Section 8(d) Health Safety Data Reporting User Guide – Primary Authorized Official

Environmental Protection Agency

Office of Pollution Prevention and Toxics

Manage Toxic Substances

Delivery Order # GS00Q09BGD0022

Task Order # EP-G11H-00154

Project # TDD 9.21

Version 2.0

October 22, 2013

Table of Contents

1 Introduction 1
1.1 Labeling Confidential Information 1
2 System Requirements 4
2.1 Supported Browsers 4
2.2 Screen Resolution 4
3 Primary Authorized Official Functions 5
3.1 Log into Section 8(d) Health & Safety Data Reporting application 5
3.2 Home Screen Navigation 6
3.3 User Management 8
3.4 Create New Submission 10
3.4.1 Section 8(d) Health & Safety Data Reporting Submissions 10
3.4.2 Create Passphrase Screen 12
3.4.3 Enter Passphrase Screen 13
3.4.4 Navigation Tree 14
3.4.5 Action Bar 17
3.4.6 General Submission Information Screen 18
3.4.7 Technical Contact Information Screen 19
3.4.8 Submitting on Behalf Of Company Screen 22
3.4.9 Chemical Substance Identity of Impurities Screen 23
3.4.10 Study Identification Screen 28
3.4.11 Full Study Report Screen 30
3.4.12 Initiated Studies Screen 33
3.4.13 Ongoing Studies Screen 38
3.4.14 Robust Summary Screen 43
3.4.15 Studies Which Are Known But Without Possession of Copies Screen 45
3.4.16 Studies Previously Sent to Federal Agencies without Confidentiality Claims Screen51
3.5 EPA Request for Further Information 56
3.5.1 Underlying Data Screen 56
3.5.2 Preliminary Report of Ongoing Studies Screen 58
3.5.3 Copies of Studies Screen 65
3.6 Submitter Requests Screen 70
3.7 Substantiation Summary 71
4 Validate 74

5 Submit to EPA via CDX 76
5.1 Submitting Official Information Screen 76
5.2 Submission Process: Validation Screen 77
5.3 Cross-Media Electronic Reporting Regulation (CROMERR) Certification Screen 78
5.4 Cross-Media Electronic Reporting Regulation (CROMERR) Login Screen 79
5.5 CROMERR Security Question Screen 80
5.6 Submit to CDX Screen 81
5.7 Cross-Media Electronic Reporting Regulation (CROMERR) Submission Screen 82
6 Download Copy of Record 84
7 Create an Amendment 86
8 Resources 88
Appendix A. Definitions, Acronyms, and Abbreviations 90
Appendix B. Submission Types, Effects, and Endpoints 91

List of Exhibits

Exhibit 3-1: Chemical Information Submission System Screen 6
Exhibit 3-2: Section 8(d) Health & Safety Data Reporting Home Screen 8
Exhibit 3-3: User Management Screen.....10
Exhibit 3-4: Section 8(d) Health & Safety Data Reporting Submissions Screen.....12
Exhibit 3-5: Create Passphrase Screen.....13
Exhibit 3-6: Enter Passphrase Screen.....14
Exhibit 3-7: Navigation Prompt.....15
Exhibit 3-8: Navigation Tree.....16
Exhibit 3-9: Action Bar – Validate.....17
Exhibit 3-10: Action Bar – Save.....17
Exhibit 3-11: Action Bar – Preview 17
Exhibit 3-12: Action Bar – Submit.....18
Exhibit 3-13: Action Bar – Links 18
Exhibit 3-14: General Submission Information Screen 19
Exhibit 3-15: Technical Contact Information Screen.....21
Exhibit 3-16: Submitting on Behalf of Company Screen 23
Exhibit 3-17: Chemical Substance Identity of Impurities Screen.....24
Exhibit 3-18: Search Substance Registry Services Pop-Up Window 26
Exhibit 3-19: Chemical Not Found in Substance Registry Services Pop-Up Window 27
Exhibit 3-20: Study Identification Screen.....29
Exhibit 3-21: Study Identification Screen for an Amendment.....30
Exhibit 3-22: Full Study Report Screen 31
Exhibit 3-23: Full Study Report Pop-Up Window 33
Exhibit 3-24: Initiated Studies Screen (Add Document) 35
Exhibit 3-25: Initiated Studies Pop-Up Window 36
Exhibit 3-26: Initiated Studies Screen (Add Study) 37
Exhibit 3-27: Ongoing Studies Screen (Add Document) 40
Exhibit 3-28: Ongoing Studies Pop-Up Window 41
Exhibit 3-29: Ongoing Studies Screen (Add Study) 42
Exhibit 3-30: Robust Summary Screen 43
Exhibit 3-31: Robust Summary Pop-Up Window 45
Exhibit 3-32: Studies Which Are Known but without Possession of Copies (Add Document).....47
Exhibit 3-33: Studies Which Are Known but without Possession of Copies Pop-Up Window.....49
Exhibit 3-34: Studies Which Are Known but without Possession of Copies Screen (Add Study)50
Exhibit 3-35: Studies Previously Sent To Federal Agencies Without Confidentiality Claims Screen (Add Document).....53
Exhibit 3-36: Studies Previously Sent To Federal Agencies Without Confidentiality Claims Pop-Up Window.....54

Exhibit 3-37: Studies Previously Sent To Federal Agencies Without Confidentiality Claims Screen (Add Study) 55
Exhibit 3-38: Underlying Data Screen 57
Exhibit 3-39: Underlying Data Pop-Up Window (with Sanitized Document Attached) 58
Exhibit 3-40: Preliminary Reports of Ongoing Studies Screen (Add Document) 61
Exhibit 3-41: Preliminary Report of Ongoing Studies Pop-Up Window (with Sanitized Document Attached) 63
Exhibit 3-42: Preliminary Report of Ongoing Studies Screen (Add Study) 64
Exhibit 3-43: Copies of Studies Screen (Add Document) 67
Exhibit 3-44: Copies of Studies Pop-up Window (with Sanitized Document Attached) 68
Exhibit 3-45: Copies of Studies Screen (Add Study) 69
Exhibit 3-46: Submitter Requests Screen 70
Exhibit 3-47: Submitter Request Pop-Up Window 71
Exhibit 3-48: Substantiation Summary Screen 72
Exhibit 3-49: Submission of Studies Substantiation Screen 73
Exhibit 4-1: Section 8(d) Health & Safety Data Reporting Validation Pop-Up Window 75
Exhibit 5-1: Submitting Official Information Screen 76
Exhibit 5-2: Submission Process: Validation Screen 77
Exhibit 5-3: Submission Process: PDF Generation Screen 78
Exhibit 5-4: Cross-Media Electronic Reporting Regulation (CROMERR) Certification Screen 79
Exhibit 5-5: Cross-Media Electronic Reporting Regulation (CROMERR) Login Screen 80
Exhibit 5-6: Cross-Media Electronic Reporting Regulation (CROMERR) Security Question Screen 81
Exhibit 5-7: Submit to CDX Screen 82
Exhibit 5-8: Cross-Media Electronic Reporting Regulation (CROMERR) Submission Screen 83
Exhibit 6-1: Download Copy of Record Screen 84
Exhibit 6-2: Download Prompt Screen 85
Exhibit 7-1: Section 8(d) Health & Safety Data Reporting Submissions Screen – Amendment 86
Exhibit 7-2: Unlock Prompt Message 87
Exhibit 8-1: Resources Screen 89

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1 Introduction

This document presents the user guide for the Office of Pollution Prevention and Toxics (OPPT) Section 8(d) Health & Safety Data Reporting application submission process. This document is the user guide for the Primary Authorized Official (AO) user of the Section 8(d) Health & Safety Data Reporting tool.

The Primary AO is the person legally responsible for the submission of 8(d) Health & Safety Data Reporting data for the reporting company. The AO, typically, is a senior official for the reporting company and may be the supervisor of the person (or persons) completing the form.

As a Primary AO, you can create a new form. You can also assign Supports to edit and complete forms on your behalf. You are responsible for submitting all required information and are legally responsible for the information submitted to EPA within each 8(d) Health & Safety Data Reporting submission.

General information on Section 8(d) Health & Safety Data Reporting 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 8(d) Health & Safety Data Reporting 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 8(d) Health & Safety Data Reporting application is the electronic, web-based tool provided by the Environmental Protection Agency (EPA) for the submission of Section 8(d) Health & Safety Data Reporting data. As a Primary AO, you can create or modify a Section 8(d) Health & Safety Data Reporting submission as well as submit it to EPA via the Central Data Exchange (CDX). You can also create Section 8(d) Health & Safety Data Reporting submission amendments and download the Copy of Record (CoR).

For questions concerning the Toxic Substances Control Act (TSCA) Section 8(d) Health & Safety Data Reporting 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 8(d) Health & Safety Data Reporting requirements, please contact the TSCA Hotline at TSCA-Hotline@epamail.epa.gov or call 202-554-1404.

1.1 Labeling Confidential Information

This user guide presents instructions and screenshots for the ‘Section 8(d) Health & Safety Data Reporting’ electronic application as if you were logged in as the Primary AO. As the Primary AO you are able to create, modify, delete, and submit an 8(d) 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 8(d) Health & Safety Data Reporting 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 8(d) Health & Safety Data Reporting. 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 8(d) Health & Safety Data Reporting 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 8(d) Health & Safety Data Reporting' application:

- Technical Contact Information
- Submitting on Behalf of Company information
- A single chemical substance that is not on the public TSCA Inventory
- Any document uploaded on the following screens:
    - Full Study
    - Initiated Studies
    - Ongoing Studies
    - Studies which are known but without possession of copies
    - Underlying Data
    - Preliminary Reports of Ongoing Studies
    - Copies of Studies
- Laboratory information on the following screens:
    - Initiated Studies
    - Ongoing Studies
    - Studies Which are Known but Without Possession of Copies
    - Studies Previously Sent to Federal Agencies Without Confidentiality Claims
    - Preliminary Reports of Ongoing Studies
- Contact information on the following screens:
    - Studies Which are Known but Without Possession of Copies
    - Studies Previously Sent to Federal Agencies Without Confidentially Claims

- Copies of Studies
- Submitter Official Information

2 System Requirements

To use the Section 8(d) Health & Safety Data Reporting application to submit a Section 8(d) Health & Safety Data Reporting submission, 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

- 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 greater.

3 Primary Authorized Official Functions

This section describes how to:

- Access the application
- Navigate to the Section 8(d) Health & Safety Data Reporting 'Home' screen
- Assign Supports to complete a submission
- Start and complete a Section 8(d) Health & Safety Data Reporting submission
- Submit to EPA via CDX
- Download the Copy of Record
- Create an amendment

The Primary AO is the person legally responsible for the submission of 8(d) Health & Safety Data Reporting data for the reporting company. The AO, typically, is a senior official for the reporting company and may be the supervisor of the person (or persons) completing the form.

As a Primary AO, you can create a new form. You can also assign Supports to edit and complete forms on your behalf. You are responsible for submitting all required information and are legally responsible for the information submitted to EPA within each 8(d) Health & Safety Data Reporting submission.

You can save the 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 document at any point; however, the 'Not For Submission' watermark will be placed on the portable document format (PDF) document each time the submission is printed.

3.1 Log into Section 8(d) Health & Safety Data Reporting application

After you create an account in CDX and click the 'Primary Authorized Official' link under the Chemical Safety and Pesticide Programs (CSPP) program service, 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 8(e) Notice, is available at http://cdx.epa.gov/About/UserGuide

Exhibit 3-1 shows the screen capture for 'Chemical Information Submission System' screen.

Exhibit 3-1: Chemical Information Submission System Screen

Navigation: Select 'TSCA Section 8(d) Health & Safety Data Reporting' from the drop-down menu and click the 'OK' button to navigate to the Section 8(d) Health & Safety Data Reporting 'Home' screen.

3.2 Home Screen Navigation

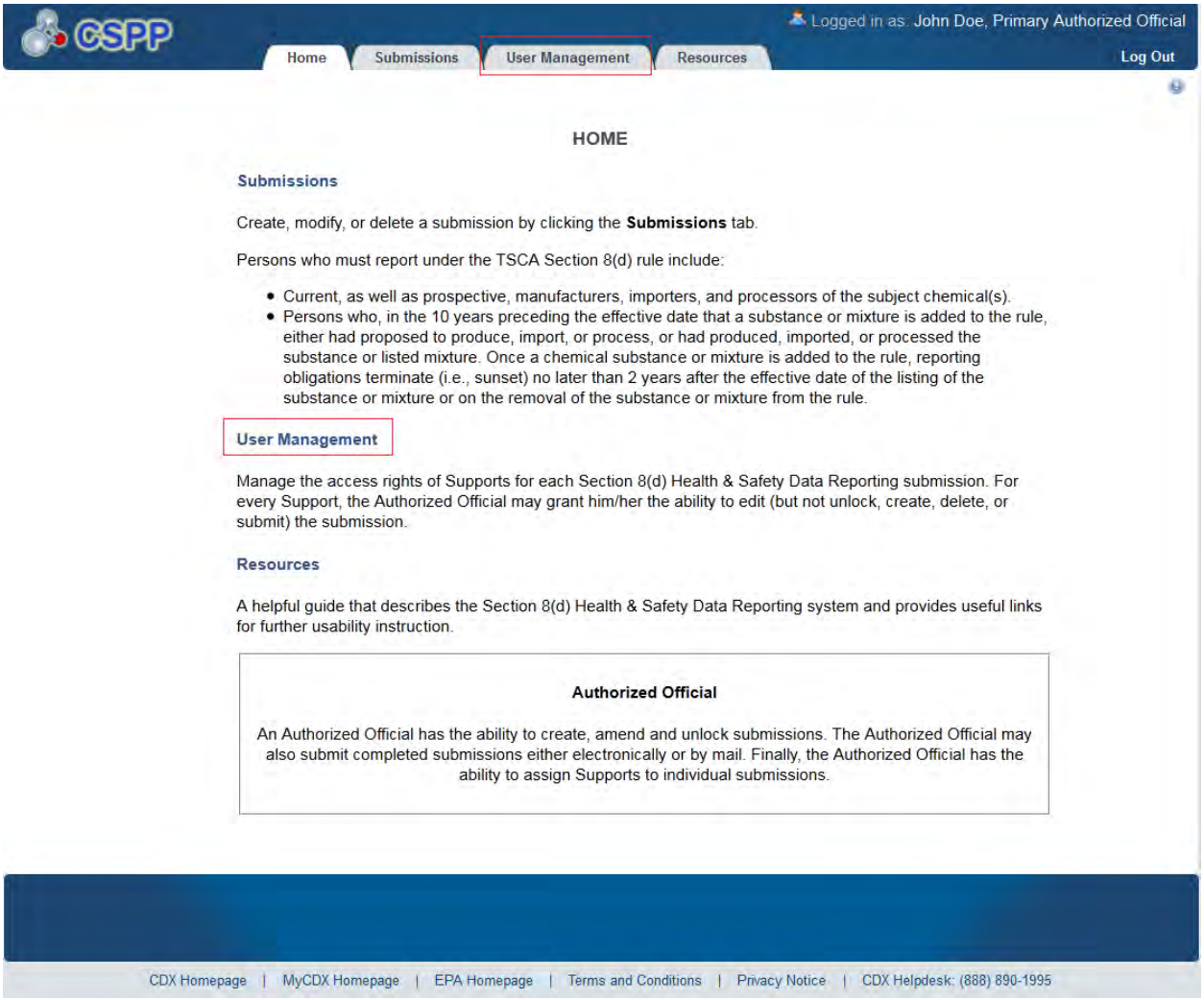
You can access the Section 8(d) Health & Safety Data Reporting 'Home' screen by selecting 'TSCA Section 8(d) Health & Safety Data Reporting' from the 'Chemical Information Submission System' screen drop-down menu and by clicking the 'OK' button.

The Section 8(d) Health & Safety Data Reporting 'Home' screen is the first screen within the Section 8(d) Health & Safety Data Reporting application. It provides you with links and tabs to access the 'Section 8(d) Health & Safety Data Reporting' submissions screen, 'User Management,' and 'Resources' screens. To navigate to any of these screens, click the screen link (hyperlinked 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 8(d) Health & Safety Data Reporting' submissions screen. You can create or modify a Section 8(d) Health & Safety Data Reporting submission using the 'Section 8(d) Health & Safety Data Reporting' submissions screen. For additional details about the 'Section 8(d) Health & Safety Data Reporting' submissions screen, please refer to **Section 3.4.1.**
- **User Management:** Click the 'User Management' link or tab to navigate to the 'User Management' screen. You can manage the access rights of Supports per submission using the 'User Management' screen. For additional details about the 'User Management' screen, please refer to **Section 3.3**.
- **Resources:** Click the 'Resources' link or tab to navigate to the 'Resources' screen. You can find the Section 8(d) Health & Safety Data Reporting user guide, as well as useful links for further usability instruction on the 'Resources' screen. For additional details about the 'Resources' screen, please refer to **Section 8**.

Exhibit 3-2 shows a screen capture for the Section 8(d) Health & Safety Data Reporting 'Home' screen:

Exhibit 3-2: Section 8(d) Health & Safety Data Reporting Home Screen



Navigation: Click the 'User Management' link or tab to access the 'User Management' screen and assign Supports.

3.3 User Management

You can access the 'User Management' screen by clicking the 'User Management' link from the Section 8(d) Health & Safety Data Reporting 'Home' screen, or by clicking the 'User Management' tab from the application header.

On the 'User Management' screen, you can assign Supports to fill out a Section 8(d) Health & Safety Data Reporting submission. You have the ability to assign one or more Supports to have access to the 'Section 8(d) Health & Safety Data Reporting' application to modify submissions you created. You must first create a new submission before you can assign Supports. For instructions on how to create a new submission, please refer to **Section 3.4**.

Submission Alias: No values will be available in this menu until a submission has been created. For instructions on how to create a new submission, please refer to **Section 3.4**. Select a submission from the 'Submission Alias' drop-down menu to begin assigning Supports. Once a submission has been selected, the 'Assign Users' group box will update to display the Supports who have identified you as their AO during CDX registration.

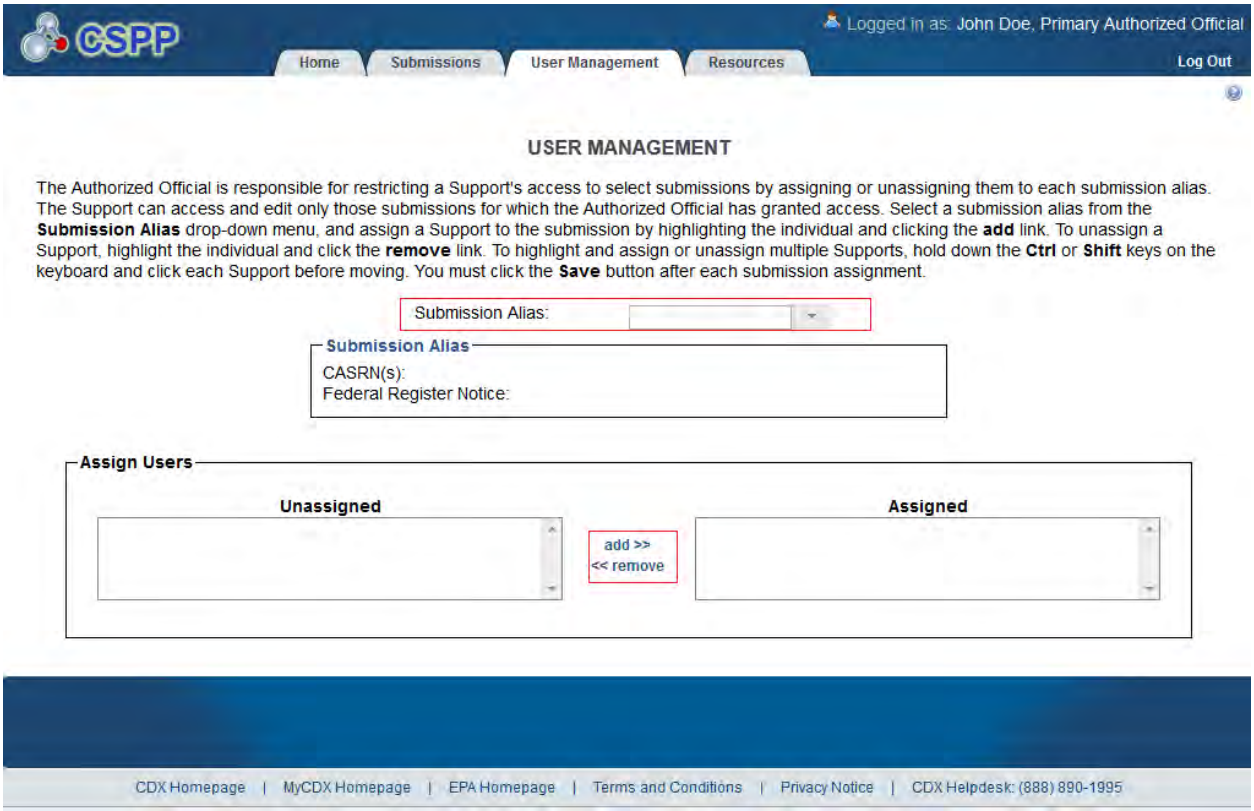
Assign Users to Submission: This box shows all the Supports you can assign to complete a Section 8(d) Health & Safety Data Reporting submission for the selected submission. To move Supports from the 'Unassigned' group box to the 'Assigned' group box, highlight individual or multiple Supports and click the 'add >>' button. To move Supports from the 'Assigned' group box to the 'Unassigned' group box, highlight individual or multiple Supports and click the '<<remove' button.

- **Unassigned:** This box contains the Supports who have identified you as their AO that can be assigned to access and edit the selected submission. To highlight multiple Supports, hold down the <Ctrl> key on your keyboard while clicking each Support. To highlight multiple consecutive Supports, hold down the <Shift> key on your keyboard while clicking the first and last Supports in the list.
- **Assigned:** This box contains the Supports who have been given permission, by you, to access and edit the selected submission. To move Supports from the 'Assigned' group box to the 'Unassigned' group box, highlight individual or multiple Supports and click the '<< remove' button. To highlight multiple Supports hold down the <Ctrl> key on your keyboard and click each Support. To highlight multiple consecutive Supports, hold down the <Shift> key on your keyboard and click the first and last Supports in the list.

When you have finished assigning Supports, click the 'Save' button to save the selection. To navigate away from the 'User Management' screen, you can click the CSPP logo, 'Home' tab 'Submissions' tab or 'Resources' tab located within the application header.

Exhibit 3-3 shows a screen capture of the 'User Management' screen:

Exhibit 3-3: User Management Screen



Navigation: Click the 'Submissions' tab located within the application header to navigate to the 'Section 8(d) Health & Safety Data Reporting' submissions screen.

3.4 Create New Submission

As a Primary AO, you can create, modify, delete a new submission, and assign your Supports to complete identified submissions.

3.4.1 Section 8(d) Health & Safety Data Reporting Submissions

You can access the 'Section 8(d) Health & Safety Data Reporting' submissions screen by clicking the 'Submissions' link from the Section 8(d) Health & Safety Data Reporting 'Home' screen or by clicking the 'Submissions' tab located within the application header.

Each column within the table of the 'Section 8(d) Health & Safety Data Reporting' submissions screen can be sorted by clicking the column headers.

Start a New Submission: To create a new Section 8(d) Health & Safety Data Reporting submission, select a Federal Register Notice (FRN) from the 'Select Applicable CFR/FRN' drop-down menu for the chemical substance you are reporting, and click the 'Start New Submission' button. You will be required to create a passphrase that will be associated with that particular submission. Make sure to create a passphrase that you will remember, as it cannot be retrieved or reset. Refer to **Section 3.4.2** for further instructions on creating a passphrase.

Edit a Submission: To modify an existing Section 8(d) Health & Safety Data Reporting submission, click the 'Submission Alias' link for a submission that has a status of 'In Progress'

within the 'Status' column. You will be required to enter the passphrase associated with that particular submission to access and continue editing the submission.

Creating Amendments: To edit a submitted Section 8(d) Health & Safety Data Reporting submission (i.e., to create an amendment), you must first unlock the particular submission by clicking the 'Lock' icon ( ) under the 'Action' column. You will be required to enter the passphrase associated with that particular submission to gain access and amend the submission. All further changes will be submitted as an amendment. Refer to **Section 7** for further instructions on creating an amendment.

The 'Section 8(d) Health & Safety Data Reporting' submissions screen displays the following column headers:

- **Submission Alias:** Displays a clickable link for submissions with a status of 'In Progress.' Clicking this link will navigate you to the 'Enter Passphrase' screen.
- **FRN/CFR:** Displays the FRN or CFR.
- **CASRN:** Displays the Chemical Abstract Services Registry Number (CASRN). The 'CASRN' column will display as blank until you have identified the submission type and started a new submission.
- **Last Modified:** Displays the date the submission was last accessed.
- **Submission Date:** Displays the date the form was submitted to CDX. This date populates only after you complete a submission.
- **Copy of Record:** Click the 'Copy of Record' icon to navigate to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Login' screen and continue the download copy of record process. The 'Copy of Record' icon is displayed only after you complete the submission. The 'Copy of Record' icon is confirmation that your submission was successfully received by EPA. Click the 'Copy of Record' icon to download the copy of record to your hard drive. Note that the 'Copy of Record' icon may take 15-20 minutes to display on the 'Section 8(d) Health & Safety Data Reporting' submissions screen. Refer to **Section 6** for further instructions on downloading the copy of record.
- **Action:** Displays a 'Delete' icon ( ) for all submissions with a status of 'In Progress.' Displays a 'Lock' icon ( ) for all submissions that have been submitted. Only an AO can unlock a submission by clicking the 'Unlocked' icon ( ).

Items per page: The 'Section 8(d) Health & Safety Data Reporting' submissions screen allows you to display a specific number of submissions per page. The 'Items per page' drop-down menu allows you to view '25,' '50,' '75,' or '100' submissions per page.

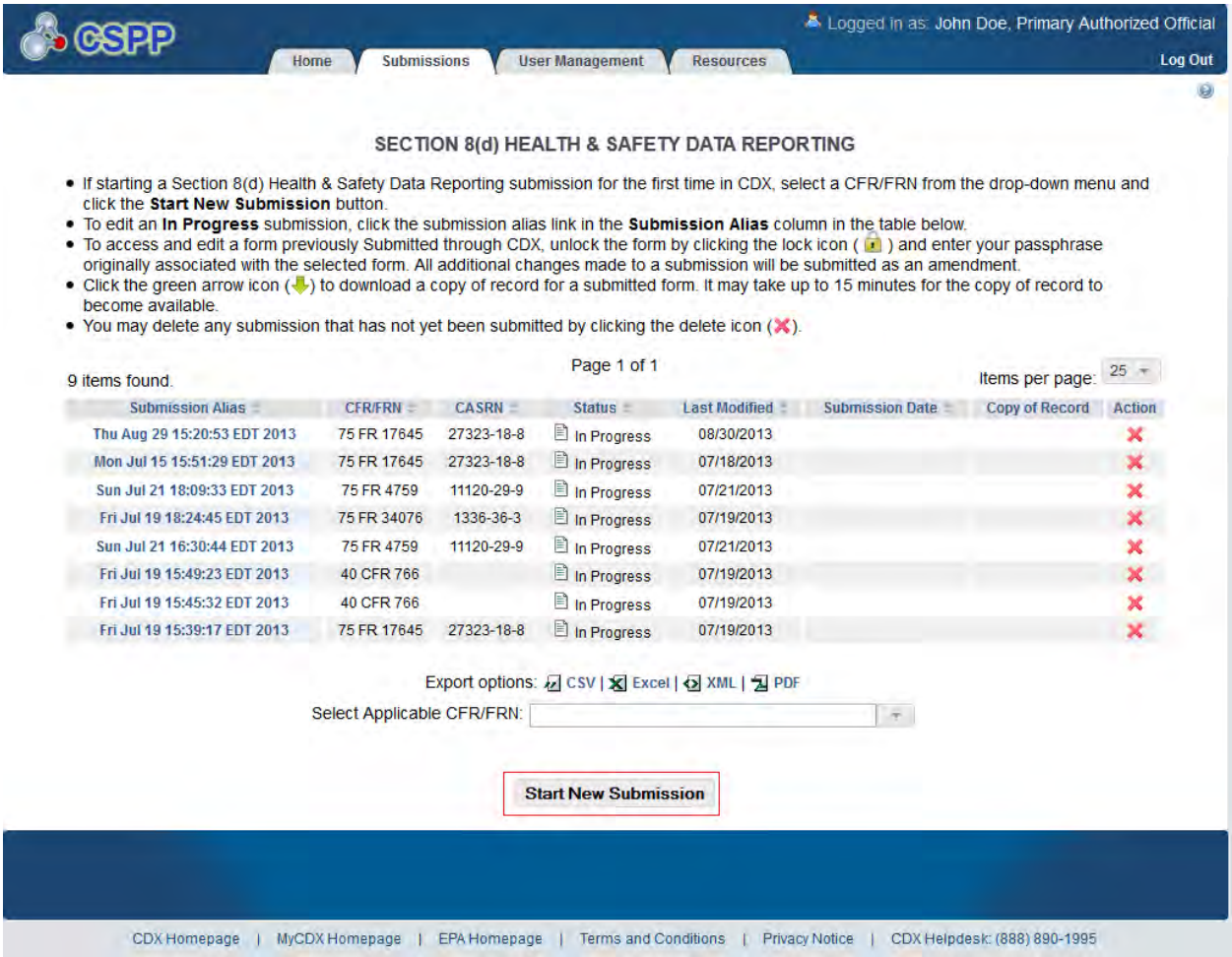
Export options: Displays 'CSV,' 'Excel,' 'XML,' and 'PDF' links for you to export the 'Section 8(d) Health & Safety Data Reporting' submissions screen in one of the specified formats as an Excel spreadsheet, Comma-Separated Values (CSV), Extensible Markup Language (XML), or Portable Document Format (PDF).

Select Applicable CFR/FRN: Displays the FRN/CFR citations that are available for the user to select and create a new submission.

Start New Submission: Click the button to start a new submission and navigate to the 'Create New Passphrase' screen.

Exhibit 3-4 shows a screen capture of the 'Section 8(d) Health & Safety Data Reporting' submissions screen:

Exhibit 3-4: Section 8(d) Health & Safety Data Reporting Submissions Screen



Navigation: Select the appropriate option from the 'Select Applicable CFR/FRN' drop-down menu and click the 'Start New Submission' button to navigate to the 'Create Passphrase' screen.

3.4.2 Create Passphrase Screen

To start a new Section 8(d) Health & Safety Data Reporting submission, select an FRN/CFR from the 'Select Applicable CFR/FRN' drop-down menu and click the 'Start New Submission' button on the 'Section 8(d) Health & Safety Data Reporting' submissions screen. The 'Create Passphrase' screen allows you to create a passphrase and associate that passphrase with the submission. The application uses the passphrase as an encryption key to protect the contents of the submission. You are responsible for remembering the passphrase and distributing it to the appropriate individuals. 'If you lose or forget the passphrase, you must create a new form and passphrase. For security reasons, the system administrator does not have access to the passphrase and will not be able to retrieve it or reset it to a new one.'

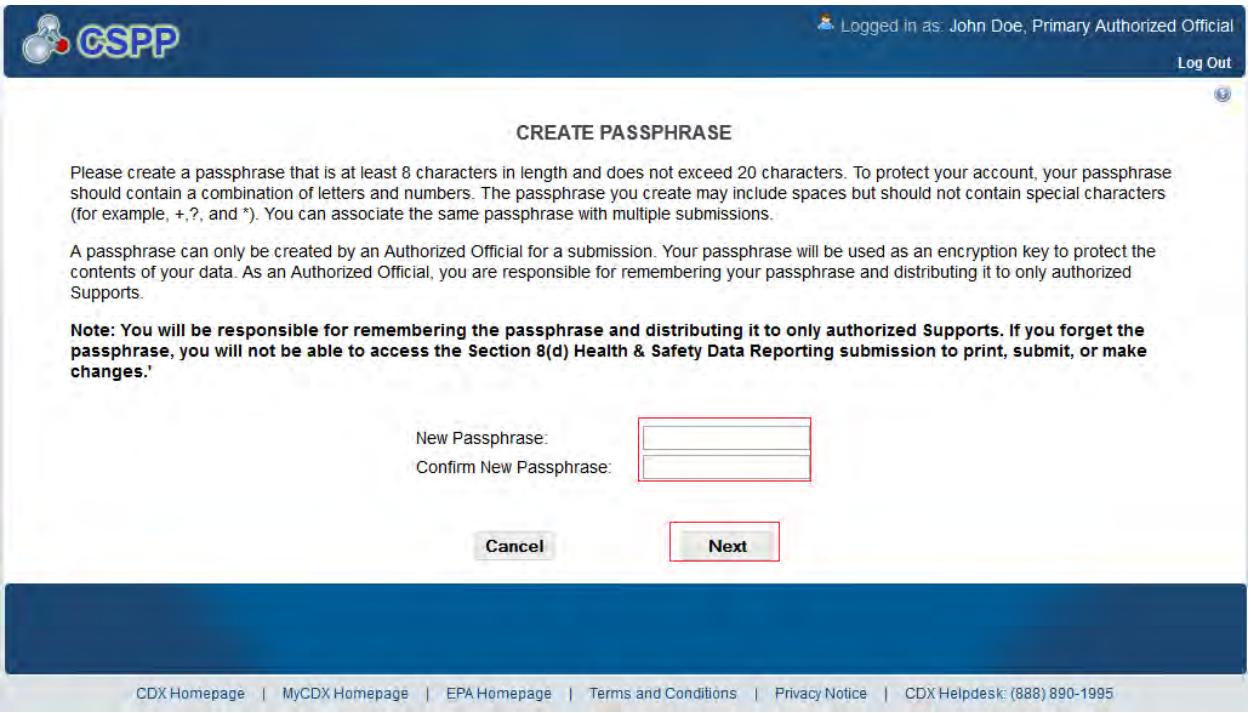
New Passphrase: To associate a passphrase with a submission, enter a passphrase that is at least 8 characters in length. To protect your account, your passphrase should contain a combination of letters and numbers. The passphrase you create may include spaces, but may not contain special

characters (for example, +, and *). You can associate the same passphrase with multiple submissions.

You will be responsible for remembering the passphrase and distributing it to only authorized Supports for the submission. If you forget the passphrase, you will not be able to access the Section 8(d) Health & Safety Data Reporting submission to print, submit, or make changes.

Exhibit 3-5 shows a screen capture of the 'Create Passphrase' screen:

Exhibit 3-5: Create Passphrase Screen



Navigation: Create a passphrase and click the 'Next' button to navigate to the 'General Submission Information' screen.

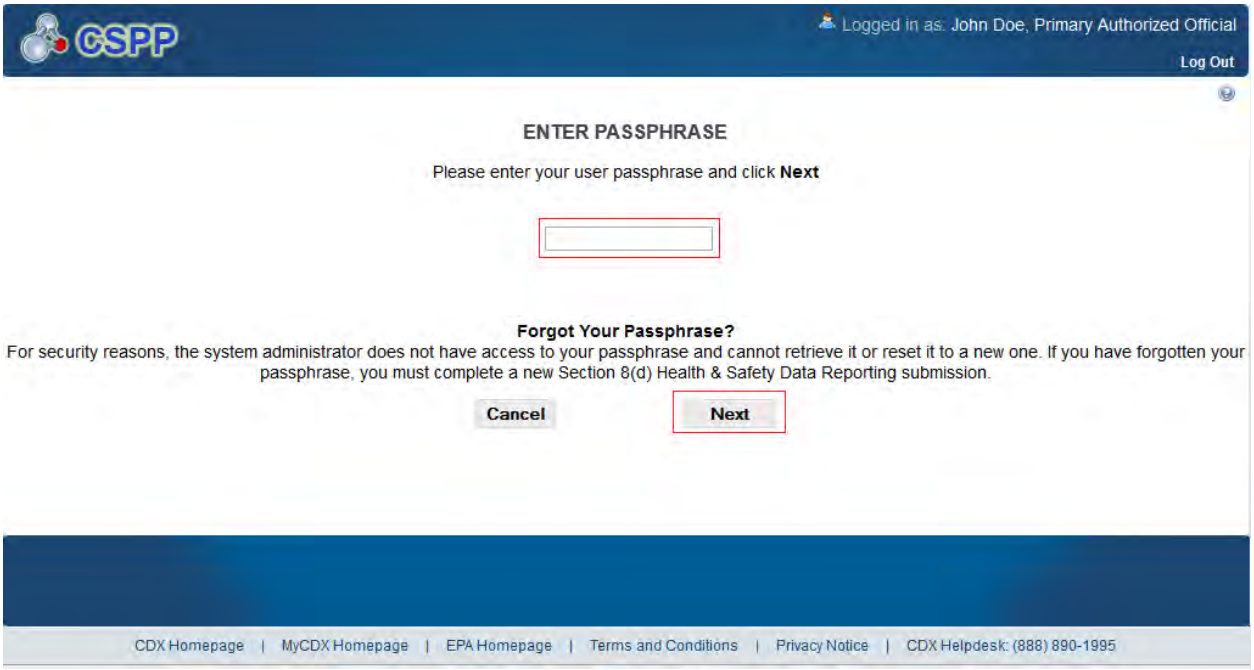
3.4.3 Enter Passphrase Screen

To access a submission that is in progress, click the 'Submission Alias' link for a submission with a status of 'In Progress' on the 'Section 8(d) Health & Safety Data Reporting' submissions screen. The 'Enter Passphrase' screen allows you to enter the passphrase that is associated with the submission.

Enter Passphrase: Enter the passphrase that you originally created and associated with the submission.

Exhibit 3-6 shows a screen capture of the 'Enter Passphrase' screen:

Exhibit 3-6: Enter Passphrase Screen



Navigation: Enter the passphrase that you originally created and associated with the submission and click the 'Next' button to navigate to the 'General Submission Information' screen.

3.4.4 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 submission 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 3-7 shows a screen capture of the navigation prompt window:

Exhibit 3-7: Navigation Prompt

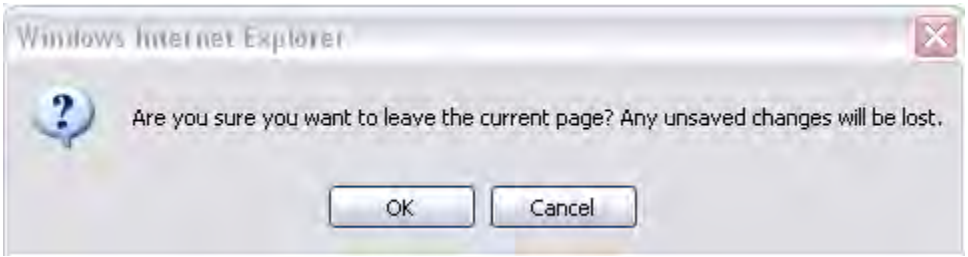
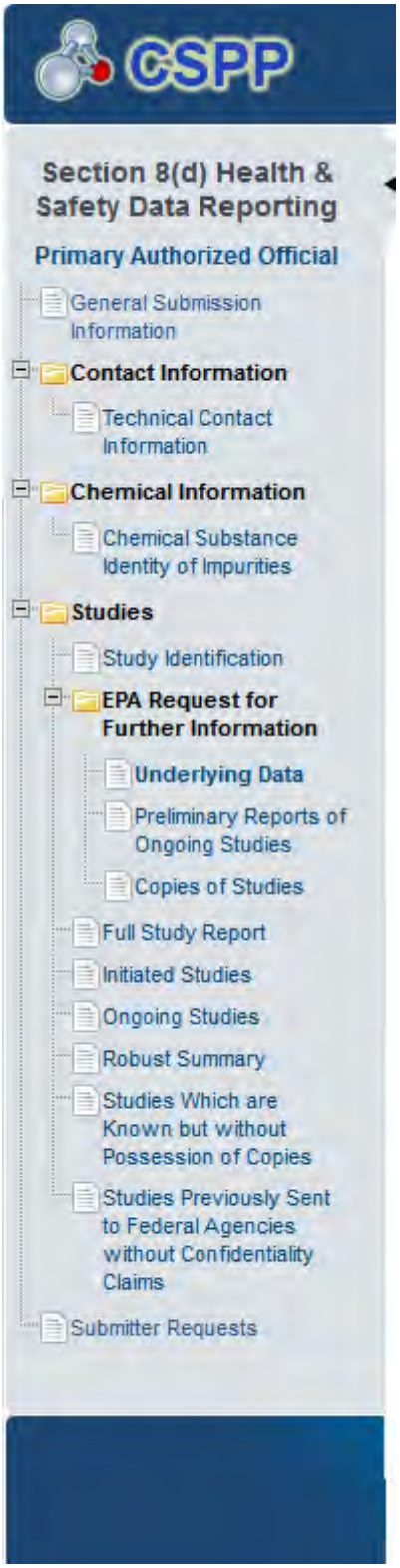


Exhibit 3-8 shows the screen capture of the navigation tree:

Exhibit 3-8: Navigation Tree



3.4.5 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 8(d) Health & Safety Data Reporting submission to check for certain types of errors in a submission. A 'Section 8(d) Health & Safety Data Reporting Validation' pop-up window generates when you click the 'Validate' icon ( ). The 'Section 8(d) Health & Safety Data Reporting Validation' pop-up window displays a report of all validation errors relating to a failed validation. Refer to **Section 4** for more information on validating a submission.

The following exhibits Exhibit 3-9, Exhibit 3-10, Exhibit 3-11, and Exhibit 3-12 show the screen captures for the action bar:

Exhibit 3-9: Action Bar – Validate

- **Save:** You can click the 'Save' icon ( ) at any stage of completing a Section 8(d) Health & Safety Data Reporting 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 3-10: Action Bar – Save

- **Preview:** You can click the 'Preview' icon ( ) at any stage of completing a Section 8(d) Health & Safety Data Reporting submission to preview the submission. After you click the 'Preview' icon ( ), a watermarked PDF version of the submission will generate.

Exhibit 3-11: Action Bar – Preview

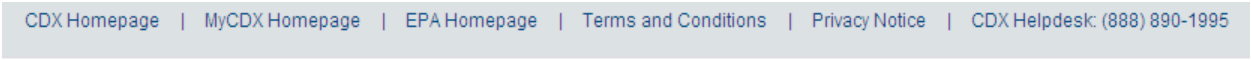
- **Submit:** You can click the 'Submit' icon ( ) to submit the Section 8(d) Health & Safety Data Reporting submission or amendments after you or an assigned Support have completed all required sections of the Section 8(d) Health & Safety Data Reporting submission. After you click the 'Submit' icon ( ), the validation process is initiated. Refer to **Section** 4 for further instructions on validation errors. You can continue with the submission process only after clearing all validation errors. Refer to **Section 3.5** for more information on submitting a Section 8(d) Health & Safety Data Reporting submission to EPA via CDX.

Exhibit 3-12: Action Bar – Submit

- **Help Links:** You can click any of the 'Help' link, located at the bottom of each screen, at any stage of completing a Section 8(d) Health & Safety Data Reporting 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 Health & Safety Data Reporting' link, you will be taken to the CDX Privacy and Security Health & Safety Data Reporting screen.

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

Exhibit 3-13: Action Bar – Links



3.4.6 General Submission Information Screen

You can access the 'General Submission Information' screen by clicking the 'Start New Submission' button and creating a new passphrase, or by accessing a Section 8(d) Health & Safety Data Reporting submission that is in progress by clicking the 'In Progress' link and entering the passphrase associated with the selected submission.

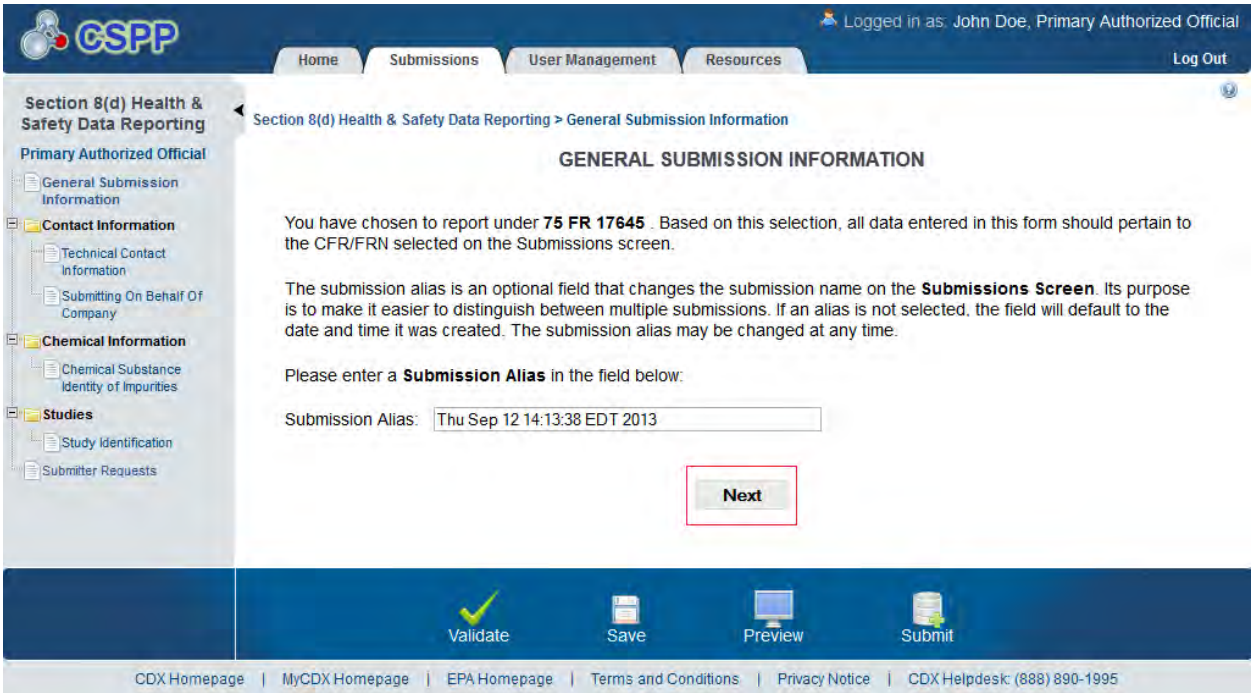
The system allows you to edit the submission alias associated with the submission. If you choose not to edit the submission alias, the field remains populated with a date and time stamp for when the submission was created.

The following text field is displayed on the 'General Submission Information' screen:

- **Submission Alias:** This field is auto-populated with a date and time stamp and displays on the 'Section 8(d) Health & Safety Data' submission screen within the 'Submission Alias' column. This field is editable should you choose to provide your own submission alias.

Exhibit 3-14 shows the screen capture for the 'General Submission Information' screen:

Exhibit 3-14: General Submission Information Screen



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

3.4.7 Technical Contact Information Screen

You can access the 'Technical Contact Information' screen by clicking the 'Next' button from the 'General Submission Information' screen or by clicking the 'Technical Contact Information' link within the navigation tree.

The 'Technical Contact Information' screen provides a 'This is a submission on behalf of another company' checkbox to indicate that you will be submitting on behalf of another company.

If you are submitting on behalf of another company, check the 'This is a submission on behalf of another company' checkbox. This functionality has been implemented to accommodate a company that may use an agent or another individual to submit on their behalf. If this checkbox is checked, the information of the manufacturing or processing establishment is entered into the 'Submitting on Behalf Of Company' screen. To claim contact information as Confidential Business Information (CBI), check the 'CBI' checkbox.

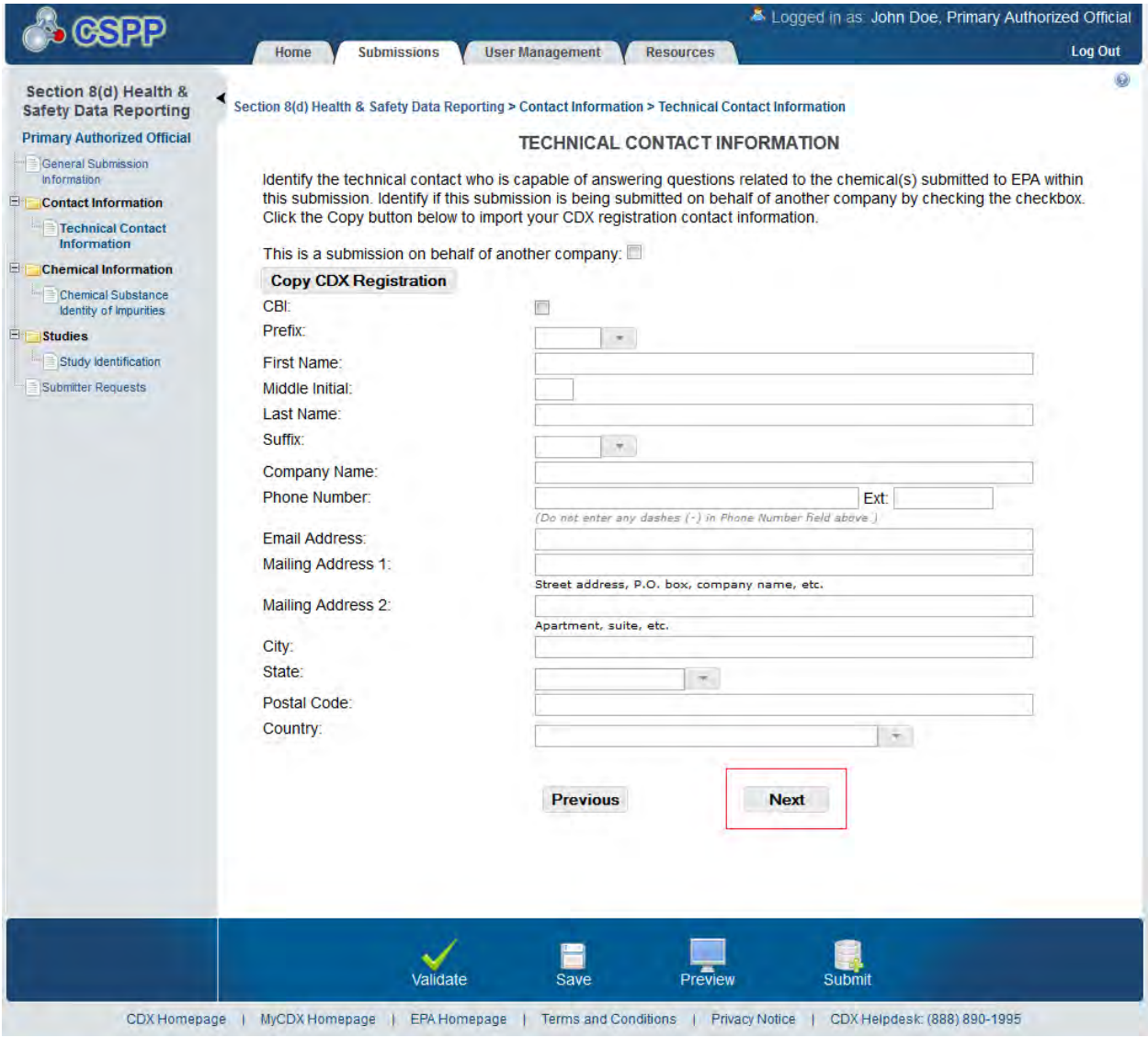
- **This is a submission on behalf of another company:** Check the 'This is a submission on behalf of another company' check box to identify that you are submitting on behalf of another company.
- **Copy CDX Registration:** Click the 'Copy CDX Registration' button to identify that you are the technical contact. The system will populate the fields with your contact information provided during CDX registration.

- **CBI:** Check the 'CBI' checkbox to claim the 'Technical Contact Information' as CBI.
- **Prefix:** The 'Prefix' drop-down menu displays all optional prefixes. If applicable, select the appropriate prefix. If you click 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 clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Middle Initial:** Enter the technical contact's middle initial. If you 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 clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Suffix:** The 'Suffix' drop-down menu displays all optional suffixes. If applicable, select the appropriate suffix. If you 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 clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Phone Number:** Enter the technical contact's daytime phone number; U.S. or international. If you clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **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 clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Mailing Address 1:** Enter the first line of the technical contact's mailing address. If you clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Mailing Address 2:** Enter the second line of the technical contact's mailing address. If you 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 clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **State:** Displays all available states. Enter the state of the technical contact's mailing address. If you 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 clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.
- **Country:** Displays all available countries. Select the country of the technical contact's mailing address. If you clicked the 'Copy CDX Registration' button, the fields populate with information entered during CDX registration. This is a required field.

Exhibit 3-15 shows the screen capture of the 'Technical Contact Information' screen:

Exhibit 3-15: Technical Contact Information Screen



Navigation: Click the 'Next' button to navigate to the 'Chemical Substance Identity of Impurities' screen. You can also access this screen by clicking the 'Chemical Substance Identity of Impurities' link within the navigation tree. If you are submitting on behalf of another company, click the 'Next' button to navigate 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 after clicking the 'Save' icon located within the bottom action bar.

3.4.8 Submitting on Behalf Of Company Screen

You can access the 'Submitting on Behalf of Company' screen by checking the 'This is a submission on behalf of another company' checkbox 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.

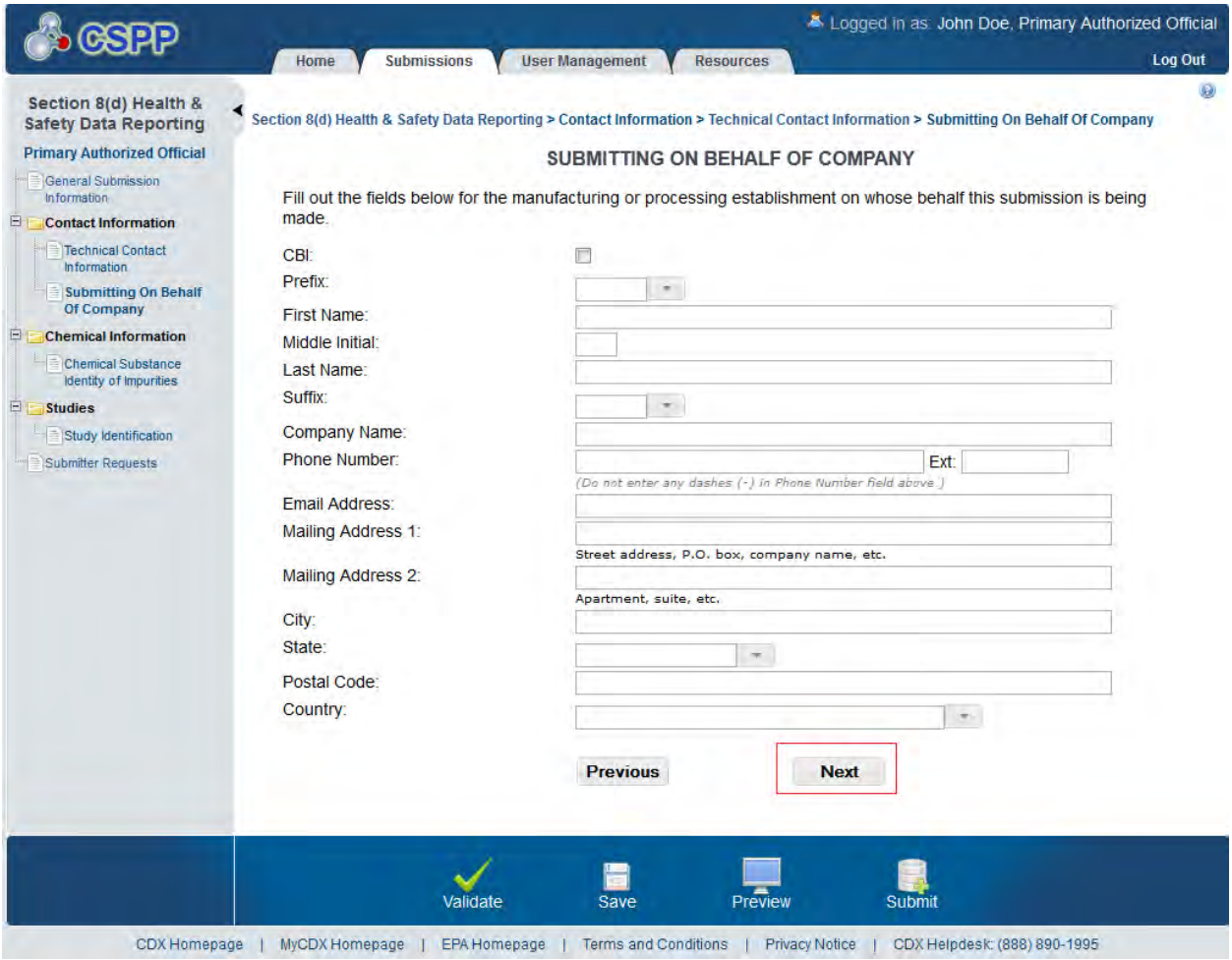
The 'Submitting on Behalf of Company' screen presents a list of fields for you to input the contact information for the manufacturing or processing establishment on whose behalf the submission is being made.

- **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 3-16 shows the screen capture of the 'Submitting on Behalf of Company' screen:

Exhibit 3-16: Submitting on Behalf of Company Screen



Navigation: Click the 'Next' button to navigate to the 'Chemical Substance Identity of Impurities' screen. You can also access this screen by clicking the 'Chemical Substance Identity of Impurities' link within the navigation tree.

3.4.9 Chemical Substance Identity of Impurities Screen

You can access the 'Chemical Substance Identity of Impurities' screen by clicking the 'Next' button from the 'Submitting on Behalf Of Company' screen, or the 'Technical Contact Information' screen. You can also access this screen by clicking the 'Chemical Substance Identity of Impurities' link within the navigation tree.

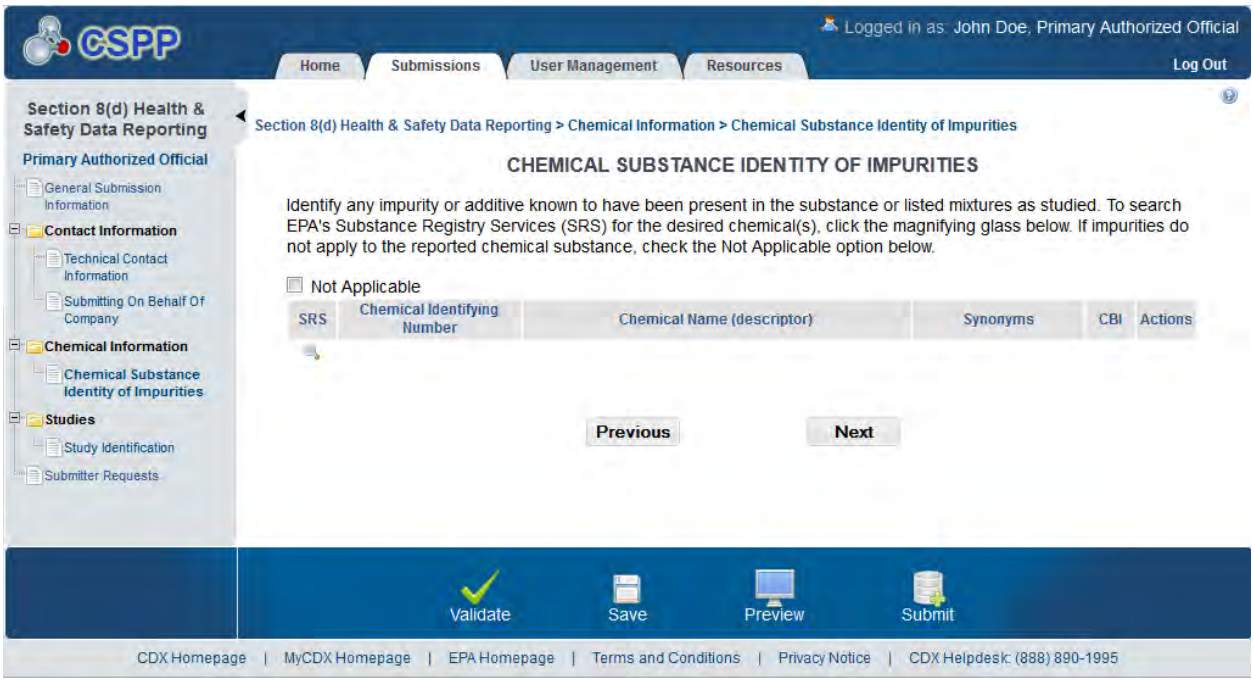
The 'Chemical Substance Identity of Impurities' screen provides fields for you to identify impurities or additives known to have been present in the substance or listed mixtures as studied. To identify chemical impurities you must access the Substance Registry Services (SRS). The

system leverages the services provided by SRS. To search SRS, click the 'Search' icon ( ) within the 'SRS' column of the Chemical Substance Identity of Impurities table. Clicking the 'Search' icon ( ) generates the SRS pop-up window. You can search for the chemical(s) being reported by the 'CASRN,' 'CAS Index Name or Synonym,' 'Accession Number,' or 'Generic Name.'

- **Not Applicable:** If the 'Not Applicable' checkbox is unchecked and you click the 'Next' button, the system will prompt you with an error message indicating a chemical must be populated by searching for a chemical or to check the 'Not Applicable' checkbox.
- **Search SRS:** Clicking the 'Search' icon **( )** will generate a 'Search SRS' pop-up window.
- **Chemical Identifying Number:** Displays the chemical identifying number for the specified chemical substance.
- **Chemical Name (descriptor):** Displays the chemical name (or descriptor) of the chemical(s) being reported on.
- **Synonym:** Displays the chemical synonym(s) identified by the user within the 'Chemical Not Found in Substance Registry Services' window.
- **CBI:** Displays the CBI status of the identified chemical substance by displaying either a 'Y' or an 'N.' A chemical substance retrieved via CASRN or CA Index Number or Other Synonym cannot be claimed as CBI. Only chemical substances retrieved via accession number or generic name, or chemical substances not found within the SRS search can be claimed as CBI. A CBI checkbox will populate the table allowing you to select the applicable chemical as CBI.
- **Actions:** Click the 'Delete' icon ( ) to remove the chemical within the specific row.

Exhibit 3-17 shows the screen capture of the 'Chemical Substance Identity of Impurities' screen:

Exhibit 3-17: Chemical Substance Identity of Impurities Screen



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

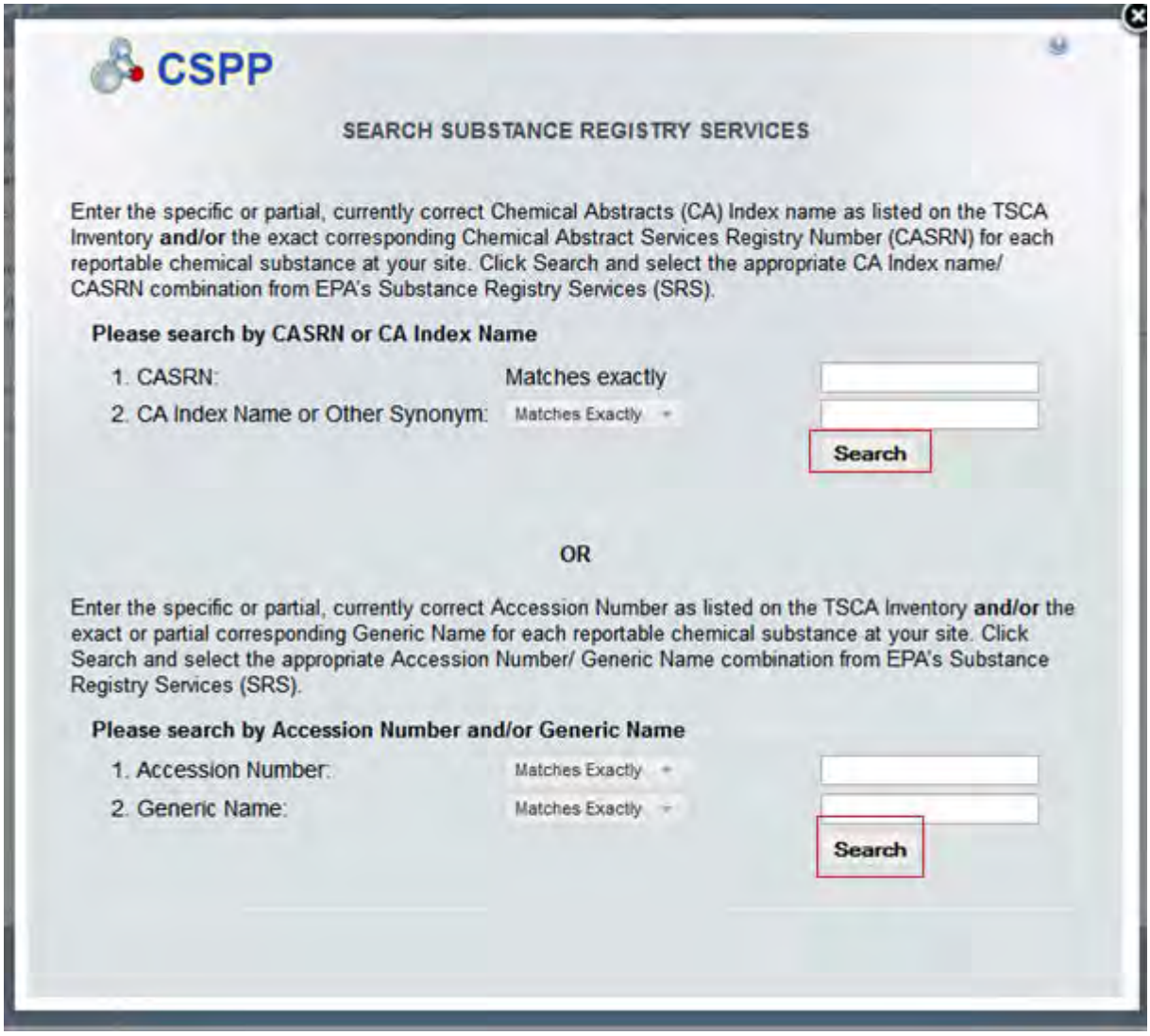
3.4.9.1 Search Substance Registry Services

To access SRS, click the ‘Search’ icon ( ). Clicking the ‘Search’ icon ( ) generates the ‘Search SRS’ pop-up window. You can search for the chemical(s) being reported by the ‘CASRN,’ ‘CA Index Name or Other Synonym,’ ‘Accession Number,’ or ‘Generic Name.’ After you have searched, selected a chemical, and clicked the ‘OK’ button, the selected chemical information will populate the Chemical Substance Identity of Impurities table. If the chemical is not listed on the public TSCA Inventory list, you may claim the chemical as CBI, once the chemical is displayed on the Chemical Substance Identity of Impurities table. See Section 3.4.9.2 below if you do not know the CAS or Accession Number.

- **CASRN:** Enter the CASRN of the chemical.
- **CA Index Name or Other Synonym:** Enter the CA Index Name or Other Synonym. Displays the following search options: ‘Contains,’ ‘Begins With,’ and ‘Matches Exactly.’
- **Accession Number:** Enter the accession number of the chemical. Displays the following search options: ‘Contains,’ ‘Begins With,’ and ‘Matches Exactly.’
- **Generic Name:** Enter the generic name. Displays the following search options: ‘Contains,’ ‘Begins With,’ and ‘Matches Exactly.’

Exhibit 3-18 shows the screen capture for the ‘Search Substance Registry Services’ pop-up window:

Exhibit 3-18: Search Substance Registry Services Pop-Up Window



Navigation: Clicking the 'Search' button will generate search results. The 'OK,' 'Cancel,' and 'X' buttons will close the 'Search SRS' pop-up window.

3.4.9.2 Chemical Not Found in Substance Registry Services

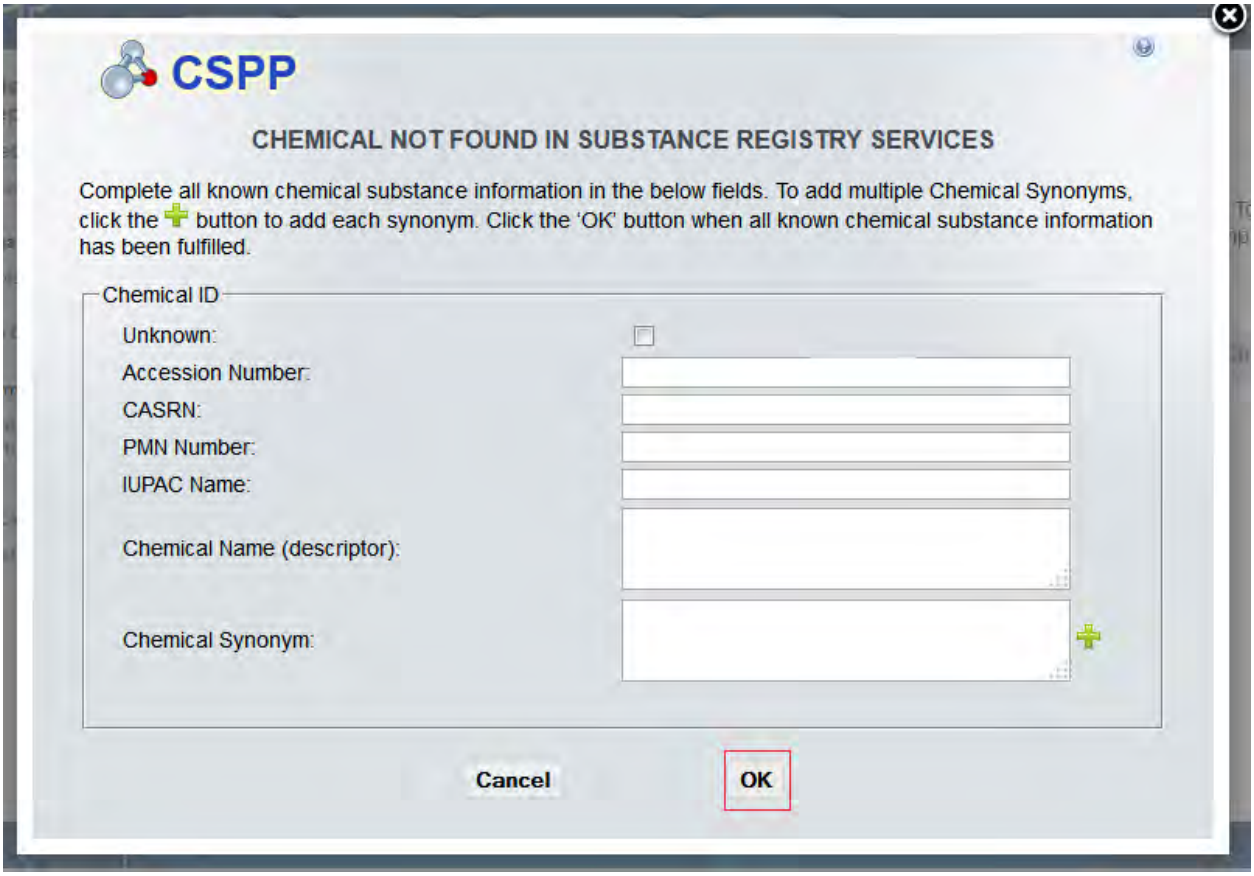
You can access the 'Chemical Not Found in Substance Registry Services' screen by entering known information into the SRS window and performing a search. If there are no results, a message will be returned stating 'There were no results returned.' If you are sure the chemical does not exist in SRS, please click the 'Create New Chemical' button to enter the chemical information. Clicking the 'Create New Chemical' button on the 'Search Substance Registry Services' screen takes you to the 'Chemical Not Found in Substance Registry Services' screen. Click the 'Cancel' button to go back to the 'Search Substance Registry Services' screen. When entering information into the 'Chemical Not Found in Substance Registry Services' screen at least one of the following four fields is required; 'Accession Number,' 'CASRN,' 'Premanufacture Notice (PMN) Number,' or 'International Union of Pure and Applied Chemistry (IUPAC) Name'

If you do not know the accession number, CASRN, PMN number, or IUPAC name, check the 'Unknown' checkbox. Once you check the 'Unknown' checkbox, the above-mentioned fields are disabled and you are only required to enter a chemical name (or descriptor).

- **Unknown:** Checking the 'Unknown' checkbox disables the 'Accession Number,' 'CASRN,' 'PMN Number,' and 'IUPAC Name' fields and requires you to enter the chemical name in the 'Chemical Name (descriptor)' field.
- **Accession Number:** If known, enter the accession number of the chemical.
- **CASRN:** If known, enter the CASRN of the chemical.
- **PMN Number:** If known, enter the PMN number of the chemical.
- **IUPAC Name:** If known, enter the IUPAC name of the chemical.
- **Chemical Name (descriptor):** Enter the chemical name/descriptor of the chemical being reported. This is a required field when the 'Unknown' checkbox is checked.

Exhibit 3-19 shows the screen capture for the 'Chemical Not Found in Substance Registry Services' pop-up window:

Exhibit 3-19: Chemical Not Found in Substance Registry Services Pop-Up Window



Navigation: Clicking the 'OK,' 'Cancel,' and 'X' buttons will close the 'Chemical Not Found In SRS' pop-up window. Click the 'OK' button to populate the table on the 'Chemical Substance Identity of Impurities' screen. Click the 'Cancel' button to navigate back to the 'Search

Substance Registry Services' pop-up window. Click the 'X' icon to close the pop-up window and your information will not be saved.

3.4.10 Study Identification Screen

You can navigate to the 'Study Identification' screen by clicking the 'Next' button from the 'Chemical Substance Identity of Impurities' screen. You can also access this screen by clicking the 'Study Identification' link within the navigation tree.

The 'Study Identification' screen provides checkboxes for you to identify the study type(s) being submitted. To identify the submission study type, check each option that applies to the Section 8(d) Health & Safety Data Reporting submission. The following checkbox options are displayed within the 'Study Identification' screen:

- **Not Applicable:** Check the 'Not Applicable' checkbox to claim that there are no applicable studies. A pop-up message displays to confirm this selection.
- **Full Study Report:** Check the 'Full Study Report' checkbox to indicate the desired submission study type.
- **Initiated Studies:** Check the 'Initiated Studies' checkbox to indicate the desired submission study type.
- **Ongoing Studies:** Check the 'Ongoing Studies' checkbox to indicate the desired submission study type.
- **Robust Summary:** Check the 'Robust Summary' checkbox to indicate the desired submission study type.
- **Studies Which are Known but are without Possession of Copies:** Check the 'Studies Which are Known but are without Possession of Copies' checkbox to indicate the desired submission study type.
- **Studies Previously Sent to Federal Agencies without Confidentiality Claims:** Check the 'Studies Previously Sent to Federal Agencies without Confidentiality Claims' checkbox to indicate the desired submission study type.

The following checkbox options are only available when you are amending a previous submission. Please refer to **Section 3.5** for additional information:

- **EPA Request for Submission of Further Information**
  - **Underlying Data:** Check the 'Underlying Data' checkbox to indicate the desired submission study type.
  - **Preliminary Report of Ongoing Studies:** Check the 'Preliminary Report of Ongoing Studies' checkbox to indicate the desired submission study type.
  - **Copies of Studies:** Check the 'Copies of Studies' checkbox to indicate the desired submission study type.

Once you have checked all appropriate submission study types and saved your selections by either clicking the 'Save,' 'Previous,' or 'Next' buttons, the navigation tree is populated with the selected study type screen titles.

Each study type is dynamically related to specific metadata and each study type chosen from the 'Study Identification' screen populates within the navigation tree as a new screen. Only the study

type options you select are displayed within the navigation tree. You can navigate to each selected study type screen by clicking the desired link within the navigation tree or navigating using the 'Previous' and 'Next' buttons. Each study type screen will display all entered information as well as all attached documentation.

Exhibit 3-20 shows the screen capture for the 'Study Identification' screen:

Exhibit 3-20: Study Identification Screen

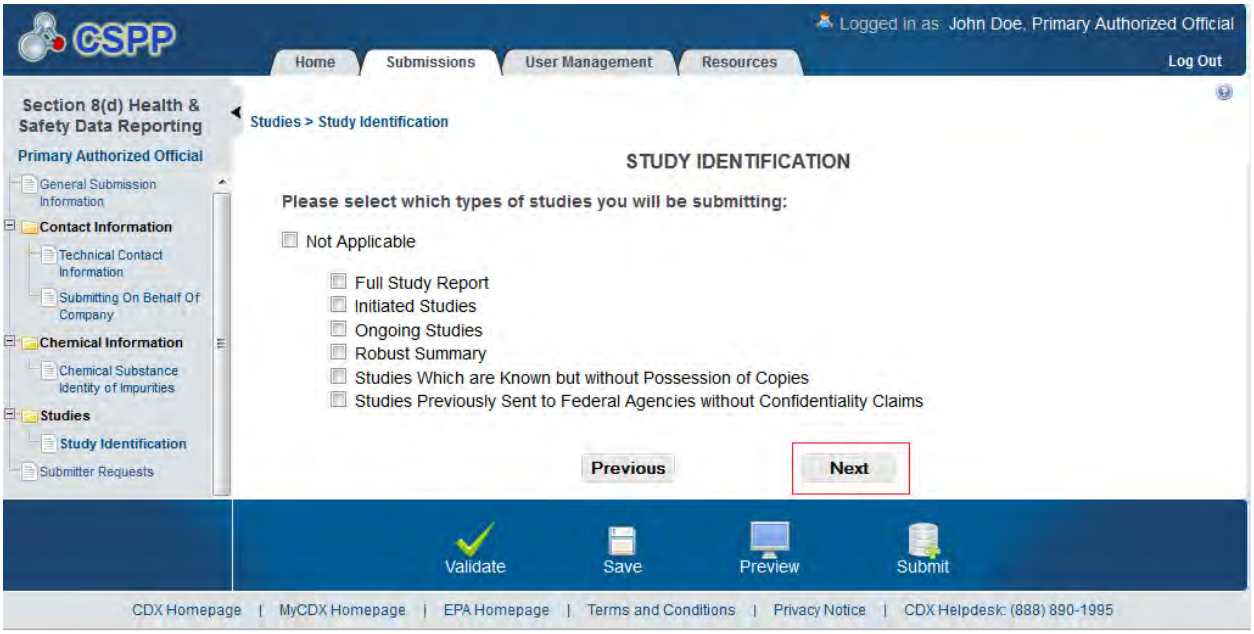
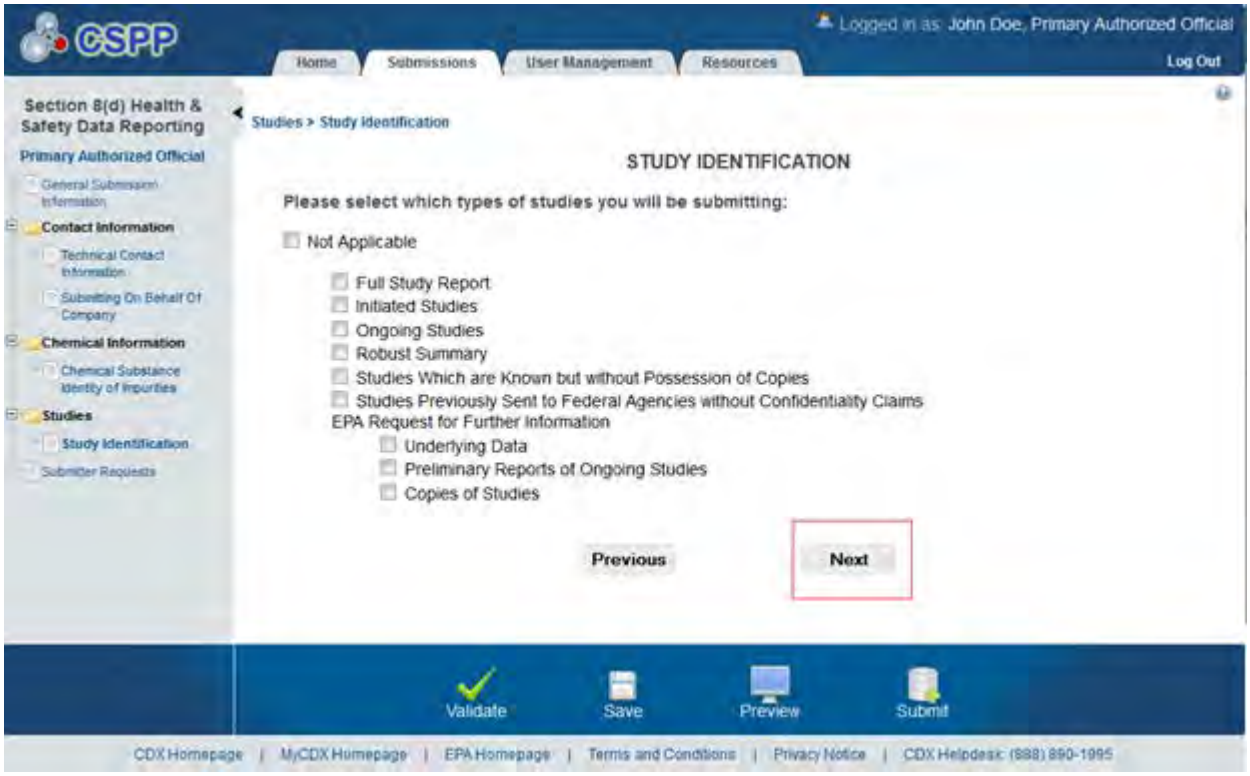


Exhibit 3-21 shows the screen capture for the 'Study Identification' screen:

Exhibit 3-21: Study Identification Screen for an Amendment



Navigation: Check the appropriate study type checkboxes for the studies you wish to submit and click the 'Next' button to navigate to the next screen from the 'Study Identification' screen. The screen following the 'Study Identification' screen depends on the item(s) selected. If you are not submitting any of the indicated study types, check the 'Not Applicable' checkbox and click the 'Next' button to navigate to the 'Submitter Request' screen.

3.4.11 Full Study Report Screen

You can access the 'Full Study Report' screen by checking the 'Full Study Report' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Full Study Report' link in the navigation tree if you previously checked the 'Full Study Report' checkbox.

To attach 'Full Study Report' documentation, click the 'Add Document' button displayed on the 'Full Study Report' screen. Clicking the 'Add Document' button generates the 'Full Study Report' pop-up window for you to upload all desired documentation. You can browse for a document from your hard drive and attach one document at a time. If you claim a document as CBI, then a sanitized copy of the document must be attached. If you fail to attach a sanitized copy of the document, the system will displays an error.

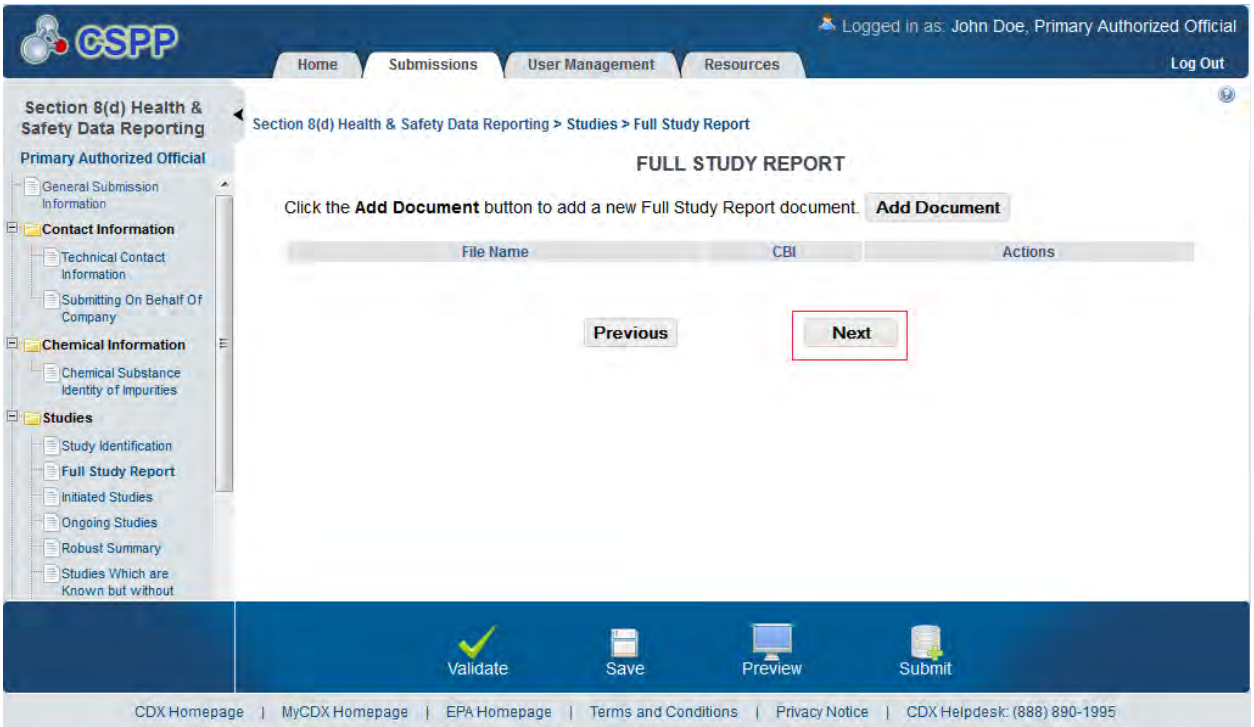
To attach multiple documents, click the 'Add Document' button on the 'Full Study Report' screen. If you claim the document as CBI then a sanitized file will need to be uploaded. Clicking the 'Browse' button will generate a pop-up window allowing you to attach a document from your hard drive. You can delete unwanted attached documents by clicking the delete icon located within the 'Action' column of the full study report table. To attach a replacement document for a document that was previously attached, click the file name link for the desired document under

the ‘File Name’ column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the ‘OK’ button.

After all required information has been completed; click the ‘Next’ button to navigate to the next study type screen that you identified on the ‘Study Identification’ screen. If you have not indicated an additional study type you will be taken to the ‘Submitter Requests’ screen.

Exhibit 3-22 shows the screen capture of the ‘Full Study Report’ screen:

Exhibit 3-22: Full Study Report Screen



Navigation: Click the ‘Next’ button to navigate to the next screen. The next screen is dependent upon your selection of submission types on the ‘Study Identification’ screen. If you have not selected another study type you will be taken to the ‘Submitter Requests’ screen upon clicking the ‘Next’ button.

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.

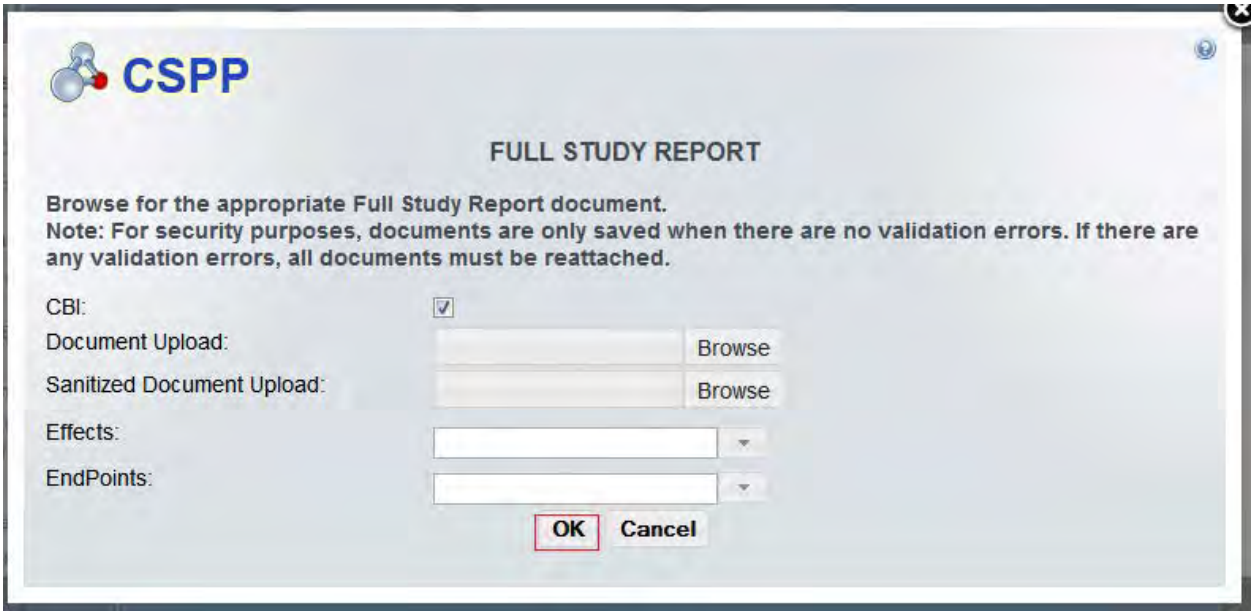
- **CBI:** Checking the ‘CBI’ checkbox will claim the uploaded document as CBI and generate a sanitized document upload field.

- **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. The drop-down menu 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 3-23 shows the screen capture of the 'Full Study Report' pop-up window:

Exhibit 3-23: Full Study Report Pop-Up Window



Navigation: Click the 'OK' button to close the 'Full Study Report' pop-up window and save the attached documents to the full study report table. Click the 'Cancel' or 'X' button to close the pop-up window and no information will be saved.

3.4.12 Initiated Studies Screen

You can access the 'Initiated Studies' screen by checking the 'Initiated Studies' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Initiated Studies' link within the navigation tree.

The 'Initiated Studies' screen provides 'Add Documents' and 'Add Studies' radio buttons. Selecting the 'Add Documents' radio button option will generate the 'Add Document' button and the initiated studies table. Clicking the 'Add Document' button generates the 'Initiated Studies' pop-up window for you to upload documentation pertaining to the initiated studies. You can claim the uploaded document as CBI by checking the 'CBI' checkbox within the 'Initiated Studies' pop-up window. A sanitized version of the document is required if you claim the attached document as CBI.

If you select the 'Add Documents' radio button option, the system generates an 'Add Document' button. To attach multiple documents, click the 'Add Document' button from the 'Initiated Studies' screen. You can delete unwanted attached documents by clicking the 'Delete' icon located within the 'Action' column of the initiate's studies table. To attach a replacement document for a document that was previously attached, click the file name link for the desired document under the 'File Name' column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button.

If you select the ‘Add Studies’ radio button, the system generates an ‘Add Study’ button. Clicking the ‘Add Study’ button generates a field set to enter all required study information. You are required to identify the beginning date of the study, the purpose of the study, types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study. This information must accompany each listed entry.

The system provides the following text fields for you to enter information:

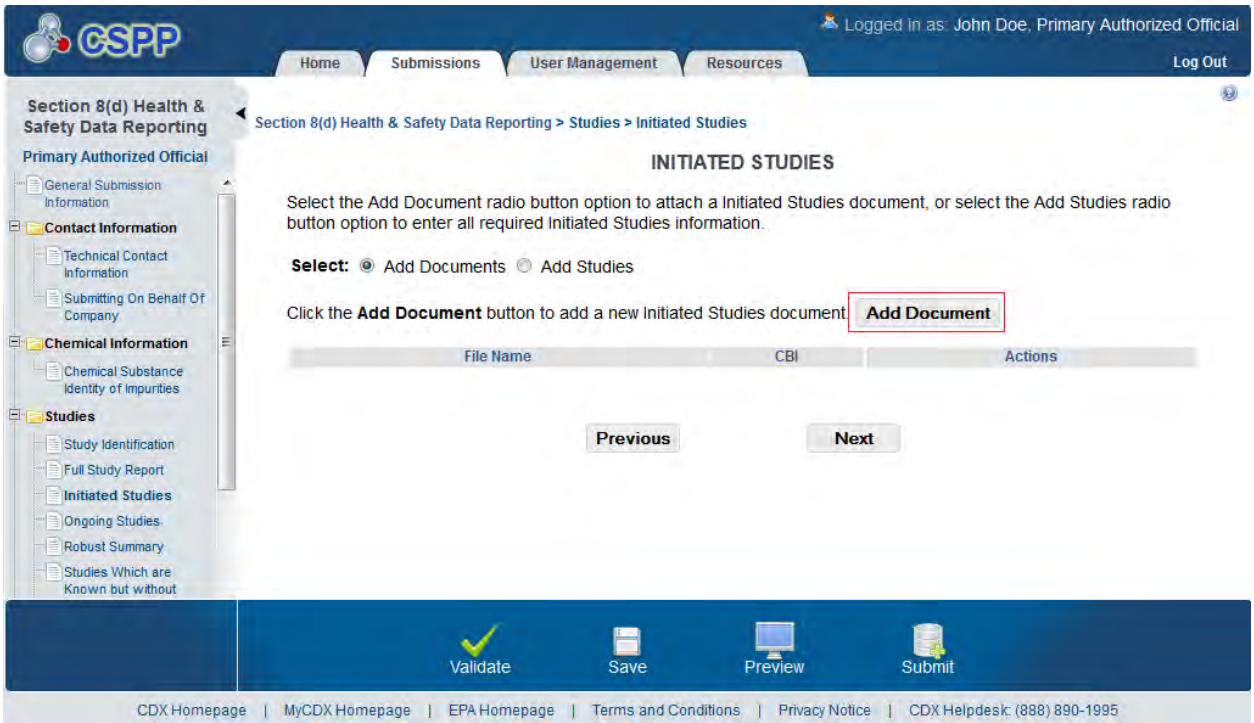
- **Add Documents:** Select the radio button to attach an initiated studies document.
- **Add Studies:** Select the radio button to enter initiated studies information.
- **Add Study:** Click the button to generate the study expandable/collapsible field set.
- **Study Title:** Enter the title of the study. This is a required field.
- **Study Start Date:** Enter the start date of the study. You can use the calendar widget to enter a date. This is a required field.
- **Study End Date:** Enter the end date of the study. You can use the calendar widget to enter a date. This is a required field.
- **Study Purpose:** Enter the purpose of the study. This is a required field.
- **Data to be Collected:** Enter the type data that will be collected throughout the duration of the specified study. This is a required field.
- **CBI:** Check the ‘CBI’ checkbox to claim the information of the laboratory conducting the study as confidential.
- **Laboratory Name:** Enter the name of the laboratory conducting the study. This is a required field.
- **Mailing Address 1:** Enter the first line of the mailing address of the laboratory conducting the study. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the laboratory conducting the study.
- **City:** Enter the city of the mailing address of the laboratory conducting the study. This is a required field.
- **State:** Select the state of the mailing address of the laboratory conducting the study. The ‘State’ field is required when ‘United States’ is selected from the ‘Country’ drop-down menu.
- **Postal Code:** Enter the postal code of the mailing address of the laboratory conducting the study. This is a required field.
- **Country:** Select the country of the mailing address of the laboratory conducting the study. This is a required field.

The system allows you to associate multiple studies to a single laboratory. Once you enter the laboratory contact information and save the entered data within the field set by clicking the ‘Save’ button, that laboratory contact information is saved to the ‘Create a new laboratory or select an existing one from the drop-down’ menu. Click the ‘Delete’ icon (✖) to delete any unwanted studies. The ‘Delete’ icon (✖) is located in the top right corner of the specified field set. Clicking the ‘Expand All’ link will expand all field sets. Likewise, clicking the ‘Collapse

All' link will collapse all field sets. To expand or collapse a field set individually, click the toggle arrow located in the top left corner of the specified field set.

Exhibit 3-24 shows the screen capture of the 'Initiated Studies' screen when you select the 'Add Document' radio button:

Exhibit 3-24: Initiated Studies Screen (Add Document)



Navigation: Click the 'Next' button to navigate to the next screen. The next screen is dependent upon your selection of submission types on the 'Study Identification' screen. If no other studies were selected you will be taken to the 'Submitter Requests' screen upon clicking the 'Next' button.

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 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 'Initiated Studies' screen, click the 'OK' button within the 'Initiates Studies' pop-up window.

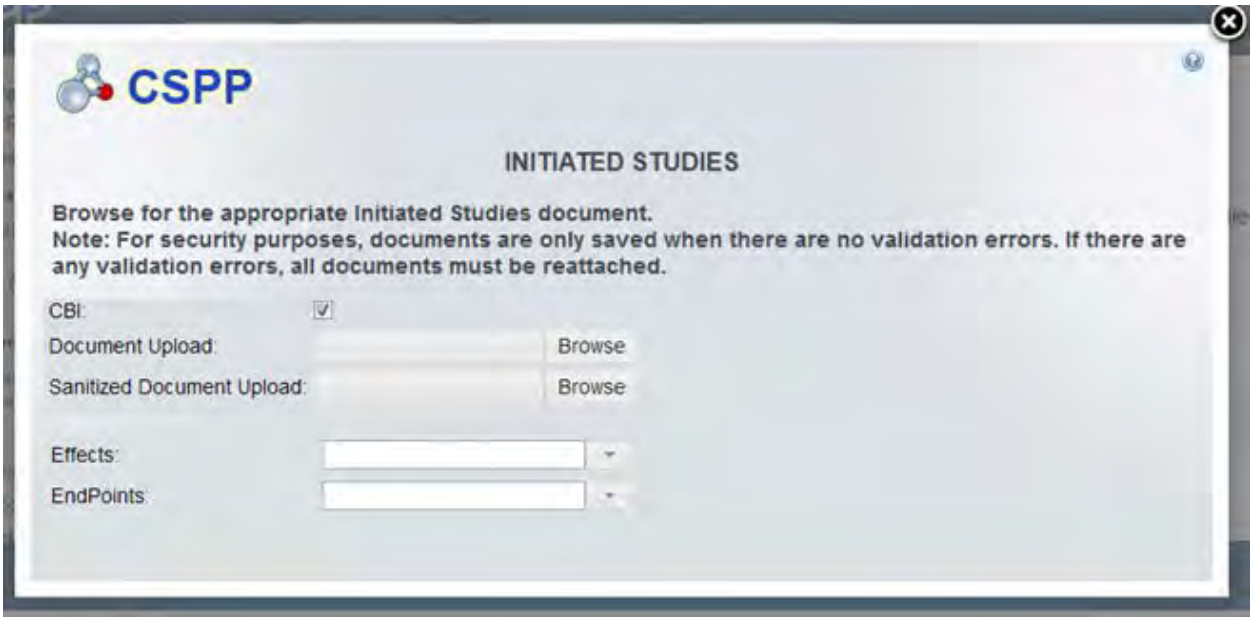
- **File Name:** Displays the file name of the initiated studies document.
- **CBI:** Indicates the CBI status of the initiated studies document by displaying either a 'Y' or an 'N.'
- **Actions:** Click the 'Delete' icon (✖) to remove a document from the system. The system displays a confirmation prompt.
- **CBI:** Check the 'CBI' checkbox to claim the uploaded document as CBI and generate a sanitized document upload field.

- **Document Upload:** Click the 'Browse' button to 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 selected. 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. This drop-down menu 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 found within each of the drop-down menus on the 'Initiated Studies' 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 3-25 shows the screen capture of the 'Initiated Studies' pop-up window:

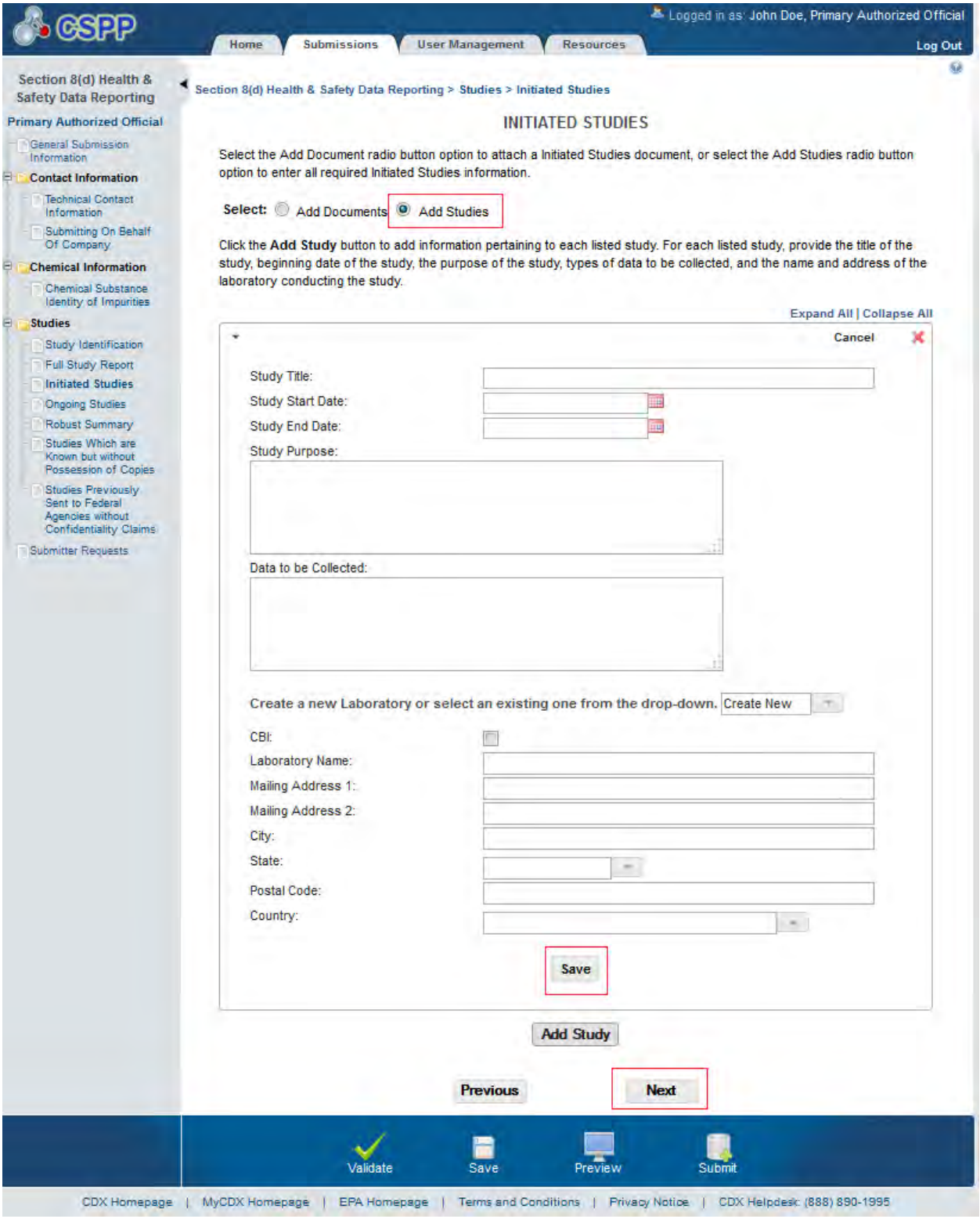
Exhibit 3-25: Initiated Studies Pop-Up Window



Navigation: Click the 'OK' button to close the 'Initiated Studies' pop-up window and save the attached document to the initiated studies table. Clicking the 'Cancel' or 'X' button will close the 'Initiated Studies' pop-up window but no entered information will be saved or displayed on the 'Initiated Studies' screen.

Exhibit 3-26 shows the screen capture of the 'Initiated Studies' screen when the 'Add Studies' radio button is selected:

Exhibit 3-26: Initiated Studies Screen (Add Study)



Navigation: Click the 'Next' button to proceed to the next screen. The next screen is dependent upon the selections you made on the 'Study Identification' screen. If no other studies were selected, you will navigate to the 'Submitter Requests' screen upon clicking the 'Next' button.

3.4.13 Ongoing Studies Screen

You can access the 'Ongoing Studies' screen by checking the 'Ongoing Studies' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Ongoing Studies' link within the navigation tree.

The 'Ongoing Studies' screen provides you with 'Add Documents' and 'Add Studies' radio buttons. Selecting the 'Add Documents' radio button generates the 'Add Document' button and the ongoing studies table. Clicking the 'Add Document' button generates the 'Ongoing Studies' pop-up window for you to upload documentation relating to the reported ongoing studies. You can delete unwanted attached documents by clicking the 'Delete' icon located within the 'Action' column of the Ongoing Studies table. To attach a replacement document for one that was previously attached, click the file name link for the desired document under the 'File Name' column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button.

If you select the 'Add Studies' radio button, the system generates the 'Add Study' button. Clicking the 'Add Study' button generates a field set to enter all required study information. You are required to identify the beginning date of the study, the purpose of the study, types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study. This information must accompany each listed entry.

The system provides the following text fields to complete:

- **Add Documents:** Select the radio button to attach an ongoing studies document. At least one radio button must be selected.
- **Add Studies:** Select the radio button to enter ongoing studies information. At least one radio button must be selected.
- **Add Study:** Click the button to generate the study expandable/collapsible field set.
- **Study Title:** Enter the title of the study. This is a required field.
- **Study Start Date:** Enter the start date of the study. You can use the calendar widget to enter a date. This is a required field.
- **Study End Date:** Enter the end date of the study. You can use the calendar widget to enter a date. This is a required field.
- **Study Purpose:** Enter the purpose of the study. This is a required field.
- **Data to be Collected:** Enter the type of data to be collected throughout the duration of the specified study. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the information of the laboratory conducting the study as confidential.
- **Laboratory Name:** Enter the name of the laboratory conducting the study. This is a required field.

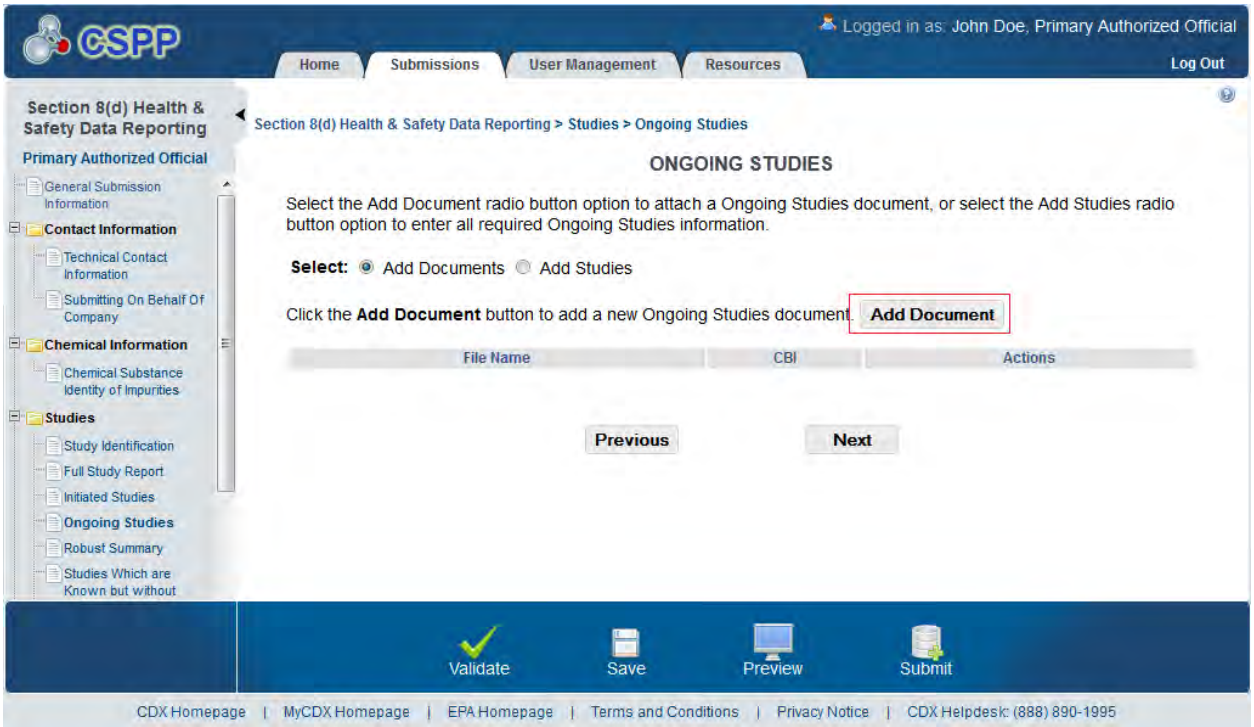
- **Mailing Address 1:** Enter the first line of the mailing address of the laboratory conducting the study. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the laboratory conducting the study.
- **City:** Enter the city of the mailing address of the laboratory conducting the study. This is a required field.
- **State:** Select the state of the mailing address of the laboratory conducting the study. This is a require field if the Country field is set to the 'United States.'
- **Postal Code:** Enter the postal code of the mailing address of the laboratory conducting the study. This is a required field.
- **Country:** Select the country of the mailing address of the laboratory conducting the study. This is a required field.

The system provides functionality for you to associate multiple studies to a single laboratory. Once you enter the laboratory contact information within the field set by clicking the 'Save' button, that contact information is saved to the 'Create a new laboratory or select an existing one from the drop-down' menu. You can click the delete icon to delete any unwanted studies which are located in the top right corner of the specified field set. Clicking the 'Expand All' link will expand all field sets. Likewise, clicking the 'Collapse All' link will collapse all field sets. To expand or collapse a field set individually, click the toggle arrow located in the top left corner of the specified field set.

After all required information has been entered into the 'Ongoing Studies' screen, you can navigate to the next study identified on the 'Study Identification' screen by clicking the 'Next' button or by clicking the next study link within the navigation tree.

Exhibit 3-27 shows the screen capture of the 'Ongoing Studies' screen when you select the 'Add Documents' radio button:

Exhibit 3-27: Ongoing Studies Screen (Add Document)



The ‘Ongoing Studies’ pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach 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 ‘Ongoing Studies’ screen, click the ‘OK’ button within the ‘Ongoing Studies’ pop-up window.

- **CBI:** Check the ‘CBI’ checkbox to 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. The drop-down menu 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.

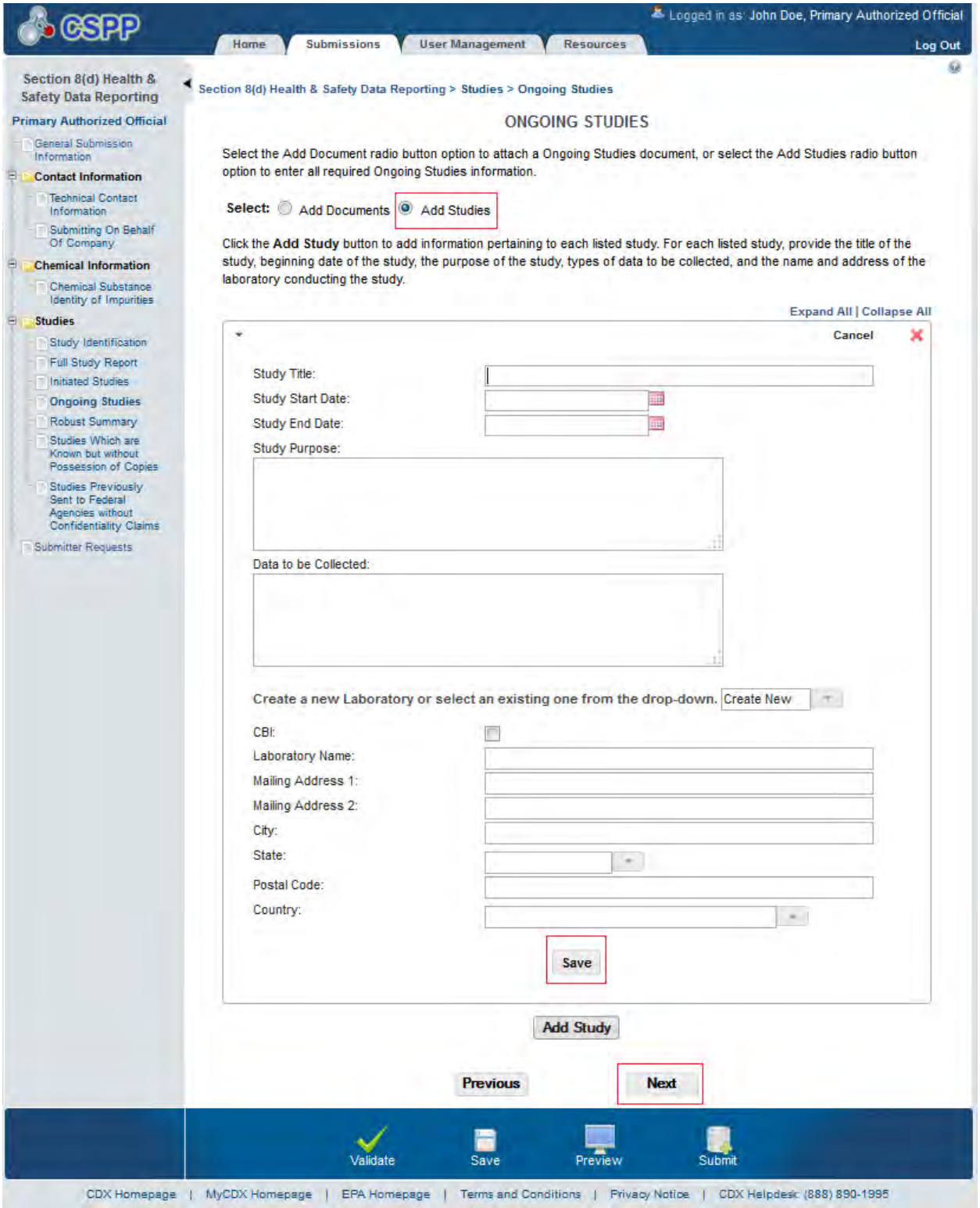
Refer to Appendix B for a complete list of values that are found within each of the drop-down menus on the ‘Ongoing Studies’ pop-up window. If you have multiple documents that share the same effects and/or endpoints, you must upload each individual document separately and select values from the drop-down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

Exhibit 3-28 shows the screen capture of the 'Ongoing Studies' pop-up window:

Exhibit 3-28: Ongoing Studies Pop-Up Window

Exhibit 3-29 shows the screen capture of the 'Ongoing Studies' Screen when you select the 'Add Studies' radio button:

Exhibit 3-29: Ongoing Studies Screen (Add Study)



Navigation: Once all required information is entered, click the 'Next' button to navigate to the next submission type screen. The next screen is dependent upon the selections you made on the

'Study Identification' screen. If no other study types were identified on the 'Study Identification screen,' click the 'Next' button to navigate to the 'Submitter Request' screen.

3.4.14 Robust Summary Screen

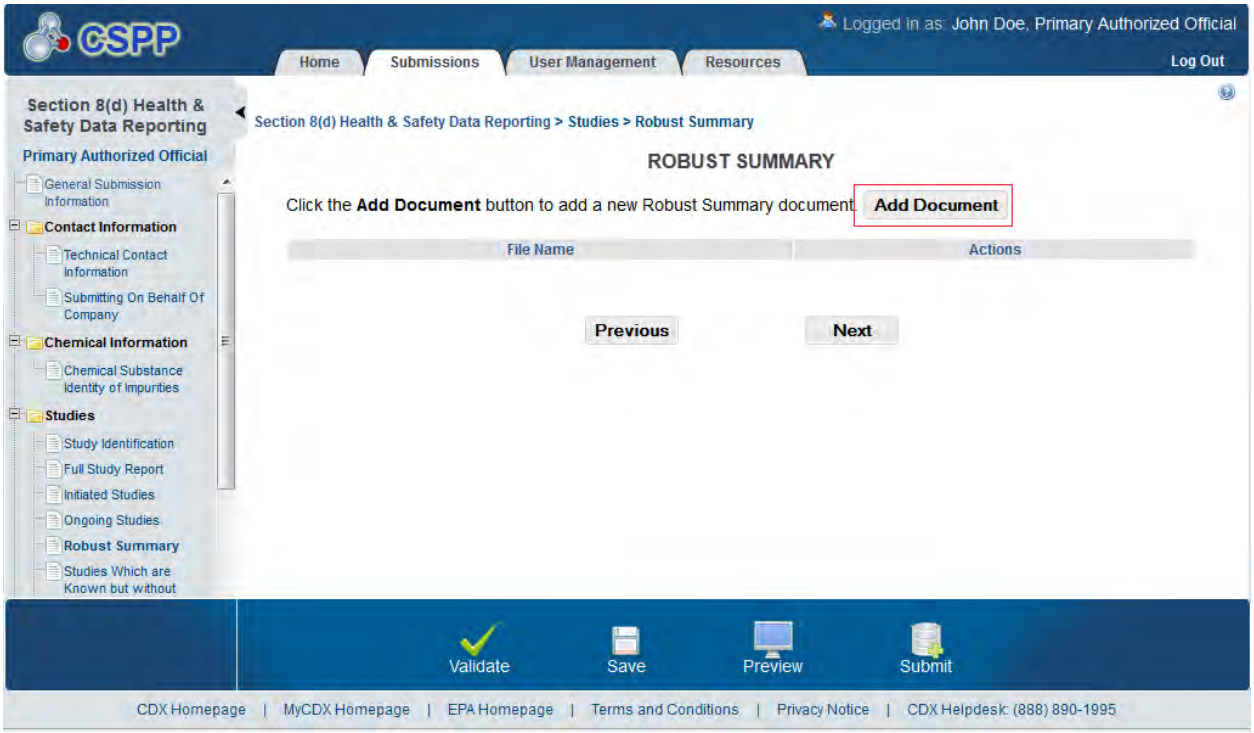
You can access the 'Robust Summary' screen by checking the 'Robust Summary' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Robust Summary' link within the navigation tree.

You can upload robust summary documentation by clicking the 'Add Document' button on the 'Robust Summary' screen. At least one document must be uploaded. Clicking the 'Add Document' button generates the 'Robust Summary' pop-up window for you to upload documents. To add additional documents, click the 'Add Document' button on the 'Robust Summary' screen. You can delete unwanted attached documents by clicking the 'Delete' icon located in the 'Action' column of the Robust Summary table. To attach a replacement document for a document that was previously attached, click the file name link for the desired document under the 'File Name' column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button and display within the table the file name, CBI claim, and possible action.

After all desired documents have been attached, click the 'Next' button to navigate to the next study type identified on the 'Study Identification' screen or the 'Submitter Request' screen if no other study types were identified.

Exhibit 3-30 shows the screen capture of the 'Robust Summary' screen:

Exhibit 3-30: Robust Summary Screen



Navigation: Once all required documentation has been attached, click the 'Next' button to navigate to the next submission type screen. The next screen is dependent upon the selections made on the 'Study Identification' screen. If no other study types were identified on the 'Study Identification' screen, you will be taken to the 'Submitter Request' screen upon clicking the 'Next' button.

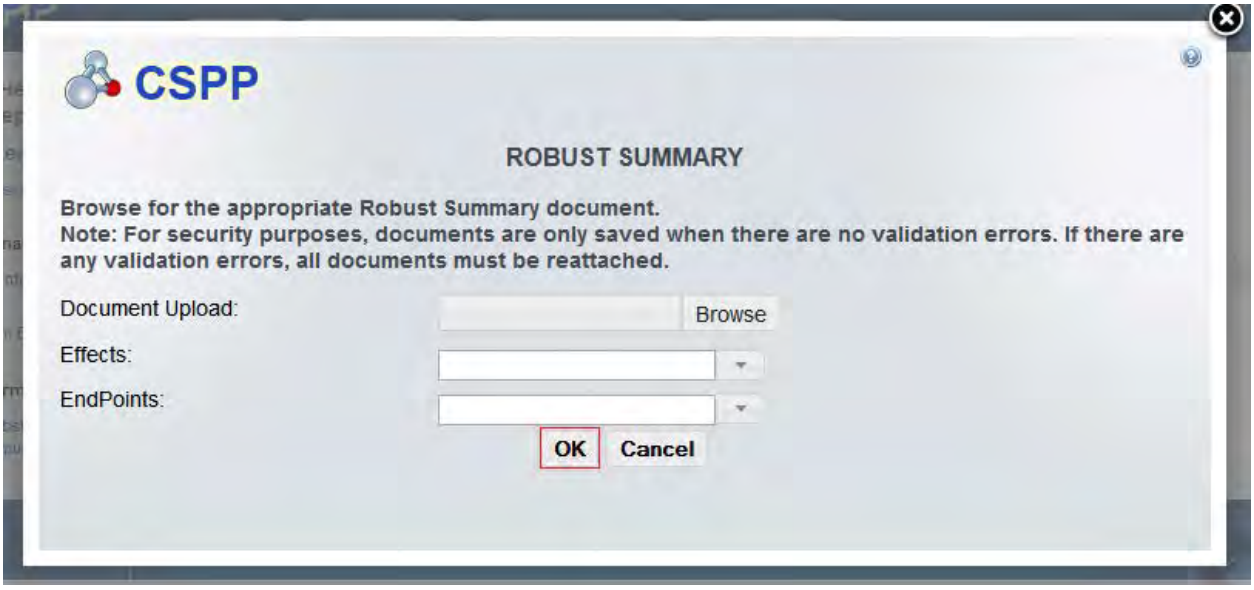
The 'Robust Summary' pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach one document. Clicking the 'Browse' button will generate the 'File Upload' window on your hard drive. Select the document you wish to attach and click the 'Open' button. To save the attached document to the 'Robust Summary' screen, click the 'OK' button within the 'Robust Summary' pop-up window.

- **File Name:** Displays the file name and file extension of a robust summary document attached on the 'Robust Summary' pop-up window.
- **Actions:** Click the 'Delete' icon (✖) to remove the attached robust summary document. A confirmation message displays to confirm removal of the document.
- **Document Upload:** 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. This drop-down menu 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 displayed within each of the drop-down menus on the 'Robust Summary' 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 3-31 shows the screen capture of the 'Robust Summary' pop-up window:

Exhibit 3-31: Robust Summary Pop-Up Window



Navigation: Once all required documentation has been attached, click the 'Next' button to navigate to the next submission type screen. The next screen is dependent upon the selections made on the 'Study Identification' screen. If no other study types were identified on the 'Study Identification' screen, you will be taken to the 'Submitter Request' screen upon clicking the 'Next' button.

3.4.15 Studies Which Are Known But Without Possession of Copies Screen

You can access the 'Studies Which are Known but without Possession of Copies' screen by checking the 'Studies Which are Known but without Possession of Copies' checkbox on the 'Study Identification' screen and clicking the 'Next' button if no other study types were selected. You can also access this screen by clicking the 'Studies Which are Known but without Possession of Copies' link within the navigation tree.

The 'Studies Which Are Known but Without Possession of Copies' screen provides you with 'Add Documents' and 'Add Studies' radio buttons. Selecting the 'Add Documents' radio button generates the 'Add Document' button and the 'Studies which are known but Without Possession of Copies' table. Clicking the 'Add Document' button generates the 'Studies which are known but Without Possession of Copies' pop-up window for you to upload related documentation. To add additional documents, click the 'Add Document' button on the 'Studies Which Are Known but without Possession of Copies' screen. You can delete unwanted attached documents by clicking the 'Delete' icon located in the 'Action' column of the Studies Which Are known but without Possession of Copies table. To attach a replacement document for a document that was previously attached, click the file name link for the desired document under the 'File Name' column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button.

If you select the 'Add Studies' radio button, the system generates the 'Add Study' button. Clicking the 'Add Study' button generates a field set to enter required study information. You

are required to identify the study title, and the name and address of the contact possessing a copy of the study. This information must accompany each listed entry.

The system provides the following text fields to complete:

- **Add Documents**: Select the radio button to attach studies which are known but without possession of copies documents. At least one radio button must be selected.
- **Add Studies**: Select the radio button to enter information regarding studies, which are known, but without possession of copies. At least one radio button must be selected.
- **Add Study**: Click the button to generate the study expandable/collapsible field set.
- **File Name**: Displays the file name and file extension of the document attached on the 'Studies Which are Known but Without Possession of Copies' pop-up window.
- **CBI**: Indicates the CBI status of a document by displaying either a 'Y' or an 'N.'
- **Actions**: Click the 'Delete' icon (✖) to remove the attachment. A warning message displays to confirm the removal of the attachment.
- **Study Title:** Enter the title of the study. This field is required.
- **CBI:** Check the 'CBI' checkbox to claim the information of the contact possessing a copy of the study as confidential.
- **Prefix:** If applicable, select the prefix of the contact possessing a copy of the study.
- **First Name:** Enter the first name of the contact possessing a copy of the indicated study. This field is required.
- **Last Name:** Enter the last name of the contact possessing a copy of the indicated study. This field is required.
- **Suffix:** If applicable, select the suffix of the contact possessing a copy of the indicated study.
- **Phone Number:** Enter the phone number of the contact possessing a copy of the indicated study. This field is required.
- **Ext:** Enter the extension to the phone number of the contact possessing a copy of the indicated study.
- **Email Address:** Enter the email address of the contact possessing a copy of the indicated study. 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 laboratory possessing a copy of the indicated study. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the laboratory possessing a copy of the indicated study.
- **City:** Enter the city of the mailing address of the contact possessing a copy of the indicated study. This field is required.
- **State:** Select the state of the mailing address of the contact possessing a copy of the indicated study. This field is required if 'United States' is selected as the country.
- **Postal Code:** Enter the postal code of the mailing address of the contact possessing a copy of the indicated study. This field is required.

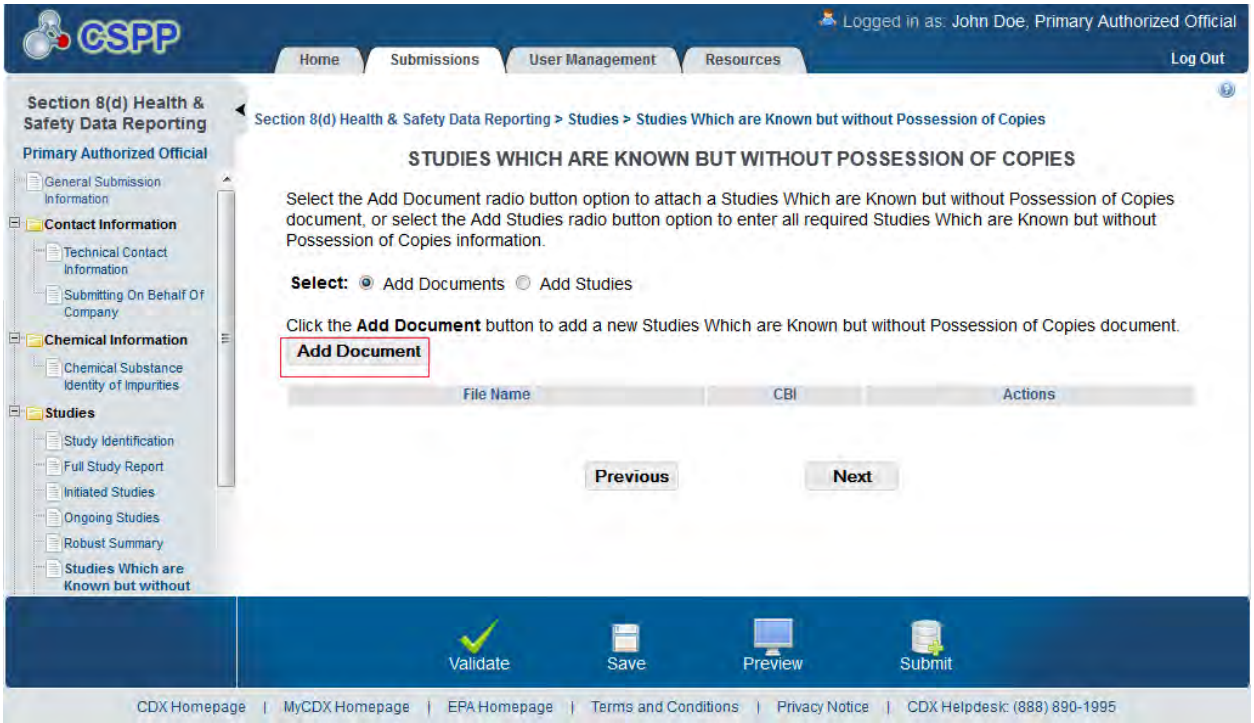
- **Country:** Select the country of the mailing address of the contact possessing a copy of the indicated study. This field is required.

The system allows you to associate multiple studies to a single contact. Once you enter the contact information and save the entered information within the field set by clicking the 'Save' button, that contact information is saved to the 'Create a new contact or select an existing one from the drop-down' menu. Click the 'Save' button to navigate to the 'Studies Which Are Known but without Possession of Copies' screen where all the added studies would be displayed. You can click the 'Delete' icon to delete any unwanted studies you have previously entered by clicking the 'Delete' icon which is located in the top right corner of the specified field set. Clicking the 'Expand All' link will expand all field sets. Likewise, clicking the 'Collapse All' link will collapse all field sets. To expand or collapse all field set individually, click the toggle arrow located in the top left corner of the specified field set.

After all information has been entered into the 'Studies Which Are Known but without Possession of Copies' screen, navigate to the next study identified on the 'Study Identification' screen by clicking the 'Next' button or by clicking the next study link within the navigation tree. If no additional study types were selected, click the 'Next' button to navigate to the 'Submitter Request' screen.

Exhibit 3-32 shows the screen capture of the 'Studies Which Are Known but without Possession of Copies' screen:

Exhibit 3-32: Studies Which Are Known but without Possession of Copies (Add Document)



The 'Studies Which are Known but Without Possession of Copies' pop-up window allows you to browse for a document from your hard drive and attach one document at a time. You must attach 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 'Studies Which are Known but Without Possession of Copies' screen, click the 'OK' button within the 'Studies Which are Known but Without Possession of Copies' pop-up window.

- **CBI:** Check the 'CBI' checkbox to 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. This drop-down menu 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 displayed within each of the drop-down menus on the 'Studies Which are Known but Without Possession of Copies' 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 3-33 shows the screen capture of the 'Studies Which Are Known but without Possession of Copies' pop-up window:

Exhibit 3-33: Studies Which Are Known but without Possession of Copies Pop-Up Window

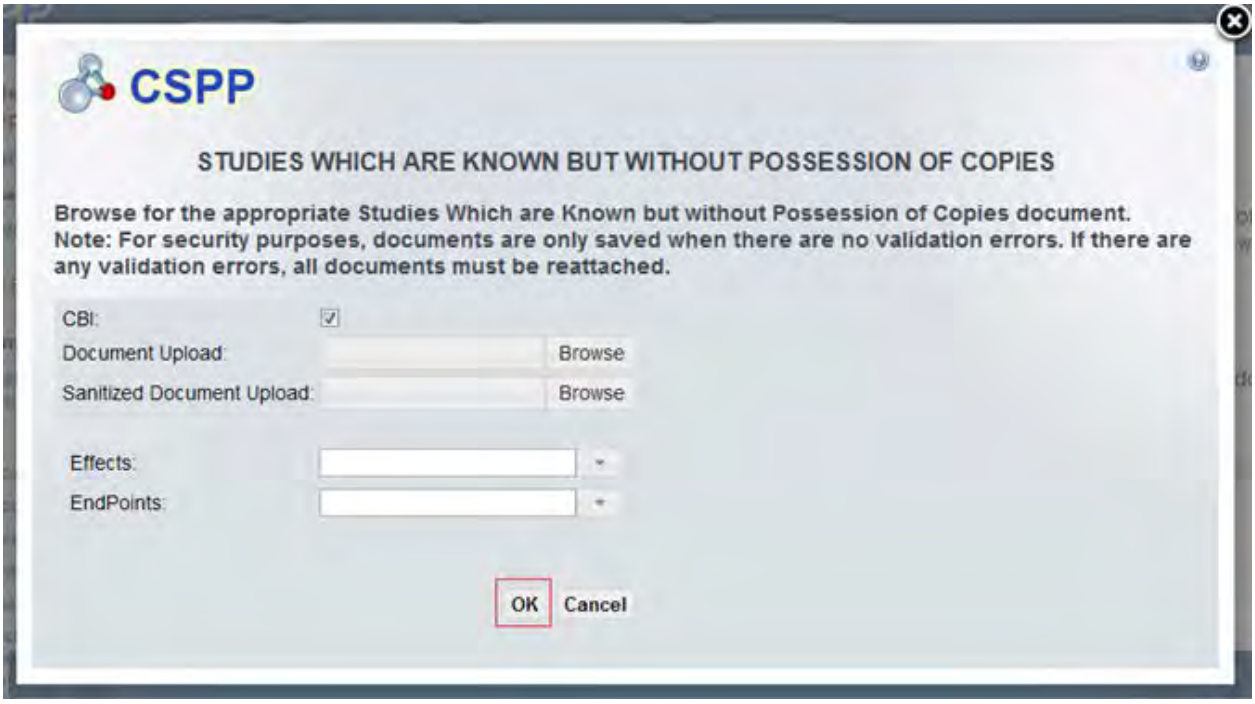
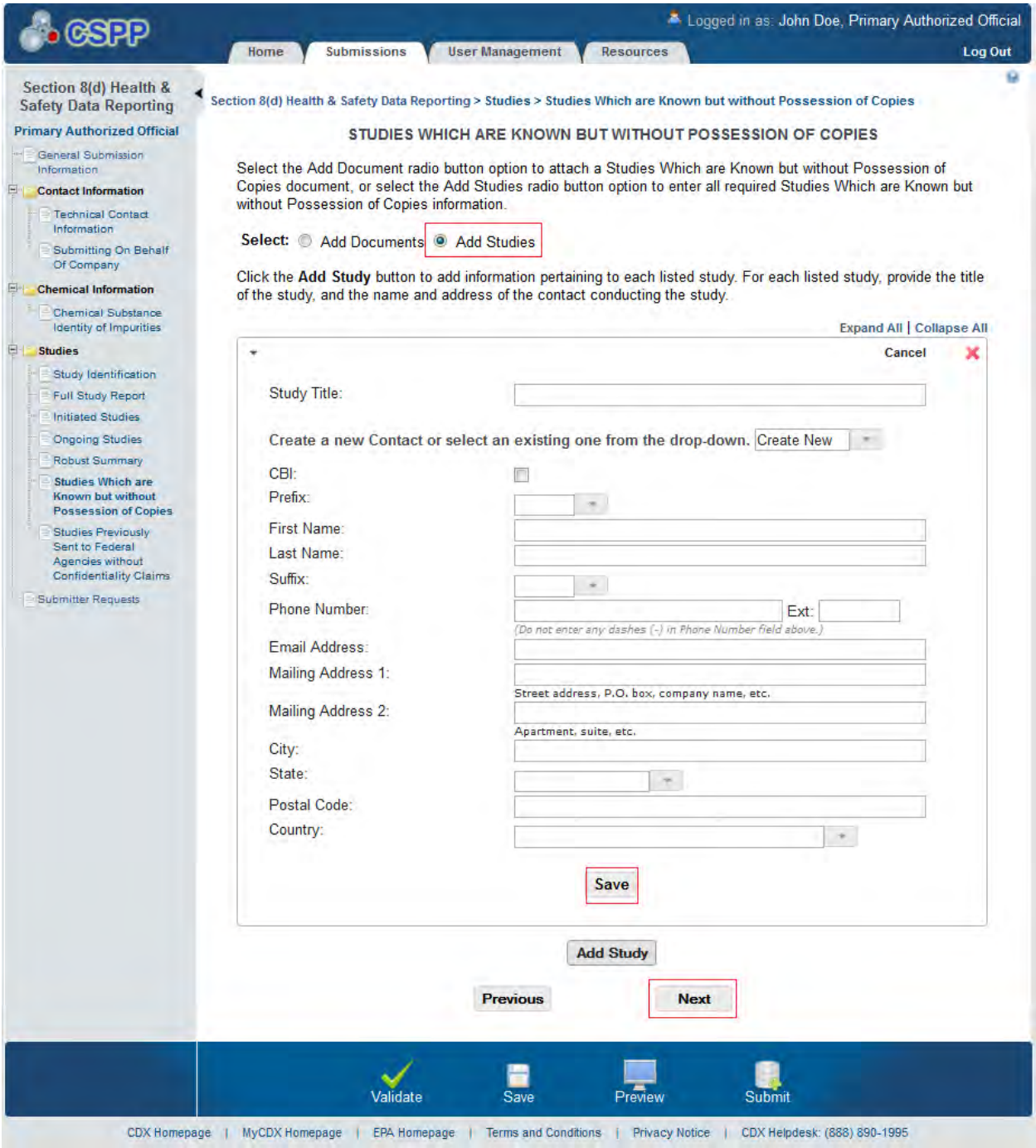


Exhibit 3-34 shows the screen capture of the 'Studies Which Are Known but without Possession of Copies' screen when you select the 'Add Studies' radio button:

Exhibit 3-34: Studies Which Are Known but without Possession of Copies Screen (Add Study)



Navigation: Once all required information is entered, click the 'Next' button to proceed to the next submission study type screen. The next screen is dependent upon the selections you made on the 'Study Identification' screen. If no other study types were identified on the 'Study Identification' screen, click the 'Next' button to navigate to the 'Submitter Request' screen.

3.4.16 Studies Previously Sent to Federal Agencies without Confidentiality Claims Screen

You can access the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' screen by checking the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' link within the navigation tree.

The 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' screen provides you with 'Add Documents' and 'Add Studies' radio buttons. Selecting the 'Add Documents' radio button generates the 'Add Document' button and the studies previously sent to federal agencies without confidentiality claims table. Clicking the 'Add Document' button generates the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' pop-up window for you to upload associated documentation. To add additional documents, click the 'Add Document' button as needed from the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' screen. You can delete unwanted attached documents by clicking the 'Delete' icon within the 'Actions' column of the studies previously sent to federal agencies without confidentiality claims table. To attach a replacement document for a document that was previously attached, click the file name link for the desired document under the 'File Name' column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button.

If you click the 'Add Studies' radio button, the system generates the 'Add Study' button. Clicking the 'Add Study' button generates a field set where you can enter required study information. You are required to identify the study title, the agency in which the study was sent, and the name and address of the contact possessing a copy of the indicated study. This information must accompany each listed entry.

The system provides the following text fields to complete:

- **Add Documents:** Select the radio button to attach a studies previously sent to federal agencies without confidentiality claims document. One radio button must be selected.
- **Add Studies:** Select the radio button to enter studies previously sent to federal agencies without confidentiality claims information. One radio button must be selected.
- **Add Study:** Click the button to generate the study expandable/collapsible field set.
- **Study Title:** Enter the title of the study. This is a required field.
- **Study Submission Date:** Enter the submission date of the study. You may use the calendar widget to help find a date. This is a required field.
- **Agency:** Select an agency from the drop down menu. This is a required field.
- **CBI:** Check the 'CBI' checkbox to claim the information of the contact possessing a copy of the study as confidential.
- **Prefix:** If applicable, select the prefix of the contact possessing a copy of the study.
- **First Name:** Enter the first name of the contact possessing a copy of the study. This is a required field.

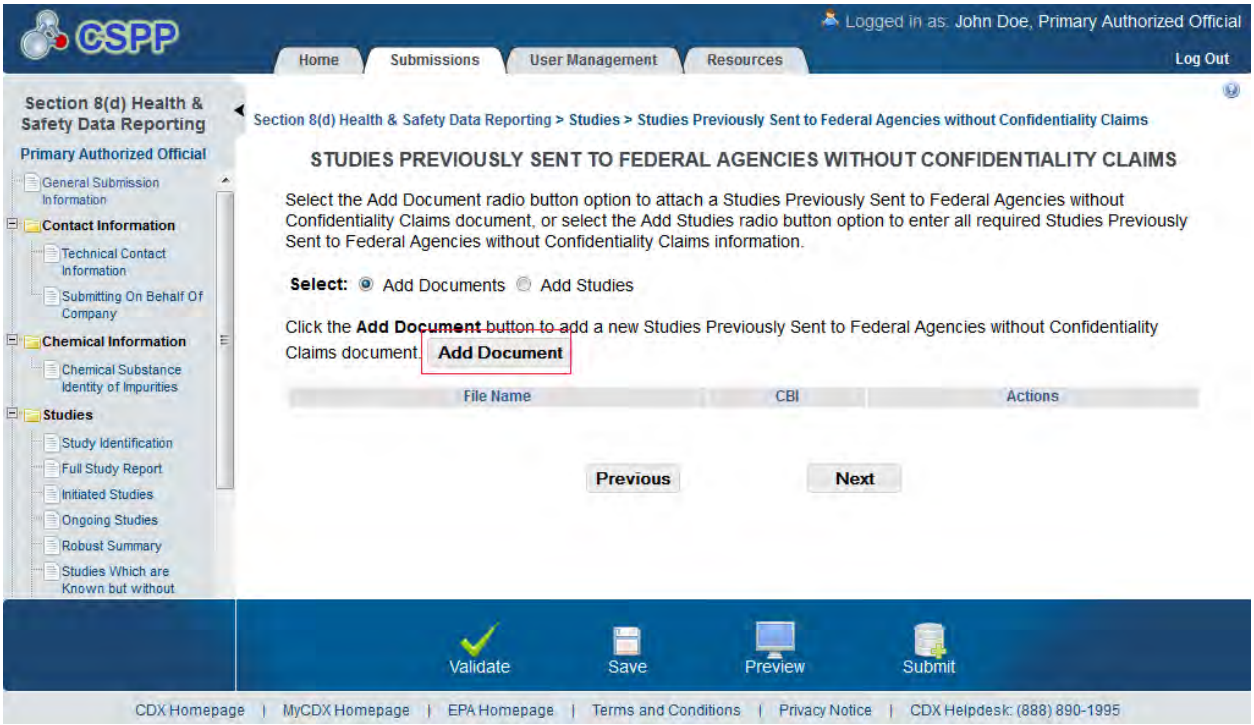
- **Last Name:** Enter the last name of the contact possessing a copy of the study. This is a required field.
- **Suffix:** If applicable, select the suffix of the contact possessing a copy of the study.
- **Phone Number:** Enter the phone number of the contact possessing a copy of the study. This is a required field.
- **Ext:** Enter the extension to the phone number of the contact possessing a copy of the study.
- **Email Address:** Enter the email address of the contact possessing a copy of the study. The email address must follow the standard email address format: john.doe@abc.com. This is a required field.
- **Mailing Address 1:** Enter the first line of the mailing address of the contact possessing a copy of the study. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the contact possessing a copy of the study.
- **City:** Enter the city of the mailing address of the contact possessing a copy of the study. This is a required field.
- **State:** Select the state of the mailing address of the contact possessing a copy of the study. This is a required field if 'United States' is selected as the country.
- **Postal Code:** Enter the postal code of the mailing address of the contact possessing a copy of the study. This is a required field.
- **Country:** Select the country of the mailing address of the contact possessing a copy of the study. This is a required field.

The system provides functionality for you to associate multiple studies to a single contact. Once you enter the contact information and save the entered data within the field set by clicking the 'Save' button, that contact information is saved to the 'Create a new contact or select an existing one from the drop-down' menu. You can delete any unwanted studies by clicking the 'Delete' icon, which is located in the top right corner of the specified field set. Clicking the 'Expand All' link will expand all field sets. Likewise, clicking the 'Collapse All' link will collapse all field sets. To expand or collapse a field set individually, click the toggle arrow located in the top left corner of the specified field set.

After all required information has been entered into the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' screen, you are ready to submit. If any information has been claimed CBI, you will be required to complete substantiation before initiating the submission process.

Exhibit 3-35 shows the screen capture of the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' screen:

Exhibit 3-35: Studies Previously Sent To Federal Agencies Without Confidentiality Claims Screen (Add Document)



The 'Studies Previously Sent to Federal Agencies Without Confidentiality Claims' 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 'Studies Previously Sent to Federal Agencies Without Confidentiality Claims' screen, click the 'OK' button within the 'Studies Previously Sent to Federal Agencies Without Confidentiality Claims' pop-up window.

- **File Name:** Displays the file name and file extension of a document attached on the 'Studies Previously Sent to Federal Agencies Without Confidentiality Claims' pop-up window.
- **CBI:** Indicates the CBI status of a document by displaying either a 'Y' or an 'N.'
- **Actions:** Click the 'Delete' icon (✖) to remove an unwanted document. A message displays to confirm removal of the document.
- **CBI:** Check the 'CBI' checkbox to 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. This drop-down menu 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 displayed within each of the drop-down menus on the 'Studies Previously Sent to Federal Agencies Without Confidentiality Claims' 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 3-36 shows the screen capture of the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' pop-up window:

Exhibit 3-36: Studies Previously Sent To Federal Agencies Without Confidentiality Claims Pop-Up Window

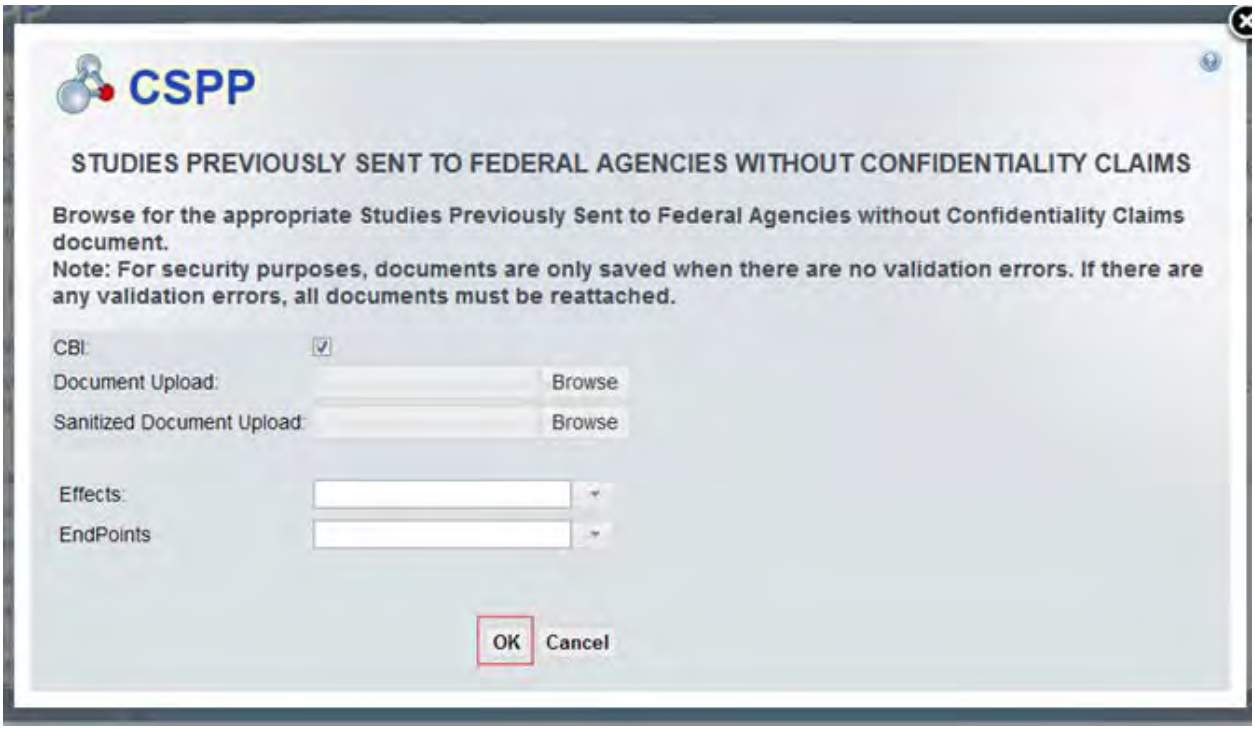
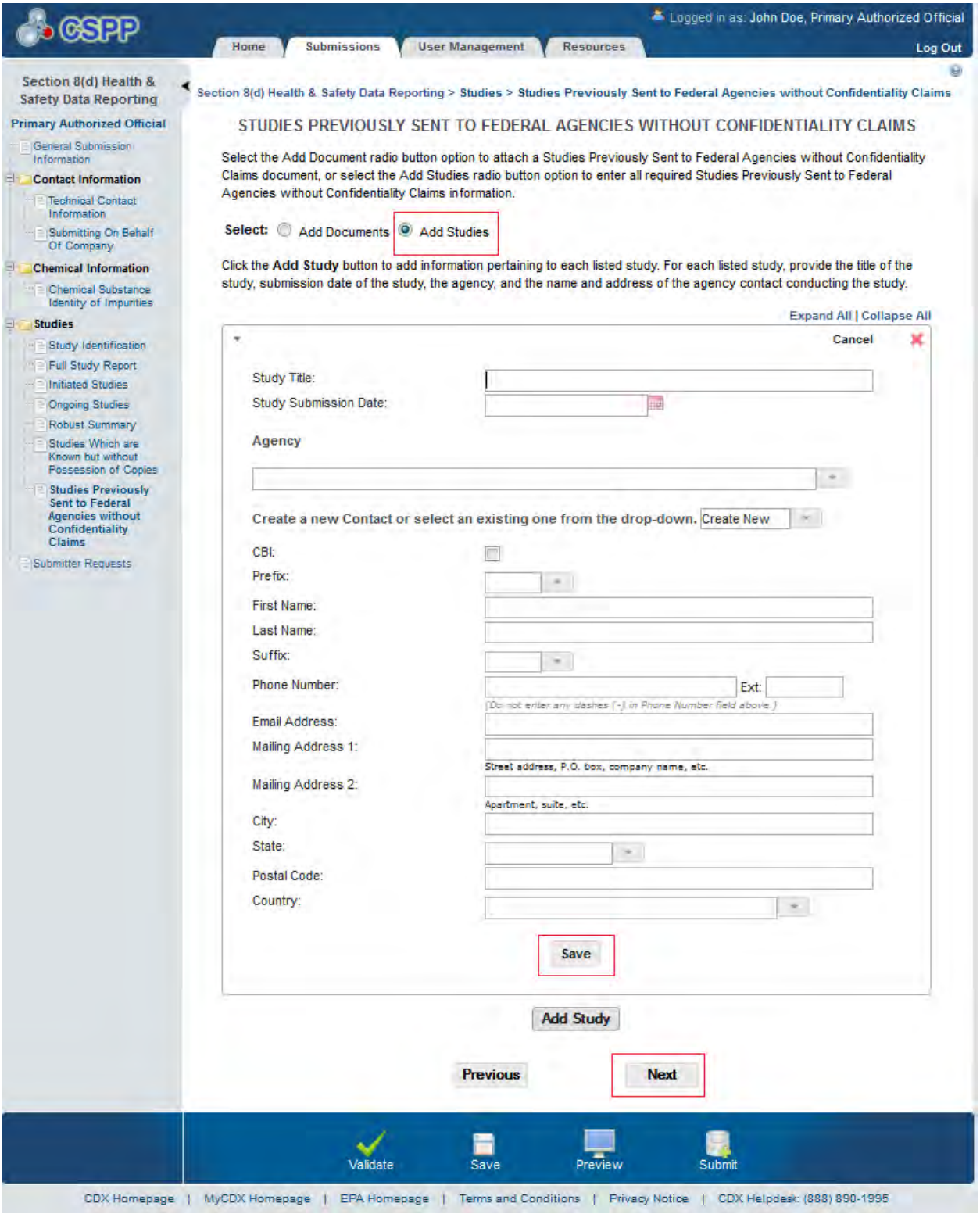


Exhibit 3-37 shows the screen capture of the 'Studies Previously Sent To Federal Agencies Without Confidentiality Claims' screen when you select the 'Add Studies' radio button:

Exhibit 3-37: Studies Previously Sent To Federal Agencies Without Confidentiality Claims Screen (Add Study)



Navigation: Once all required information has been entered, you are finished with the data entry process. If information has been claimed as CBI, you will be required to complete the substantiation screen for the AO to submit the form successfully. Please refer to **Section 3.7** for information regarding the substantiation section.

3.5 EPA Request for Further Information

The following screens are only available to you when you are amending a previous submission.

3.5.1 Underlying Data Screen

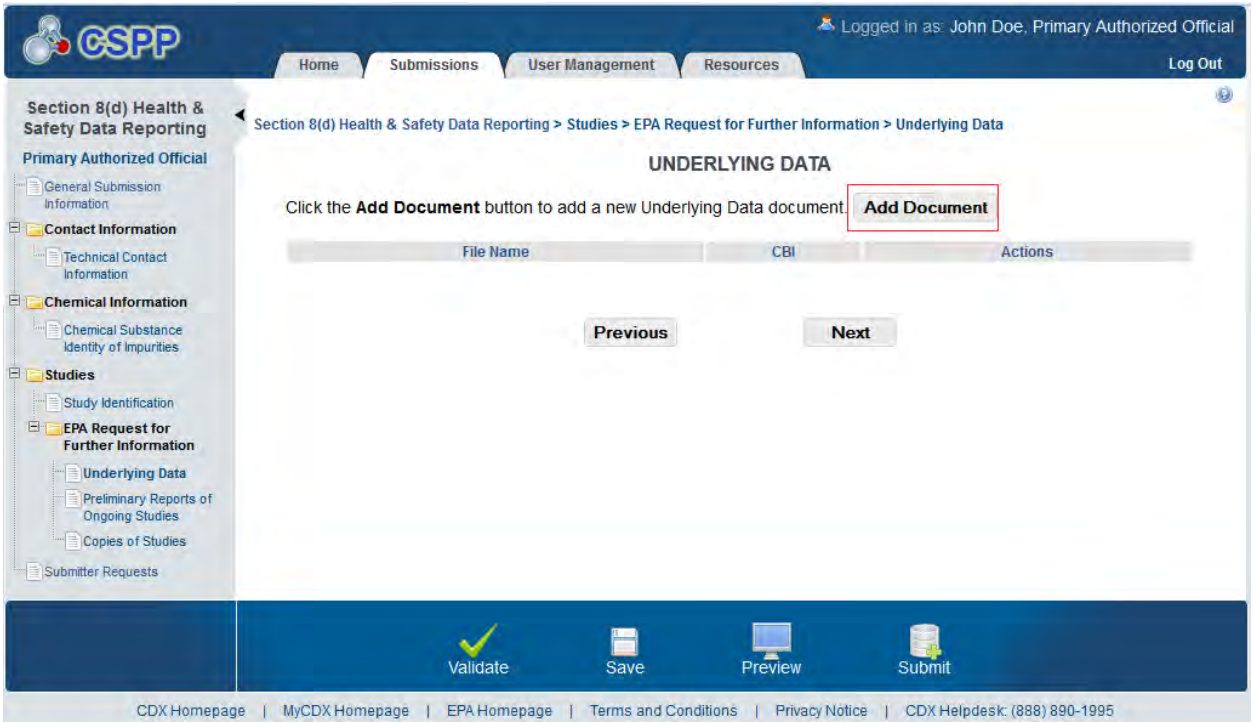
You can access the 'Underlying Data' screen by checking the 'Underlying Data' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Underlying Data' link within the navigation tree.

You can upload underlying data documents by clicking the 'Add Document' button. Clicking the 'Add Document' button generates a pop-up window for you to upload a document. To add additional documents, click the 'Add Document' button each time from the 'Underlying Data' screen. You can delete any unwanted attached documents by clicking the 'Delete' icon within the 'Actions' column of the underlying data table on the 'Underlying Data' screen. To attach a different document after one has previously been attached, click the file name link for the desired document under the 'File Name' column. Once you click the 'File Name' link of the desired document, this generates the pop-up window that will display to attach the new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button.

After all desired documents have been attached; click the 'Next' button to navigate to the next study type identified on the 'Study Identification' screen. If no other study types have been identified, click the 'Next' button to navigate to the 'Submitter Request' screen.

Exhibit 3-38 shows the screen capture of the 'Underlying Data' screen:

Exhibit 3-38: Underlying Data Screen



The 'Underlying Data' 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 'Underlying Data' screen, click the 'OK' button within the 'Underlying Data' pop-up window.

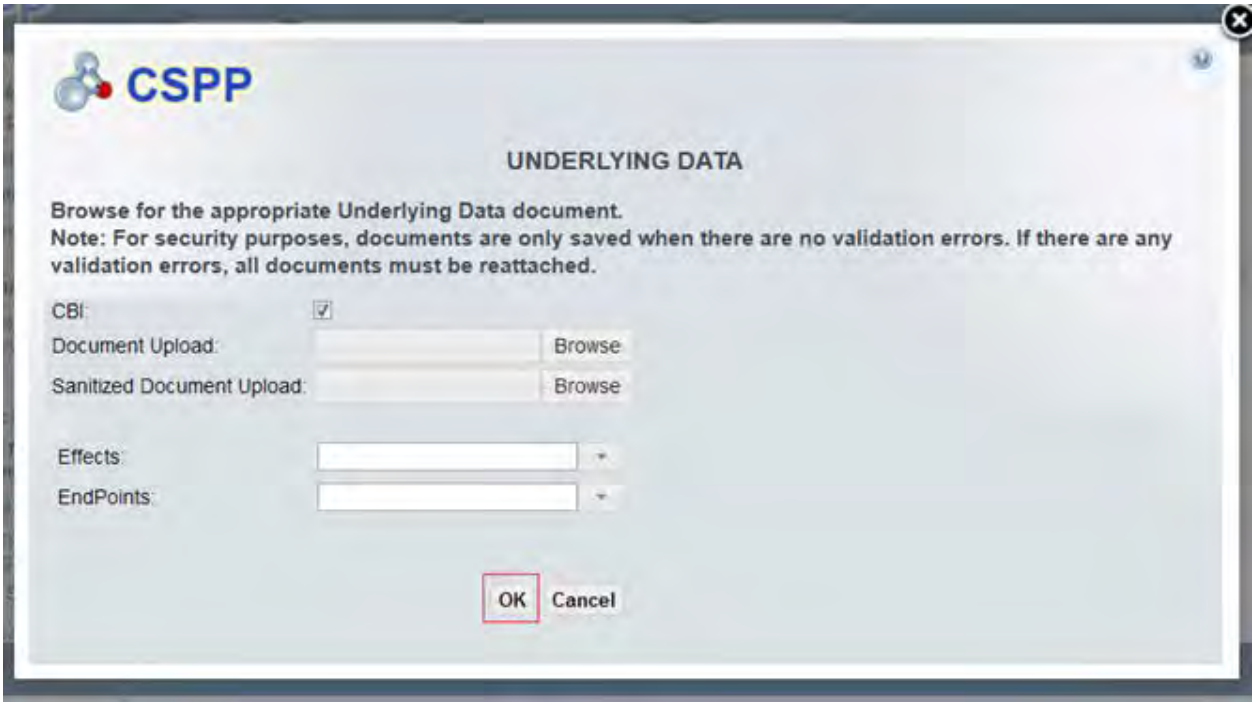
- **Add Document:** Click the button to generate the 'Underlying Data' pop-up window and attach an underlying data document.
- **File Name:** Displays the file name and file extension of the document attached on the 'Underlying Data' pop-up window.
- **CBI:** Indicates the CBI status of a document by displaying either a 'Y' or an 'N.'
- **Actions:** Click the 'Delete' icon (✖) to remove the document from the system. A message displays to confirm the removal of the document.
- **CBI:** Check the 'CBI' checkbox to 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. This drop-down menu 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 displayed within each of the drop-down menus on the 'Underlying Data' 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 3-39 shows the screen capture of the 'Underlying Data' pop-up window:

Exhibit 3-39: Underlying Data Pop-Up Window (with Sanitized Document Attached)



Navigation: Upload all required documents and click the 'OK' button to close the window and populate the underlying data table. If you click 'Cancel' or the 'X' button, the window will close but no data will be saved. Once all documents have been uploaded, click the 'Next' button to move to the next screen from the 'Underlying Data' screen.

3.5.2 Preliminary Report of Ongoing Studies Screen

You can access the 'Preliminary Reports of Ongoing Studies' screen by checking the 'Preliminary Reports of Ongoing Studies' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Preliminary Reports of Ongoing Studies' link within the navigation tree.

The 'Preliminary Reports of Ongoing Studies' screen is required for users who list studies as ongoing or initiated. The 'Preliminary Reports of Ongoing Studies' screen provides the user with

‘Add Documents’ and ‘Add Studies’ radio buttons. If you select the ‘Add Documents’ radio button the system generates the ‘Add Document’ button and the preliminary reports of ongoing studies table. Clicking the ‘Add Document’ button generates a pop-up window for you to upload documents. To add additional documents click the ‘Add Document’ button from the ‘Preliminary Reports of Ongoing Studies’ screen. You can delete unwanted attached documents by clicking the ‘Delete’ icon within the ‘Actions’ column of the preliminary reports of ongoing studies table. To attach a replacement document for a document that was previously attached, click the file name link for the desired document under the ‘File Name’ column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the ‘OK’ button.

If you select the ‘Add Study’ radio button, the system will generate the ‘Add Study’ button. Clicking the ‘Add Study’ button will generate a field set that displays text fields for you to enter required study information. You are required to identify the beginning date of the study, the purpose of the study, types of data to be collected, the anticipated date of completion, and the name and address of the laboratory conducting the study. This information must accompany each listed entry.

The system provides the following text fields to complete:

- **Add Documents:** Select the radio button to attach a preliminary reports of ongoing studies document.
- **Add Studies:** Select the radio button to enter preliminary reports of ongoing studies information.
- **Study Title:** Enter the title of the study. This is a required field.
- **Study Start Date:** Enter the start date of the study. You can use the calendar widget to help find a specific date. This is a required field.
- **Study End Date:** Enter the end date of the study. You can use the calendar widget to help find a specific date. This is a required field.
- **Study Purpose:** Enter the purpose of the study. This is a required field.
- **Data to be Collected:** Enter the type of data to be collected throughout the duration of the specified study. This is a required field.
- **Create a new Laboratory or select an existing one from the drop-down:** Displays laboratories which have previously been entered within the same form, or allows you to enter a new laboratory. This field is optional.
- **CBI:** Check the ‘CBI’ checkbox to claim the information of the laboratory conducting the study as confidential.
- **Laboratory Name:** Enter the name of the laboratory conducting the study. This is a required field.
- **Mailing Address 1:** Enter the first line of the mailing address of the laboratory conducting the study. This is a required field.
- **Mailing Address 2:** Enter the second line of the mailing address of the laboratory conducting the study.

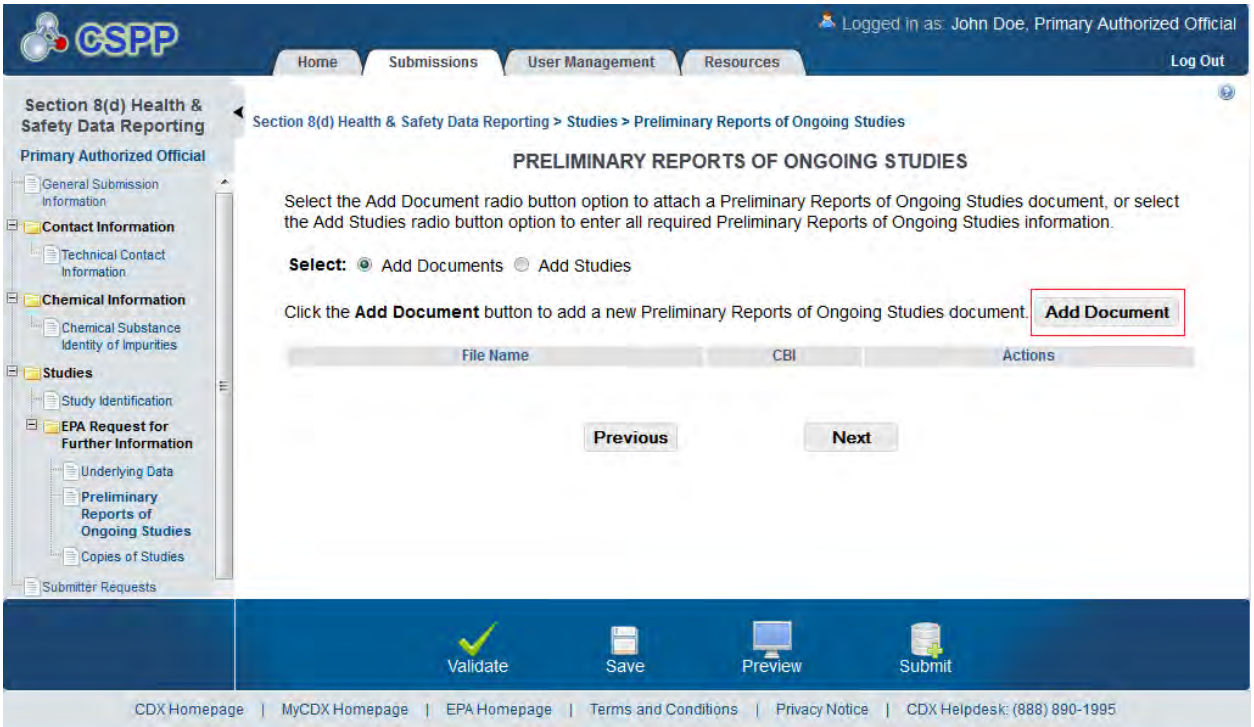
- **City:** Enter the city of the mailing address of the laboratory conducting the study. This is a required field.
- **State:** Select the state of the mailing address of the laboratory conducting the study. This is a required field if the country is identified as 'United States.'
- **Postal Code:** Enter the postal code of the mailing address of the laboratory conducting the study. This is a required field.
- **Country:** Select the country of the mailing address of the laboratory conducting the study. This is a required field.

The system provides functionality for you to associate multiple studies to a single laboratory. Once you enter laboratory contact information and save the data entered within the field set by clicking the 'Save' button, that contact information is saved to the 'Create a new laboratory or select an existing one from the drop-down' menu. You can click the 'Delete' icon located in the top right corner of the specified field set to delete any unwanted studies. Clicking the 'Expand All' link will expand all field sets. Likewise, clicking the 'Collapse All' link will collapse all field sets. To expand or collapse a field set individually, click the toggle arrow located in the top left corner of the specified field set.

After all information has been entered into the 'Preliminary Reports of Ongoing Studies' screen, navigate to the next study identified on the 'Study Identification' screen by clicking the 'Next' button or by clicking the next study link in the navigation tree. If no other study types were identified, you will be taken to 'Submitter Request' screen upon clicking the 'Next' button.

Exhibit 3-40 shows the screen capture of the 'Preliminary Reports of Ongoing Studies' screen:

Exhibit 3-40: Preliminary Reports of Ongoing Studies Screen (Add Document)



The 'Preliminary Reports of Ongoing Studies' 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 'Preliminary Reports of Ongoing Studies' screen, click the 'OK' button within the 'Preliminary Reports of Ongoing Studies' pop-up window.

- **CBI:** Check the 'CBI' checkbox to claim the uploaded document as CBI and generate a sanitized document upload field.
- **Document Upload:** Click the 'Browse' button to 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. Click the 'Browse' button to 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. This drop-down menu 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 ‘Preliminary Reports of Ongoing Studies’ 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 3-41 shows the screen capture of the 'Preliminary Reports of Ongoing Studies' pop-up window:

Exhibit 3-41: Preliminary Report of Ongoing Studies Pop-Up Window (with Sanitized Document Attached)

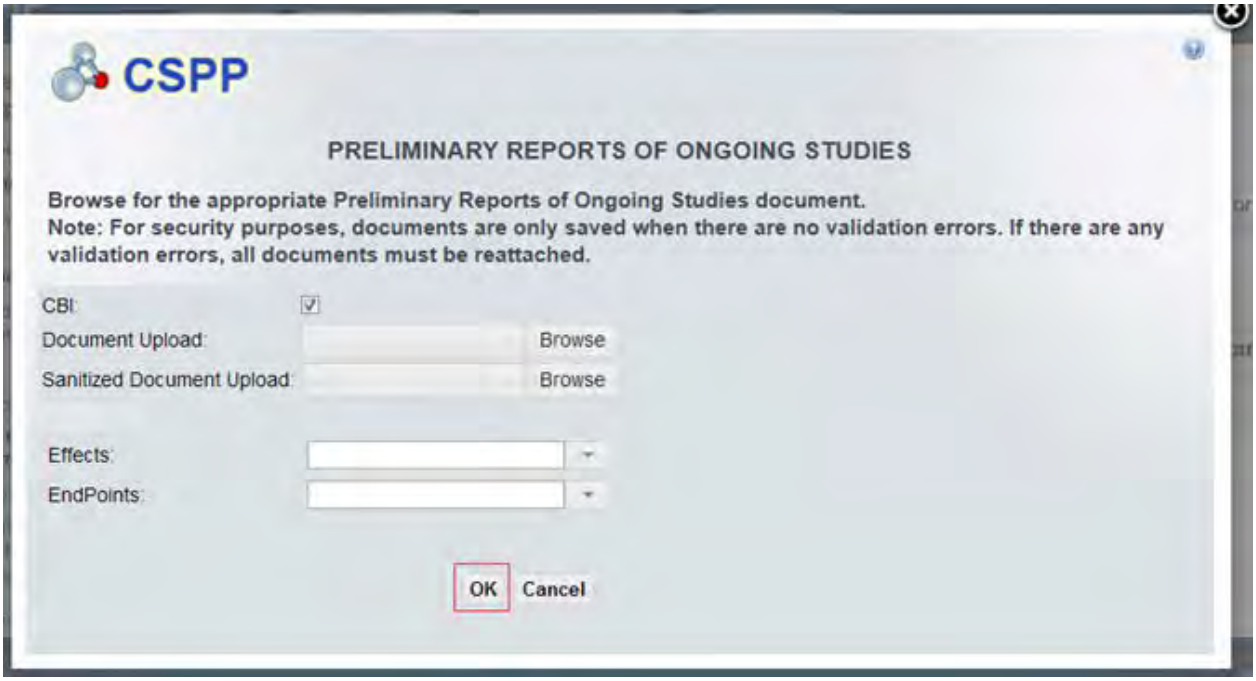
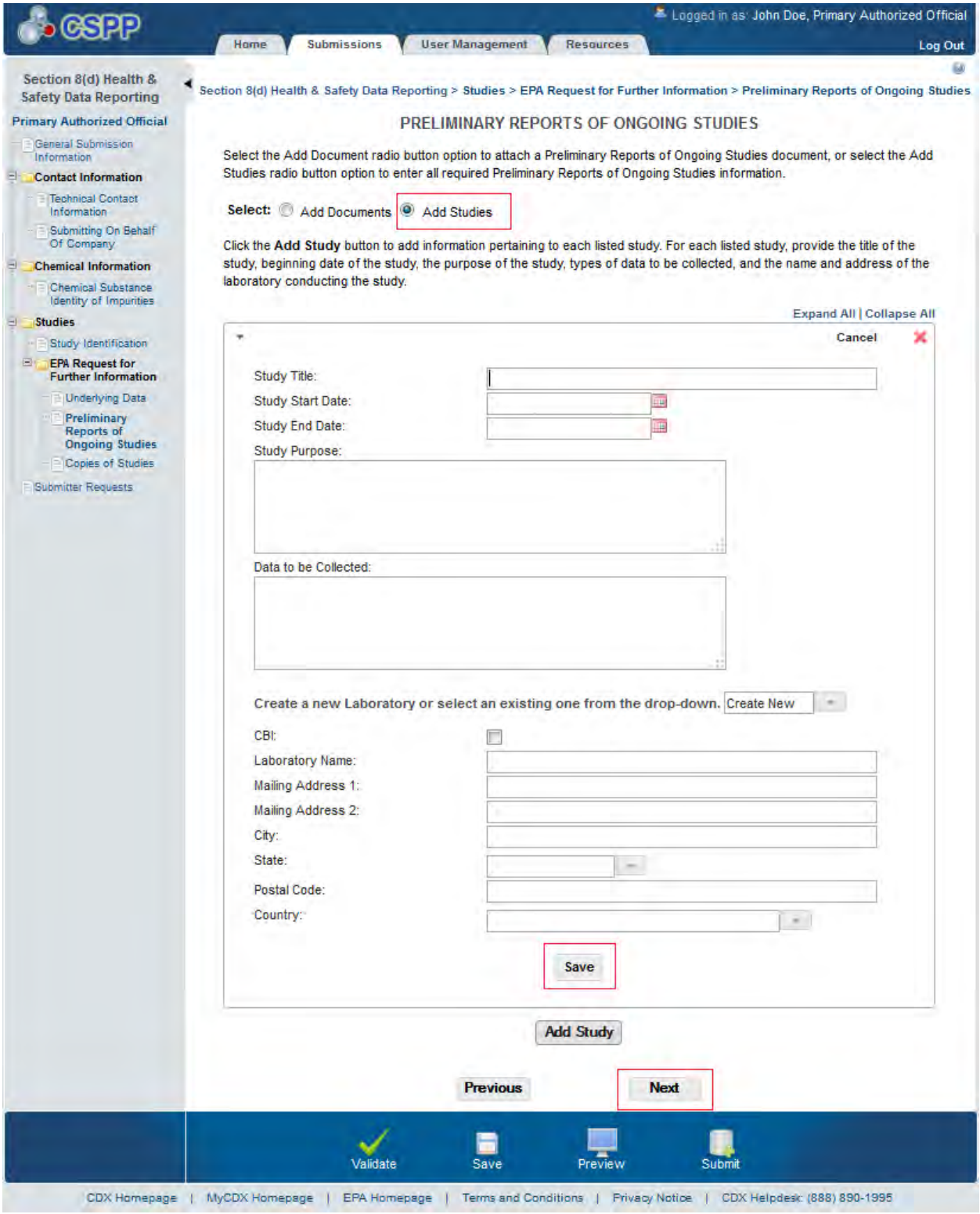


Exhibit 3-42 shows the screen capture of the 'Preliminary Reports of Ongoing Studies' screen when you select the 'Add Studies' radio button:

Exhibit 3-42: Preliminary Report of Ongoing Studies Screen (Add Study)



Navigation: Once all required information is entered, click the 'Next' button to navigate to the next screen. The next screen is dependent upon the study types you identified on the 'Study Identification' screen.

3.5.3 Copies of Studies Screen

You can access the 'Copies of Studies' screen by checking the 'Copies of Studies' checkbox on the 'Study Identification' screen and clicking the 'Next' button. You can also access this screen by clicking the 'Copies of Studies' link within the navigation tree.

The 'Copies of Studies' screen provides you with 'Add Documents' and 'Add Studies' radio button options. Selecting the 'Add Documents' radio button generates the 'Add Document' button and the copies of studies table. Clicking the 'Add Document' button generates the 'Copies of Studies' pop-up window for you to upload documents. To add additional documents you can click the 'Add Document' button as needed from the 'Copies of Studies' screen. You can delete unwanted attached documents by clicking the 'Delete' icon located in the 'Actions' column of the 'Copies of Studies' table. To attach a replacement document for a document that was previously attached, click the file name link for the desired document under the 'File Name' column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button.

If you select the 'Add Study' radio button the system generates a field set to enter study information. Clicking the 'Add Studies' radio button generates a field set that displays text fields for you to enter required study information. You are required to identify the study title, and the name and address of the contact who possesses a copy of the indicated study. This information must accompany each listed entry.

The system provides the following text fields to complete:

- **Add Documents:** Select the radio button to attach copies of studies documentation. One radio button must be selected.
- **Add Studies**: Select the radio button to enter copies of studies information. One radio button must be selected.
- **Study Title:** Enter the title of the study. This field is required.
- **CBI:** Check the 'CBI' checkbox to identify the information of the individual who possesses a copy of the indicated study as confidential.
- **Prefix:** If applicable, select the prefix of the individual who possesses a copy of the indicated study.
- **First Name:** Enter the first name of the individual who possesses a copy of the indicated study. This field is required.
- **Last Name:** Enter the last name of the individual who possesses a copy of the indicated study. This field is required.
- **Suffix:** If applicable, select the suffix of the individual who possesses a copy of the indicated study.
- **Phone Number:** Enter the phone number of the individual who possesses a copy of the indicated study. This field is required.

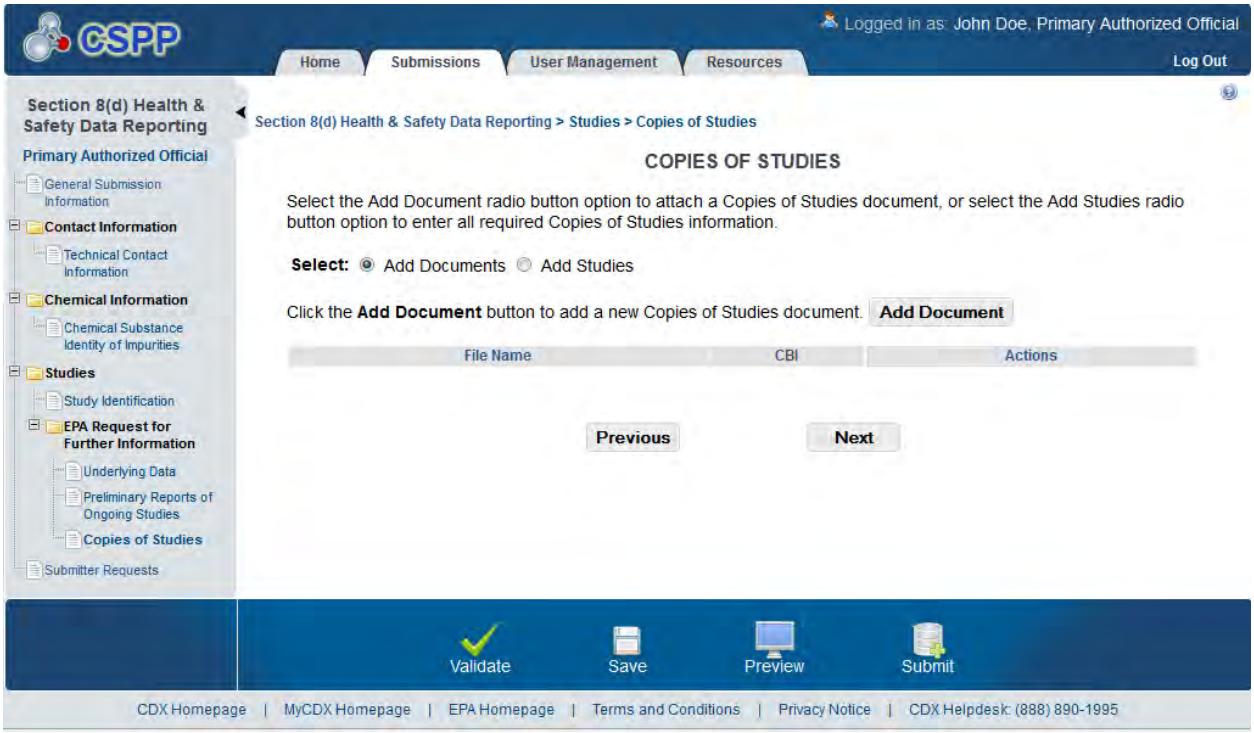
- **Ext:** Enter the extension to the phone number of the individual who possesses a copy of the indicated study.
- **Email Address:** Enter the email address of the individual who possesses a copy of the study. The email address must follow the standard email address format: john.doe@abc.com. This field is required.
- **Mailing Address 1:** Enter the first line of the mailing address of the individual who possesses a copy of the study. This field is required.
- **Mailing Address 2:** Enter the second line of the mailing address of the individual who possesses a copy of the study.
- **City:** Enter the city of the mailing address of the individual who possesses a copy of the study. This field is required.
- **State:** Select the state of the mailing address of the individual who possesses a copy of the study. This field is required if the country selected is 'United States.'
- **Postal Code:** Enter the postal code of the mailing address of the individual who possesses a copy of the study. This field is required.
- **Country:** Select the country of the mailing address of the individual who possess a copy of the study. This field is required.

The system provides functionality for you to associate multiple studies to a single contact. Once you enter contact information and save the data entered within the field set by clicking the 'Save' button, that contact information is saved to the 'Create a new contact or select an existing one from the drop-down' menu. You can click the 'Delete' icon located in the top right corner of the specified field set to delete any unwanted studies. Clicking the 'Expand All' link will expand all field sets. Likewise, clicking the 'Collapse All' link will collapse all field sets. To expand or collapse a field set individually, you can click the toggle arrow located in the top left corner of the specified field set.

After all required information has been entered into the 'Copies of Studies' screen, you can navigate to the next study identified on the 'Study Identification' screen by clicking the 'Next' button or by clicking the next study link from within the navigation tree.

Exhibit 3-43 shows the screen capture of the 'Copies of Studies' screen:

Exhibit 3-43: Copies of Studies Screen (Add Document)



The 'Copies of Studies' 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 'Copies of Studies' screen, click the 'OK' button within the 'Copies of Studies' pop-up window.

- **CBI:** Check the 'CBI' checkbox to claim the uploaded document as CBI and generate a sanitized document upload field.
- **Document Upload:** Click the 'Browse' button to 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. Click the 'Browse' button to 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. This drop-down menu 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 3-44 shows the screen capture of the 'Copies of Studies' pop-up window:

Exhibit 3-44: Copies of Studies Pop-up Window (with Sanitized Document Attached)

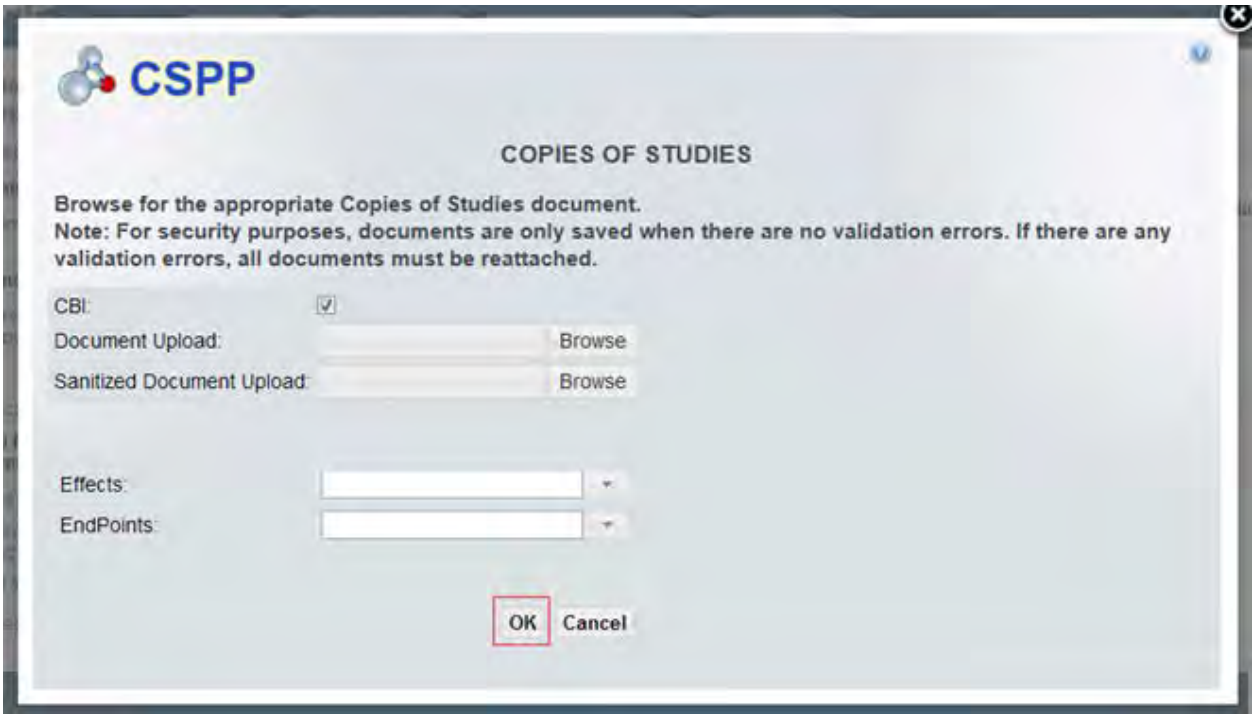
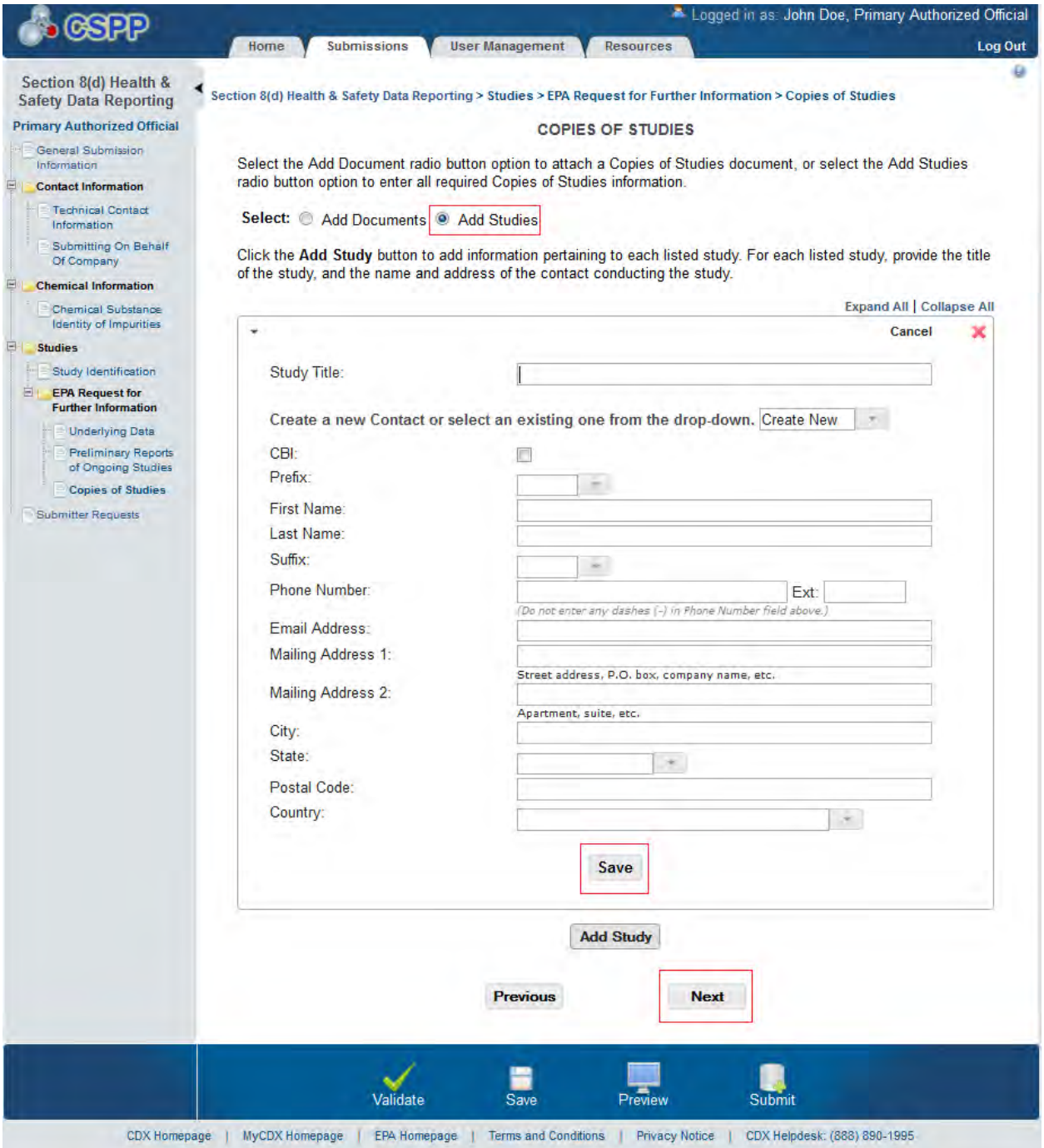


Exhibit 3-45 shows the screen capture of the 'Copies of Studies' screen when you select the 'Add Studies' radio button:

Exhibit 3-45: Copies of Studies Screen (Add Study)



Navigation: Once all required information is entered, click the 'Next' button to navigate to the next screen. The next screen is dependent upon the study types you identified on the 'Study Identification' screen. If no other study types were identified you will navigate to the 'Submitter Requests' screen upon clicking 'Next.'

3.6 Submitter Requests Screen

You can access the 'Submitter Requests' screen by clicking the 'Submitter Requests' link within the navigation tree, or by clicking the 'Next' button from the previous screen.

The 'Submitter Requests' screen provides functionality for you to request a time extension or withdrawal of a submission. Clicking the 'Add Document' button generates the 'Submitter Request' pop-up window. You can delete unwanted attached documents by clicking the 'Delete' icon located in the 'Actions' column of the submitter requests table. To attach or edit a previously attached document, click the file name link of the desired document under the 'File Name' column. Once you click the file name link of the desired document, the attachment pop-up window generates for you to attach a new document. Attaching a new document will overwrite the existing document. The changes will commit once you click the 'OK' button.

- **File Name:** Displays the file name and file extension of the document attached on the 'Submitter Request' pop-up window.
- **Request Type:** Displays the request type selected from the 'Submitter Request' pop-up window.
- **Actions:** Click the 'Delete' icon (✖) to remove the document from the system. A warning message displays to confirm removal of the document.

Exhibit 3-46 shows the screen capture of the 'Submitter Requests' screen:

Exhibit 3-46: Submitter Requests Screen

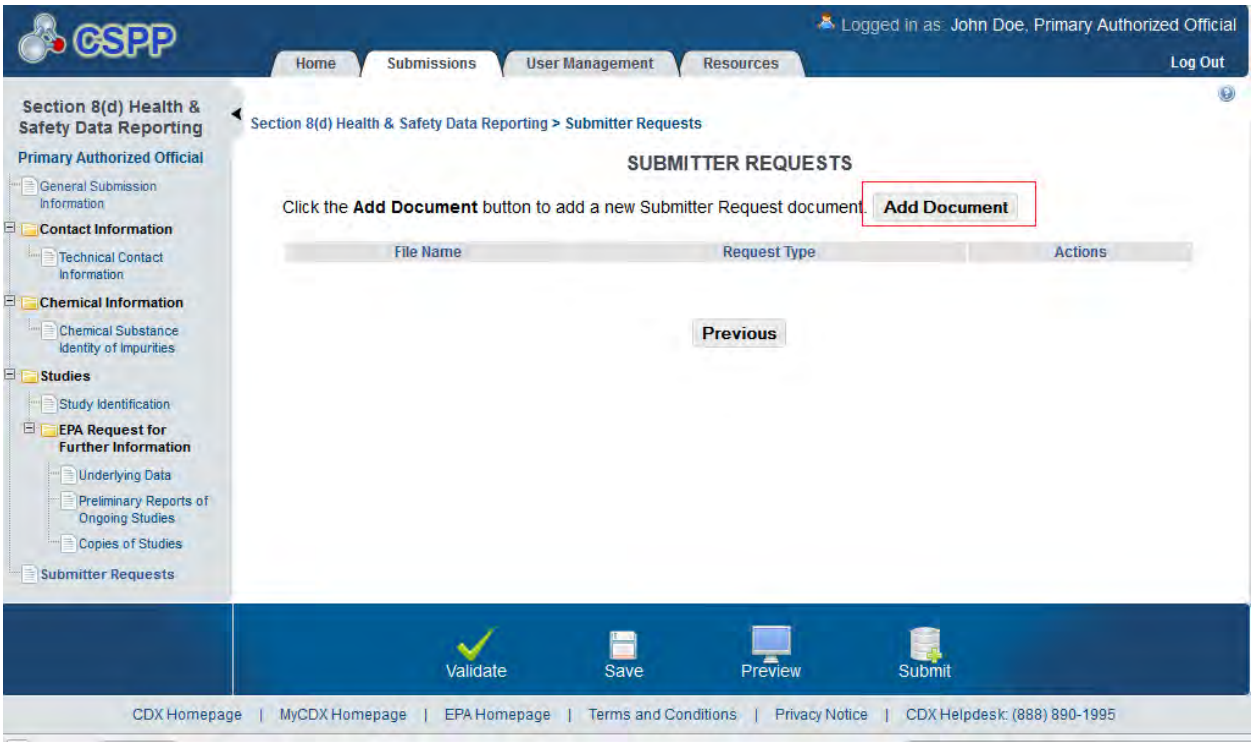


Exhibit 3-47 shows the screen capture of the 'Submitter Request' pop-up window:

Exhibit 3-47: Submitter Request Pop-Up Window

Navigation: Click the 'OK' button to close the 'Submitter Request' pop-up window and save the selected document. Clicking the 'Cancel' or 'X' button will close the window, however no data will be saved. Once all documentation has been uploaded, click 'Submit' button to begin the submission process. If data has been claimed as CBI, click the 'Next' button to complete the 'Substantiation Summary' screen.

3.7 Substantiation Summary

You can access the 'Substantiation Summary' screen by identifying CBI claims within the application.

If a user claims any item as CBI, a prompt will display informing the user 'Substantiation is required.' Please complete the substantiation by clicking the link within the navigation tree on the left to complete substantiation for this item, or by clicking the 'Next' button from the 'Submitter Request' screen. To pass validation, substantiation must be completed for all items claimed as CBI before submission. The 'Substantiation Summary' link within the navigation tree provides access to the 'Substantiation Summary' screen. 'Substantiation Status' indicates whether the user has completed substantiation. Click the 'Pending' link within the 'Substantiation Status' column if the status of the submission is 'Pending'. Once the substantiation has been completed, the status will change to 'Complete.'

Exhibit 3-48 shows the screen capture for the 'Substantiation Summary' screen:

Exhibit 3-48: Substantiation Summary Screen

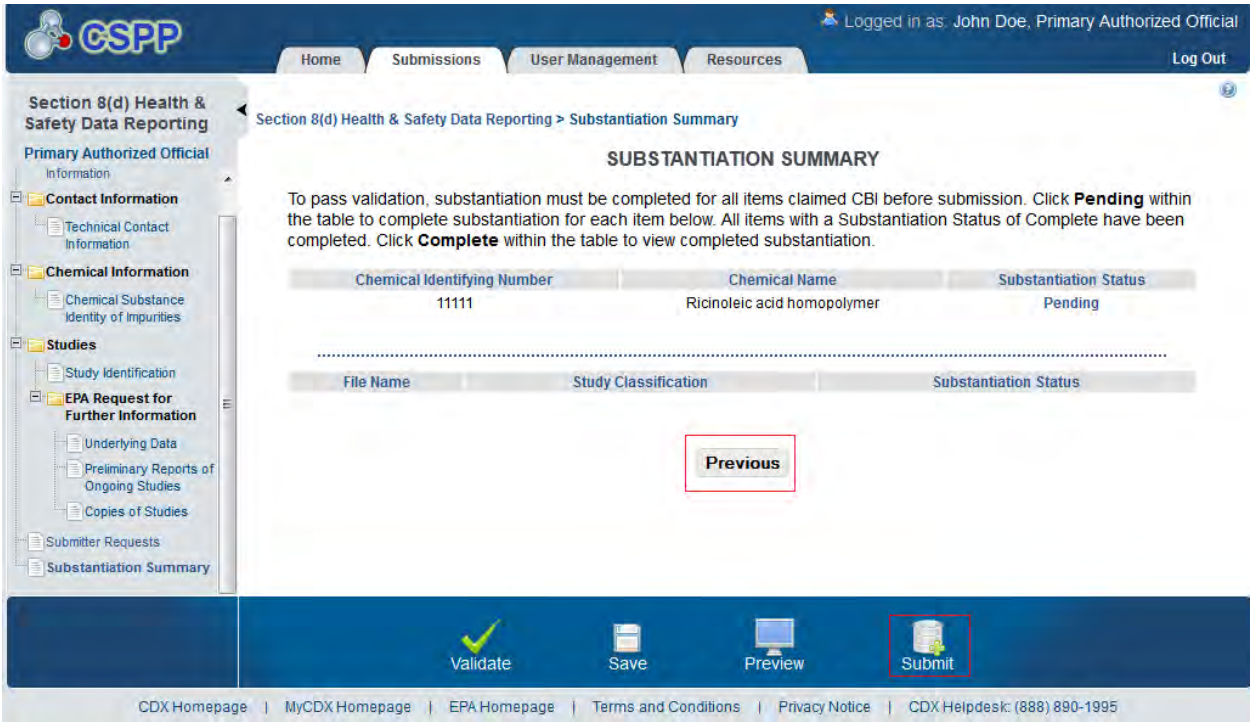
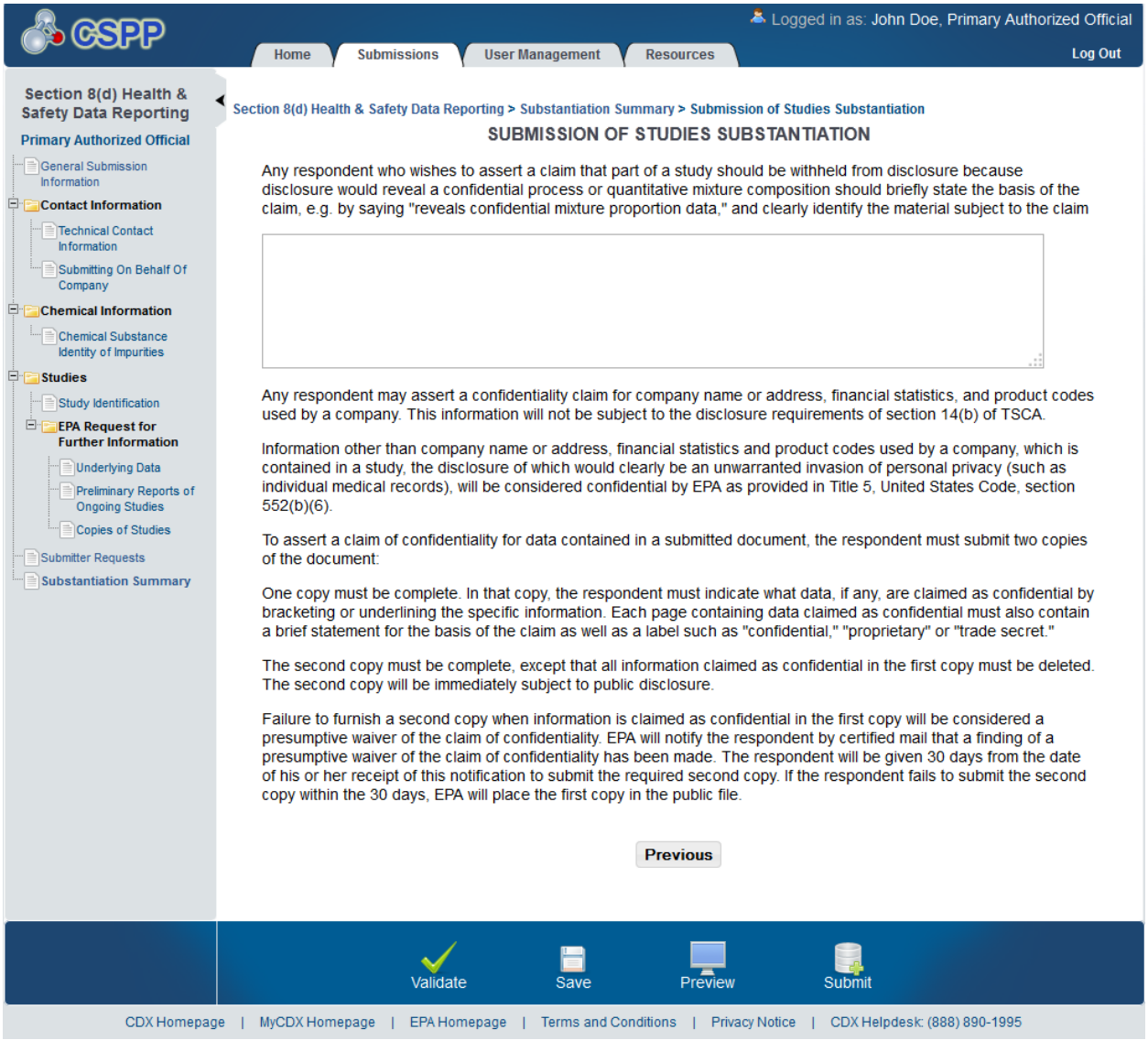


Exhibit 3-49 shows the screen capture of the 'Submission of Studies Substantiation' screen:

Exhibit 3-49: Submission of Studies Substantiation Screen



Navigation: Once all substantiation statuses are complete, click the 'Submit' icon to begin the submission process.

4 Validate

You can click the 'Validate' icon ( ) at any stage of completing a Section 8(d) Health & Safety Data Reporting submission. The 'Section 8(d) Health & Safety Data Reporting Validation' pop-up window displays when you click the 'Validate' icon ( ). The 'Section 8(d) Health & Safety Data Reporting Validation' pop-up window displays a report of all validation errors and warning messages. During the validation process, the application validates each screen of the Section 8(d) Health & Safety Data Reporting 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 8(d) Health & Safety Data Reporting Validation' pop-up window. If the information you fixed passes validation, the error will be removed from the 'Section 8(d) Health & Safety Data Reporting Validation' pop-up window. You must fix all validation errors in order to submit the submission to CDX successfully.

You can close the 'Section 8(d) Health & Safety Data Reporting Validation' pop-up window by clicking the 'X' button located at the top right of the window.

Exhibit 4-1 shows the screen capture for the 'Section 8(d) Health & Safety Data Reporting Validation' pop-up window:

Exhibit 4-1: Section 8(d) Health & Safety Data Reporting Validation Pop-Up Window

5 Submit to EPA via CDX

As the Primary AO, you have the ability to sign and submit Section 8(d) Health & Safety Data Reporting submissions to EPA. Any assigned Supports for your submissions do not have access rights to submit to EPA via CDX.

Once you complete all required information and correct all items failing validation, the system will allow you to successfully submit.

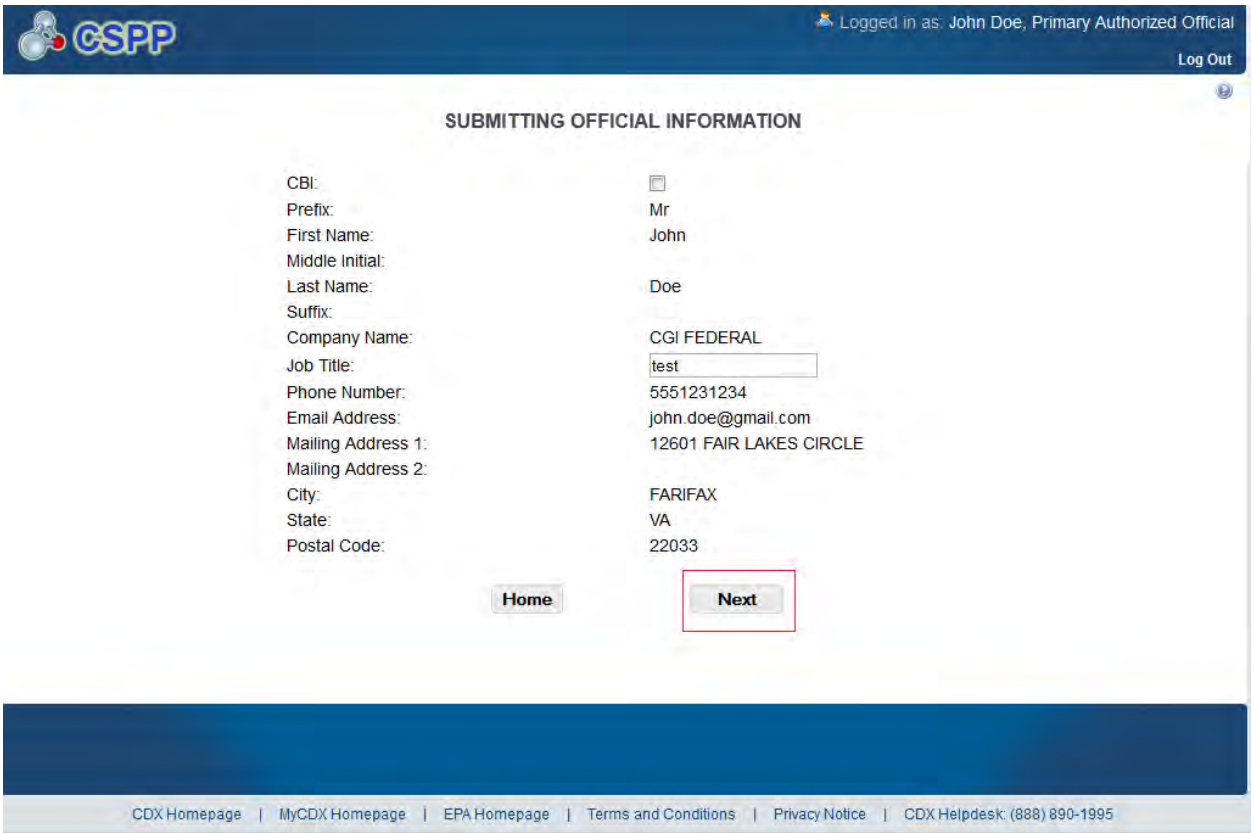
5.1 Submitting Official Information Screen

Click the 'Submit' icon ( ) located in the bottom action bar of the Section 8(d) Health & Safety Data Reporting application to access the 'Submitting Official Information' screen. This screen is only displayed to the Primary AO upon submission.

After clicking the 'Submit' icon ( ), the system requires you to review your contact information provided during CDX registration. The system also requires you to identify your job title.

Exhibit 5-1 shows the screen capture of the 'Submitting Official Information' screen:

Exhibit 5-1: Submitting Official Information Screen



Navigation: Click the 'Next' button to continue the submission process and proceed to the 'Submission Process: Validation' screen.

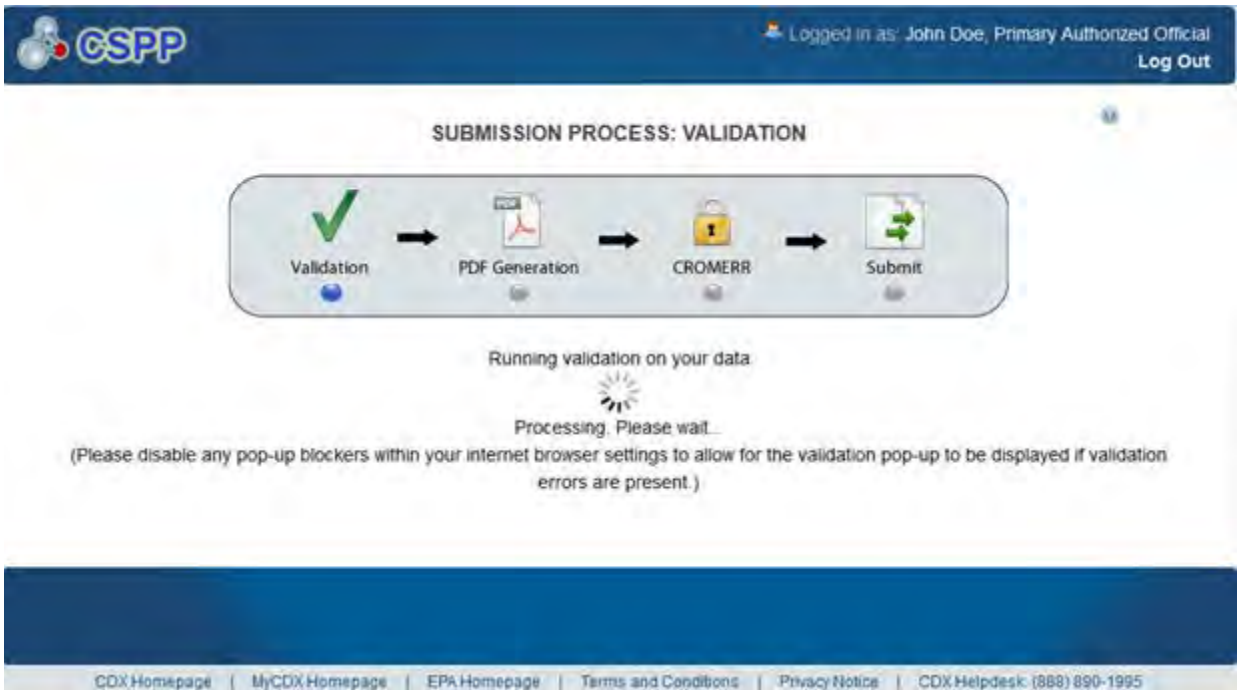
5.2 Submission Process: Validation Screen

You can access the 'Submission Process: Validation' screen by clicking the 'Next' button from the 'Submitting Official Information' screen.

This step in the submission process will validate the information entered within the Section 8(d) Health & Safety Data Reporting submission.

Exhibit 5-2 shows the screen capture of the 'Submission Process: Validation' screen:

Exhibit 5-2: Submission Process: Validation Screen



After the Section 8(d) Health & Safety Data Reporting submission is verified, a PDF is generated for the user to view.

Exhibit 5-3 shows the screen capture of the 'Submission Process: PDF Generation' screen:

Exhibit 5-3: Submission Process: PDF Generation Screen

Navigation: Click the 'Continue' button to continue the submission process and proceed to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Certification' screen. Click the 'View PDF' button to view a copy of the Section 8(d) Health & Safety Data Reporting submission.

5.3 Cross-Media Electronic Reporting Regulation (CROMERR) Certification Screen

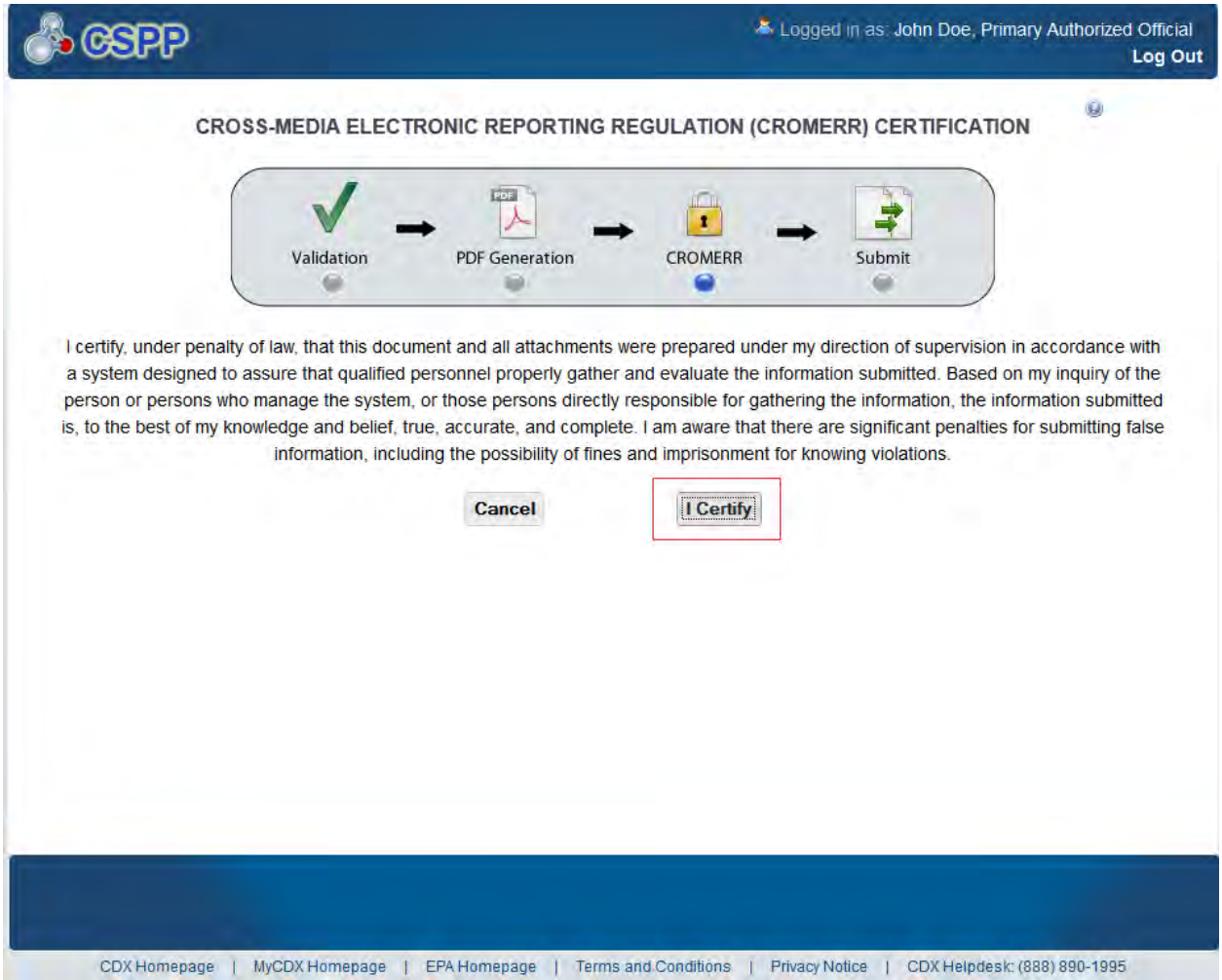
You can access the 'Cross-Media Electronic Reporting Regulation (CROMERR) Certification' screen by clicking the 'Continue' button on the 'Submission Process: PDF Generation' screen.

CROMERR provides the legal framework for electronic reporting under all of EPA's environmental regulations.

After clicking the 'Continue' button, the system requires the user to certify that the submission is CROMERR compliant. By clicking the 'I Certify' button on the 'Cross-Media Electronic Reporting Regulation (CROMERR) Certification' screen, the user authenticates all of the information entered in the submission. Clicking the 'Cancel' button will allow the user to navigate back to the Section 8(d) Health & Safety Data Reporting application.

Exhibit 5-4 shows the screen capture for the 'Cross-Media Electronic Reporting Regulation (CROMERR) Certification' screen:

Exhibit 5-4: Cross-Media Electronic Reporting Regulation (CROMERR) Certification Screen



Navigation: Click the 'I Certify' button to continue the submission process and proceed to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Login' screen.

5.4 Cross-Media Electronic Reporting Regulation (CROMERR) Login Screen

You can access the 'CROMERR Login' screen by clicking the 'I Certify' button on the 'CROMERR Certification' screen.

To submit the Section 8(d) Health & Safety Data Reporting submission, log in to CDX using the credentials you provided during CDX registration:

- **Please login with your CDX password:** Enter your CDX registration password.

Exhibit 5-5 shows the screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Login’ screen:

Exhibit 5-5: Cross-Media Electronic Reporting Regulation (CROMERR) Login Screen

Navigation: Enter your CDX registration password and click the ‘Next’ button to continue the submission process and proceed to the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen.

5.5 CROMERR Security Question Screen

You can access the ‘CROMERR Security Question’ screen by entering your CDX registration password and clicking the ‘Next’ button on the ‘CROMERR Login’ screen.

The ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen randomly selects and displays one of the five CROMERR eSIG-PIN questions that you answered on the 20-5-1 question screen during CDX registration. Answer the CROMERR security question and click the ‘Next’ button.

Exhibit 5-6 shows the screen capture of the ‘Cross-Media Electronic Reporting Regulation (CROMERR) Security Question’ screen:

Exhibit 5-6: Cross-Media Electronic Reporting Regulation (CROMERR) Security Question Screen

Navigation: Answer the security question and click the ‘Next’ button to continue the submission process and proceed to the ‘Submit to CDX’ screen.

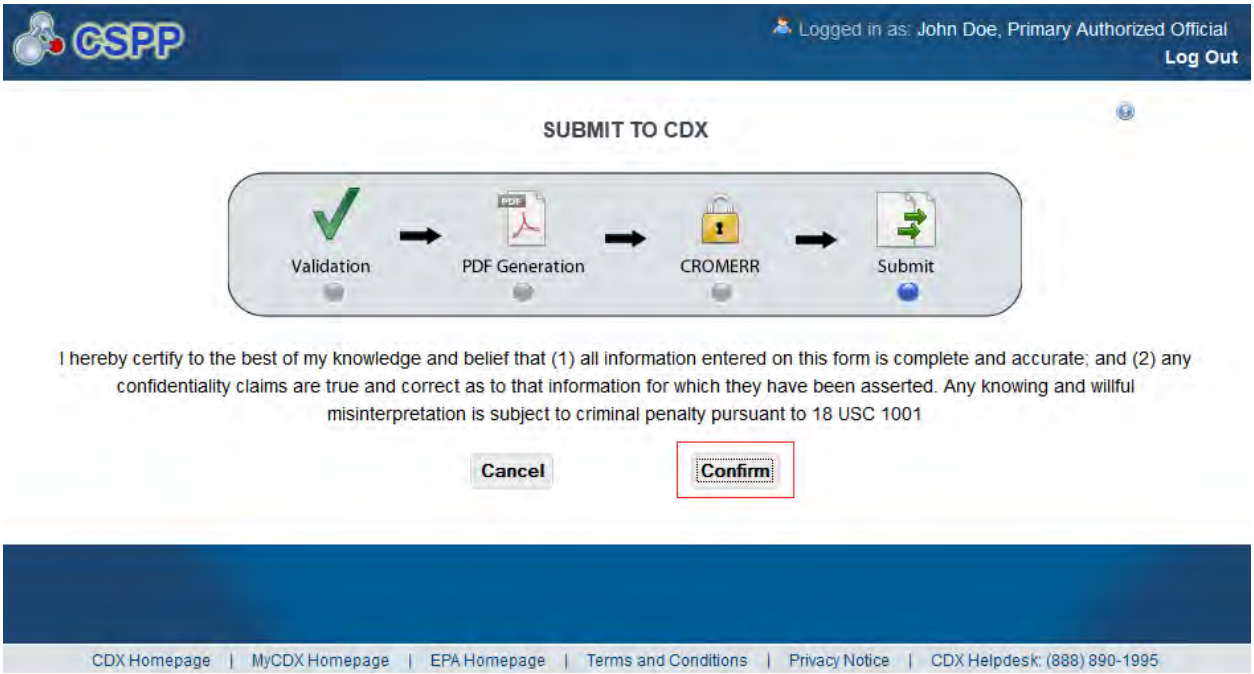
5.6 Submit to CDX Screen

You can access the ‘Submit to CDX’ screen after answering the 20-5-1 security question and clicking the ‘Next’ button on the ‘CROMERR Security Question’ screen.

On the ‘Submit to CDX’ screen, you will see a certification message. Read the message and acknowledge it by clicking the ‘Confirm’ button. Once you click the ‘Confirm’ button, your submission will be submitted to CDX.

Exhibit 5-7 shows the screen capture of the 'Submit to CDX' screen:

Exhibit 5-7: Submit to CDX Screen



Navigation: Click the 'Confirm' button to navigate to the 'Cross-Media Electronic Reporting Regulation (CROMERR) Submission' screen.

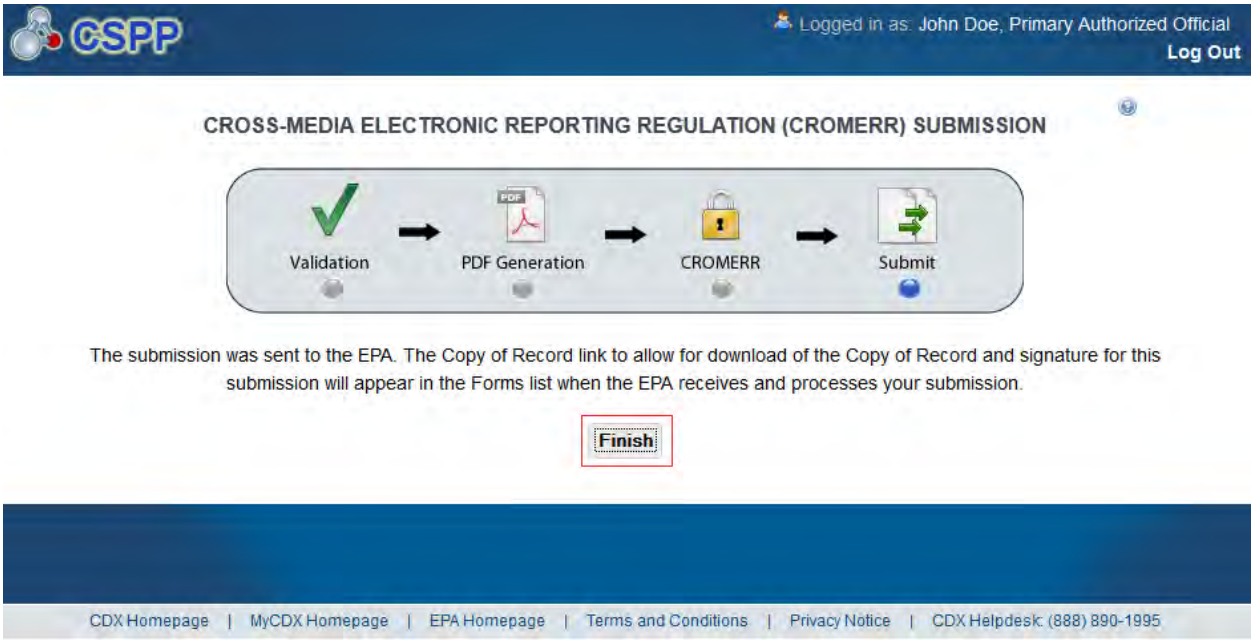
5.7 Cross-Media Electronic Reporting Regulation (CROMERR) Submission Screen

You can access the 'Cross-Media Electronic Reporting Regulation (CROMERR) Submission' screen by acknowledging the certification to submit to CDX by clicking the 'Confirm' button on the 'Submit to CDX' screen.

On the 'Cross-Media Electronic Reporting Regulation (CROMERR) Submission' screen, you will see a message indicating the submission has been successfully submitted to CDX.

Exhibit 5-8 shows the screen capture of the 'Cross-Media Electronic Reporting Regulation (CROMERR) Submission' screen:

Exhibit 5-8: Cross-Media Electronic Reporting Regulation (CROMERR) Submission Screen



Navigation: Click the 'Finish' button to navigate to the Section 8(d) Health & Safety Data Reporting 'Home' screen. Click the 'Submissions' tab or link to find your locked, submitted submission. The 'Section 8(d) Health & Safety Data Reporting' submissions screen will display the submission with a 'Lock' icon (🔒) under the 'Action' column and will display a status of 'Submitted.'

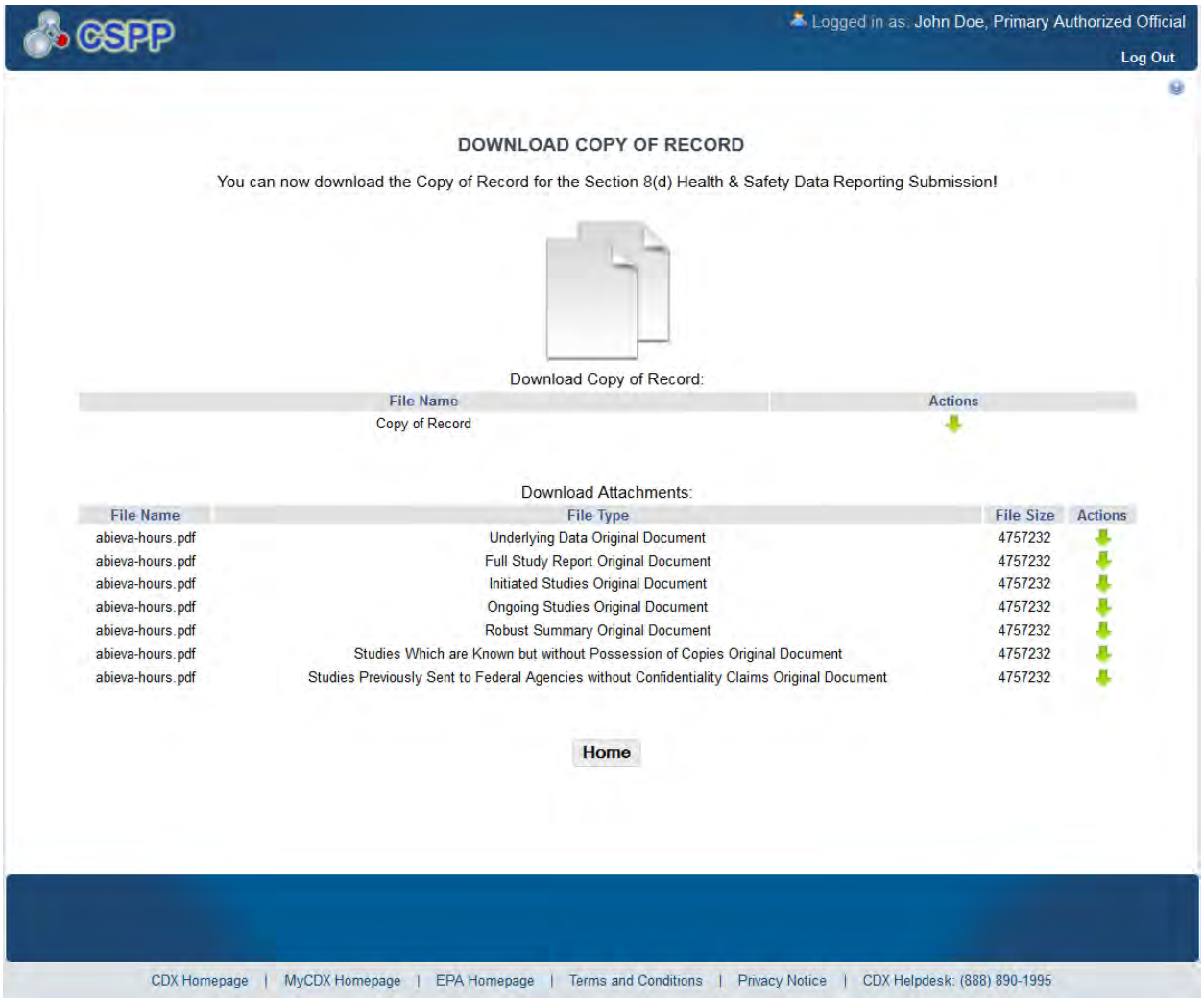
6 Download Copy of Record

To download a copy of record, navigate to the 'Section 8(d) Health & Safety Data Reporting' submissions screen and locate a submission with a status of 'Submitted.'

Click the 'Copy of Record' icon from the 'Section 8(d) Health & Safety Data Reporting' submissions screen. You will be taken to the 'Enter Passphrase' screen to login to CDX using your CDX passphrase. Note that if you recently submitted your Section 8(d) Health & Safety Data Reporting submission to CDX, the 'Copy of Record' icon may take 15-20 minutes to display. In addition, you must refresh your submissions screen by clicking the refresh button on the address bar of the browser in order for the 'Copy of Record' icon to display.

Exhibit 6-1 shows the screen capture of the 'Download Copy of Record' screen:

Exhibit 6-1: Download Copy of Record Screen

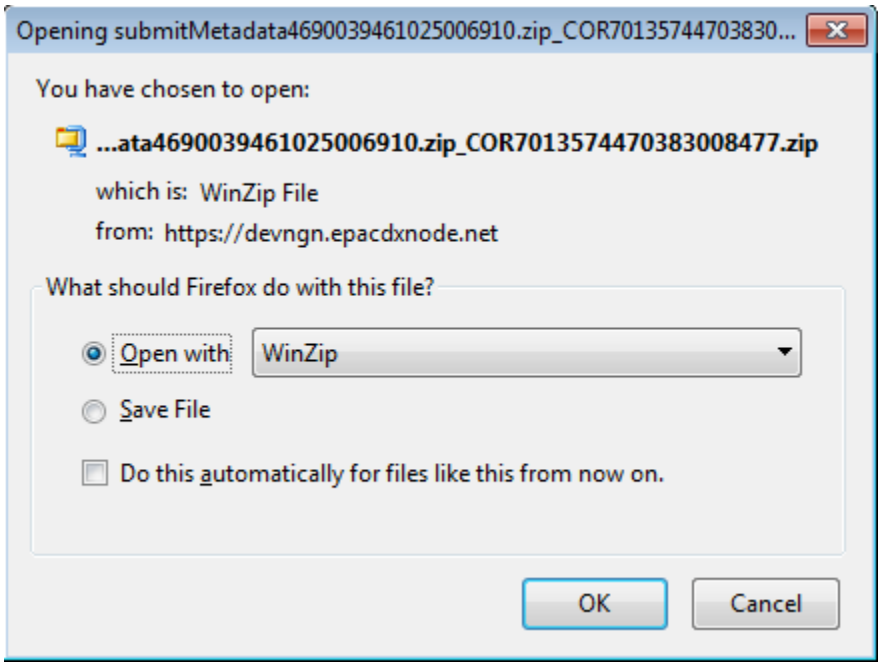


The 'Download Copy of Record' screen displays the 'File Name,' 'File Type,' 'File Size,' and 'Actions' columns in a table format. You can click the 'Copy of Record' icon in the 'Actions' column to download the individual document, PDF version of the submitted submission, or the XML version of the Section 8(d) Health & Safety Data Reporting submission. When you click

the ‘Copy of Record’ icon, the system will allow you to view or download the individual files that were uploaded during the submission process.

Exhibit 6-2 shows a screen capture of the download prompt screen:

Exhibit 6-2: Download Prompt Screen

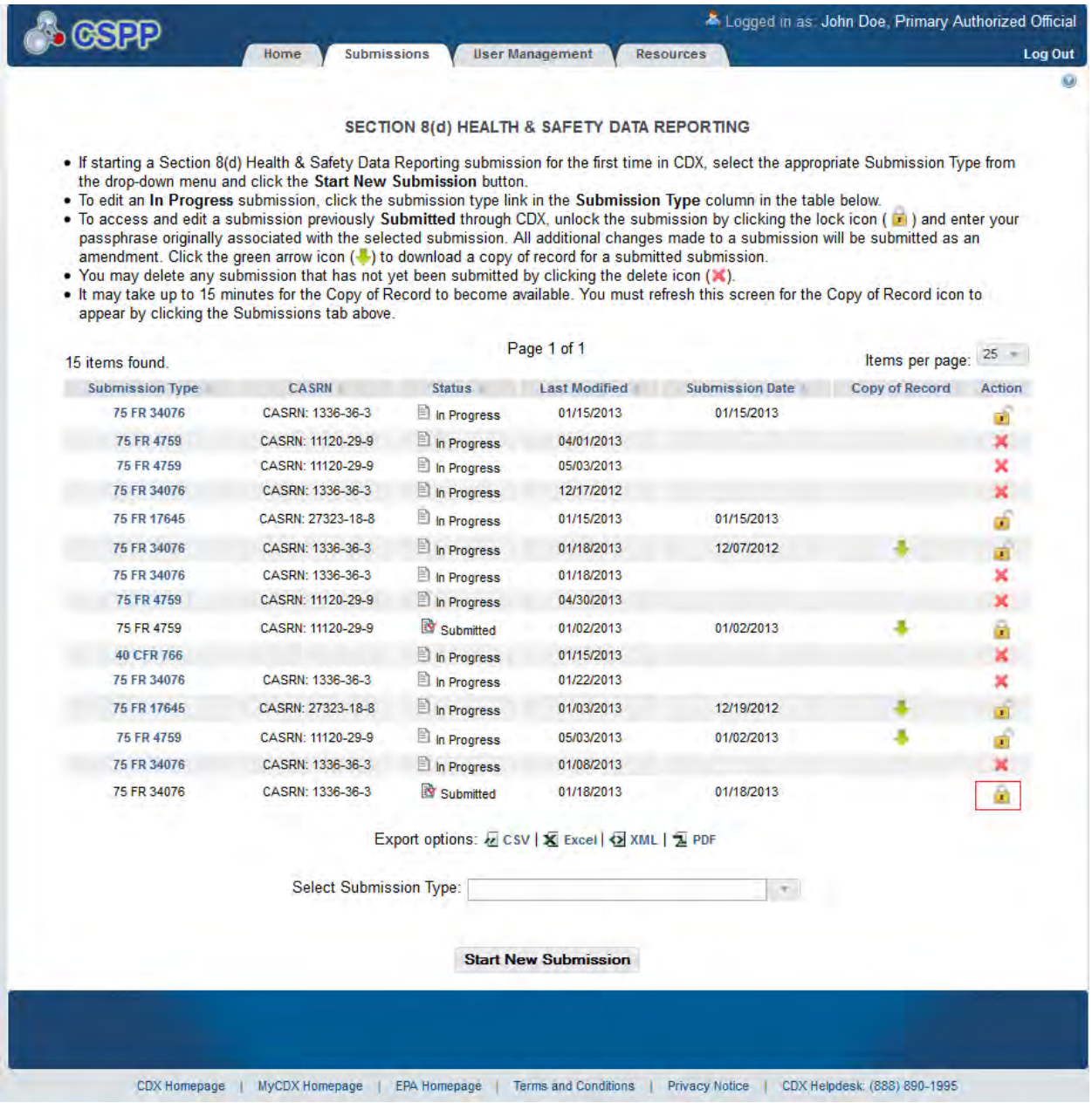


7 Create an Amendment

To amend a submitted Section 8(d) Health & Safety Data Reporting submission, navigate to the 'Section 8(d) Health & Safety Data Reporting' submissions screen and locate a submission with a status of 'Submitted.' In addition to displaying a status of 'Submitted' under the 'Status' column, the 'Lock' icon (🔒) will display under the 'Action' column. Click the 'Lock' icon (🔒) under the 'Action' column to start an amendment.

Exhibit 7-1 shows the screen capture of the 'Section 8(d) Health & Safety Data Reporting' submissions screen:

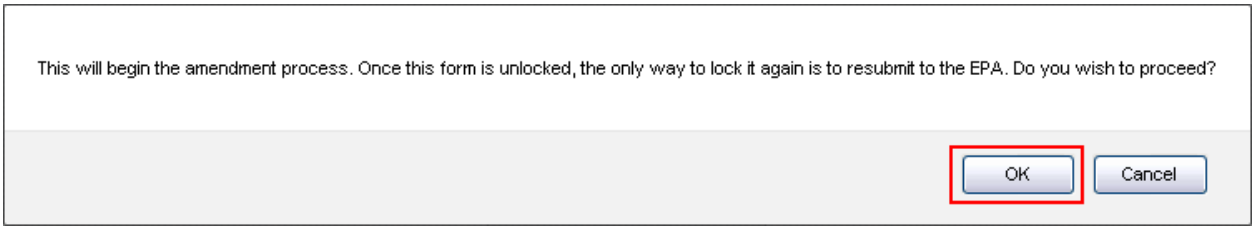
Exhibit 7-1: Section 8(d) Health & Safety Data Reporting Submissions Screen – Amendment



Navigation: After clicking the 'Lock' icon ( ), you will receive a prompt to confirm the amendment process. If you unlock a submission, you will be required to resubmit the submission to CDX after you have completed editing the submission. If you do not want to continue with the amendment, click the 'Cancel' button to cancel the amendment process and return to the 'Section 8(d) Health & Safety Data Reporting' submissions screen. Click the 'OK' button to close the prompt and continue with the amendment.

Exhibit 7-2 shows the screen capture of the 'Unlock Prompt' message:

Exhibit 7-2: Unlock Prompt Message



After you click the 'OK' button, you will be taken to the 'Enter Passphrase' screen. You must enter the passphrase originally associated with the submission to start the amendment process. After you enter the passphrase and click the 'Next' button, you will be taken to the 'Technical Contact Information' screen. Refer to **Section 3.4.3** for further instructions on the 'Enter Passphrase' screen.

After a submission has been unlocked, the 'Section 8(d) Health & Safety Data Reporting' submissions screen will display a status of 'In Progress' under the 'Status' column, and the 'Unlocked' icon ( ) will display under the 'Action' column; however, you will not see these changes until you navigate back to the 'Section 8(d) Health & Safety Data Reporting' submissions screen.

8 Resources

You can access the ‘Resources’ screen by clicking the ‘Resources’ tab located in the application header. You can also access the ‘Resources’ screen by clicking the ‘Resources’ link from the Section 8(d) Health & Safety Data Reporting ‘Home’ screen. The ‘Resources’ screen provides you with links to all of the Section 8(d) Health & Safety Data Reporting application user guides as well as additional helpful links. Click the ‘User Guide’ links to access the Section 8(d) Health & Safety Data Reporting user guide document.

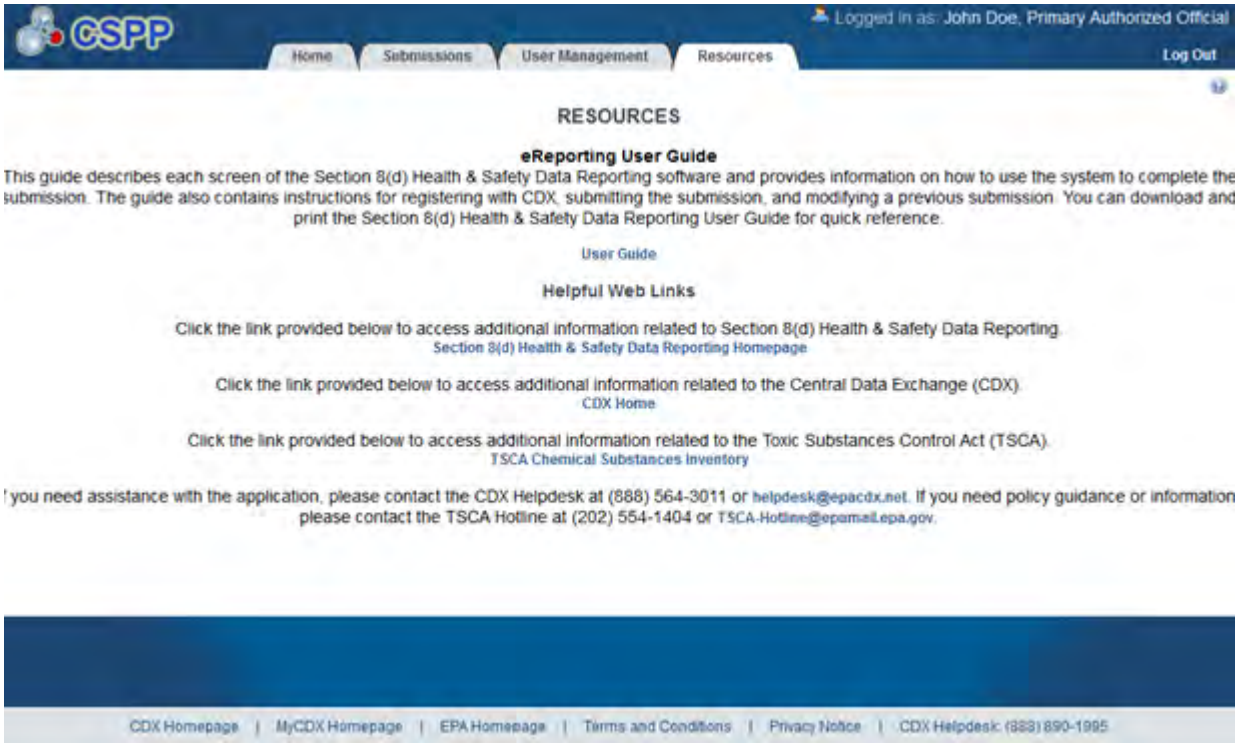
Section 8(d) Health and Safety Data Reporting Homepage: If you click this link, a new internet browser window will generate displaying the ‘Section 8(d) Health and Safety Data Reporting’ screen.

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 8-1 shows the screen capture of the 'Resources' screen:

Exhibit 8-1: Resources Screen



Appendix A. Definitions, Acronyms, and Abbreviations

The following is a list of all the definitions, acronyms, and abbreviations used in this document and their full name.

Definitions, Acronyms, and Abbreviations

Acronym	Full Name
AO	Authorized Official
CA	Chemical Abstract
CASRN	Chemical Abstract Services Registry Number
CBI	Confidential Business Information
CDX	Central Data Exchange
CFR	Code of Federal Regulation
CoR	Copy of Record
CROMERR	Cross-Media Electronic Reporting Regulation
CSPP	Chemical Safety and Pesticide Programs
CSV	Comma Separated Values
EPA	Environmental Protection Agency
EST	Eastern Standard Time
FRN	Federal Register Notice
IUPAC	International Union of Pure and Applied Chemistry
OPPT	Office of Pollution Prevention and Toxics
PDF	Portable Document Format
PMN	Premanufacture Notice
SRS	Substance Registry Services
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