



**U.S. FOOD & DRUG
ADMINISTRATION**

**Food and Drug Administration (FDA)
Office of Regulatory Affairs (ORA)
National Food Safety Data Exchange (NFSDX)**

**State Integration Guide
for Submission of Contracted Inspection Results**

Version 1.6

April 4, 2022

Revision History

Version Number	Implemented By	Revision Date	Approved By	Approval Date	Description of Change
1.0	FDA	11/26/18			Initial Document
1.1	FDA	4/10/19			Updated for Contracted Inspection Results with Optional BSE and/or Seafood HACCP data
1.2	FDA	4/21/2020			Updated for Schema 11.0
1.3	FDA	1/25/2021			Updated for Schema 11.1
1.4	FDA	7/14/2021			Updated for Schema 11.2
1.5	FDA	8/9/2021			Updated with the reference to the Rel. 9.1 Firm Service update Added FAQ section Updated Technical Support Information
1.6	FDA	4/4/2022			Updated with the reference to Contact ID functionality for Rel.11.1

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1. PURPOSE AND SCOPE

1.1. SYSTEM OVERVIEW

To improve the efficiency and efficacy of exchanging information with regulatory partners and to meet the federally mandated requirements of the Food Safety Modernization Act (FSMA), FDA developed the National Food Safety Data Exchange (NFSDX), also known as the Data Exchange, system to provide the capability to electronically exchange data and information across regulatory entities.

The NFSDX: 1) provides secure and immediate access to relevant regulatory information, 2) enhances the ability of the food safety community to share that information in a timely manner, and 3) provides analysis and other collaboration tools to assist investigators and regulatory partners working cases cooperatively with other agencies. The data exchange supports the Integrated Food Safety System (IFSS) to achieve mutual reliance amongst partner agencies and assure high rates of compliance with food safety laws and regulations.

1.2. PURPOSE OF THIS DOCUMENT

The purpose of this document is to define the interface details for sharing data between NFSDX and State regulatory partners. It specifies all possible inputs and outputs from the systems for all potential actions. Its intended audiences are the regulatory partners' project teams, including development teams and other stakeholders interested in NFSDX.

The scope of the State Integration Guide for Submission of Contracted Inspection Results with optional Bovine Spongiform Encephalopathy (BSE) and/or Seafood Hazard Analysis Critical Control Point (HACCP) data is to define the interface details for sharing data between NFSDX and State regulatory partners. It specifies all possible inputs and outputs from the systems for all potential actions. Its intended audiences are the regulatory partners' project teams, including development teams and other stakeholders interested in NFSDX.

1.3. SCOPE

The scope of this State Integration Guide for Submission of Contracted Inspection Results with Optional BSE and/or Seafood HACCP, POC, POC TMO, and IA Protocol Data is limited to the instructions for submitting Contracted Inspection results with optional BSE and/or Seafood HACCP, POC, POC TMO, and IA Protocol Data to FDA via NFSDX. These details are intended to assist the States that submit these Contracted Inspection results to integrate with NFSDX.

1.4. REQUIREMENTS AND ASSUMPTIONS

States will be expected to meet and understand the following requirements and assumptions in order to submit Contracted Inspection data via NFSDX:

- The State system is capable of communicating using Simple Object Access Protocol (SOAP) based web services
- The State's Extensible Markup Language (XML) message will always contain a SOAP header with username and password credentials and the transaction type, and a

payload containing Transaction Header elements and the State's Contracted Inspection elements, including BSE and Seafood HACCP data

- Once State agency participation in the data exchange is approved, the State agency receives a zip file, *ORA DX Contracted Inspection with Attachments State Integration Package Rel 11.1 Schema 11.2.zip*, containing the following files:
 - Contracted Inspection-related files
 - SIG_ContrInsp_BSE_Seafood_POC_IA.docx
 - SIG_Suppl_BSE_Seafood_POC_IA.docx
 - ContInsp Data Elements Business Rules.xlsx
 - PAC (Program Assignment Code) Codes and Descriptions.xlsx for a quick reference
 - eSAF_State_with Operation Statuses.PDF - a flowchart to depict how the Contracted Inspection submissions and the Contracted Inspection submission updates work regarding the Operation Status
 - Contracted Attachments-related files
 - SIG_ContractInsp_Attach.docx
 - SIG_Suppl_ContractInsp_Attach.docx
 - Attachment Data Elements Business Rules.xlsx
 - Common Files
 - NFSDX Schema v11.2.zip
 - NfsdxService11.2.WSDL file
 - ReferenceDataSTATES.xml

WSDL file describes the NFSDX synchronous web service for both the Pre-Production and Production environments. Other supporting files, NFSDX Schema v11.2.zip, ContInsp Data Elements Business Rules.xlsx, and ReferenceDataSTATES.xml, are described in detail in Appendices B and D.

The Supplement to the State Integration Guide for Submission of Contracted Inspection results with Soap request and response examples will be provided upon request.

Contracted Inspection Attachments-related files are described in detail in the Contracted Inspection Attachments State Integration Guide.

1.5. GLOSSARY OF TERMS

Definitions of abbreviated terms and acronyms used within this document are listed in [Appendix A: Glossary of Terms of Terms](#).

1.6. TECHNICAL SUPPORT

If you have any questions about this information and/or need help from the NFSDX team, please use the information listed in [Appendix E: NFSDX Technical Support](#) to contact technical support.

2. SYSTEM INTERFACE DETAILS

2.1. STATES-NFSDX INTERFACE OVERVIEW

The States–NFSDX interface allows States to submit Contracted Inspection results with optional BSE and/or Seafood HACCP data to the FDA system of record and receive business validation and error messages, using data exchange protocols such as SOAP and HTTPS. NFSDX provides message delivery services to the States to indicate the success or failure of the data validation and/or data delivery process. The following systems support this process:

- State System – Provides Contracted Inspection results with optional BSE and/or Seafood HACCP data to complete FDA assignments
- NFSDX – Processes Contracted Inspection results with optional BSE and/or Seafood HACCP data and sends it to the FDA system of record for validation and storage through exposed web service endpoints

2.2. STATES-NFSDX BUSINESS FLOW

The States–NFSDX interface allows NFSDX to receive Contracted Inspection results with optional BSE and/or Seafood HACCP data from participating States and route the data to the FDA system of record. NFSDX provides XML-based standards for States to submit inspection data and supports auditing capabilities by storing transactional data such as calling system, organization, etc. The XML schema defined in [Appendix B: Inspection Data Message Schema and Reference Data](#) is used to receive and submit inspection data. The NFSDX business flow covers the following processes: 1) State user authentication, 2) State submission of valid Contracted Inspection results with optional BSE and/or Seafood HACCP data to FDA, and 3) State notification of submission process outcome.

The diagram in **Exhibit 1** below provides a visual illustration of the business process flow for Submission of Contracted Inspection results with optional BSE and/or Seafood HACCP data to NFSDX.

The NFSDX business flow is summarized as follows:

1. NFSDX receives Contracted Inspection results with optional BSE and/or Seafood HACCP data submission request from the State and authenticates the State user. In the case of invalid State credentials, NFSDX rejects the submission and notifies the State that access was denied. In the case of successful authentication, the Contracted Inspection results with optional BSE and/or Seafood HACCP data are processed in XML format from the State.
2. NFSDX validates the Contracted Inspection XML results with optional BSE and/or Seafood HACCP data against the ORA XML schema. If the submitted XML file fails

schema validation, NFSDX sends notification back to the State that validation failed. In the case of successful XML validation, the Contracted Inspection results with optional BSE and/or Seafood HACCP data go through business rules validation. If the Contracted Inspection results with optional BSE and/or Seafood HACCP data passes business validation, the data is stored in the FDA system of record.

- Once the Contracted Inspection results with optional BSE and/or Seafood HACCP data is processed, depending on the outcome, the notification of successful or unsuccessful delivery/failed business validation is sent back to the State. Every transaction is recorded in the NFSDX audit log.

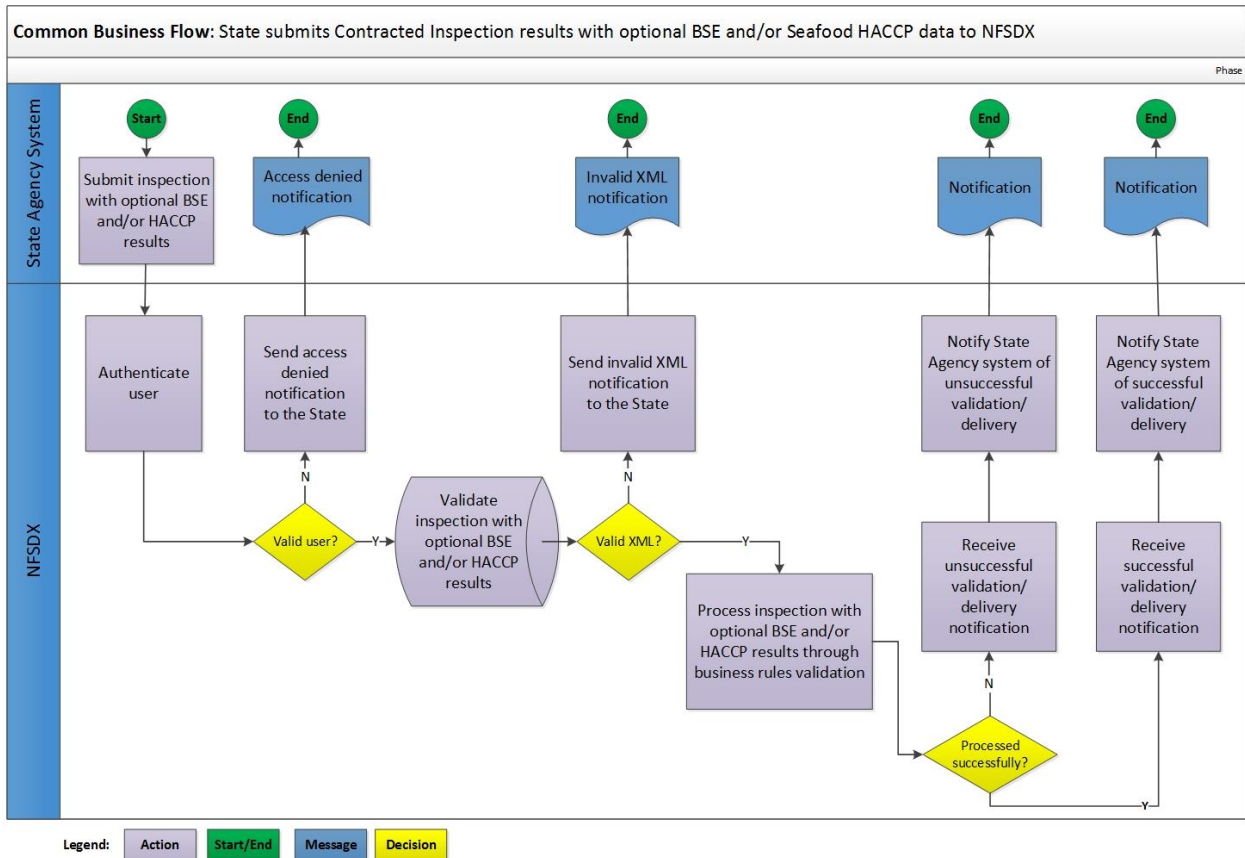


Exhibit 1: Business flow for States submitting Contracted Inspection results with optional BSE and/or Seafood HACCP data to NFSDX

2.3. NFSDX WEB SERVICE ENDPOINTS

The NFSDX system will provide web service endpoints for the States to submit Contracted Inspection results with optional BSE and/or Seafood HACCP data.

Environment	Endpoint
Pre-Production	https://nfsdx.preprod.fda.gov/inspection/NFSDXService/NfsdxProxyService
Production	https://nfsdx.fda.gov/inspection/NFSDXService/NfsdxProxyService

The WSDL file and the associated XML schema files will be provided to the states when development activities are approved to begin.

2.4. SUPPORTED OPERATIONS

The following table lists all operations supported by States–NFSDX interface.

Client / Server	Operation	Inputs	Outputs	Description
STATE → NFSDX	SubmitInspectionData	Inspection Data	Response Message	State submits Inspection results with optional BSE and/or Seafood HACCP data to the FDA system of record via NFSDX.
STATE → NFSDX	UpdateInspectionData	Inspection Data	Response Message	State submits updated Inspection results with optional BSE and/or Seafood HACCP data to the FDA system of record via NFSDX.

2.5. STATES-NFSDX DATA TRANSFER

The following table lists the data that is transferred through the States–NFSDX interface.

Interface From	Interface To	Interface Type	Frequency	Data Format	Protocol	Data Transferred
State	NFSDX	Web Service	Real-time	XML	SOAP / HTTPS	Inspection Data Request (for both submit and update) messages. Appendix B: Inspection Data Message Schema and Reference Data for the Inspection Data Request schema.
NFSDX	State	Web Service	Real-time	XML	SOAP / HTTPS	Inspection Data (for both submit and update) Response messages. Refer to Appendix B: Inspection Data Message Schema and Reference Data for the Response Message schema.

2.6. STATES-NFSDX INTEGRATION STEPS FOR SUBMITTING OR UPDATING INSPECTION DATA

The steps involved in NFSDX integration are as follows.

1. The State client constructs a SOAP message containing:
 - A SOAP header which includes username and password credentials. (Please refer to [Section 3.4](#) for details about SOAP header security requirements)
 - A SOAP header which includes the transaction type: inspection11.2. Please note that the entry is case-sensitive
 - A SOAP payload which includes transaction header elements and State Contracted Inspection results with optional BSE and/or Seafood HACCP data elements. Conditionally required, Intentional Adulteration (IA) protocol data, and Top Management Official (TMO) Point of Contact (POC) data are also included. (Please refer to Appendix B: Inspection Data Message Schema and Reference Data for a list of the State Contracted Inspection results with optional BSE and/or Seafood HACCP data elements that are supported)
2. The State client invokes the NFSDX web service endpoint using the HTTPS protocol to submit the SOAP message. The following table lists the endpoints for each environment that the State should call when submitting Contracted Inspection data to NFSDX.

Environment	Endpoint
Pre-Production	https://nfsdx.preprod.fda.gov/inspection/NFSDXService/NfsdxProxyService
Production	https://nfsdx.fda.gov/inspection/NFSDXService/NfsdxProxyService

3. NFSDX authenticates State client credentials.
4. NFSDX validates the SOAP message payload against the XSD schema listed in [Appendix B: Inspection Data Message Schema and Reference Data](#).
5. NFSDX passes the Contracted Inspection results with optional BSE and/or Seafood HACCP data to the FDA system of record for business validation and processing, captures a response message, and forwards the response back to the State.
6. When an error occurs in the NFSDX system , a “Failure” response message will be constructed in NFSDX and sent to the state.

2.7. STATE SUBMITS INSPECTION DATA TO FDA

The table below shows the Submit Inspection Result operation supported by the States–NFSDX interface.

Client / Server	Operation	Inputs	Outputs	Description
STATE → NFSDX	SubmitInspectionData	Inspection Data	Response Message	Submit Inspection results with optional BSE and/or Seafood HACCP data to the FDA system of record via NFSDX.

The submit request message from the State will include three elements:

1. SOAP Header – The mandatory fields for the SOAP header are username and password, and the transaction type of inspection

```
<info:TransactionType
xmlns:info="http://fda.gov/ora/DataSharing/schema/Info">inspection11.2</info:TransactionType>
```

```
<info:ApplicationID
xmlns:info="http://fda.gov/ora/DataSharing/schema/Info">104</info:ApplicationID>
```

2. Transaction Header – The mandatory fields for the Transaction header are ApplicationID, TransactionID, and TransactionTimeStamp
3. Payload – Contracted Inspection results with optional BSE and/or Seafood HACCP data are expected in the Payload section. For the list of required and optional Contracted Inspection data payload elements, please refer to the *ContInsp Data Elements Business Rules.xlsx* spreadsheet in [Appendix B: Inspection Data Message Schema and Reference Data](#).

Starting with Schema 11.2, for the selected (Human Food) Program Assignment Codes (PACs), the payload must include IA Protocol data. The PACs requiring IA Protocol data are listed in Appendix F: PACs Requiring Intentional Adulteration Protocol.

The [IntentionalAdulterationInfo] object captures the answers to IA protocol questions. If the PAC does not require IA, then the IA XML data element/object should not be included in the request.

The table below describes the States’ Submit Request Message elements in more detail.

Element Name	Location	Description
Username	SOAP Header	The State username; assigned by the NFSDX team to the State.
Password	SOAP Header	The State password; assigned by the NFSDX team to the State.
Transaction Type	SOAP Header	The transaction type: inspection
ApplicationID	Transaction Header	The NFSDX team will provide each State or State system with an ApplicationID.
TransactionID	Transaction Header	Unique identifier of a transaction. It is unique for each request/operation. (Example: 200001) provided by the client system.
SourceTransactionID	Transaction Header	Optional in request; unique identifier of a source transaction. It is unique for each request/operation set by the client system. (Example: 200001)
TransactionTimeStamp	Transaction Header	Date and Time of the request in Universal Time Coordinated (UTC) format set by the client system.

Element Name	Location	Description
OraSchemaVersion	Transaction Header	Schema Version number used for by the request provided by the NFSDX team and set by the client system.
NotificationEndpointUrl	Notification Endpoint	Notification endpoint for asynchronous service provided by the NFSDX team (not currently being used).
Contracted Inspection Data Elements	Payload Section	Payload section is provided by the client system. For a detailed list of the Contracted Inspection results with optional BSE and/or Seafood HACCP data elements, see the spreadsheet <i>Inspection_elements_with_BSEandSeafood.xlsx</i> in Appendix B: Inspection Data Message Schema and Reference Data .

2.8. STATE SUBMITS FIRM UPDATES USING FIRM POINT OF CONTACT (POC) ID(S) AS PART OF THE ORIGINAL SUBMISSION

The Payload may also contain Firm Update details. Data elements <FEI> and <FirmLegalName> are mandatory in FirmInfoType object of the schema. However, for Firm updates to be recognized by the business validation system, Contracted Inspection data XML should also include the <FirmAddressList> which is an optional object in FirmInfoType. The following elements are mandatory for the Firm update and must be included in the FirmAddressList object in the submitted XML:

- AddressLine1
- CityName
- ISOCountryCD

The POC information is optional unless the PAC requires that a Top Management Official (TMO) be identified – in this case the POC information is required. Starting with Schema 11.2, when submitting a Contracted Inspection for selected PACs requiring a TMO, the Payload must provide the firm’s POC information with the TMO designation or a justification for the lack thereof by populating the data element ReasonTMONotIdentified; e.g., “Top Management Official cannot be designated.”

The PACs that require submitting the TMO are listed in Appendix G: PACs Requiring TMO POC.

The PACs that DO NOT require submitting TMO are listed in the Appendix H: PACs not Requiring TMO POC.

Create, update, and delete operations on POC and TMO POC could be performed as part of the initial submission or as part of the updated submission. Several examples on how to perform create, update, and delete operations on POC and POC TMO data are found in the Supplement to the State Integration Guide for Submission of Contracted Inspection Results.

Current Firm POCs/TMOs can be retrieved from the Data Exchange using the SearchFDAFirms or GetFdaFirmDetails operations (with the ResponseObjectType flag set to “Full”). These operations are available as part of requesting and receiving FDA Firm data via NFSDX. To use this capability, request the onboarding State Integration Guide package for Firm Search based on Schema 8.1.3.

All other data elements in the Firm section of the schema are optional when providing firm information updates.

The following table lists the steps to obtain Firm POC IDs using Firm Search operations, to propose updates to or deletion of the existing Firm POCs, or, based on the Contracted Inspection findings, to add a new Firm’s POCs.

All Firm-related updates, including Firm POC, are subject to review and approval by FDA per the existing review process. Questions and answers to the potential Firm POC request and submission scenarios are described in the following table.

NOTE: In the following table, “existing Firm POC” refers to the Firm POC(s) currently associated with the inspected Establishment/Firm in the FDA database, and “new Firm POC” refers to the Firm POC(s) that the state would like to add to the Firm, based on the inspection results.

#	Question/Scenario	Answer
1.	I want to get the existing Firm POC ID(s) and POC key values (Name, Phone Number, etc.).	<p>Option 1: Submit GetFDAFirmDetails operation with the ResponseObjectType flag set to “Full”. The GetFDAFirmDetails operation is available via FDA Firm Search capability to retrieve Firm information for a given FEI.</p> <p>The call returns the PNT_CNTCT_ID (aka POC ID) along with other POC data (name, phone and/or email, TMO flag, if applicable) for existing Firm POC(s).</p> <p>Option 2: Submit SearchFdaFirms operation with the ResponseObjectType flag set to “Full”. The SearchFdaFirms operation is available via FDA Firm Search capability to retrieve Firm information for a given FEI.</p> <p>The call returns the PNT_CNTCT_ID (aka POC ID) along with other existing Firm POC data (name, phone and/or email, TMO flag, if applicable) for existing Firm POC(s).</p>

#	Question/Scenario	Answer
2.	For the existing Firm POC, what Firm POC ID should I submit as part of the Firm update?	Submit Firm POC ID (PNT_CNTCT_ID) retrieved by GetFDAFirmDetails or SearchFdaFirms operation for the inspected FEI. Make sure you use the correct POC ID otherwise the submission will be rejected. All existing Firm POCs need to be submitted with the appropriate action (Update or Delete). For no change to an existing POC, use Update for the PersonContactOperation flag.
3.	For a new Firm POC I propose to add, what POC ID should I submit as part of the Firm update?	For a new Firm POC, set POC ID (PNT_CNTCT_ID) to 0. Otherwise, the submission will be rejected.
4.	For the existing Firm POC, what do I set PersonContactOperation flag to?	For the existing Firm POC, set the PersonContactOperation flag to Update or Delete, depending on the desired outcome. For no change to an existing Firm POC, use Update for the PersonContactOperation flag.
5.	To add a new POC to the inspected Firm, what do I set PersonContactOperation flag to?	For a new Firm POC, set PersonContactOperation flag to Create.
6.	I have Firm updates to submit but I do not have any existing Firm POC changes to report.	In the payload, do not include the PersonContactsList section in the request unless the Firm POC updated is required based on the PAC code (see Appendix G, PACs Requiring TMO POC).
7.	I have existing Firm POC changes to report as part of the proposed Firm updates.	Retrieve existing Firm POC IDs and POC data using Firm Search GetFDAFirmDetails or the SearchFdaFirms operation. Include all existing Firm POC ID(s) with the applicable POC data changed, as needed, in your submission payload. Set Action Flag PersonContactOperation to Update.

#	Question/Scenario	Answer
		You must include all existing Firm Contacts, otherwise your submission will be rejected.
8.	I want to delete Firm POC(s) as part of the proposed Firm update.	<p>Retrieve existing Firm POC IDs and POC data using Firm Search GetFDAFirmDetails or the SearchFdaFirms operation.</p> <p>Include all existing Firm POC ID(s) with the applicable POC data in your submission. For the ones selected for deletion, set Action Flag PersonContactOperation to Delete.</p> <p>You must include all existing Firm Contacts, otherwise your submission will be rejected.</p>
9.	I want to add a new Firm POC.	<p>To propose a new Firm POC, provide POC data (name, phone and/or email, etc.) in your submission, set Contact ID to 0, and set the Action Flag PersonContactOperation to Create.</p> <p>NOTE: Always include all existing Firm POC ID(s) with the applicable POC data in your submission. For the existing Firm POC, set the Action Flag PersonContactOperation to Delete or Update, depending on the desired outcome.</p>
10	I want to update my previous submission of existing or new Firm POC data.	<p>There are no incremental updates: every subsequent update entirely overwrites the previous one.</p> <p>If you want to update only one of multiple POCs, you still need to submit all the existing Firm POCs with POC IDs and the corresponding POC data, and then set the Action Flag PersonContactOperation to Delete or Update, depending on the desired outcome.</p> <p>To propose a new Firm POC in your subsequent update, provide POC data (name, phone and/or email, etc.) in the</p>

#	Question/Scenario	Answer
		payload, set Contact ID to 0, and the Action Flag PersonContactOperation to Create.
11	I submitted a new Firm Contact POC in my initial submission, and now I want to delete it.	To delete a newly created Firm POC, do not include it in the subsequent Firm update. There are no incremental updates; every subsequent update entirely overwrites the previous one.
12	I want to submit Firm POC updates the “old” way, without using POC IDs.	<p>States are encouraged to use POC ID when submitting Firm POC data as this is the most accurate way to update and report POC information.</p> <p>However, to submit Firm POCs without POC ID (the “No POC ID way”), please follow the guidelines below:</p> <ol style="list-style-type: none"> 1. Make sure that none of the POC entries have a Firm POC ID. You cannot “mix and match” Firm POCs with and without POC IDs in your submission. 2. Provide POC data for the existing Firm POC(s) in the payload: existing Firms’ POCs will be looked up via the key values (name, phone, etc.). 3. The “No POC ID” way implies an incremental update; e.g., if the State added a new POC with the Create operation, then any subsequent (incremental) updates must use the Action Flag PersonContactOperation set to Update to make edits to this record. A subsequent update with the Action Flag PersonContactOperation set to Delete will remove this record from the proposed changes to the Firm POC data. 4. It is not necessary to include all existing Firms’ POCs: Firm POC records not included in the submission will be left unchanged.

#	Question/Scenario	Answer
		5. The Action Flag PersonContactOperation set can be blank. If left blank, it will default to Create.

2.9. STATE UPDATES INSPECTION DATA

States may use this operation to update previously submitted State Contracted Inspection results with optional BSE and/or Seafood HACCP data.

The table below shows the Update Inspection Result operation supported by the States–NFSDX interface.

Client / Server	Operation	Inputs	Outputs	Description
STATE → NFSDX	UpdateInspectionData	Inspection Data	Response Message	Update Inspection data in the FDA system of record

An update can be performed when data corrections are needed or to resubmit a previously submitted inspection which has been returned by the FDA system of record for updates. Please note that for the update operation, the request XML with updated inspection data should include all the data elements from the initial submission, including the ones that are being added or modified as part of the update operation. An example of code States to update previously submitted Contracted Inspection results with optional BSE and/or Seafood HACCP data will be made available States upon request.

The update request message from the State will include three elements:

1. SOAP Header – The mandatory fields for the SOAP header are username and password, and the transaction type of inspection

```
<info:TransactionType
xmlns:info="http://fda.gov/ora/DataSharing/schema/Info">inspection11.2</info:TransactionType>
<info:ApplicationID
xmlns:info="http://fda.gov/ora/DataSharing/schema/Info">104</info:ApplicationID>
```
2. Transaction Header – The mandatory fields for the Transaction header are ApplicationID, TransactionID, and TransactionTimeStamp
3. Payload – Contracted Inspection results with optional BSE and/or Seafood HACCP data are expected in the Payload section. For an update, the State is expected to submit all data elements, including the data elements being updated.

The Payload contains inspection results with optional BSE and/or Seafood HACCP data elements (if applicable), both updated and previously submitted. For the list of required and optional Contracted Inspection data payload elements, please refer to the

ContractedInsp Data Elements Business Rules.xlsx spreadsheet in [Appendix B: Inspection Data Message Schema and Reference Data](#).

Starting with Schema 11.2, for the selected (Human Food) PACs, the payload must include IA Protocol data. The PACs requiring IA Protocol data are listed in Appendix F: PACs Requiring Intentional Adulteration Protocol.

The [IntentionalAdulterationInfo] object captures the answers to IA protocol questions. If the PAC does not require IA, then the IA XML data element/object should not be included in the request.

The table below describes the States' update request message elements in more detail.

Element Name	Location	Description
Username	SOAP Header	The State username; assigned by the NFSDX team to the State.
Password	SOAP Header	The State password; assigned by the NFSDX team to the State.
Transaction Type	SOAP Header	The transaction type: inspection
ApplicationID	Transaction Header	The NFSDX team will provide each State or State system with an ApplicationID.
TransactionID	Transaction Header	Unique identifier of a transaction. It is unique for each request/operation. (Example: 200001)
SourceTransactionID	Transaction Header	Unique identifier of a source transaction. It is unique for each request/operation set by the client system. (Example: 200001)
TransactionTimeStamp	Transaction Header	Date and Time of the request in UTC format set by the client system.
OraSchemaVersion	Transaction Header	Schema Version number used for generating the request.
NotificationEndpointUrl	Notification Endpoint	Not currently being used.
Contracted Inspection results with optional BSE and/or Seafood HACCP Data Elements	Payload Section	Payload section is provided by the client system. For a detailed list of the Contracted Inspection results with optional BSE and/or Seafood HACCP data elements, see the spreadsheet <i>ContractedInsp Data Elements Business Rules.xlsx</i> in Appendix B.

2.10. STATE SUBMITS FIRM UPDATES USING FIRM POINT OF CONTACT (POC) ID(S) AS PART OF THE UPDATED SUBMISSION

The Payload may also contain Firm Update details. Data elements <FEI> and <FirmLegalName> are mandatory in FirmInfoType object of the schema. However, for Firm updates to be recognized by the business validation system, Contracted Inspection data XML should also

include the <FirmAddressList> which is an optional object in FirmInfoType. The following elements are mandatory for the Firm update and must be included in the FirmAddressList object in the submitted XML:

- AddressLine1
- CityName
- ISOCountryCD

The POC information is optional unless the PAC requires that a Top Management Official (TMO) be identified – in this case the POC information is required. Starting with Schema 11.2, when submitting a Contracted Inspection for selected PACs requiring a TMO, the Payload must provide the firm’s POC information with the TMO designation or a justification for the lack thereof by populating the data element ReasonTMONotIdentified; e.g., “Top Management Official cannot be designated.”

The PACs that require submitting the TMO are listed in Appendix G: PACs Requiring TMO POC. The PACs that DO NOT require submitting the TMO are listed in the Appendix H: PACs not Requiring TMO POC.

Create, update, and delete operations on POC and TMO POC could be performed as part of the initial submission or as part of the updated submission. Several examples on how to perform create, update, and delete operations on POC and POC TMO data are found in the Supplement to the State Integration Guide for Submission of Contracted Inspection Results.

Current Firm POCs/TMOs can be retrieved from the Data Exchange using the SearchFDAFirms or GetFdaFirmDetails operations (with the ResponseObjectType flag set to “Full”). These operations are available as part of requesting and receiving FDA Firm data via NFSDX. To use this capability, request the onboarding State Integration Guide package for Firm Search based on Schema 8.1.3.

All other data elements in the Firm section of the schema are optional when providing firm information updates.

The following table lists the steps to obtain Firm POC IDs using Firm Search operations, to propose updates to or deletion of the existing Firm POCs, or, based on the Contracted Inspection findings, to add a new Firm’s POCs.

All Firm-related updates, including Firm POC, are subject to review and approval by FDA per the existing review process. Questions and answers to the potential Firm POC request and submission scenarios are described in the following table.

NOTE: In the following table, “existing Firm POC” refers to the Firm POC(s) currently associated with the inspected Establishment/Firm in the FDA database, and “new Firm POC” refers to the Firm POC(s) that the state would like to add to the Firm, based on the inspection results.

	Question/Scenario	Answer
1	I want to get the existing Firm POC ID(s) and POC key values (Name, Phone Number, etc.).	<p>Option 1: Submit GetFDAFirmDetails operation with the ResponseObjectType flag set to “Full”. The GetFDAFirmDetails operation is available via FDA Firm Search capability to retrieve Firm information for a given FEI.</p> <p>The call returns the PNT_CNTCT_ID (aka POC ID) along with other POC data (name, phone and/or email, TMO flag, if applicable) for existing Firm POC(s).</p> <p>Option 2: Submit SearchFdaFirms operation with the ResponseObjectType flag set to “Full”. The SearchFdaFirms operation is available via FDA Firm Search capability to retrieve Firm information for a given FEI.</p> <p>The call returns the PNT_CNTCT_ID (aka POC ID) along with other existing Firm POC data (name, phone and/or email, TMO flag, if applicable) for existing Firm POC(s).</p>
2	For the existing Firm POC, what Firm POC ID should I submit as part of the Firm update?	<p>Submit Firm POC ID (PNT_CNTCT_ID) retrieved by GetFDAFirmDetails or SearchFdaFirms operation for the inspected FEI. Make sure you use the correct POC ID otherwise the submission will be rejected. All existing Firm POCs need to be submitted with the appropriate action (Update or Delete). For no change to an existing POC, use Update for the PersonContactOperation flag.</p>
3	For a new Firm POC I propose to add, what POC ID should I submit as part of the Firm update?	<p>For a new Firm POC, set POC ID (PNT_CNTCT_ID) to 0. Otherwise, the submission will be rejected.</p>
4	For the existing Firm POC, what do I set PersonContactOperation flag to?	<p>For the existing Firm POC, set the PersonContactOperation flag to Update or Delete, depending on the desired outcome. For no change to an existing Firm POC, use</p>

	Question/Scenario	Answer
		Update for the PersonContactOperation flag.
5	To add a new POC to the inspected Firm, what do I set PersonContactOperation flag to?	For a new Firm POC, set PersonContactOperation flag to Create.
6	I have Firm updates to submit but I do not have any existing Firm POC changes to report.	In the payload, do not include the PersonContactsList section in the request unless the Firm POC updated is required based on the PAC code (see Appendix G, PACs Requiring TMO POC).
7	I have existing Firm POC changes to report as part of the proposed Firm updates.	Retrieve existing Firm POC IDs and POC data using Firm Search GetFDAFirmDetails or the SearchFdaFirms operation. Include all existing Firm POC ID(s) with the applicable POC data changed, as needed, in your submission payload. Set Action Flag PersonContactOperation to Update. You must include all existing Firm Contacts, otherwise your submission will be rejected.
8	I want to delete Firm POC(s) as part of the proposed Firm update.	Retrieve existing Firm POC IDs and POC data using Firm Search GetFDAFirmDetails or the SearchFdaFirms operation. Include all existing Firm POC ID(s) with the applicable POC data in your submission. For the ones selected for deletion, set Action Flag PersonContactOperation to Delete. You must include all existing Firm Contacts, otherwise your submission will be rejected.
9	I want to add a new Firm POC.	To propose a new Firm POC, provide POC data (name, phone and/or email, etc.) in your submission, set Contact ID to 0, and set the Action Flag PersonContactOperation to Create.

	Question/Scenario	Answer
		<p>NOTE: Always include all existing Firm POC ID(s) with the applicable POC data in your submission. For the existing Firm POC, set the Action Flag PersonContactOperation to Delete or Update, depending on the desired outcome.</p>
10	<p>I want to update my previous submission of existing or new Firm POC data.</p>	<p>There are no incremental updates: every subsequent update entirely overwrites the previous one.</p> <p>If you want to update only one of multiple POCs, you still need to submit all the existing Firm POCs with POC IDs and the corresponding POC data, and then set the Action Flag PersonContactOperation to Delete or Update, depending on the desired outcome.</p> <p>To propose a new Firm POC in your subsequent update, provide POC data (name, phone and/or email, etc.) in the payload, set Contact ID to 0, and the Action Flag PersonContactOperation to Create.</p>
11	<p>I submitted a new Firm Contact POC in my initial submission, and now I want to delete it.</p>	<p>To delete a newly created Firm POC, do not include it in the subsequent Firm update. There are no incremental updates; every subsequent update entirely overwrites the previous one.</p>
12	<p>I want to submit Firm POC updates the “old” way, without using POC IDs.</p>	<p>States are encouraged to use POC ID when submitting Firm POC data as this is the most accurate way to update and report POC information.</p> <p>However, to submit Firm POCs without POC ID (the “No POC ID way”), please follow the guidelines below:</p> <ol style="list-style-type: none"> 1. Make sure that none of the POC entries have a Firm POC ID. You cannot “mix and match” Firm POCs with and without POC

	Question/Scenario	Answer
		<p>IDs in your submission.</p> <ol style="list-style-type: none"> 2. Provide POC data for the existing Firm POC(s) in the payload: existing Firms' POCs will be looked up via the key values (name, phone, etc.). 3. The "No POC ID" way implies an incremental update, e.g., if the State added a new POC with the Create operation, then any subsequent (incremental) updates must use the Action Flag PersonContactOperation set to Update to make edits to this record. A subsequent update with the Action Flag PersonContactOperation set to Delete will remove this record from the proposed changes to the Firm POC data. 4. It is not necessary to include all existing Firms' POCs: Firm POC records not included in the submission will be left unchanged. 5. The Action Flag PersonContactOperation set can be blank. If left blank, it will default to Create.

2.11. NFSDX-STATE RESPONSE MESSAGES: SUCCESS RESPONSE VS FAILURE RESPONSE

The structure of the response message sent from NFSDX–State interface is dependent upon whether the response message received from FDA is a success or failure. Note that for all response messages sent by NFSDX to the States, the following confidentiality disclaimer will be included in the response: *FDA CONFIDENTIAL INFORMATION DISCLAIMER: Any information accessed or printed by this system is provided for official use only by the U.S. Food and Drug Administration (FDA), remains property of the FDA, and must be used exclusively in accordance with the written assurance to protect the confidentiality of the information signed by you and/or your agency. It may contain protected, privileged, or confidential non-public information and cannot be disseminated, distributed, or copied outside of your agency or otherwise provided to persons who are not covered under the associated information sharing agreement unless FDA provides written permission allowing further disclosure. Unauthorized disclosure of confidential commercial or personal privacy information obtained from FDA could be a civil or criminal violation and may carry legal consequences for the disclosing official.*

2.11.1. SUCCESS RESPONSE MESSAGE

For a request that results in successful delivery of the Contracted Inspection results with optional BSE and/or Seafood HACCP data, the message will contain *Status* and *Message* in the *Status Response* location, with the *Status* set to *Success*, as indicated in the table below.

Note that the Success Response Message structure is similar for both Submit and Update operations.

Element Name	Location	Description
ApplicationID	Transaction Header	Unique Identifier of the application initiating the transaction. This is a pre-assigned ID set by the NFSDX system.
TransactionID	Transaction Header	Unique identifier of a transaction generated by the NFSDX system. It is unique for each request/operation. (Example: 900001)
SrcTransactionID	Transaction Header	The NFSDX system will supply the original value of as provided by the client system in TransactionID the original request for which this response is being generated. This will establish a correlation between request and response.
TransactionTimeStamp	Transaction Header	Date and Time of the origin of the response in UTC format set by the NFSDX system. (Example: 2016-12-13T12:50:26.356-05:00)
Status	Status Response	Status of the processing of the original request. (Failure in the given example).
StatusList	Status Response	List that contains one or more StatusDetails.
StatusDetails	Status Response	Each StatusDetails contains a StatusCode and StatusDescription.
Status Code	Status Response	Status code is always set to 0 in case of a successful response.
Status Description	Status Response	Description of the Successful Status (e.g., "Successfully updated the Inspection results").

An example of the SOAP XML that States might receive indicating a successful response message will be made available to the States upon request.

2.11.2. FAILURE RESPONSE MESSAGE

For a request that results in a system or validation error, the message will contain *Status Code* and *Status Description* in the *Status Response* location, with the *Status* set to *Failure*, as indicated in the table below.

Note that the Failure Response Message structure is similar for both Submit and Update operations.

Element Name	Location	Description
ApplicationID	Transaction Header	Unique Identifier of the application initiating the transaction. This is a pre-assigned ID for NFSDX system.
TransactionID	Transaction Header	Unique identifier of a transaction generated by the NFSDX system. It is unique for each request/operation. (Example: 900001)
SrcTransactionID	Transaction Header	The NFSDX system will provide the original value of TransactionID as provided by the client system in the original request for which this response is being generated. This will establish a correlation between request and response.
TransactionTimeStamp	Transaction Header	Date and Time of the origin of the response in UTC format set by the NFSDX system. (Example: 2016-12-13T12:50:26.356-05:00)
Status	Status Response	Status of the processing of the original request (Failure in the given example).
StatusList	Status Response	List that contains one or more StatusDetails.
StatusDetails	Status Response	Each StatusDetails contains a StatusCode and StatusDescription.
StatusCode	Status Response	Error code if there was an issue processing the original request. Refer to Appendix C: NFSDX Error Messages for a complete list of possible error codes.
StatusDescription	Status Response	Description of the error if there was an issue processing the original request. Refer to Appendix C: NFSDX Error Messages for a complete list of possible error messages.

Example of the SOAP response message indicating a failure response (either with one error captured or with multiple errors captured) will be made available to the States upon request. The response message (output) that is forwarded by NFSDX to the State for each operation follows the XML schema format as defined in [Appendix B: Inspection Data Message Schema and Reference Data](#).

2.12. NFSDX ERROR HANDLING FOR XML SCHEMA VALIDATION ERRORS

Currently all OSB schema-level validation errors return SOAP fault messages that are intended for the technical team. Oracle Service Bus (OSB) validates the incoming request against the schema, and if the validation fails, it generates a SOAP fault message that includes the error number, standard text, and a brief statement on what has caused the failed validation so that the technical team can resolve schema validation failures as part of unit and functional testing. The error code returned is “OSB-382505: OSB Validate action failed validation.” These SOAP fault messages capture missed mandatory elements (data not provided), incorrect data format

(e.g., putting character instead of digit), incorrect length (e.g., 10 digits provided instead of allowable 6 digits), etc.

A few examples of SOAP general fault response messages that States might receive will be made available to the States upon request.

2.13. NFSDX ERROR HANDLING AND RECOVERY

The following table lists possible error conditions and recovery steps that apply to all operations supported by NFSDX. Please refer to [Appendix C: NFSDX Error Messages](#) for a complete list of error codes and messages. The business rules that drive these error codes and messages are listed in [Appendix D: Business Rules and Error Messages](#).

Error Condition	Recovery
A username or password was not supplied in the payload	The failed authentication attempt is logged. A fault/error message is returned to the client. The client should check the username and password and resubmit the request.
NFSDX does not find the State system user name and password in the FDA repository	The failed authentication attempt is logged. A fault/error message is returned to the client. The client should check the username and password and resubmit the request.
The client system's password is invalid or does not conform to FDA specifications	The failed authentication attempt is logged. A fault/error message is returned to the client. The client should check the username and password and resubmit the request.
The client system's account is disabled or inactive	The failed authentication attempt is logged. A fault/error message is returned to the client. The client should check the username and password and resubmit the request.
The request message fails schema validation	The error is logged, and an error message is returned to the client listing the elements that failed validation. The client should correct the data and resubmit the request.
System error	A generic message with the request to retry the request or contact system administrator is returned to the client.

3. SYSTEM INTERFACE SECURITY FOR USERNAME/PASSWORD AUTHENTICATION

This section describes the security measures that must be adhered to by the systems that are exchanging or providing data.

3.1. STATES' AUTHENTICATION

Login credentials will be provided to the State and authentication will be performed by NFSDX. The State system will submit a username and password in each request message. When connecting to NFSDX, the State user will be authenticated by the NFSDX security layer. Failed authentications will be logged into an audit table and an access denied message will be returned to the State.

3.2. SOAP FAULT MESSAGE FOR FAILED AUTHENTICATION

The State system should be able to handle a SOAP fault message when the State system credentials fail NFSDX authentication. The State will receive an error for the failed

authentication due to an incorrect State username or password. An example SOAP fault response message of the failed authentication error that States might receive will be made available to the States upon request.

3.3. SOAP FAULT MESSAGE FOR FAILED AUTHORIZATION

The State system should be able to handle a SOAP fault message when the State credentials pass NFSDX authentication, but the State credentials are not valid for the service operation for submitting Contracted Inspection to the FDA system of record. The State will receive a fault message for the failed authorization due to the unauthorized State calling to submit Inspection data to FDA. Example SOAP fault response message that States might receive indicating a failed authorization error will be made available to the States upon request.

3.4. SECURITY HEADER

All request messages must include the security information in the SOAP header. Example of the SOAP security header will be made available to the States upon request.

3.5. SECURITY HEADER IN THE .NET OBJECTS

The Security Header can also be implemented using the .NET Objects. Examples of the .NET Security Header can be found in the Supplement to the State Integration Guide for Submission of Contracted Inspection Results.

3.6. ENCRYPTION

The security of the information being transmitted is protected through the use of Transport Layer Security (TLS)/Secure Sockets Layer (SSL)-based encryption.

APPENDIX A: GLOSSARY OF TERMS

The table below provides a list of abbreviated terms and acronyms used in this document.

Term	Definition
BSE	Bovine Spongiform Encephalopathy
eSAF	Electronic State Access to FACTS
FACTS	Field Accomplishments and Compliance Tracking System
FDA	Food and Drug Administration
FEI	Firm Establishment Identifier
FSMA	Food Safety Modernization Act
HACCP	Seafood Hazard Analysis Critical Control Point
HTTP	Hyper Text Transfer Protocol
HTTPS	Hyper Text Transfer Protocol encrypted by Transport Layer Security
IA	Intentional Adulteration
ID	Identifier
IFSS	Integrated Food Safety System
NFSDX	National Food Safety Data Exchange
ORA	Office of Regulatory Affairs
POC	Point of Contact
SOAP	Simple Object Access Protocol
SSL	Secure Sockets Layer
TLS	Transport Layer Security
TMO	Top Management Official
UAT	User Acceptance Testing
URL	Uniform Resource Locator
UTC	Universal Time Coordinated
WSDL	Web Services Description Language
XML	Extensible Markup Language
XSD	XML Schema Definition

APPENDIX B: INSPECTION DATA MESSAGE SCHEMA AND REFERENCE DATA

The inspection schema and supporting schemas can be found in the attachment *NFSDX Schema v11.2.zip*, provided as part of the *ORA DX Contracted Inspection with Attachments State Integration Package Rel 11.1 Schema 11.2.zip*.

A second attachment to this guide includes the *ContInsp Data Elements Business Rules.xlsx* spreadsheet.

The spreadsheet will also map the data element to the inspection business rule(s) that apply to that data element.

When submitting Contracted Inspection data for the selected data elements, States will be using reference codes and descriptions that have a defined set of permissible values. These values (both codes and descriptions or, where applicable, descriptions only) are listed in the *ReferenceDataSTATES.xml* file provided as part of the State Integration package. Note that this reference code list may be updated on an ad hoc basis because of business needs or database updates and/or on a scheduled basis, as part of a Schema release to the States.

The table below lists which Contracted Inspection XML elements use predefined values and will guide the States in determining whether to provide either the code or description when submitting Contracted Inspection results with optional BSE and/or Seafood HACCP data.

Domain	XML Element Name	State to Share Code or Description?
Inspection	InspectionType	Description
Inspection	InspectionBasis	Description
Inspection	Product CD*	Code
Inspection	EstablishmentType	Description
Inspection	PAC	Code
Inspection	InspectionConclusion	Description
Inspection	InspectionRefusal	Description
Firm	OperationalStatus	Description
Firm	EstablishmentSize	Description
Firm/Address	AddressType	Description
Firm/Address	County	Description
Firm/Address	StateCD	Code
Firm/Address	ISOCountryCD	Code
Firm	EstablishmentSize	Description
Firm	FirmLegalStatus	Description
BSE Checklist	BSEChecklistStatusType	Description
BSE Checklist	InspectedFirmTypeType	Description
BSE Checklist	TallowUsedInFeedType	Description
BSE Checklist	FeedContainsPMTType	Description
BSE Checklist	VoluntarySafeguardsType	Description

Domain	XML Element Name	State to Share Code or Description?
BSE Checklist	ExemptedSourcesForAnimalProteins	Description
BSE Checklist	ImportedPMUsed	Description
BSE Checklist	ReceivedFeedPMLabeledWithCautionType	Description
BSE Checklist	OutgoingFeedPMLabeledWithCautionType	Description
BSE Checklist	RendererFirmTypeType	Description
BSE Checklist	DifferentiationMethods	Description
BSE Checklist	SeparationMethods	Description
BSE Checklist	DispositionMethods	Description
BSE Checklist	OutgoingFeedsTransportationOptionType	Description
BSE Checklist	PMFeedsOptionsType	Description
BSE Checklist	APFeedsOptionsType	Description
BSE Checklist	DeviationsNoted	Description
Seafood HACCP	SeafoodHaccpFormStatusType	Description
Seafood HACCP	InspectedFirmType, Q7b	Description
Seafood HACCP	Product CD*	Code
Seafood HACCP	PAC	Code
Seafood HACCP	FoodSafetyHazardType, Q15	Description
Seafood HACCP	FoodSafetyHazardType, Q16	Description
Seafood HACCP	FoodSafetyHazardType, Q17	Description
Seafood HACCP	FoodSafetyHazardType, Q18	Description
Seafood HACCP	FoodSafetyHazardType, Q19	Description
Seafood HACCP	FoodSafetyHazardType, Q20	Description
Seafood HACCP	FoodSafetyHazardType, Q21	Description
Seafood HACCP	FoodSafetyHazardType, Q22	Description
Seafood HACCP	FoodSafetyHazardType, Q23	Description
Seafood HACCP	ProcessMonitoringInstrumentsCalibratedProperly, Q24	Description
Seafood HACCP	HaccpPlanIncludeInProcessTestingVerification, Q25	Description
Seafood HACCP	HaccpPlanIncludeEndProductTestingVerification, Q26	Description
Seafood HACCP	FoodSafetySanitationType, Q27	Description
Seafood HACCP	FoodSafetySanitationType, Q28	Description
Seafood HACCP	FoodSafetySanitationType, Q29	Description
Seafood HACCP	FoodSafetySanitationType, Q30	Description
Seafood HACCP	FoodSafetySanitationType, Q31	Description
Seafood HACCP	FoodSafetySanitationType, Q32	Description
<p>*The list of product codes will not be included in the reference data XML, as it is a long list prone to frequent changes. The codes of the individual segments that form the product code also will not be shared, since the States are able to obtain that information in Product Builder.</p>		

APPENDIX C: NFSDX ERROR MESSAGES

All available error messages and error codes produced by NFSDX and then captured and forwarded to State by NFSDX, are listed in the table below.

Error Code	Error Message
NFSDX-ERR-100	Invalid Application ID was provided.
NFSDX-ERR-102	Invalid Application ID was provided for the username.
NFSDX-ERR-106	Invalid Inspection Type provided in the inspection results.
NFSDX-ERR-107	Invalid Inspection Basis provided in the inspection results.
NFSDX-ERR-108	Invalid Inspection Conclusion provided in the inspection results.
NFSDX-ERR-109	Invalid Establishment Type provided in the inspection results.
NFSDX-ERR-110	Invalid Operational Status provided in the inspection results.
NFSDX-ERR-112	Invalid Address Type provided in the inspection results.
NFSDX-ERR-113	Invalid Establishment Size provided in the inspection results.
NFSDX-ERR-114	Invalid Firm Legal Status provided in the inspection results.
NFSDX-ERR-115	Invalid State Code provided in the inspection results.
NFSDX-ERR-116	Invalid Inspection Refusal provided in the inspection results.
NFSDX-ERR-117	Invalid Establishment Type provided in the inspection results firm updates.
NFSDX-ERR-118	Invalid County/State Code combination provided in the inspection results.
NFSDX-ERR-200	Invalid BSE Checklist Status provided in the inspection results.
NFSDX-ERR-201	Invalid answer provided for the Type of firm inspected question. Refer to BSE Checklist Section 1, Question 1a.
NFSDX-ERR-202	Invalid answer provided for Tallow in animal feed formulations question. Refer to BSE Checklist Section 1, Question 2.
NFSDX-ERR-203	Invalid answer provided for Feed Contains Prohibited Material question. Refer to BSE Checklist Section 1, Question 3.
NFSDX-ERR-204	Invalid answer provided for Voluntary Safeguard(s) question. Refer to BSE Checklist Section 1, Question 3a.
NFSDX-ERR-205	Invalid answer provided for Exempted Source(s) for Animal Proteins question. Refer to BSE Checklist Section 1, Question 3a.
NFSDX-ERR-206	Invalid answer provided for Using Imported Prohibited Material question. Refer to BSE Checklist Section 1, Question 3b.
NFSDX-ERR-207	Invalid answer provided for Received feeds or feed ingredients containing prohibited materials labeled with the caution statement question. Refer to BSE Checklist Section 1, Question 6.
NFSDX-ERR-208	Invalid answer provided for Outgoing feeds or feed ingredients containing prohibited materials labeled with the caution statement question. Refer to BSE Checklist Section 2, Question 7.
NFSDX-ERR-209	Invalid answer provided for the Separation system or clean-out processes and any procedures to avoid commingling and cross-contamination (with the exception of pet food sold at retail and laboratory animal feed) question. Refer to BSE Checklist Section 2, Question 10b.

Error Code	Error Message
NFSDX-ERR-210	Invalid answer provided for Renderer Firm Type(s) question. Refer to BSE Checklist Section 3, Question 12.
NFSDX-ERR-211	Invalid answer provided for the Methods that the firm uses to differentiate cattle by age question. Refer to BSE Checklist, Section 3, Question 16a.
NFSDX-ERR-212	Invalid answer provided for the Methods that the firm uses to separate CMPAF from material that may be used in feed question. Refer to BSE Checklist Section 3, Question 17a.
NFSDX-ERR-213	Invalid answer provided for the Method the firm uses to dispose of the CMPAF question. Refer to BSE Checklist Section 3, Question 18a.
NFSDX-ERR-214	Invalid answer provided for Outgoing feeds or feed ingredients transported in bulk form question. Refer to BSE Checklist Section 4, Question 20a.
NFSDX-ERR-215	Invalid answer provided for Outgoing feeds transported in bagged/packaged form question. Refer to BSE Checklist Section 4, Question 20b.
NFSDX-ERR-216	Invalid answer provided for Firm utilizing its own transportation vehicles for the delivery of any outgoing bulk feeds or feed ingredients question. Refer to BSE Checklist Section 4, Question 20c.
NFSDX-ERR-217	Invalid answer provided for Firm utilizing other firms' transportation vehicles for the delivery of any outgoing bulk feeds or feed ingredients question. Refer to BSE Checklist Section 4, Question 20d.
NFSDX-ERR-218	Invalid answer provided for Observing the caution statement on feeds labeled as containing prohibited material(PM) question. Refer to BSE Checklist Section 5, Question 21a.
NFSDX-ERR-219	Invalid answer provided for Maintaining copies of labeling for feeds containing animal protein (AP) (Not including retail pet food for cats and dogs) question. Refer to BSE Checklist Section 5, Question 21b.
NFSDX-ERR-220	Invalid answer provided for Maintaining copies of purchase invoices for feeds containing animal protein (Not including retail pet food for cats and dogs) question. Refer to BSE Checklist Section 5, Question 21c.
NFSDX-ERR-221	Invalid answer provided for Feeding non-ruminant species (Not including cats and dogs) feeds which contains or may contain prohibited material question. Refer to BSE Checklist Section 5, Question 21e.
NFSDX-ERR-222	Invalid answer provided for Deviation(s) noted at the time of inspection question. Refer to BSE Checklist Section 6, Question 22a.
NFSDX-ERR-223	Invalid Country of Origin provided. Refer to BSE Checklist Section 1, Question 3b.
NFSDX-ERR-300	Invalid Seafood HACCP Form Status provided in the inspection results.
NFSDX-ERR-301	Invalid Sanitation Control Item(s) provided in the Seafood HACCP Form Section III, Question 27.

Error Code	Error Message
NFSDX-ERR-302	Invalid Sanitation Control Item(s) provided in the Seafood HACCP Form Section III, Question 28.
NFSDX-ERR-303	Invalid Sanitation Control Item(s) provided in the Seafood HACCP Form Section III, Question 29.
NFSDX-ERR-304	Invalid Sanitation Control Item(s) provided in the Seafood HACCP Form Section III, Question 30.
NFSDX-ERR-305	Invalid Sanitation Control Item(s) provided in the Seafood HACCP Form Section III, Question 31.
NFSDX-ERR-306	Invalid Sanitation Control Item(s) provided in the Seafood HACCP Form Section III, Question 32.
NFSDX-ERR-307	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 15.
NFSDX-ERR-308	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 16.
NFSDX-ERR-309	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 17.
NFSDX-ERR-310	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 18.
NFSDX-ERR-311	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 19.
NFSDX-ERR-312	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 20.
NFSDX-ERR-313	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 21.
NFSDX-ERR-314	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 22.
NFSDX-ERR-315	Invalid Food Safety Hazard Control(s) provided in the Seafood HACCP Form Section II, Question 23.
NFSDX-ERR-316	Invalid Establishment Type provided in the Seafood HACCP form.
NFSDX-ERR-317	Invalid Verification response provided in the Seafood HACCP form Section II, Question 24.
NFSDX-ERR-318	Invalid Verification response provided in the Seafood HACCP form Section II, Question 25.
NFSDX-ERR-319	Invalid Verification response provided in the Seafood HACCP form Section II, Question 26.
NFSDX-ERR-320	Invalid Sanitation Control response provided in the Seafood HACCP form Section III, Question 33.
NFSDX-ERR-900	Your request has encountered a system error. Please try again. If the problem persists, please contact the ORA Applications Helpdesk at AppsDesk@fda.hhs.gov .

Error Code	Error Message
NFSDX-ERR-910	Your request has encountered a system error. Please try again. If the problem persists, please contact the ORA Applications Helpdesk at AppsDesk@fda.hhs.gov .
NFSDX-ERR-920	Your request has encountered a system error. Please try again. If the problem persists, please contact the ORA Applications Helpdesk at AppsDesk@fda.hhs.gov .
NFSDX-ERR-930	Your request contains an invalid transaction type. Please check your data and resubmit. If the problem persists, please contact the ORA Applications Helpdesk at AppsDesk@fda.hhs.gov .
NFSDX-ERR-940	Your request has encountered a system error. Please try again. If the problem persists, please contact the ORA Applications Helpdesk at AppsDesk@fda.hhs.gov .

APPENDIX D: BUSINESS RULES AND ERROR MESSAGES

The Contracted Inspection results business rules, corresponding error codes, and error messages produced by FDA, as captured and forwarded to State agency by NFSDX, are described on the second tab *ContrInsp Business Rules List*, in the Excel spreadsheet *ContrInsp Data Elements Business Rules.xlsx* provided as part of the *ORA DX Contracted Inspection with Attachments State Integration Package Rel 11.1 Schema 11.2.zip*.

The Parameters values with curly brackets { } represent (where applicable) data element value(s) submitted in the Contracted Inspection results with optional BSE and/or Seafood HACCP data XML, or a database value the submitted XML data element is being compared to during the business validation process.

APPENDIX E: NFSDX TECHNICAL SUPPORT

If experiencing technical issues with NFSDX, consult the table below for technical support.

Technical Support Contact Information
<p>Use either of the following options to contact technical support:</p> <ul style="list-style-type: none">• Call the ORA Applications Desk at 240-247-8803. ORA Applications Desk phone support is available 24x7, 365 days a year.• Send an email to the ORA Applications Desk at AppsDesk@fda.hhs.gov. ORA Applications Desk email support is available 8:00AM–9:00PM (EST) Monday – Friday (except federal holidays).

APPENDIX F: PACS REQUIRING INTENTIONAL ADULTERATION PROTOCOL

Note that this PAC list may be updated on an ad hoc basis because of business needs or database updates, and/or on a scheduled basis as part of a Schema release to the States. Should an update happen, States will receive the updated list from the FDA Outreach Coordinator.

PAC	PAC Description
03S005	STATE CONTRACT AF & LACF INSPECTIONS
03S040	STATE CONTRACT CGMP INSPECTIONS
03S041	STATE CONTRACT LIMITED PCHF INSPECTIONS
03S042	STATE CONTRACT COMPREHENSIVE PCHF INSPECTIONS
03S043	(Only for CY 20.21) STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES
03S044	STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT FACILITIES SOLELY ENGAGED IN STORAGE OF UNEXPOSED PACKAGED FOOD THAT REQUIRE TIME/TEMPERATURE CONTROLS FOR SAFETY

APPENDIX G: PACS REQUIRING TMO POC

Note that this PAC list may be updated on an ad hoc basis because of business needs or database updates, and/or on a scheduled basis as part of a Schema release to the States. Should an update happen, States will receive the updated list from the FDA Outreach Coordinator.

PAC Code	PAC Code Description
03S002	STATE CONTRACT SEAFOOD HACCP INSPECTIONS
03S004	STATE CONTRACT JUICE HACCP INSPECTIONS
03S005	STATE CONTRACT AF & LACF INSPECTIONS
03S040	STATE CONTRACT CGMP INSPECTIONS
03S041	STATE CONTRACT LIMITED PCHF INSPECTIONS
03S042	STATE CONTRACT COMPREHENSIVE PCHF INSPECTIONS
03S043	(Only for CY 20.21) STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES
03S044	STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT FACILITIES SOLELY ENGAGED IN STORAGE OF UNEXPOSED PACKAGED FOOD THAT REQUIRE TIME/TEMPERATURE CONTROLS FOR SAFETY
03S045	STATE CONTRACT PCHF FOLLOW-UP INSPECTIONS
03S836	STATE CONTRACT EGG FARM ASSIGNMENT INSPECTIONS
03S849	STATE CONTRACT LISTERIA & SALMONELLA IN RTE FOODS INSPECTION/ENVIRONMENTAL SAMPLING ASSIGNMENT
03S876	STATE CONTRACT OEI IMPROVEMENT FOODS
71S004	STATE CONTRACT MEDICATED FEED MANUFACTURING CGMP INSPECTIONS (LICENSED FACILITIES)
71S011	STATE CONTRACT BSE INSPECTIONS
71S014	STATE CONTRACT PCAF CGMP INSPECTIONS
71S015	STATE CONTRACT GMP/FULL SCOPE PCAF INSPECTIONS
71G011	COOPERATIVE AGREEMENT BSE CHECKLIST INSPECTIONS

APPENDIX H: PACS NOT REQUIRING TMO POC

Note that this PAC list may be updated on an ad hoc basis because of business needs or database updates, and/or on a scheduled basis as part of a Schema release to the States. Should an update happen, States will receive the updated list from the FDA Outreach Coordinator.

PAC	PAC Description
03S800	NON-CONTRACT STATE WORK
03S913	STATE CONTRACT CORONAVIRUS ACTIVITIES HUMAN FOODS
71G012	COOPERATIVE AGREEMENT MEDICATED FEED INSPECTION NON LICENSED FACILITIES
71S016	STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT ANIMAL FOOD QUALIFIED FACILITIES
71S017	STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT ANIMAL FOOD STORAGE FACILITIES SOLELY ENGAGED IN UNEXPOSED PACKAGED FOOD THAT REQUIRE TIME/TEMPERATURE CONTROLS FOR SAFETY
71S018	STATE CONTRACT ANIMAL FOOD SANITARY TRANSPORTATION INSPECTIONS
71S023	STATE CONTRACT VETERINARY FEED DIRECTIVE INSPECTIONS
71S894	STATE CONTRACT ANIMAL FOOD RISK DATA
71S913	STATE CONTRACT CORONAVIRUS ACTIVITIES CVM
82S008	STATE CONTRACT MEDICAL DEVICE LEVEL 1 INSPECTIONS
82S009	STATE CONTRACT MEDICAL DEVICE LEVEL 2 INSPECTIONS
03S001	STATE CONTRACT FOOD GMP INSPECTIONS
03S845	STATE CONTRACT CT FOOD INSPECTIONS
03S003	STATE CONTRACT FOOD ALLERGEN INSPECTIONS
03S014	STATE CONTRACT PCHF CGMP INSPECTIONS
03S015	STATE CONTRACT GMP/FULL SCOPE PCHF INSPECTIONS
03S877	STATE CONTRACT GMP/PC DATA FORM HUMAN FOODS
03S879	STATE CONTRACT SPROUT SAFETY ACTIVITIES
03S903	STATE CONTRACT CGMP INSPECTIONS

PAC	PAC Description
03S904	(Only for CY 19.20) STATE CONTRACT CGMP/MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES
03S905	STATE CONTRACT CGMP/MODIFIED REQUIREMENTS INSPECTIONS AT REFRIGERATED WAREHOUSES
71S012	STATE CONTRACT MEDICATED FEED MANUFACTURING CGMP INSPECTIONS (NON LICENSED FACILITIES)
71S006	STATE CONTRACT ILLEGAL RESIDUES (TISSUE)
71S877	STATE CONTRACT GMP/PC DATA FORM ANIMAL FOODS
03M800	MFRPS NON-CONTRACT STATE INSPECTIONS

APPENDIX I: FREQUENTLY ASKED QUESTIONS (FAQ)

Question	Answer
<p>What is the NFSDX Security Policy referenced in the State Integration Guide?</p>	<p>Security Policy: https://docs.oracle.com/cd/E12839_01/web.1111/b32511/policies.htm#CHDEEJIE</p> <p>This policy contains the following policy assertion: oracle/wss_username_token_client_template. See "oracle/wss_username_token_client_template" for more information about the assertion. For information about configuring the policy, see "oracle/wss_username_token_client_policy".oracle/wss_username_token_service_policy</p>
<p>What to include in the payload header to authenticate state?</p>	<p>State credentials are required in the payload header to authenticate state. This policy uses the credentials in the WS-Security Username Token SOAP header to authenticate state. Both plain text and digest mechanisms are supported. This policy can be attached to any SOAP-based endpoint.</p>
<p>Is there a package to convert the WSDL?</p>	<p>No conversion tools are provided in the State Integration Package. FDA uses JAVA but other states use .NET. It is possible to generate the code with the wsdl files provided. Refer to standard converting tools available.</p>
<p>What is Application ID, Transaction ID, SourceTransaction ID?</p>	<ul style="list-style-type: none"> • Application ID is a unique identifier of the application initiating the transaction. The NFSDX team will provide each State or State system with an Application ID. • Request Transaction ID is a unique identifier provided by the state. This ID could be unique sequence number or GUID. The Response Transaction ID is a unique identifier of a transaction generated by the NFSDX system. The request Transaction ID and the Response Transaction ID are saved and linked in NFSDX for logging and traceability. • SourceTransaction ID is not used in the request. The Response SourceTransaction ID is the Transaction ID provided by the state in the request. This is sent in the NFSDX response and allows linking the transaction from the state to the response from NFSDX for logging and traceability.