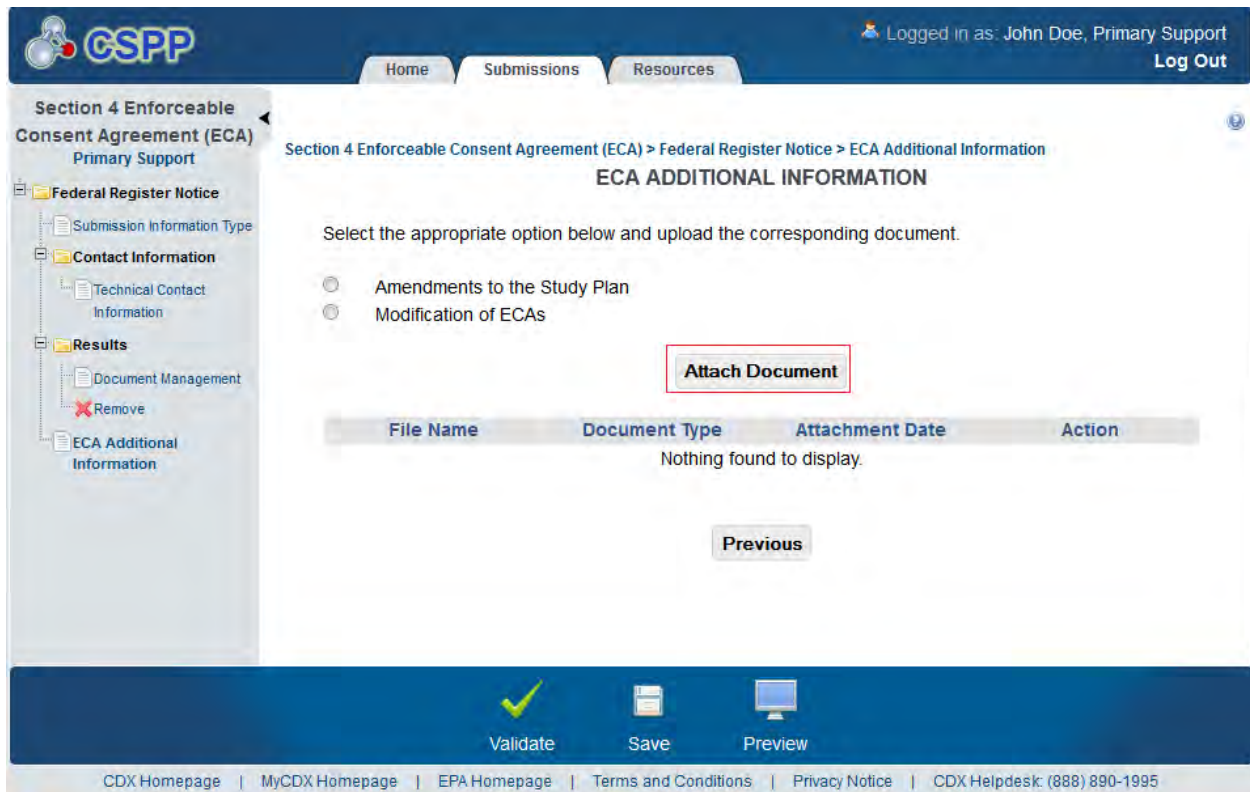
- **Amendments to the Study Plan:** Select the radio button to indicate the additional information type.
- **Modification of ECAs:** Select the radio button to indicate the additional information type.
- **Add Document:** Clicking the 'Add Document' button displays the 'Amendments to the Study Plan' or 'Modification of ECAs' pop-up window.
- **File Name:** Displays the name of the attached file if applicable. Clicking the file name link generates the pop-up window and allows you to view the attached document or information.
- **Document Type:** Displays the additional information type.
- **Attachment Date:** Displays the date the document was attached.
- **Action:** Clicking the 'Delete' icon () will generate a prompt confirming deletion. To delete the specified row and all contents, click the 'OK' button within the prompt.

Exhibit 5-12 shows the screen capture of the ‘ECA Additional Information’ screen:

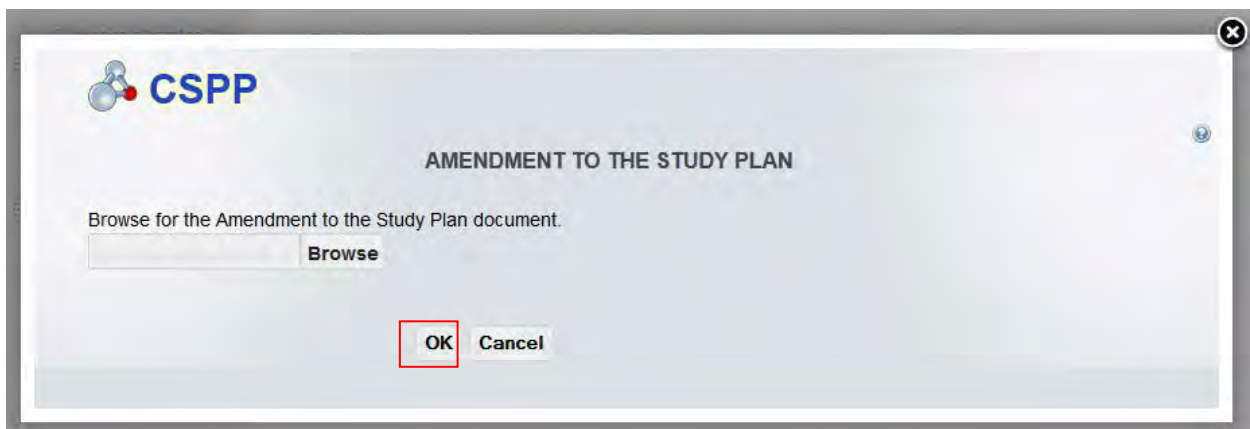
Exhibit 5-12 ECA Additional Information Screen



Navigation: Once all information has been uploaded, click the ‘Submit’ icon located within the footer to begin the submission process.

Exhibit 5-13 shows the screen capture of the ‘Amendment to the Study Plan’ pop-up window:

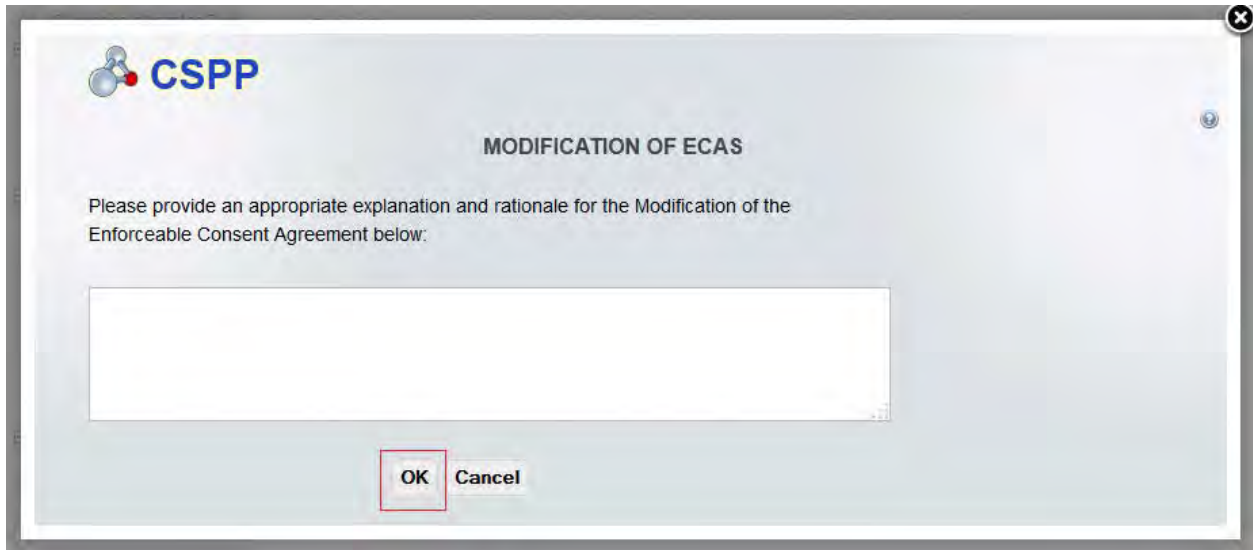
Exhibit 5-13 Amendment to the Study Plan Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ buttons to return to the ‘ECA Additional Information’ screen.

Exhibit 5-14 shows the screen capture of the ‘Modification of ECAs’ pop-up window:

Exhibit 5-14 Modification of ECAs Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ buttons to return to the ‘ECA Additional Information’ screen.

6 Memorandum of Understanding (MOU)

6.1 Submission Information Type Screen

You can access the 'Submission Information Type' screen by clicking the 'Next' button from either the 'Create New Passphrase' or the 'Enter Passphrase' screen. Once you are within the 'Memorandum of Understanding' flow of the Section 4 application, the 'Submission Information Type' screen can also be accessed by clicking the 'Submission Information Type' link located within the navigation tree.

The 'Submission Information Type' screen allows you to select the submission information type that you will be submitting to EPA. This screen consists of the following fields:

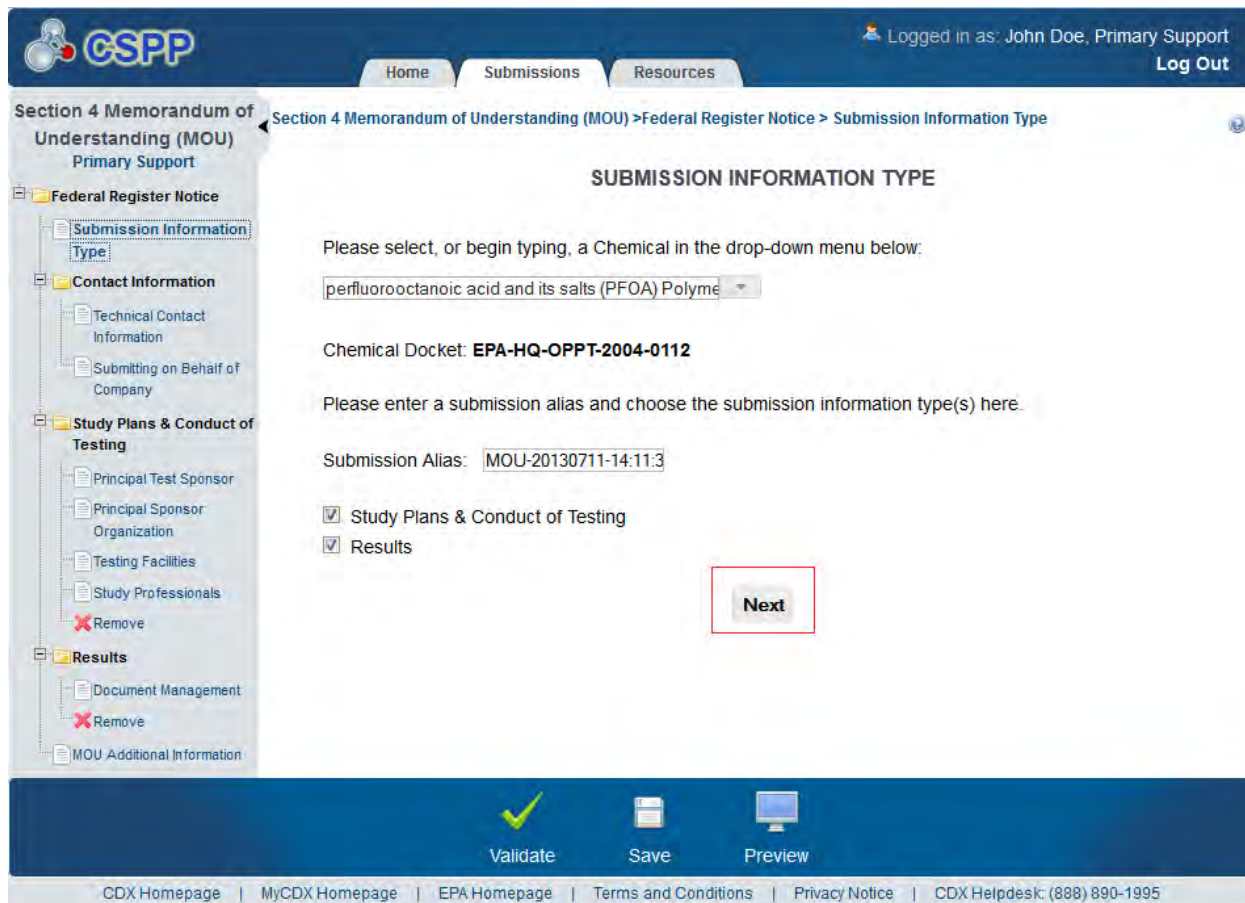
- **Please select, or begin typing, a Chemical in the drop-down menu below:** Displays all chemicals associated with an MOU. This field is required.
- **Chemical Docket:** This field displays once a chemical is selected. It displays the docket number associated with the selected chemical.
- **Submission Alias:** This field is auto-populated with a date and time stamp and is displayed on the 'Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766' submissions screen within the 'Submission Alias' column. This field is editable should you choose to provide your own submission alias.
- **Study Plans & Conduct of Testing:** Checking the 'Study Plans & Conduct of Testing' checkbox identifies that you are fulfilling the requirements to submit a study plan to EPA. Once you have checked the 'Study Plans & Conduct of Testing' checkbox and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'Study Plans & Conduct of Testing' folder is generated within the navigation tree allowing you to access the 'Study Plans & Conduct of Testing' screens required to be completed.
- **Results:** Checking the 'Results' checkbox indicates that you are fulfilling the requirements to submit results to EPA. Once you have checked the 'Results' checkbox and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'Results' folder is generated within the navigation tree allowing you to access the 'Results' screens required to be completed.

If you have previously identified a submission type, have accessed the submission type screens, and then unchecked the previously checked submission information type (i.e. Study Plans & Conduct of Testing), you will receive a prompt indicating that all associated information will be lost. Clicking the 'OK' button within the prompt will delete all data associated with that submission information type.

Once you have identified the type(s) of information you will be submitting to EPA, you are able to access the screens required to be completed.

Exhibit 6-1 shows the screen capture of the ‘Submission Information Type’ screen:

Exhibit 6-1 Submission Information Type Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

6.2 Technical Contact Information Screen

The ‘Technical Contact Information’ screen allows you to submit on behalf of another company or if you are not submitting on behalf of another company. To identify if you are submitting on behalf of another company, the system provides the radio button ‘This is a submission on behalf of another company.’ The system will not allow you to select more than one radio button per submission.

This functionality has been implemented to accommodate a company that may use an agent or another individual. If this radio button is selected, the information of the contractor/consultant’s company is to be entered into the ‘Submitting on Behalf Of Company’ screen. If you are not submitting on behalf of another company and have selected the ‘N/A’ radio button, you are taken to the ‘Principal Test Sponsor’ screen.

- **N/A:** Selecting the ‘N/A’ radio button allows you to signify that you are not making a submission on behalf of another company.

- **This is a submission on behalf of another company:** Selecting the ‘This is a submission on behalf of another company’ radio button allows you to identify yourself as an individual submitting on behalf of another company.
- **Copy CDX Registration:** Clicking the ‘Copy CDX Registration’ button will automatically populate the fields with your contact information provided during CDX registration.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **First Name:** Enter the technical contact’s first name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Middle Initial:** Enter the technical contact’s middle initial. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **Last Name:** Enter the technical contact’s last name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes. If applicable, select the appropriate suffix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **Company Name:** Enter the technical contact’s company name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Phone Number:** Enter the technical contact’s daytime phone number; U.S. or international. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Ext:** Enter the extension to the technical contact’s daytime phone number.
- **Email Address:** Enter the technical contact’s email address. The email address must follow the standard email address format: john.doe@abc.com. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 1:** Enter the first line of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 2:** Enter the second line of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **City:** Enter the city of the technical contact’s mailing address. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.

- **State:** Enter the state of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field if the 'Country' field is defined as 'United States.'
- **Postal Code:** Enter the postal code of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **Country:** Enter the country of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.

Exhibit 6-2 shows the screen capture of the ‘Technical Contact Information’ screen:

Exhibit 6-2 Technical Contact Information Screen

Section 4 Memorandum of Understanding (MOU) > Federal Register Notice > Contact Information > Technical Contact Information

Logged in as: John Doe, Primary Support Log Out

Section 4 Memorandum of Understanding (MOU) Primary Support

Federal Register Notice

- Submission Information Type
- Technical Contact Information
- Submitting on Behalf of Company

Study Plans & Conduct of Testing

- Principal Test Sponsor
- Principal Sponsor Organization
- Testing Facilities
- Study Professionals
- Remove

Results

- Document Management
- Remove
- MOU Additional Information

TECHNICAL CONTACT INFORMATION

Identify the technical contact who is capable of answering questions related to the chemical(s) submitted to EPA within this submission. Identify if this submission is being submitted on behalf of another company by selecting the appropriate radio button. If submitting on behalf of is not applicable, select the N/A radio button. Click the 'Copy CDX Registration' button to copy your information from CDX Registration.

N/A
 This is a submission on behalf of another company

Click here to copy your information from CDX Registration: [Copy CDX Registration](#)

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

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Navigation: If you are submitting on behalf of another company and click the ‘Next’ button, you are taken to the ‘Submitting on Behalf of Company’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree. If you are submitting study plans & conduct of testing information and are not submitting on behalf of another entity, you are taken to the ‘Principal Test Sponsor’ screen. You can also access this screen by clicking the ‘Principal Test Sponsor’ link within the navigation tree.

6.3 Submitting on Behalf Of Company Screen

You can access the ‘Submitting on Behalf of Company’ screen by selecting the ‘This is a submission on behalf of another company’ radio button and by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree.

The ‘Submitting on Behalf Of Company’ screen presents a list of fields that allow you to input the contact information for the manufacturing or processing establishment on whose behalf the submission is being made.

- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix.
- **First Name:** Enter the first name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Middle Initial:** Enter the middle initial of the manufacturing or processing establishment contact for which the submission is being made.
- **Last Name:** Enter the last name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the suffix of the manufacturing or processing establishment contact for which the submission is being made. If applicable, select the appropriate suffix.
- **Company Name:** Enter the company name of the manufacturing or processing establishment. This field is required.
- **Phone Number:** Enter the daytime phone number of the manufacturing or processing establishment contact for whom the submission is being made; U.S. or international. This field is required.
- **Email Address:** Enter the email address of the manufacturing or processing establishment contact for which the submission is being made. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the manufacturing or processing establishment contact.
- **City:** Enter the city of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **State:** Enter the state of the mailing address of the manufacturing or processing establishment contact. This is a required field if the ‘Country’ field is defined as ‘United States.’
- **Postal Code:** Enter the postal code of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **Country:** Enter the country of the manufacturing or processing establishment contact’s mailing address. This field is required.

Exhibit 6-3 shows the screen capture of the ‘Submitting on Behalf of Company’ screen:

Exhibit 6-3 Submitting on Behalf of Company Screen

Navigation: If you are submitting study plans & conduct of testing information and click the ‘Next’ button, you are taken to the ‘Principal Test Sponsor’ screen. You can also access this screen by clicking the ‘Principal Test Sponsor’ link within the navigation tree.

6.4 Study Plans & Conduct of Testing

If you have identified you are submitting information for study plans and conduct of testing, you are required to complete the following screens to satisfy the reporting requirements.

6.4.1 Principal Test Sponsor Screen

The ‘Principal Test Sponsor’ screen presents a list of fields that allow you to input the contact information for the principal test sponsor.

- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix.

- **First Name:** Enter the principal test sponsor contact's first name. This field is required.
- **Middle Initial:** Enter the principal test sponsor contact's middle initial.
- **Last Name:** Enter the principal test sponsor contact's last name. This field is required.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes and captures the principal test sponsor contact's suffix. If applicable, select the appropriate suffix.
- **Company Name:** Enter the principal test sponsor contact's company name. This field is required.
- **Phone Number:** Enter the principal test sponsor contact's daytime phone number; U.S. or international. This field is required.
- **Email Address:** Enter the principal test sponsor contact's email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the mailing address of the principal test sponsor's company. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the principal test sponsor's company.
- **City:** Enter the city of the mailing address of the principal test sponsor's company. This field is required.
- **State:** Enter the state of the mailing address of the principal test sponsor contact's company. This is a required field if the 'Country' field is defined as 'United States.'
- **Postal Code:** Enter the postal code of the principal test sponsor contact's company. This field is required.
- **Country:** Enter the country of the mailing address of principal test sponsor contact's company. This field is required.

Exhibit 6-4 shows the screen capture of the ‘Principal Test Sponsor’ screen:

Exhibit 6-4 Principal Test Sponsor Screen

Navigation: Click the ‘Next’ button to navigate to the ‘Principal Sponsor Organization’ screen. You can also access this screen by clicking the ‘Principal Sponsor Organization’ link within the navigation tree.

6.4.2 Principal Sponsor Organization Screen

The ‘Principal Sponsor Organization’ screen allows you to enter the contact information for each administrative official and project manager within the principal test sponsor’s organization. To add each professional click the ‘Add Sponsor Organization’ button. This will generate a new set of text fields. Once you have entered data into one field set, you must click the ‘Save’ button located within that field set prior to adding another member. If the data previously entered and saved within a field set needs to be edited, you can click the ‘Edit’ button located in the upper right corner of that field set. If a field set needs to be deleted, you can click the ‘Delete’ icon () that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the field set header. If you wish to expand/collapse all field sets simultaneously, click the 'Expand All' or 'Collapse All' links located at the top right of all field sets.

- **Prefix:** The 'Prefix' drop-down menu displays all optional prefixes and captures the member contact's prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the member contact's first name. This field is required.
- **Middle Initial:** Enter the member contact's middle initial.
- **Last Name:** Enter the member contact's last name. This field is required.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes and captures the member contact's suffix. If applicable, select the appropriate suffix.
- **Company Name:** Enter the member contact's company name. This field is required.
- **Job Title:** Enter the member contact's job title. This field is required.
- **Phone Number:** Enter the member contact's daytime telephone number; U.S. or international. This field is required.
- **Email Address:** Enter the member contact's email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the member contact's mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the member contact's mailing address.
- **City:** Enter the city of the member contact's mailing address. This field is required.
- **State:** Enter the state of the member contact's mailing address. This field is required when 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the member contact's mailing address. This field is required.
- **Country:** Enter the country of the member contact's mailing address. This field is required.

Exhibit 6-5 shows the screen capture of the ‘Principal Sponsor Organization’ screen:

Exhibit 6-5 Principal Sponsor Organization Screen

Section 4 Memorandum of Understanding (MOU) > Federal Register Notice > Study Plans & Conduct of Testing > Principal Sponsor Organization

PRINCIPAL SPONSOR ORGANIZATION

Fill out the information below for the Administrative Official(s) and Project Manager(s) in the Principal Sponsor's Organization below.

Expand All | Collapse All

▼ Firm - Cancel ✖

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Job Title:

Phone Number: Ext.:

(Do not enter any dashes (-) in Phone Number field above)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Save

Click **Add Sponsor Organization** to add a new sponsor organization. **Add Sponsor Organization**

Previous **Next**

Validate Save Preview

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Navigation: Click the ‘Next’ button to navigate to the ‘Testing Facilities’ screen. You can also access this screen by clicking the ‘Testing Facilities’ link within the navigation tree.

6.4.3 Testing Facilities Screen

The ‘Testing Facilities’ screen allows you to enter contact information for each facility responsible for testing as well as a contact information for each facility. To add a facility and

contact, click the ‘Add Testing Facility’ button to generate a new field set. Once you have entered data into one field set, you must click the ‘Save’ button located within that field set prior to adding another facility and contact. If the data previously entered and saved within a field set needs to be edited, you can click the ‘Edit’ button located in the upper right corner of that field set. If a facility needs to be deleted, you can click the ‘Delete’ icon (✖) that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the field set header. If you wish to expand/collapse all field sets simultaneously, click the ‘Expand All’ or ‘Collapse All’ links located at the top right of all field sets.

- **Testing Facility:** Enter the testing facility’s name. This field is required.
- **Phone Number:** Enter the testing facility’s phone number. This field is required.
- **Ext:** Enter the extension to the testing facility’s phone number.
- **Mailing Address 1:** Enter the first line of the testing facility’s mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the testing facility’s mailing address.
- **City:** Enter the city of the testing facility’s mailing address. This field is required.
- **State:** Enter the state of the testing facility’s mailing address. This field is required when ‘United States’ is identified as the country.
- **Postal Code:** Enter the postal code of the testing facility’s mailing address. This field is required.
- **Country:** Enter the country of the testing facility’s mailing address. This field is required.
- **Select the testing facility contact role:** Select the job title of the testing facility’s contact from the drop-down menu. This drop-down menu contains the following values: ‘Administrative Official,’ and ‘Project Manager.’ This field is required.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes and captures the testing facility contact’s prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the testing facility contact’s first name. This field is required.
- **Middle Initial:** Enter the testing facility contact’s middle initial.
- **Last Name:** Enter the testing facility contact’s last name. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the testing facility contact’s suffix. If applicable, select the appropriate suffix.
- **Phone Number:** Enter the testing facility’s contact’s daytime phone number; U.S. or international. This field is required.
- **Email Address:** Enter the testing facility contact’s email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the testing facility contact’s mailing address. This field is required.

- **Mailing Address 2:** Enter the second line of the testing facility contact's mailing address.
- **City:** Enter the city of the testing facility contact's mailing address. This field is required.
- **State:** Enter the state of the testing facility contact's mailing address. This field is required when 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the testing facility contact's mailing address. This field is required.
- **Country:** Enter the country of the mailing address of the testing facility's contact. This field is required.

Exhibit 6-6 and Exhibit 6-7 show the screen captures of the ‘Testing Facilities’ screen:

Exhibit 6-6 Testing Facilities Screen (Scroll 1)

CDX | Logged in as: John Doe, Primary Support | [Home](#) | [Submissions](#) | [Resources](#) | [Log Out](#)

Section 4 Memorandum of Understanding (MOU) > Federal Register Notice > Study Plans & Conduct of Testing > Testing Facilities

TESTING FACILITIES

Fill out the information below for the responsible testing facilities.

[Expand All](#) | [Collapse All](#)

Facility - Cancel ✖

Testing Facility:

Phone Number: Ext:
(Do not enter any dashes (-) in Phone Number field above.)

Mailing Address 1:
Street address, P.O. box, company name, etc.

Mailing Address 2:
Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Select the testing facility contact role:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Phone Number: Ext:
(Do not enter any dashes (-) in Phone Number field above)

Email Address:

Validate
 Save
 Preview

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Exhibit 6-7: Testing Facilities Screen (Scroll 2)

The screenshot displays the 'Testing Facilities' screen. On the left is a navigation tree under 'Section 4 Memorandum of Understanding (MOU) Primary Support', with 'Testing Facilities' highlighted. The main form area contains the following fields:


- State: (dropdown)
- Postal Code: (text)
- Country: (dropdown)
- Select the testing facility contact role: (dropdown)
- Prefix: (dropdown)
- First Name: (text)
- Middle Initial: (text)
- Last Name: (text)
- Suffix: (dropdown)
- Phone Number: (text) Ext: (text)
- (Do not enter any dashes (-) in Phone Number field above)
- Email Address: (text)
- Mailing Address 1: (text)
- Street address, P.O. box, company name, etc.
- Mailing Address 2: (text)
- Apartment, suite, etc.
- City: (text)
- State: (dropdown)
- Postal Code: (text)
- Country: (dropdown)

At the bottom of the form is a 'Save' button. Below the form, a text instruction reads: 'Click the **Add Testing Facility** button to add a new testing facility.' To the right of this text is an 'Add Testing Facility' button. Below the instruction are 'Previous' and 'Next' buttons. At the bottom of the page is a blue bar with 'Validate', 'Save', and 'Preview' buttons, each with an icon. The footer contains links: 'CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995'. The top right corner shows 'Logged in as: John Doe, Primary Support' and a 'Log Out' link.

Navigation: Click the 'Next' button to navigate to the 'Study Professionals' screen. You can also access this screen by clicking the 'Study Professionals' link within the navigation tree.

6.4.4 Study Professionals Screen

The 'Study Professionals' screen allows you to provide contact information and a summary of the training and experience for each professional involved in the study. To add a study professional click the 'Add Study Professional' button to generate a new field set. Once you have entered data into one field set, you must click the 'Save' button located within that field set prior to adding another professional. If the data previously entered and saved within a field set needs to be edited, you can click the 'Edit' button located in the upper right corner of that field set. If a

professional needs to be deleted, you can click the ‘Delete’ icon () that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the field set header. If you wish to expand/collapse all field sets simultaneously, click the ‘Expand All’ or ‘Collapse All’ links located at the top right of all field sets.

- **Select the Study Professional Role:** Select the study professional’s role from the drop-down menu. This drop-down menu contains the following values: ‘Chemist,’ ‘Laboratory Assistant,’ ‘Microbiologist,’ ‘Pathologist,’ ‘Study Director,’ ‘Toxicologist,’ ‘Veterinarian,’ and ‘Other.’ This field is required.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes and captures the study professional’s prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the study professional’s first name. This field is required.
- **Middle Initial:** Enter the study professional’s middle initial.
- **Last Name:** Enter the study professional’s last name. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the study professional’s suffix. If applicable, select the appropriate suffix.
- **Company Name:** Enter the study professional’s company name. This field is required.
- **Phone Number:** Enter the study professional’s daytime phone number; U.S. or international. This field is required.
- **Email Address:** Enter the study professional’s email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the study professional’s mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the study professional’s mailing address.
- **City:** Enter the city of the study professional’s mailing address. This is a required field.
- **State:** Enter the state of the study professional’s mailing address. This field is required when ‘United States’ is identified as the country.
- **Postal Code:** Enter the postal code of the study professional’s mailing address. This field is required.
- **Country:** Enter the country of the study professional’s mailing address. This is a required field.
- **Experience Summary:** Enter a summary of the study professional’s experience.

Exhibit 6-8 and Exhibit 6-9 show the screen captures of the ‘Study Professionals’ screen:

Exhibit 6-8 Study Professionals Screen (Scroll 1)

CSPP Logged in as: John Doe, Primary Support [Log Out](#)

Home Submissions Resources

Section 4 Memorandum of Understanding (MOU) > Federal Register Notice > Study Plans & Conduct of Testing > Study Professionals

STUDY PROFESSIONALS

Provide a brief summary of the training and experience of each professional involved in the study below.

[Expand All](#) | [Collapse All](#)

Study Professional Cancel ✖

Select the Study Professional Role:

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above.)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Experience Summary:

Validate
 Save
 Preview

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Exhibit 6-9: Study Professionals Screen (Scroll 2)

The screenshot displays the 'Study Professionals' screen. At the top, the user is logged in as 'John Doe, Primary Support'. The navigation menu on the left includes 'Section 4 Memorandum of Understanding (MOU) Primary Support', 'Federal Register Notice', 'Contact Information', 'Study Plans & Conduct of Testing', 'Results', and 'MOU Additional Information'. The main form area contains the following fields:

- Prefix: [Dropdown]
- First Name: [Text]
- Middle Initial: [Text]
- Last Name: [Text]
- Suffix: [Dropdown]
- Company Name: [Text]
- Phone Number: [Text] Ext: [Text]
- (Do not enter any dashes (-) in Phone Number field above.)
- Email Address: [Text]
- Mailing Address 1: [Text]
- Street address, P.O. box, company name, etc.
- Mailing Address 2: [Text]
- Apartment, suite, etc.
- City: [Text]
- State: [Dropdown]
- Postal Code: [Text]
- Country: [Dropdown]
- Experience Summary: [Text Area]

At the bottom of the form is a 'Save' button. Below the form, there is a text prompt: 'Click the **Add Study Professional** button to add a new study professional.' followed by an 'Add Study Professional' button. Below this are 'Previous' and 'Next' buttons. The footer contains 'Validate', 'Save', and 'Preview' buttons, along with a navigation bar with links to 'CDX Homepage', 'MyCDX Homepage', 'EPA Homepage', 'Terms and Conditions', 'Privacy Notice', and 'CDX Helpdesk: (888) 890-1995'.

Navigation: Click the 'Next' button to navigate to the 'Document Management' screen. You can also access this screen by clicking the 'Document Management' link within the navigation tree if the Results' checkbox was checked on the 'Submission Information Type' screen.

6.5 Results

If you identified that you are submitting results, you are required to complete the following screens to satisfy the reporting requirements.

6.5.1 Document Management Screen

The 'Document Management' screen allows you to upload documents related to Section 4 reporting requirements. To add Section 4 results documentation, click the 'Attach Document'

button. Clicking the ‘Attach Document’ button displays the ‘Document Management’ pop-up window.

The ‘Document Management’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field.

The ‘Document Management’ table displays the file name of the document and the date the document was attached. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon located under the ‘Action’ column for a given row. Clicking the file name links within the ‘File Name’ column generates the ‘Document Management’ pop-up window. This allows you to view and edit previously attached documents.


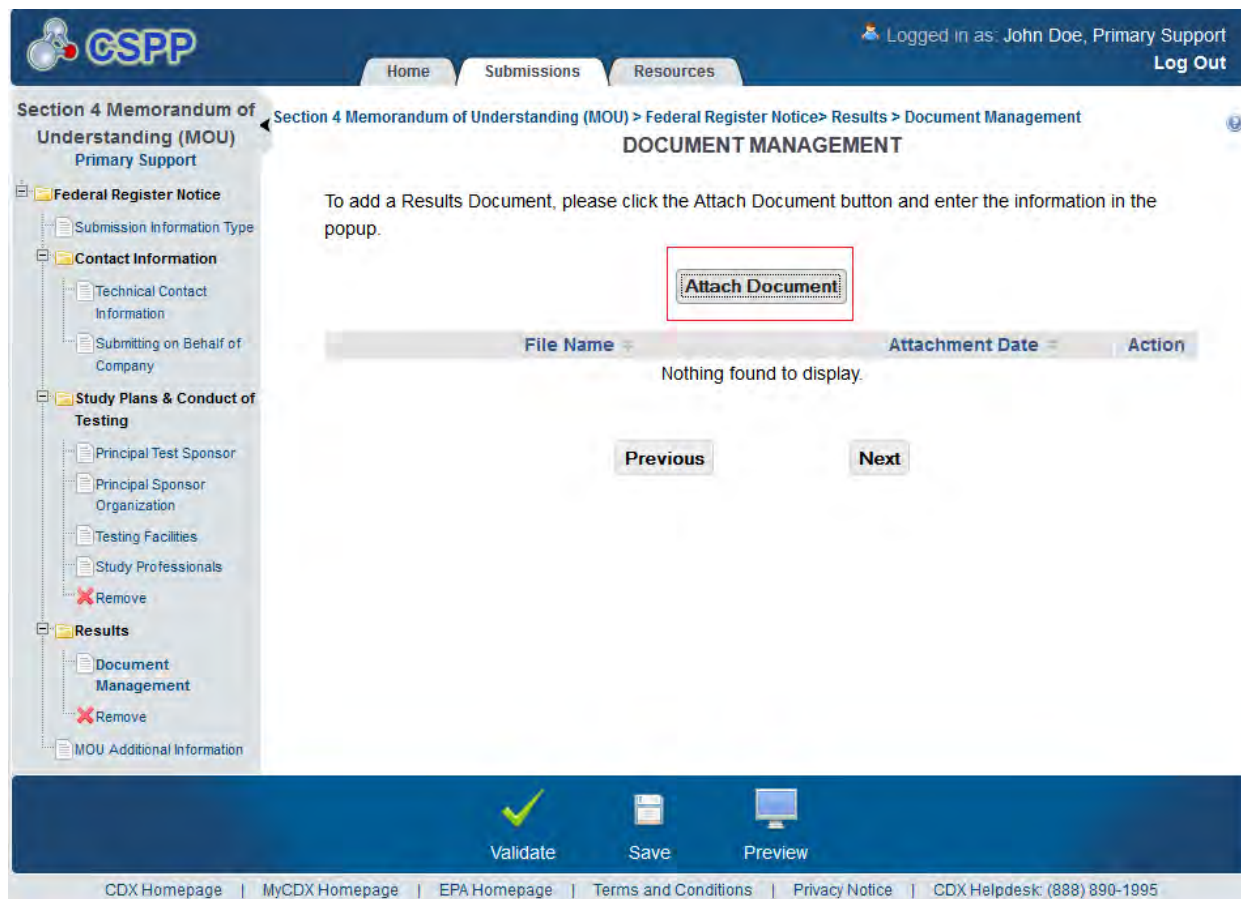
- **Add Document:** Clicking the ‘Add Document’ button displays the ‘Document Management’ pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the ‘Document Management’ pop-up window and allows you to view the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **Action:** Clicking the ‘Delete’ icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the ‘OK’ button within the prompt.

Exhibit 6-10 shows the screen capture of the ‘Document Management’ screen:

Exhibit 6-10 Document Management Screen



Navigation: Click the ‘Next’ button to navigate to the ‘MOU Additional Information’ screen. You can also access this screen by clicking the ‘MOU Additional Information’ link within the navigation tree.

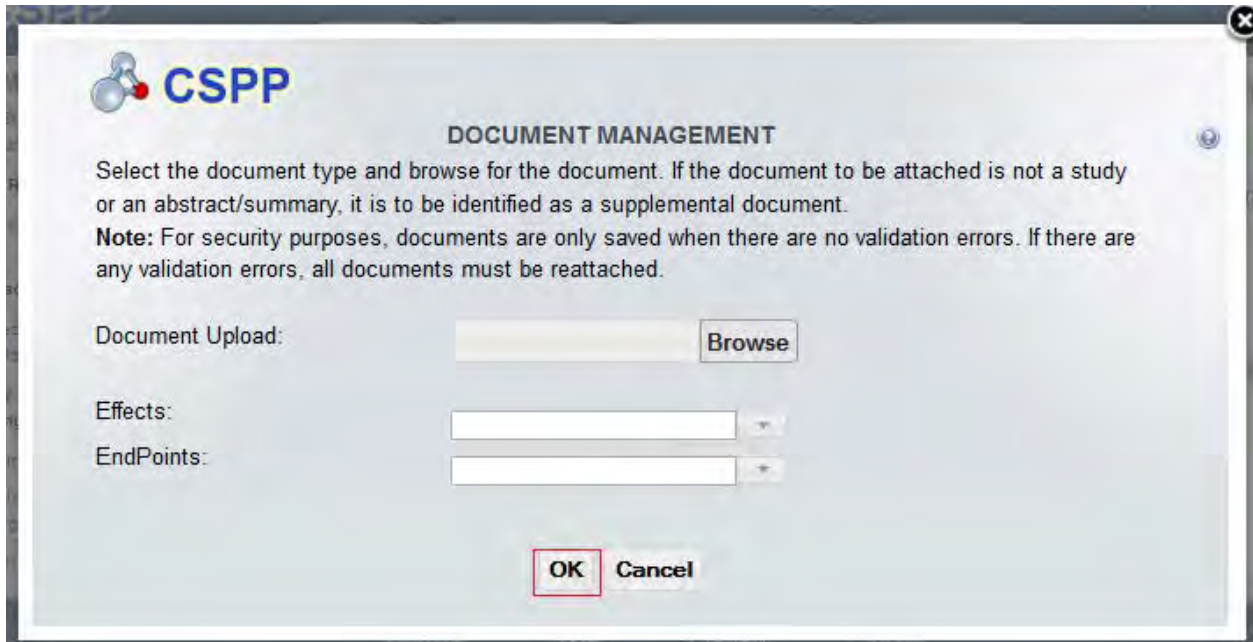
The ‘Document Management’ pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach at least one document. Clicking the ‘Browse’ button will generate the ‘File Upload’ window on your hard drive. Select the document you wish to attach and click the ‘Open’ button. If a document is marked as ‘CBI’ then a sanitized copy of the document must be attached. To save the attached document to the ‘Document Management’ screen, click the ‘OK’ button within the ‘Document Management’ pop-up window.

- **Original Document:** Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Effects:** Select the effect specific to the chemical report. Displays the following options: ‘Health Effects,’ ‘Environmental Fate,’ ‘Ecotoxicity,’ and ‘Physical Chemical Properties.’
- **Endpoints:** Select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the ‘Effects’ drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Appendix B for a complete list of values that are found within each of the drop-down menus on the ‘Document Management’ pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 6-11 shows the screen capture of the ‘Document Management’ pop-up window:

Exhibit 6-11 Document Management Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ buttons to return to the ‘Document Management’ screen.

6.5.2 MOU Additional Information Screen

The ‘MOU Additional Information’ screen allows you to upload documents related to Section 4 reporting requirements. To add additional information select the appropriate additional information type and click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘MOU Additional Information’ pop-up window. If you select the ‘Amendments to the Study Plan’ radio button and click the ‘Attach Document’ button, the ‘Amendments to the Study Plan’ pop-up window generates. If you select the ‘Modification of MOUs’ radio button and click the ‘Attach Document’ button, the ‘Modification of MOUs’ pop-up window generates.

The ‘Amendments to the Study Plan’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can search for the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. Once you have attached all desired documentation, click the ‘OK’ button to return to the ‘MOU Additional Information’ screen.

The ‘Modification of MOUs’ pop-up window allows you to provide an explanation and rationale for the modification of the MOU within a text box. Once you have provided an explanation click the ‘OK’ button to return to the ‘MOU Additional Information’ screen.

The MOU additional information table displays the file name of the document, the document type, and the date the document was attached. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon located under the ‘Action’ column for a given row.

Clicking the file name links within the 'File Name' column generates the pop-up window. This allows you to view and edit previously attached documents or information.


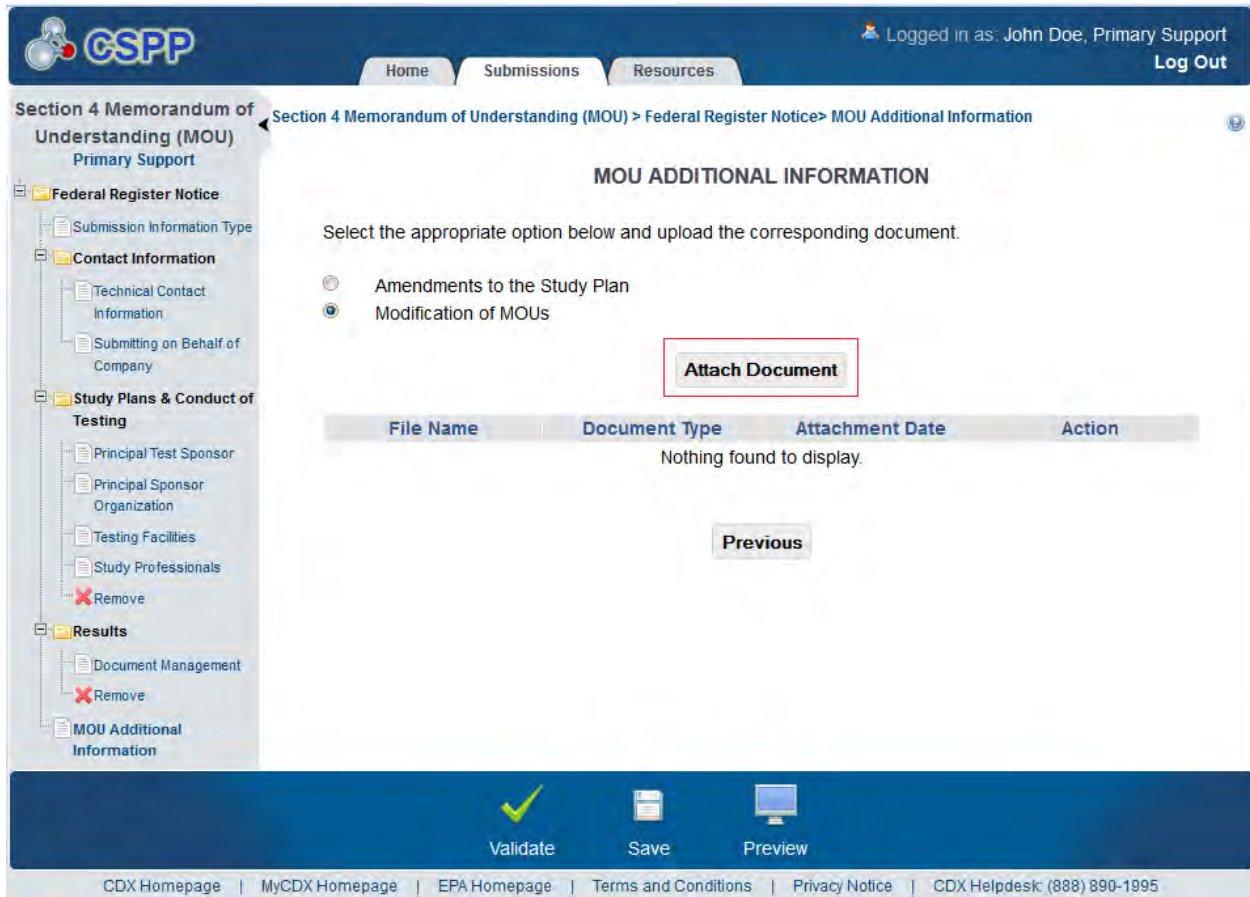
- **Amendments to the Study Plan:** Select the radio button to indicate the additional information type.
- **Modification of MOUs:** Select the radio button to indicate the additional information type.
- **Attach Document:** Clicking the 'Attach Document' button displays the 'Amendments to the Study Plan' or 'Modification of MOUs' pop-up window.
- **File Name:** Displays the name of the attached file if applicable. Clicking the file name link generates the pop-up window and allows you to view the attached document or information.
- **Document Type:** Displays the additional information type indicated on the page.
- **Attachment Date:** Displays the date the document was attached.
- **Action:** Clicking the 'Delete' icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the 'OK' button within the prompt.

Exhibit 6-12 shows the screen capture of the ‘MOU Additional Information’ screen:

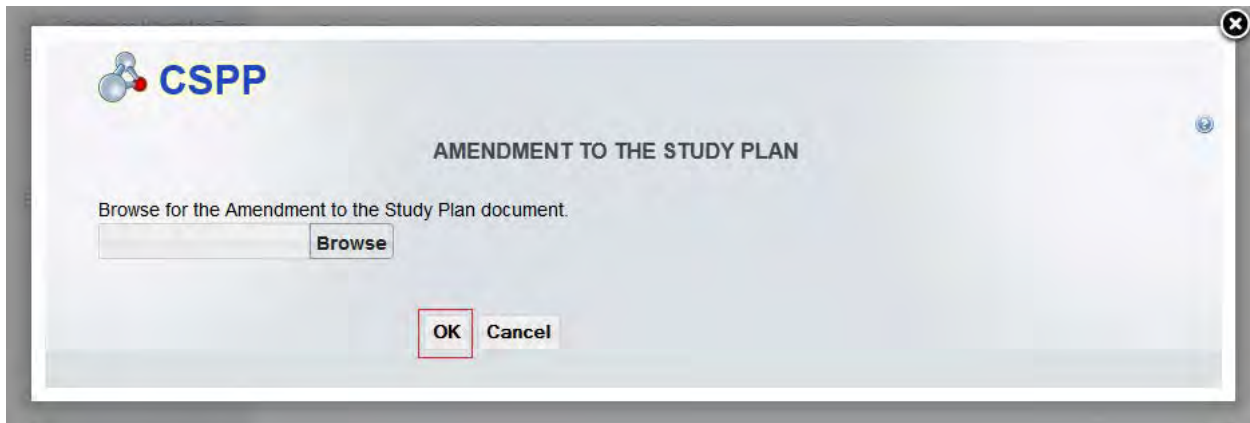
Exhibit 6-12 MOU Additional Information Screen



Navigation: Click the ‘Previous’ button to navigate to the ‘Document Management.’ If you have completed all required fields, click the ‘Save’ icon located in the bottom action bar to save all entered information.

Exhibit 6-13 shows the screen capture of the ‘Amendment to the Study Plan’ pop-up window:

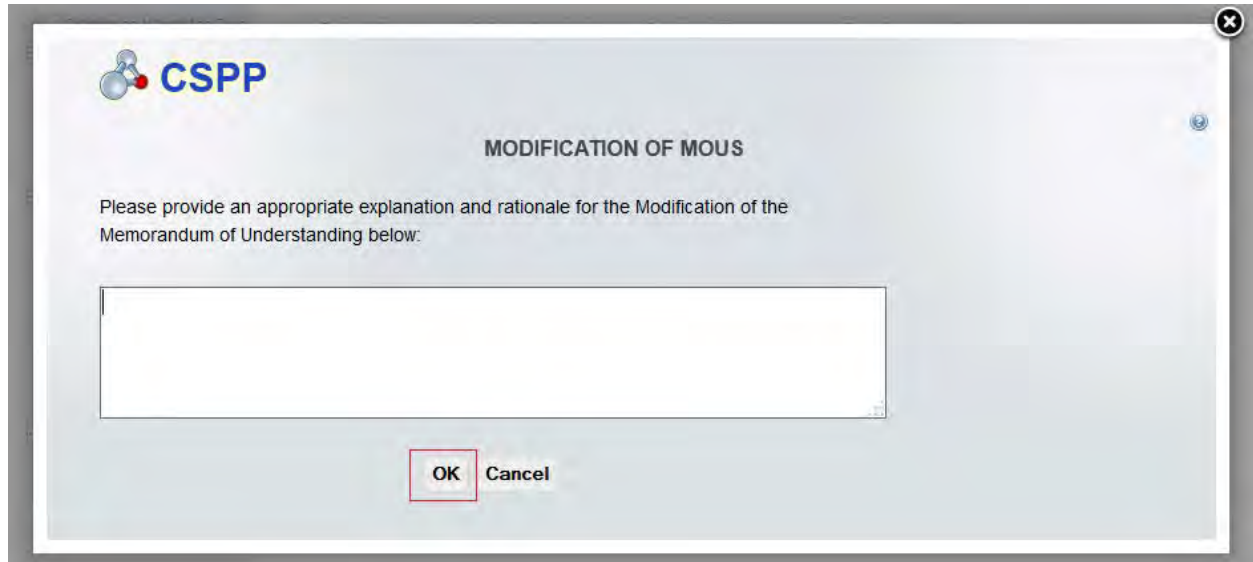
Exhibit 6-13 Amendment to the Study Plan Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ buttons to return to the ‘MOU Additional Information’ screen.

Exhibit 6-14 shows the screen capture of the ‘Modification of MOUs’ pop-up window:

Exhibit 6-14 Modification of MOUs Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ buttons to return to the ‘MOU Additional Information’ screen.

7 40 CFR 766 Dibenzodioxins/Dibenzofurans

7.1 Submission Information Type Screen

You can access the 'Submission Information Type' screen by clicking the 'Next' button from the 'Enter Passphrase' screens. Once you are within the '40 CFR 766' flow of the Section 4 application, the 'Submission Information Type' screen can also be accessed by clicking the 'Submission Information Type' link located within the navigation tree.

The 'Submission Information Type' screen allows you to select the submission information type that you will be submitting to EPA. This screen consists of the following fields:

- **Submission Alias:** This field is auto-populated with a date and time stamp and is displayed on the 'Section 4 Test Rules, ECAs, MOUs, and 40 CFR 766' submissions screen within the 'Submission Alias' column. This field is editable should you choose to provide your own submission alias. This field is required
- **Letter of Intent:** Checking the 'Letter of Intent' checkbox indicates that you are fulfilling the requirements to submit a letter of intent to EPA. Once you have checked the 'Letter of Intent' checkbox and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'Letter of Intent' folder is generated within the navigation tree allowing you to access the letter of intent screens required to be completed.
- **Protocol:** Checking the 'Protocol' checkbox indicates that you are fulfilling the requirements to submit protocols to EPA. Once you have checked the 'Protocol' checkbox and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'Protocol' folder is generated within the navigation tree allowing you to access the protocol screens required to be completed.
- **Results:** Checking the 'Results' checkbox indicates that you are fulfilling the requirements to submit results to EPA. Once you have checked the 'Results' checkbox and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'Results' folder is generated within the navigation tree allowing you to access the results screens required to be completed.
- **User Requests:** Checking the 'User Requests' checkbox indicates that you are submitting a request to EPA. Checking the 'User Requests' checkbox will enable the 'Waiver,' 'Exclusion,' and 'Exemption' radio button options. If you indicate that you are submitting a 'User Request' the 'Letter of Intent,' 'Protocol,' and 'Results' checkboxes will become disabled.
 - **Waiver:** Selecting the 'Waiver' radio button indicates that you are fulfilling the requirements to submit a waiver to EPA. Once you have checked the 'User Requests' checkbox and selected the 'Waiver' radio button and either saved the information on this screen by clicking the 'Save' icon or by clicking the 'Next' button, the 'User Requests' folder is generated within the navigation tree allowing you to access the 'Waiver' screen.
 - **Exclusion:** Selecting the 'Exclusion' radio button indicates that you are fulfilling the requirements to submit an exclusion to EPA. Once you have checked the 'User Requests' checkbox and selected the 'Exclusion' radio button and either saved the information on this screen by clicking the 'Save' icon or by clicking the

‘Next’ button, the ‘User Requests’ folder is generated within the navigation tree allowing you to access the ‘Exclusion’ screen.

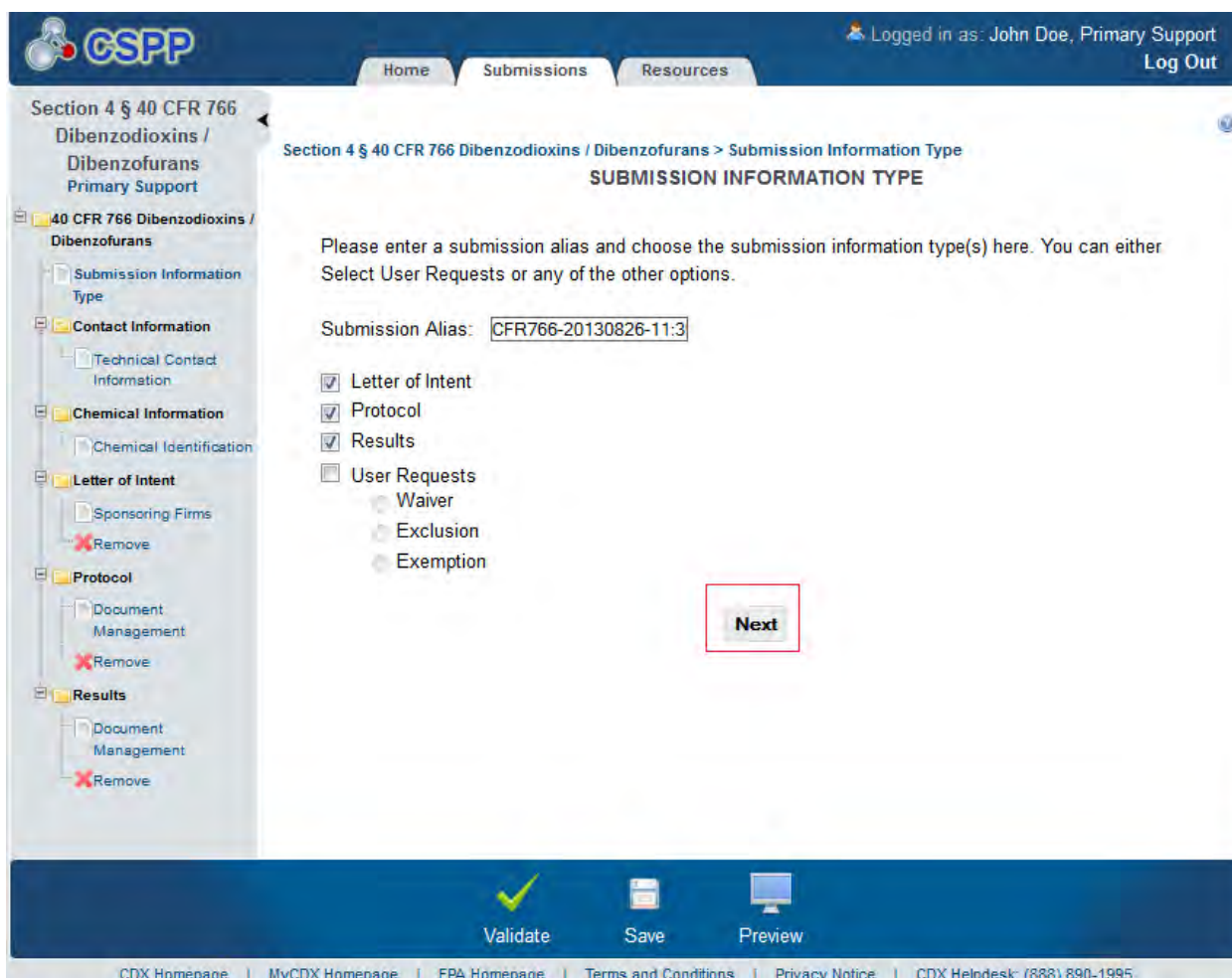
- **Exemption:** Selecting the ‘Exemption’ radio button indicates that you are fulfilling the requirements to submit an exemption to EPA. Once you have checked the ‘User Requests’ checkbox and selected the ‘Exemption’ radio button and either saved the information on this screen by clicking the ‘Save’ icon or by clicking the ‘Next’ button, the ‘User Requests’ folder is generated within the navigation tree allowing you to access the ‘Exemption’ screen.

If you have previously identified a submission type, accessed the submission type screens, and then unchecked the previously checked submission information type (i.e. Study Plan), you will receive a prompt indicating that all associated information will be lost. Clicking the ‘OK’ button within the prompt will delete all data associated with that submission information type.

Once you have identified the type(s) of information you will be submitting to EPA, you are able to access the screens required to be completed.

Exhibit 7-1 shows the screen capture of the ‘Submission Information Type’ screen:

Exhibit 7-1 Submission Information Type Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Technical Contact Information’ link within the navigation tree.

7.2 Technical Contact Information Screen

The ‘Technical Contact Information’ screen allows you to submit on behalf of another company or submit on behalf of a consortium. To identify if you are submitting on behalf of another entity, the system provides ‘This is a submission on behalf of a consortium’ and ‘This is a submission on behalf of another company’ radio buttons. The system will not allow you to submit on behalf of a single company and on behalf of a consortium. If you are not submitting on behalf of another entity, you must select the ‘N/A’ radio button.

If you are not submitting on behalf of another entity and have selected the ‘N/A’ radio button, you are taken to the ‘Chemical Identification’ screen. If you are submitting on behalf of a consortium, select the ‘This is a submission on behalf of a consortium’ radio button. If the radio button for ‘This is a submission on behalf of a consortium’ is selected, you are taken to the ‘Submitting on Behalf of Consortium’ screen. If you are submitting on behalf of another company, select the ‘This is a submission on behalf of another company’ radio button. This functionality has been implemented to accommodate a company that may use an agent or another individual. If this radio button is selected, the information of the contractor/consultant’s company is to be entered into the ‘Submitting on Behalf Of Company’ screen.

- **N/A:** Selecting the ‘N/A’ radio button allows you to signify that you are neither making a submission on behalf of a consortium nor making a submission on behalf of another company.
- **This is a submission on behalf of a consortium:** Selecting the ‘This is a submission on behalf of a consortium’ radio button allows you to identify yourself as an individual submitting on behalf of a consortium.
- **This is a submission on behalf of another company:** Selecting the ‘This is a submission on behalf of another company’ radio button allows you to identify yourself as an individual submitting on behalf of another company.
- **Copy CDX Registration:** Clicking the ‘Copy CDX Registration’ button will automatically populate the fields with your contact information provided during CDX registration.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.
- **First Name:** Enter the technical contact’s first name. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration. This field is required.
- **Middle Initial:** Enter the technical contact’s middle initial. If you have clicked the ‘Copy CDX Registration’ button, the fields populate with information entered during CDX registration.

- **Last Name:** Enter the technical contact's last name. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes. If applicable, select the appropriate suffix. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- **Company Name:** Enter the technical contact's company name. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **Phone Number:** Enter the technical contact's daytime phone number; U.S. or international. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **Email Address:** Enter the technical contact's email address. The email address must follow the standard email address format: john.doe@abc.com. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 1:** Enter the first line of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **Mailing Address 2:** Enter the second line of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration.
- **City:** Enter the city of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **State:** Enter the state of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field if the 'Country' field is defined as 'United States.'
- **Postal Code:** Enter the postal code of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This field is required.
- **Country:** Enter the country of the technical contact's mailing address. If you have clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.

Exhibit 7-2 shows the screen capture of the 'Technical Contact Information' screen:

Exhibit 7-2 Technical Contact Information Screen

Section 4 § 40 CFR 766 Dibenzenodioxins / Dibenzofurans > Contact Information > Technical Contact Information

TECHNICAL CONTACT INFORMATION

Identify the technical contact who is capable of answering questions related to the chemical(s) submitted to EPA within this submission. Identify if this submission is being submitted on behalf of another company or consortium by selecting the appropriate radio button. If submitting on behalf of is not applicable, select the N/A radio button. Click the 'Copy CDX Registration' button to copy your information from CDX Registration.

N/A
 This is a submission on behalf of a consortium
 This is a submission on behalf of another company

Click here to copy your information from CDX Registration: [Copy CDX Registration](#)

CBI:
 Prefix:
 First Name:
 Middle Initial:
 Last Name:
 Suffix:
 Company Name:
 Phone Number: Ext:
(Do not enter any dashes (-) in Phone Number field above)
 Email Address:
 Mailing Address 1:
Street address, P.O. box, company name, etc.
 Mailing Address 2:
Apartment, suite, etc.
 City:
 State:
 Postal Code:
 Country:

[Previous](#) [Next](#)

[Validate](#) [Save](#) [Preview](#)

[CDX Homepage](#) | [MyCDX Homepage](#) | [EPA Homepage](#) | [Terms and Conditions](#) | [Privacy Notice](#) | [CDX Helpdesk: \(888\) 890-1995](#)

Navigation: If you are submitting on behalf of a consortium, you are taken to the ‘Submitting on Behalf of Consortium’ screen. If you are submitting on behalf of another company and click the ‘Next’ button, you are taken to the ‘Submitting on Behalf of Company’ screen. If you are submitting a Letter of Intent and are not submitting on behalf of another entity, you are taken to the ‘Chemical Identification’ screen. If you are completing a protocol or results and are not submitting on behalf of another entity, you are taken to the ‘Document Management’ screen. If you are completing a waiver, exclusion or extension, and have selected the ‘N/A’ radio button, click the ‘Next’ button to navigate to the specific user request screen.

7.3 Submitting on Behalf of Consortium Screen

You can access the ‘Submitting on Behalf of Consortium’ screen by selecting the ‘This is a submission on behalf of a consortium’ radio button and by clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Consortium’ link within the navigation tree.

The ‘Submitting on Behalf of Consortium’ screen allows you to enter contact information for each consortium member. The system provides you with the ability to identify the consortium name. The contact information of the logged in user will pre-populate the first consortium field set; this information is editable. To add a consortium member, click the ‘Add’ button to display fields that can be populated and saved. You can click the ‘Save’ button for each consortium member added to capture all information entered on the screen. A minimum of two consortium members must be added to pass validation. There must be at least two consortium members for an entered consortium

The following fields are displayed on the ‘Submitting on Behalf of Consortium’ screen:

- **Consortium Name:** Enter the name of the consortium.
- **Consortium CBI:** Checking the ‘Consortium CBI’ checkbox will claim the consortium as CBI.
- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes and captures the consortium member contact’s prefix. If applicable, select the appropriate prefix.
- **First Name:** Enter the consortium member contact’s first name. This field is required.
- **Middle Initial:** Enter the consortium member contact’s middle initial.
- **Last Name:** Enter the consortium member contact’s last name. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the consortium member contact’s suffix. If applicable, select the appropriate suffix.
- **Company Name:** Enter the consortium member contact’s company name. This field is required.
- **Phone Number:** Enter the consortium member contact’s daytime phone number; U.S. or international. This field is required.
- **Ext:** Enter the extension to the consortium member contact’s daytime phone number.
- **Email Address:** Enter the consortium member contact’s email address. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the consortium member contact’s mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the consortium member contact’s mailing address.
- **City:** Enter the city of the consortium member contact’s mailing address. This field is required.
- **State:** Enter the state of the consortium member contact’s mailing address. This field is required when ‘United States’ is identified as the country.

- **Postal Code:** Enter the postal code of the consortium member contact’s mailing address. This field is required.
- **Country:** Enter the country of the consortium contact’s mailing address. This field is required.

Exhibit 7-3 shows the screen capture for the ‘Submitting on Behalf of Consortium’ screen:

Exhibit 7-3 Submitting on Behalf of Consortium Screen

Section 4 § 40 CFR 766 Dibenzenodioxins / Dibenzenofurans Primary Support

Section 4 § 40 CFR 766 Dibenzenodioxins / Dibenzenofurans > Contact Information > Submitting on Behalf of Consortium

SUBMITTING ON BEHALF OF CONSORTIUM

Provide the consortium name and click the Add button to enter member contact information.

Consortium Name:

Consortium CBI:

Expand All | Collapse All

CGI FEDERAL (John Doe) Edit

Cancel

Prefix:

First Name:

Middle Initial:

Last Name:

Suffix:

Company Name:

Phone Number: Ext:

(Do not enter any dashes (-) in Phone Number field above)

Email Address:

Mailing Address 1:

Street address, P.O. box, company name, etc.

Mailing Address 2:

Apartment, suite, etc.

City:

State:

Postal Code:

Country:

Save

Click the **Add** button to add a new consortium member.

Previous

Validate Save Preview

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Navigation: Click the ‘Next’ button to navigate to the ‘Chemical Identification’ screen if submitting a letter of intent. You can also access this screen by clicking the ‘Chemical Identification’ link within the navigation tree.

7.4 Submitting on Behalf of Company Screen

You can access the ‘Submitting on Behalf Of Company’ screen by selecting the ‘This is a submission on behalf of another company’ radio button and clicking the ‘Next’ button from the ‘Technical Contact Information’ screen. You can also access this screen by clicking the ‘Submitting on Behalf of Company’ link within the navigation tree.

The ‘Submitting on Behalf Of Company’ screen presents you with a list of fields that allows you to input the contact information for the manufacturing or processing establishment on whose behalf the submission is being made.

The following fields are displayed on the ‘Submitting on Behalf of Company’ screen:

- **Prefix:** The ‘Prefix’ drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix.
- **First Name:** Enter the first name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Middle Initial:** Enter the middle initial of the manufacturing or processing establishment contact for which the submission is being made.
- **Last Name:** Enter the last name of the manufacturing or processing establishment contact for which the submission is being made. This field is required.
- **Suffix:** The ‘Suffix’ drop-down menu displays all optional suffixes and captures the suffix of the manufacturing or processing establishment contact for which the submission is being made. If applicable, select the appropriate suffix.
- **Company Name:** Enter the company name of the manufacturing or processing establishment. This field is required.
- **Phone Number:** Enter the daytime phone number of the manufacturing or processing establishment contact for whom the submission is being made; U.S. or international. This field is required.
- **Email Address:** Enter the email address of the manufacturing or processing establishment contact for which the submission is being made. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the manufacturing or processing establishment contact.
- **City:** Enter the city of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **State:** Enter the state of the mailing address of the manufacturing or processing establishment contact. This is a required field if the ‘Country’ field is defined as ‘United States.’

- **Postal Code:** Enter the postal code of the mailing address of the manufacturing or processing establishment contact. This field is required.
- **Country:** Enter the country of the mailing address of the manufacturing or processing establishment contact. This field is required.

Exhibit 7-4 shows the screen capture of the ‘Submitting on Behalf of Company’ screen:

Exhibit 7-4 Submitting on Behalf of Company Screen

Navigation: If you are submitting a letter of intent and click the ‘Next’ button, you are taken to the ‘Chemical Identification’ screen. If you are submitting a study plan or results, you are taken to the ‘Document Management’ screen.

7.5 Chemical Identification Screen

You can access the ‘Chemical Identification’ screen by clicking the ‘Next’ button from the ‘Technical Contact Information,’ ‘Submitting on Behalf of Company,’ or the ‘Submitting on Behalf of Consortium’ screens. The ‘Chemical Identification’ screen can also be accessed by clicking the ‘Chemical Identification’ link located within the navigation tree under the ‘Letter of Intent’ folder.

The ‘Chemical Identification’ screen requires you to identify the chemical substance the sponsor(s) intends to use in each of the tests. To identify the chemical substance select a chemical from the ‘Please select, or being typing, a **CASRN** in the drop-down menu below.’ The system allows you to claim the chemical as CBI, by checking the ‘CBI’ checkbox.

Exhibit 7-5 shows the screen capture of the ‘Chemical Identification’ screen:

Exhibit 7-5 Chemical Identification Screen

Navigation: Click the ‘Next’ button to navigate to the ‘Sponsoring Firms’ screen if you checked the Letter of Intent checkbox on the ‘Submission Information Type’ screen. You can also access this screen by clicking the ‘Sponsoring Firms’ link within the navigation tree.

7.6 Letter of Intent

If you have identified that you are submitting a letter of intent, you are required to complete the following screens to satisfy the reporting requirements.

7.6.1 Sponsoring Firms Screen

To access the ‘Sponsoring Firms’ screen click the ‘Next’ button from the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Sponsoring Firms’ link located within the navigation tree under the ‘Letter of Intent’ folder.

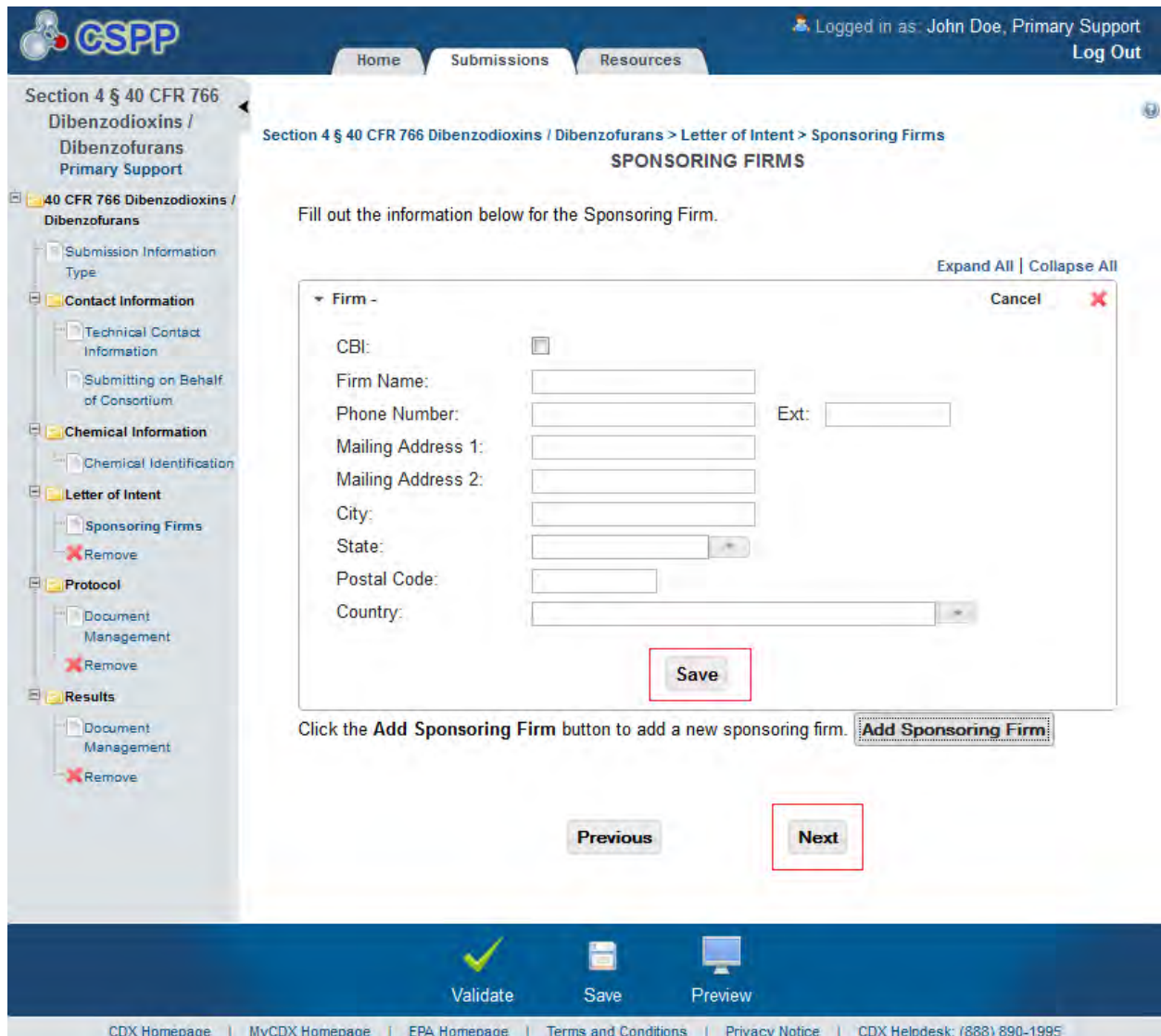
The 'Sponsoring Firms' screen requires you to identify each sponsoring firm involved in the testing of the identified chemical substances. To identify a sponsoring firm click the 'Add Sponsoring Firm' button. Clicking the 'Add Sponsoring Firm' button generates a sponsoring firm field set. Once you have entered data into a sponsoring firm field set, you must click the 'Save' button located within that field set prior to adding another firm. If the data previously entered and saved within a field set needs to be edited, you can click the 'Edit' button located in the upper right corner of that field set. If a sponsoring firm needs to be deleted, you can click the 'Delete' icon that is also located in the upper right corner of each field set.

The system allows you to expand/collapse each field set by clicking the sponsoring firm field set header. If you wish to expand/collapse all field sets simultaneously, click the 'Expand All' or 'Collapse All' links located at the top right of all consortium field sets.

- **CBI:** Check the checkbox to claim the sponsoring firm as CBI.
- **Firm:** Enter the sponsoring firm's company name. This field is required.
- **Phone Number:** Enter the sponsoring firm's daytime phone number; U.S. or international. This field is required.
- **Ext:** Enter the sponsoring firm's extension to the listed daytime phone number.
- **Mailing Address 1:** Enter the first line of the sponsoring firm's mailing address. This field is required.
- **Mailing Address 2:** Enter the second line of the sponsoring firm's mailing address.
- **City:** Enter the city of the sponsoring firm's mailing address. This field is required.
- **State:** Enter the state of the sponsoring firm's mailing address. This field is required when 'United States' is identified as the country.
- **Postal Code:** Enter the postal code of the sponsoring firm's mailing address. This field is required.
- **Country:** Enter the country of the sponsoring firm's mailing address. This field is required.

Exhibit 7-6 shows the screen capture of the ‘Sponsoring Firms’ screen:

Exhibit 7-6 Sponsoring Firms Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Document Management’ screen if you have identified that you are submitting a protocol or results. If you are only completing a ‘Letter of Intent,’ click the ‘Submit’ icon located in the action bar to begin the submission process.

7.7 Protocol

If you have identified you are submitting a protocol, you are required to complete the following screens to satisfy the reporting requirements.

7.7.1 Protocol Document Management Screen

The ‘Protocol Document Management’ screen allows you to upload documents related to Section 4 reporting requirements. To add protocol documentation, click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘Protocol Document Management’ pop-up window.

The 'Protocol Document Management' pop-up window allows you to upload files from your hard drive. Click the 'Browse' button to generate the 'File Upload' window. The 'File Upload' window allows you to search for the desired document from your hard drive. Once you have identified the document to be attached, click the 'Open' button. Clicking the 'Open' button will close the 'File Upload' window and display the attached document within the 'Browse' field. To claim attached documentation CBI, check the 'CBI' checkbox. If you claim the attached documentation as CBI, you are able to attach the sanitized version of the attached document. To do so, follow the steps outlined above. Once you have attached all desired documentation, click the 'OK' button to return to the 'Protocol Document Management' screen.

The document management table displays the file name of the document, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the 'Delete' icon located under the 'Action' column for a given row. Clicking the file name links within the 'File Name' column generates the 'Protocol Document Management' pop-up window. This allows you to view and edit previously attached documents.


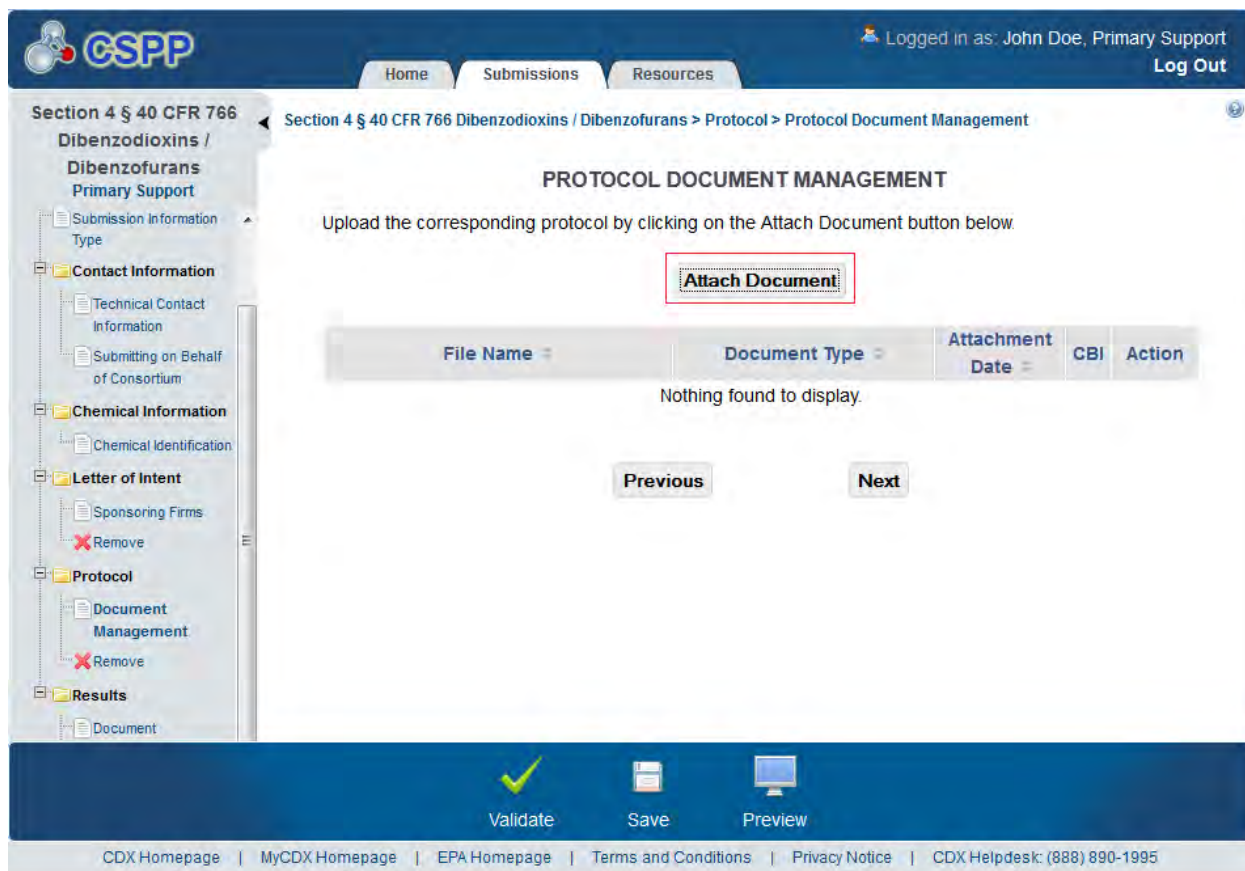
- **Attach Document:** Clicking the 'Attach Document' button displays the 'Protocol Document Management' pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the 'Protocol Document Management' pop-up window and allows you to view the attached document.
- **Document Type:** Displays the type of document attached.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed as CBI by displaying a 'Y' or an 'N.'
- **Action:** Clicking the 'Delete' icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the 'OK' button within the prompt.

Exhibit 7-7 shows the screen capture of the ‘Protocol Document Management’ screen:

Exhibit 7-7 Protocol Document Management Screen



Navigation: Click the ‘Next’ button to navigate to the ‘Document Management’ screen if you have identified that you are submitting results to EPA. If you are only submitting a protocol click the ‘Submit’ icon located in the action bar to begin the submission process.

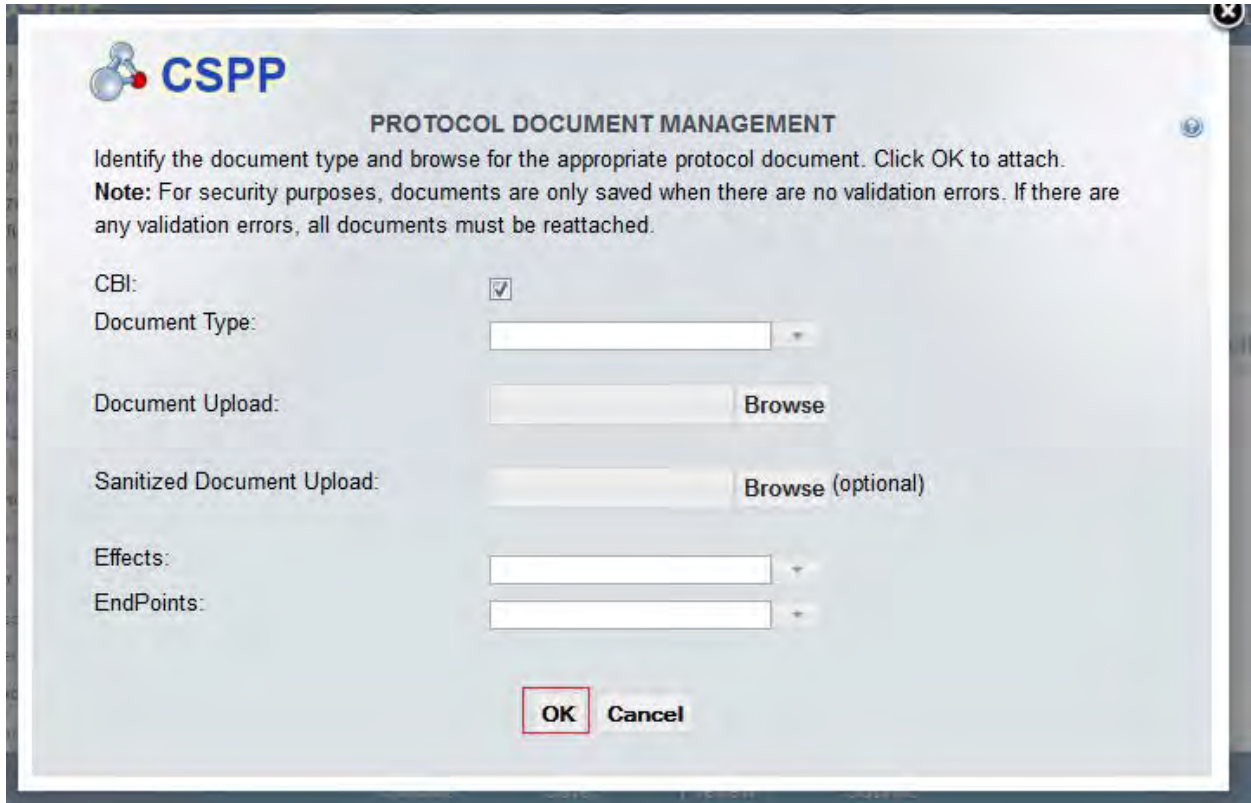
- **CBI:** Checking this ‘CBI’ checkbox will claim the document as CBI and generate a sanitized document upload field.
- **Document Upload:** Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive.
- **Sanitized Document Upload:** Clicking the ‘Browse’ button will generate the ‘File Upload’ window for you to search for a particular file on your hard drive. This field is only generated when the ‘CBI’ checkbox is checked and is optional.
- **Effects:** Select the effect specific to the chemical report. Displays the following options: ‘Health Effects,’ ‘Environmental Fate,’ ‘Ecotoxicity,’ and ‘Physical Chemical Properties.’
- **Endpoints:** Select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the ‘Effects’ drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Appendix B for a complete list of values that are found within each of the drop-down menus on the ‘Protocol Document Management’ pop-up window. If you have multiple

documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 7-8 shows the screen capture of the ‘Protocol Document Management’ pop-up window:

Exhibit 7-8 Protocol Document Management Pop-Up Window



Navigation: Click the ‘OK’ button to return to the ‘Document Management’ screen.

7.8 Results

If you have identified you are submitting results, you are required to complete the following screens to satisfy the reporting requirements.

7.8.1 Document Management Screen

The ‘Document Management’ screen allows you to upload documents related to Section 4 reporting requirements. To add Section 4 results documentation, click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘Document Management’ pop-up window.

The ‘Document Management’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. To claim attached documentation as CBI, check the ‘CBI’ checkbox. If you claim the attached documentation as CBI you are able to attach the sanitized version of the attached document. To do so, follow the steps outlined above.

Once you have attached all desired documentation, click the ‘OK’ button to return to the ‘Document Management’ screen.

The document management table displays the file name of the document, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon located under the ‘Action’ column for a given row. Clicking the file name links within the ‘File Name’ column generates the ‘Document Management’ pop-up window. This allows you to view and edit previously attached documents.


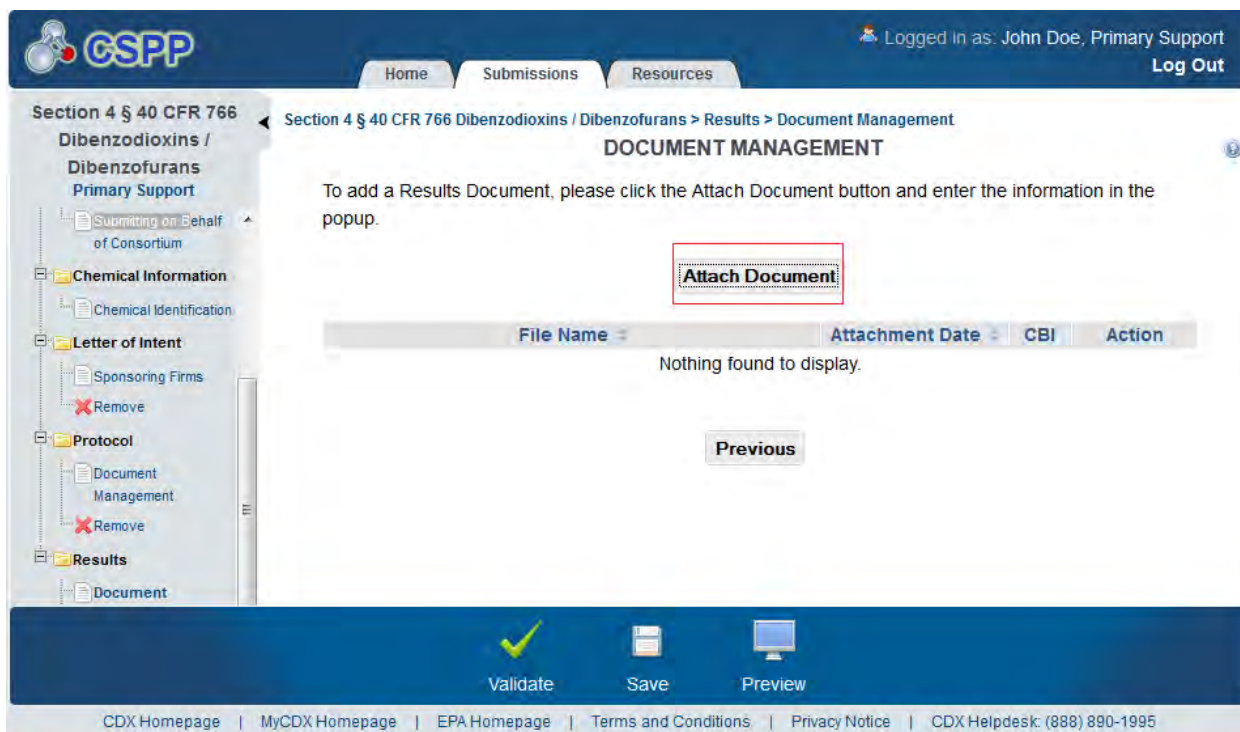
- **Attach Document:** Clicking the ‘Attach Document’ button displays the ‘Document Management’ pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the ‘Document Management’ pop-up window and allows you to view the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed as CBI by displaying a ‘Y’ or an ‘N.’
- **Action:** Clicking the ‘Delete’ icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the ‘OK’ button within the prompt.

Exhibit 7-9 shows the screen capture of the ‘Document Management’ screen:

Exhibit 7-9 Document Management Screen



Navigation: Click the ‘Previous’ button to navigate to the ‘Document Management’ screen if you have identified you are submitting a protocol to EPA. If you have completed all required fields, click the ‘Submit’ icon located in the action bar to begin the submission process.

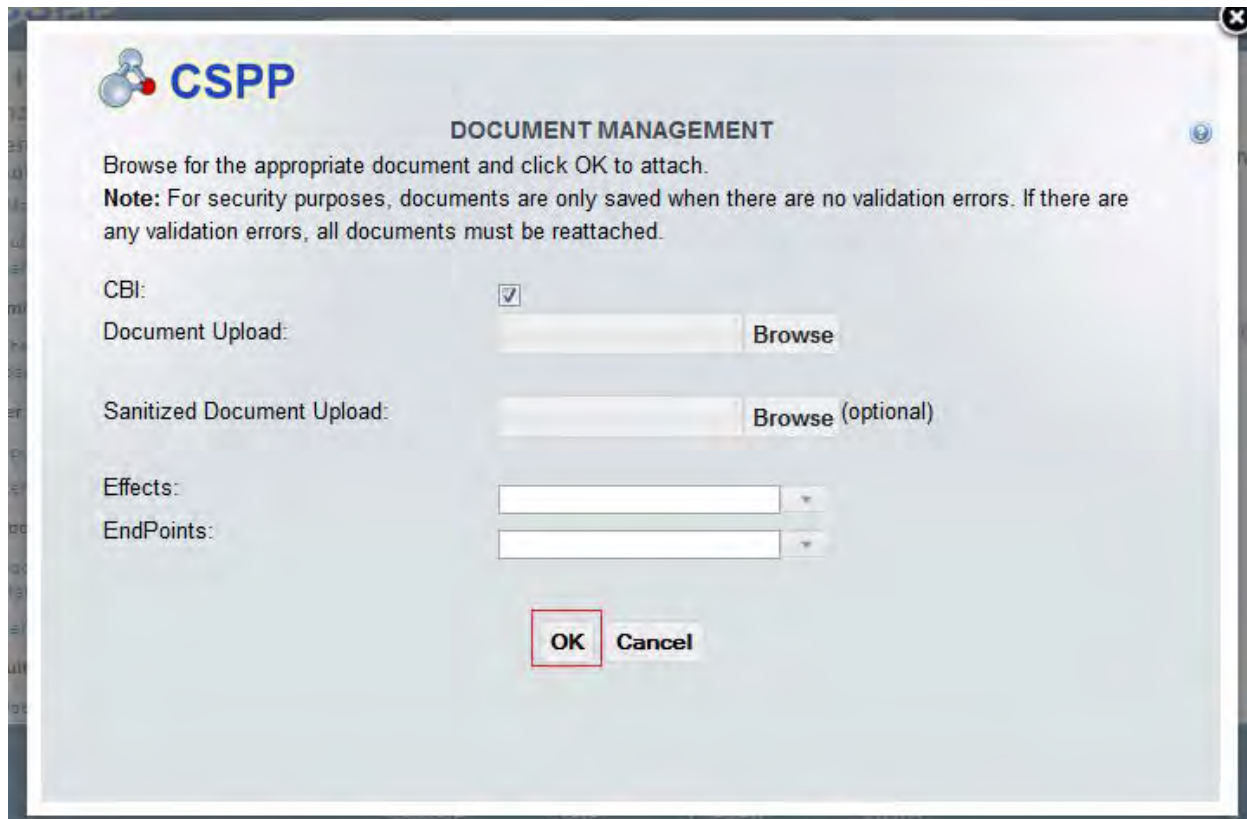
The 'Document Management' pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach at least one document. Clicking the 'Browse' button will generate the 'File Upload' window on your hard drive. Select the document you wish to attach and click the 'Open' button. If a document is marked as 'CBI' then a sanitized copy of the document must be attached. To save the attached document to the 'Document Management' screen, click the 'OK' button within the 'Document Management' pop-up window.

- **CBI:** Checking this 'CBI' checkbox will claim the document as CBI and generate a sanitized document upload field.
- **Document Upload:** Clicking the 'Browse' button will generate the 'File Upload' window for you to search for a particular file on your hard drive.
- **Sanitized Document Upload:** Clicking the 'Browse' button will generate the 'File Upload' window for you to search for a particular file on your hard drive. This field is only generated when the 'CBI' checkbox is checked and is optional.
- **Effects:** Select the effect specific to the chemical report. Displays the following options: 'Health Effects,' 'Environmental Fate,' 'Ecotoxicity,' and 'Physical Chemical Properties.'
- **Endpoints:** Select an endpoint that is specific to the chemical report. The endpoints will be specific to the effect chosen from the 'Effects' drop-down menu. If no effect is chosen, no endpoints will display.

Refer to Appendix B for a complete list of values that are found within each of the drop-down menus on the 'Document Management' pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down menus.

Exhibit 7-10 shows the screen capture of the ‘Document Management’ pop-up window:

Exhibit 7-10 Document Management Pop-Up Window



Navigation: Click the ‘OK’ button to return to the ‘Document Management’ screen.

7.9 User Requests

If you have identified you are submitting a user request, you are required to complete the following screens to satisfy the reporting requirements.

7.9.1 Waiver Screen

You can access the ‘Waiver’ screen by clicking the ‘Next’ button from the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Waiver’ link within the navigation tree.

The ‘Waiver’ screen requires you to identify the appropriate qualifying waiver reason and allows you to upload documents related to Section 4 reporting requirements. To add Section 4 waiver documentation, click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘Waiver Document Management’ pop-up window.

The ‘Waiver Document Management’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can search for the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. To claim attached documentation as CBI, check the ‘CBI’ checkbox. If you claim the attached documentation as

CBI you are required to attach the sanitized version of the attached document. To do so, follow the steps outlined above. Once you have attached all desired documentation, click the 'OK' button to return to the 'Waiver' screen.

The waiver table displays the file name of the document, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the 'Delete' icon located under the 'Action' column for a given row. Clicking the file name links within the 'File Name' column generates the 'Waiver Document Management' pop-up window. This allows you to view and edit previously attached documents.


- **The chemical substance is produced only in quantities of 100 kilograms or less per year, only for research and development purposes:** Selecting this radio button option identifies this as the qualifying reason for the waiver request.
- **The cost of testing would drive the chemical substance off the market, or prevent resumption of manufacture or import of the chemical substance, if it is not currently manufactured, and the chemical substance will be produced so that no unreasonable risk will occur due to its manufacture, import, processing, distribution, use, or disposal. (In this case, the manufacturer must submit to EPA all data supporting the determination.):** Selecting this radio button option identifies this as the qualifying reason for the waiver request.
- **Attach Document:** Clicking the 'Attach Document' button displays the 'Waiver Document Management' pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the 'Waiver Document Management' pop-up window and allows you to view and edit the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed as CBI by displaying a 'Y' or an 'N.'
- **Action:** Clicking the 'Delete' icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the 'OK' button within the prompt.

Exhibit 7-11 shows the screen capture of the ‘Waiver’ screen:

Exhibit 7-11 Waiver Screen

Section 4 § 40 CFR 766 Dibenzenodioxins / Dibenzenofurans Primary Support

Section 4 § 40 CFR 766 Dibenzenodioxins / Dibenzenofurans > User Requests > Waiver

WAIVER

To request a waiver, please identify the appropriate qualifying reason and then click the Attach Document button to attach any supporting documentation.

- The chemical substance is produced only in quantities of 100 kilograms or less per year, only for research and development purposes
- The cost of testing would drive the chemical substance off the market, or prevent resumption of manufacture or import of the chemical substance, if it is not currently manufactured, and the chemical substance will be produced so that no unreasonable risk will occur due to its manufacture, import, processing, distribution, use, or disposal. (In this case, the manufacturer must submit to EPA all data supporting the determination.)

Attach Document

File Name	Attachment Date	CBI	Action
Nothing found to display.			

Previous

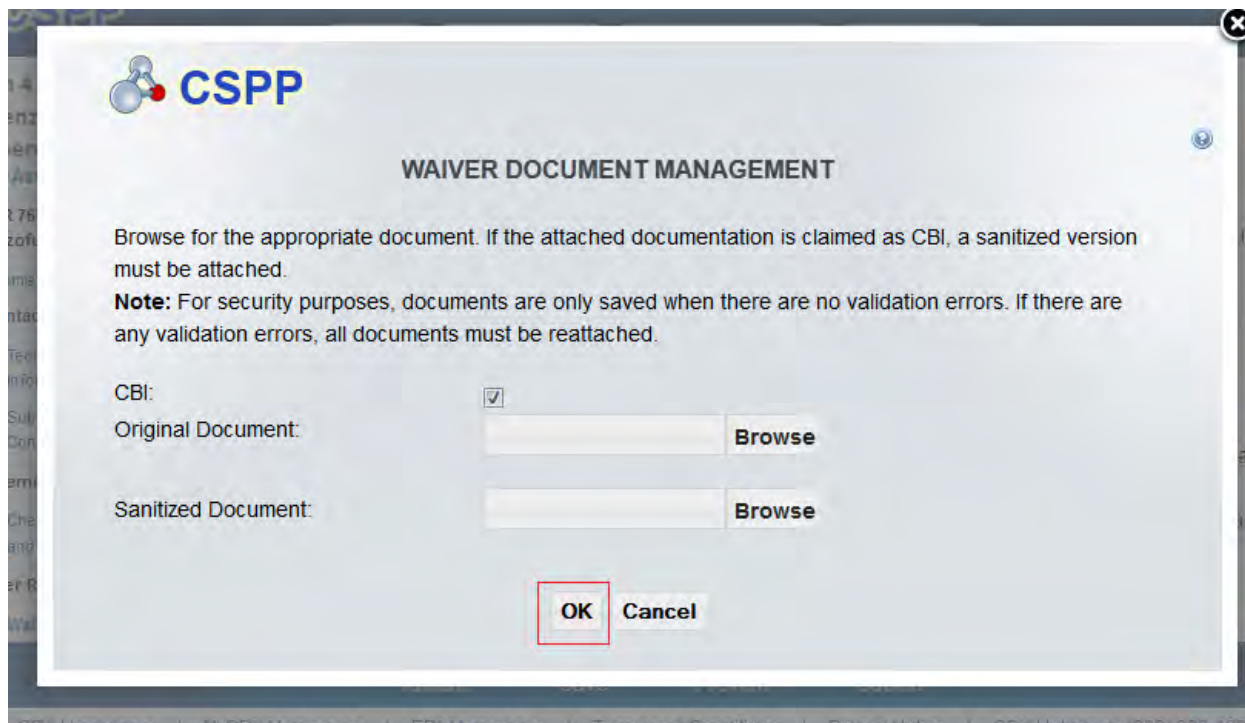
Validate
Save
Preview

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Navigation: Click the ‘Previous’ button to navigate to the ‘Chemical Identification’ screen.

Exhibit 7-12 shows the screen capture of the ‘Waiver Document Management’ pop-up window:

Exhibit 7-12 Waiver Document Management Pop-Up Window



Navigation: Click the ‘OK’ button to return to the ‘Waiver’ screen.

7.9.2 Exclusion Screen

You can access the ‘Exclusion’ screen by clicking the ‘Next’ button from the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Exclusion’ link within the navigation tree.

The ‘Exclusion’ screen requires you to identify the appropriate qualifying exclusion reason and allows you to upload documents related to Section 4 reporting requirements. To add Section 4 exclusion documentation, click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘Exclusion Document Management’ pop-up window.

The ‘Exclusion Document Management’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. To claim attached documentation CBI, check the ‘CBI’ checkbox. If you claim the attached documentation as CBI you are able to attach the sanitized version of the attached document. To do so, follow the steps outlined above. Once you have attached all desired documentation, click the ‘OK’ button to return to the ‘Exclusion’ screen.

The exclusion table displays the file name of the document, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon located under the ‘Action’ column for a given row.

Clicking the file name links within the 'File Name' column generates the 'Exclusion Document Management' pop-up window. This allows you to view and edit previously attached documents.


- **Testing of the appropriate grade of the chemical substance has already been carried out, either analytical testing at the lowest LOQ possible, with appropriate QA/QC, or a well-designed bioassay with appropriate QA/QC:** Selecting this radio button option identifies this as the qualifying reason for the exclusion request.
- **Process and reaction conditions of the chemical substance such that no HDDs/HDFs could be produced under those conditions:** Selecting this radio button option identifies this as the qualifying reason for the exclusion request.
- **Attach Document:** Clicking the 'Attach Document' button displays the 'Exclusion Document Management' pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the 'Exclusion Document Management' pop-up window and allows you to view the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed as CBI by displaying a 'Y' or an 'N.'
- **Action:** Clicking the 'Delete' icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the 'OK' button within the prompt.

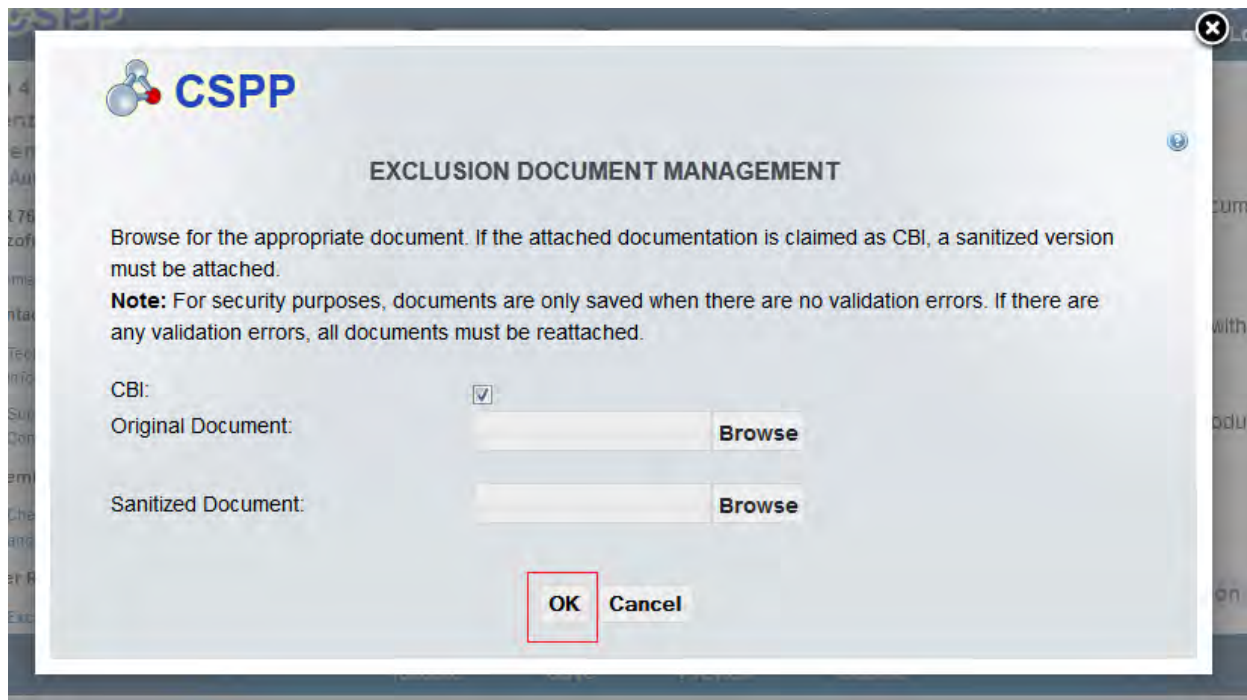
Exhibit 7-13 shows the screen capture of the ‘Exclusion’ screen:

Exhibit 7-13 Exclusion Screen

Navigation: Click the ‘Previous’ button to navigate to the ‘Chemical Identification’ screen.

Exhibit 7-14 shows the screen capture of the ‘Exclusion Document Management’ pop-up window:

Exhibit 7-14 Exclusion Document Management Pop-Up Window



Navigation: Click the ‘OK’ or ‘Cancel’ button to return to the ‘Exclusion’ screen.

7.9.3 Exemption Screen

You can access the ‘Exemption’ screen by clicking the ‘Next’ button from the ‘Chemical Identification’ screen. You can also access this screen by clicking the ‘Exemption’ link within the navigation tree.

The ‘Exemption’ screen allows you to upload documents related to Section 4 reporting requirements. To add Section 4 exemption documentation, click the ‘Attach Document’ button. Clicking the ‘Attach Document’ button displays the ‘Exemption Document Management’ pop-up window.

The ‘Exemption Document Management’ pop-up window allows you to attach documentation by clicking the ‘Browse’ button. This will generate the ‘File Upload’ window where you can select the desired document from your hard drive. Once you have identified the document to be attached, click the ‘Open’ button. Clicking the ‘Open’ button will close the ‘File Upload’ window and display the attached document within the ‘Browse’ field. To claim attached documentation as CBI, check the ‘CBI’ checkbox. If you claim the attached documentation as CBI, you are required to attach the sanitized version of the attached document. To do so, follow the steps outlined above. Once you have attached all desired documentation, click the ‘OK’ button to return to the ‘Exemption’ screen.

The exemption table displays the file name of the document, the date the document was attached, and whether the document was claimed as CBI. The system allows you to delete unwanted documents by clicking the ‘Delete’ icon located under the ‘Action’ column for a given row.

Clicking the file name links within the ‘File Name’ column generates the ‘Exemption Document Management’ pop-up window. This allows you to view and edit previously attached documents.


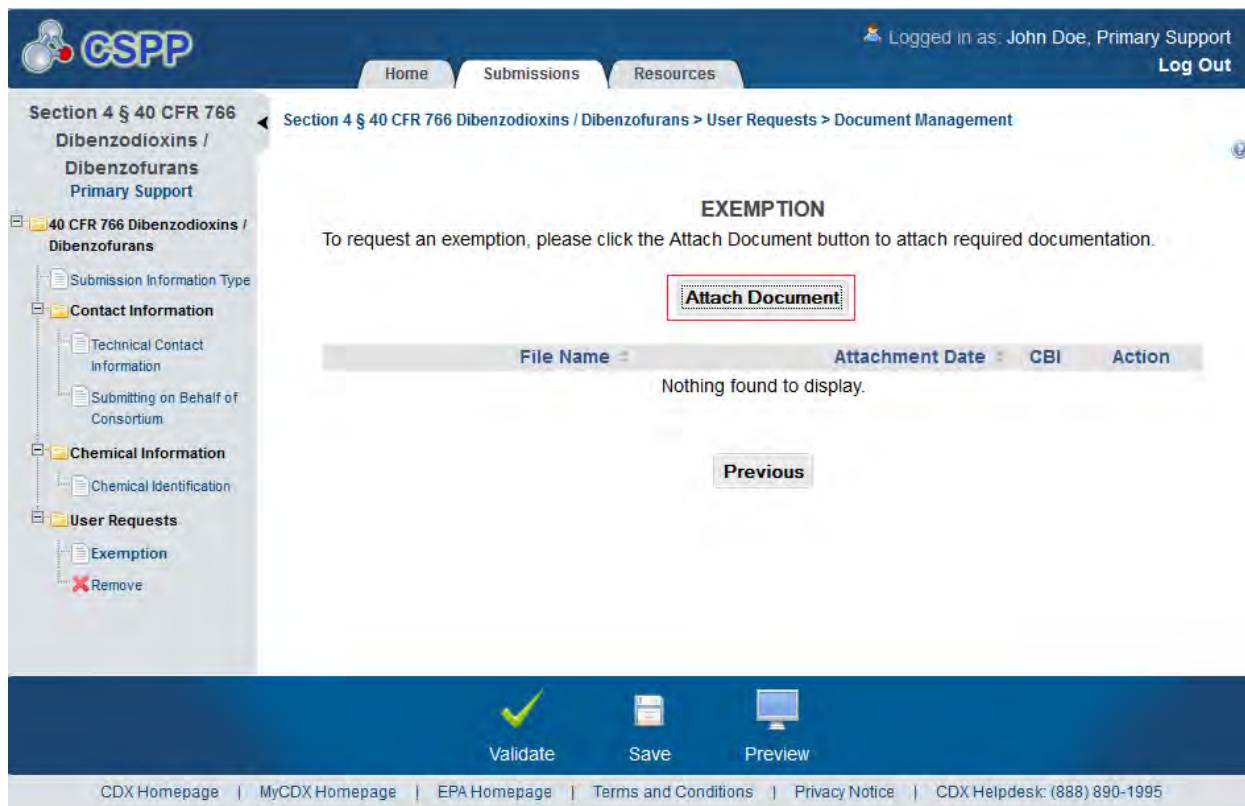
- **Attach Document:** Clicking the ‘Attach Document’ button displays the ‘Exemption Document Management’ pop-up window.
- **File Name:** Displays the name of the attached file. Clicking the file name link generates the ‘Exemption Document Management’ pop-up window and allows you to view the attached document.
- **Attachment Date:** Displays the date the document was attached.
- **CBI:** Displays whether the attached document was claimed as CBI by displaying a ‘Y’ or an ‘N.’
- **Action:** Clicking the ‘Delete’ icon () will generate a prompt confirming deletion. To delete the specified row and all contents within click the ‘OK’ button within the prompt.

Exhibit 7-15 shows the screen capture of the ‘Exemption’ screen:

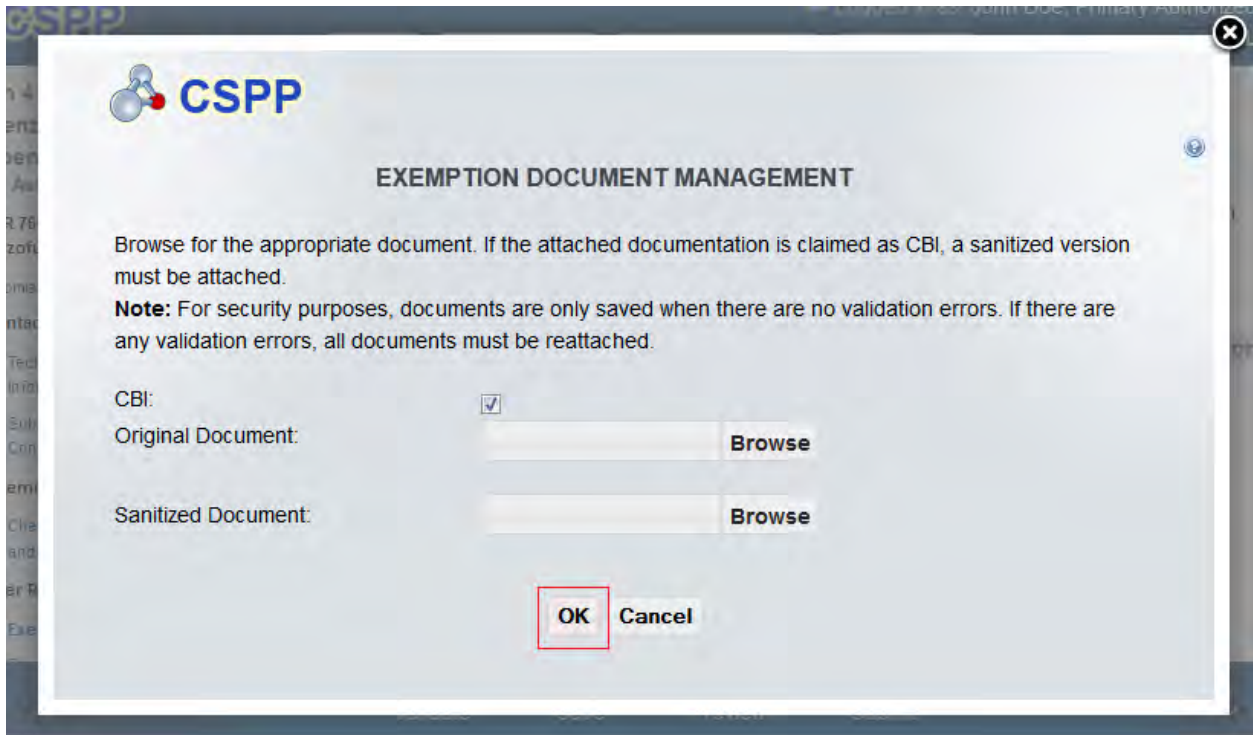
Exhibit 7-15 Exemption Screen



Navigation: Click the ‘Previous’ button to navigate to the ‘Chemical Identification’ screen.

Exhibit 7-16 shows the screen capture of the ‘Exemption Document Management’ pop-up window:

Exhibit 7-16 Exemption Document Management Pop-Up Window



Navigation: Click the ‘OK’ button to return to the ‘Exemption’ screen.

8 Validate

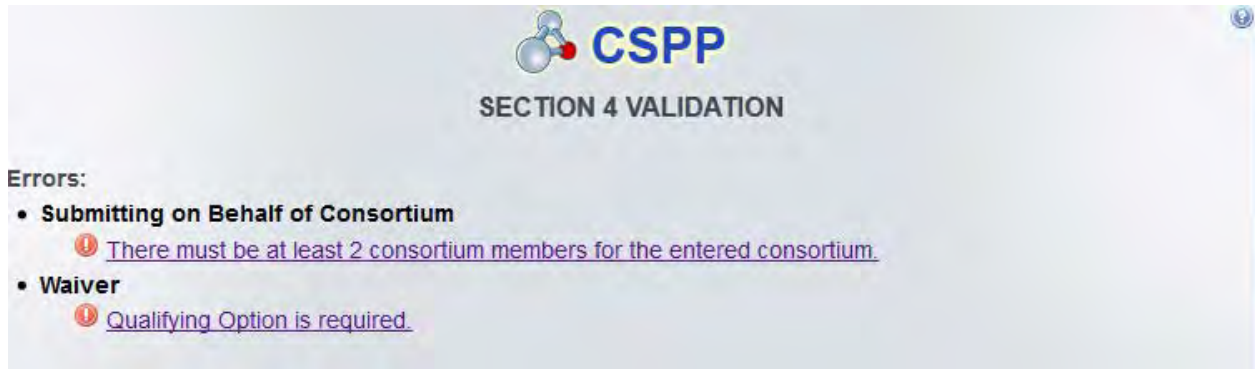
You can click the 'Validate' icon (✓) at any stage of completing a Section 4 submission. The 'Section 4 Validation' pop-up window displays when you click the 'Validate' icon (✓). The 'Section 4 Validation' pop-up window displays a report of all validation errors. During the validation process, the application validates each screen of the Section 4 submission to find missing and invalid data.

- **Validation Errors:** Errors are denoted by an 'Error' icon (ⓘ) and can be fixed by clicking the error link. The links will display the *Screen Title Name* (e.g., Technical Contact Information) and the associated error. After you click a link, the main application screen will display the section where the error occurred so you can easily fix the error. Once you have fixed the error, click the 'Validate' icon (✓) again to refresh the 'Section 4 Validation' pop-up window. If the information you fixed passes validation, the error will be removed from the 'Section 4 Validation' pop-up window. You must fix all validation errors for the submission to be successfully submitted through CDX by your AO.

You can close the 'Section 4 Validation' pop-up window by clicking the 'X' button located at the top right of the window.

Exhibit 8-1 shows the screen capture for the ‘Section 4 Validation’ pop-up window:

Exhibit 8-1 Section 4 Validation Pop-Up Window



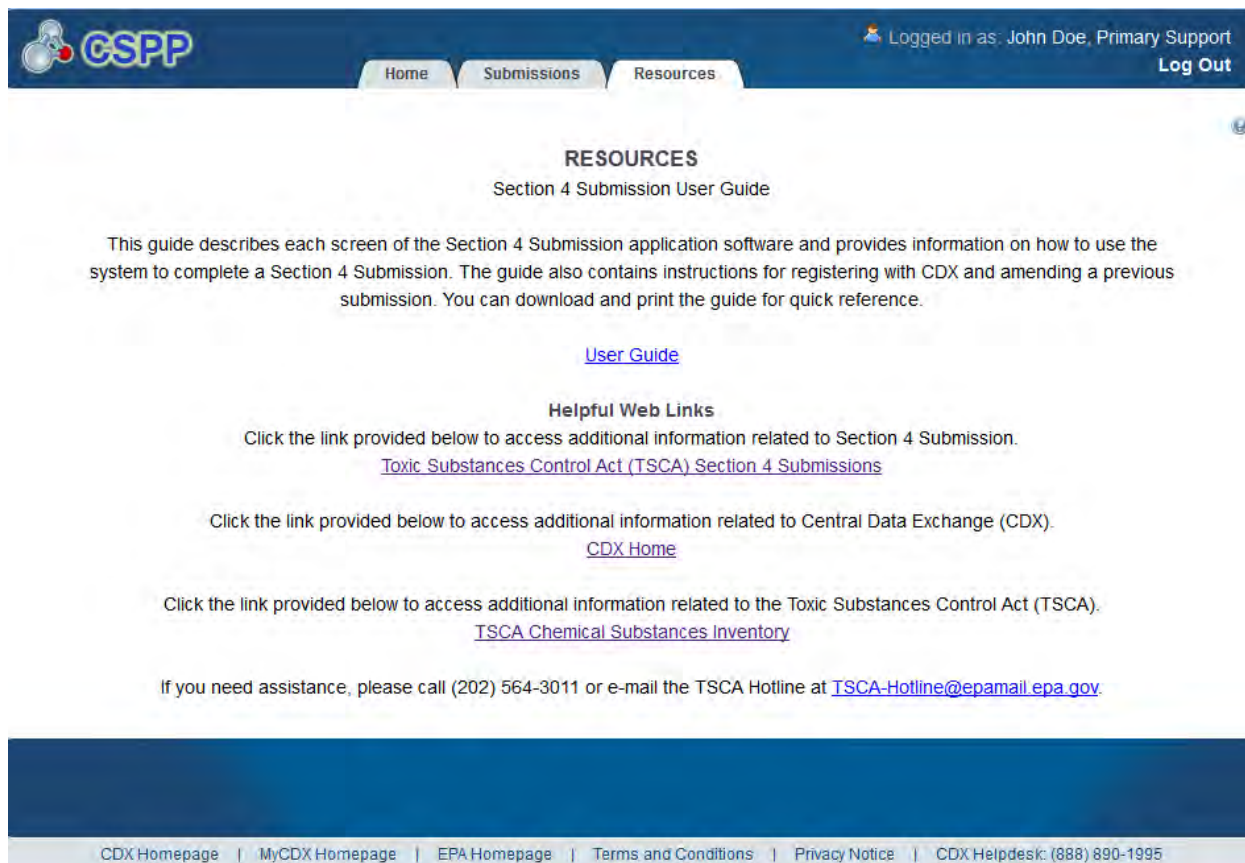
9 Resources

You can access the ‘Resources’ screen at any time during the submission process by clicking the ‘Resources’ tab located at the top of the screen. You can also access the ‘Resources’ screen by clicking the ‘Resources’ link from the Section 4 ‘Home’ screen. The ‘Resources’ screen provides you with links to the Section 4 user guide as well as additional helpful links. Click the ‘User Guide’ link to access the Section 4 user guide document.

- **User Guide:** If you click this link, a new internet browser window will generate displaying the Section 4 – Primary Support user guide.
- **Toxic Substances Control Act (TSCA) Section 4 Submission:** If you click this link, a new internet browser will generate displaying the ‘TSCA Section 4 Test Rules’ web page.
- **CDX Home:** If you click this link, a new internet browser window will generate displaying the CDX Homepage.
- **TSCA Chemical Substances Inventory:** If you click this link, a new internet browser window will generate displaying the TSCA Chemical Substances Inventory screen.

Exhibit 9-1 shows the screen capture of the ‘Resources’ screen:

Exhibit 9-1 Resources Screen



RESOURCES
Section 4 Submission User Guide

This guide describes each screen of the Section 4 Submission application software and provides information on how to use the system to complete a Section 4 Submission. The guide also contains instructions for registering with CDX and amending a previous submission. You can download and print the guide for quick reference.

[User Guide](#)

Helpful Web Links

Click the link provided below to access additional information related to Section 4 Submission.
[Toxic Substances Control Act \(TSCA\) Section 4 Submissions](#)

Click the link provided below to access additional information related to Central Data Exchange (CDX).
[CDX Home](#)

Click the link provided below to access additional information related to the Toxic Substances Control Act (TSCA).
[TSCA Chemical Substances Inventory](#)

If you need assistance, please call (202) 564-3011 or e-mail the TSCA Hotline at TSCA-Hotline@epamail.epa.gov.

CDX Homepage | MyCDX Homepage | EPA Homepage | Terms and Conditions | Privacy Notice | CDX Helpdesk: (888) 890-1995

Appendix A. Definitions, Acronyms, and Abbreviations

The following table displays all the definitions, acronyms, and abbreviations used in this document and their full name.

Definitions, Acronyms, and Abbreviations

Acronym	Full Name
AO	Authorized Official
CBI	Confidential Business Information
CDX	Central Data Exchange
CFR	Code of Federal Regulations
CoR	Copy of Record
CROMERR	Cross-Media Electronic Reporting Regulation Security System
CSPP	Submissions for Chemical Safety and Pesticide Programs
CSV	Comma-Separated Values
ECA	Enforceable Consent Agreements
FRN	Federal Register Notice
EPA	Environmental Protection Agency
MOU	Memorandum of Understanding
OPPT	Office of Pollution Prevention and Toxics
PDF	Portable Document Format
TSCA	Toxic Substances Control Act
XML	Extensible Markup Language

Appendix B. Submission Types, Effects, and Endpoints

The following appendix displays all possible options within each drop-down menu on the 'Document Management' pop-up window.

First Dropdown:

- Title: Submission Type
- Contains the following values
 - Initial Submission
 - Follow-Up Submission
 - Final Submission

Second Dropdown

- Title: Summary/Abstract Submission
- Contains the following values
 - Yes
 - No

Third Dropdown

- Title: Effects
- Contains the following values
 - Health Effect
 - Ecotoxicity
 - Environmental Fate
 - Physical-Chemical Properties

Fourth Dropdown

- Title: Endpoints
- Contains the following values
 - For Health Effect (shows when Health Effect is selected from third dropdown)
 - Basic Toxic kinetics
 - Dermal Absorption
 - Acute Toxicity: oral
 - Acute Toxicity: inhalation
 - Acute Toxicity: dermal
 - Acute Toxicity: other routes
 - Skin irritation/corrosion
 - Eye irritation
 - Skin sensitization
 - Respiratory sensitization
 - Repeated Dose toxicity: oral
 - Repeated Dose toxicity: inhalation

- Repeated Dose Toxicity: dermal
- Repeated Dose Toxicity: other routes
- Genetic Toxicity in vitro
- Genetic Toxicity in vivo
- Carcinogenicity
- Toxicity to Reproduction
- Developmental Toxicity/teratogenicity
- Toxicity to reproduction: other studies
- Neurotoxicity
- Immunotoxicity
- Specific investigations: other studies
- Health surveillance data
- Epidemiological data
- Direct observations: clinical cases, poisoning incidents and other
- Sensitization data (humans)
- Exposure related observations in humans: other data
- Toxic effects on livestock and pets
- Additional toxicological information
- Other
- For Ecotoxicity (shows when Ecotoxicity is selected from third dropdown)
 - Short-term toxicity to fish
 - Long-term toxicity to fish
 - Short-term toxicity to aquatic invertebrates
 - Long-term toxicity to aquatic invertebrates
 - Toxicity to aquatic algae and cyanobacteria
 - Toxicity to aquatic plants other than algae
 - Toxicity to microorganisms
 - Toxicity to other aquatic organisms
 - Sediment toxicity
 - Toxicity to soil macroorganisms except arthropods
 - Toxicity to terrestrial arthropods
 - Toxicity to terrestrial plants
 - Toxicity to soil microorganisms
 - Toxicity to birds
 - Toxicity to other above-ground organisms
 - Biological effects monitoring
 - Biotransformation and kinetics
 - Additional ecotoxicological information
 - Other

- For Environmental Fate (shows when Environmental Fate is selected from third dropdown)
 - Photo transformation in air
 - Hydrolysis
 - Photo transformation in water
 - Photo transformation in soil
 - Biodegradation in water: screening test
 - Biodegradation in water and sediment: simulation tests
 - Biodegradation in soil
 - Mode of degradation in actual use
 - Bioaccumulation: aquatic/sediment
 - Bioaccumulation: terrestrial
 - Adsorption/desorption
 - Henry's Law constant
 - Distribution Modeling
 - Other Distribution Data
 - Monitoring Data
 - Field Studies
 - Additional Information on Environmental Fate and Behavior
 - Other
- For Physical-Chemical Properties (shows when Physical-Chemical Properties is selected from third dropdown)
 - Appearance/Physical
 - Melting Point
 - Boiling Point
 - Density
 - Particle size distribution
 - Vapor Pressure
 - Partition Coefficient
 - Water Solubility
 - Solubility in Organic Solvent
 - Surface Tension
 - Flash Point
 - Auto Flammability
 - Flammability
 - Explosiveness
 - Oxidizing Properties
 - Oxidation Reduction Potential
 - Stability in organic solvents and identity of relevant degradation products
 - Storage stability and reactivity towards container material

- Stability: thermal, sunlight, metals
- pH
- Dissociation constant
- Viscosity
- Additional physic-chemical information
- Other