



**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 adding Attachment Operations
to the Contracted Inspection Results**

Version 1.2

May 27, 2021

Revision History

Version Number	Implemented By	Revision Date	Approved By	Approval Date	Description of Change
1.0	FDA	1/29/2021			Initial document for adding Attachment Operations to Contracted Inspections
1.1	FDA	3/2/2021			Update NFSDX WSDL operation to be DeleteInspectionAttachmentOperation and RetrievalInspectionAttachmentOperation to RetrievalInspectionAttachmentOperation.
1.2	FDA	5/27/2021			Updated for schema 11.2

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1.0 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.

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 THE 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.

1.3 SCOPE

The scope of this document is limited to the instructions for adding Attachment operations to the Contracted Inspection exchanged with FDA via NFSDX. These details are intended to assist the States that would like to exchange Attachment data as part of these Contracted Inspection results while integrating with NFSDX.

1.4 REQUIREMENTS AND ASSUMPTIONS

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

- The State is required to have a valid Non-Disclosure Agreement (NDA) with FDA in place prior to integrating with Contracted Inspection Attachments Data Exchange (DX) capability
- The submitted Attachment file should be virus-free; otherwise the Attachment will be rejected by NFSDX
- The submitted Attachment should not exceed the allowed file size of 250MB
- The sequence of Contracted Inspection operations, including Attachment operations, is as follows:
 - The State accepts FDA-issued Assignment, thus setting Assignment Status to Accepted (done outside NFSDX)

- The State submits Contracted Inspection results to FDA via NFSDX (*SubmitInspectionData operation*) with Operation Status set to “Preliminary Results”
Please note that the Operation status can also be set to “Awaiting FDA Review.” However, with the Operation status set to “Awaiting FDA Review,” the State will not be able to update the Contracted Inspection results or upload/delete attachments
- With the Operation status set to “Preliminary Results,” the State uploads the Attachment to the existing/previously-submitted Contracted Inspection (*UploadInspectionAttachmentOperation*)
The State can also perform this operation if FDA returned the Contracted Inspection results back to the State for corrections, setting the Operation status to “Returned by FDA”
- With the Operation status set to “Preliminary Results,” the State submits a request to delete Attachment(s) from the existing/previously-submitted Contracted Inspection via NFSDX (*DeleteInspectionAttachmentOperation*)
The State can also perform this operation if FDA returned the Contracted Inspection results back to the State for corrections, setting the Operation status to “Returned by FDA”
- With the Operation status set to “Preliminary Results” or “Returned by FDA,” the State updates Contracted Inspection results via NFSDX (*UpdateInspectionData operation*) and sets the Operation status to “Awaiting FDA Review.” This indicates that the Contracted Inspection results are ready for FDA Review
- The State submits a request to retrieve a list of Attachment(s) associated with the existing Contracted Inspection (*RetrieveInspectionAttachmentOperation*). The Attachments list does not include actual Attachments, but the Attachment attributes (metadata); e.g., file name, file type, document type, etc. The Operation Status for performing this operation is irrelevant. The list of Attachment(s) can be retrieved with any Operation status
- 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, the transaction type and application ID, and a payload containing Attachment operation-related elements
- Once State Agency participation in the data exchange is approved, the State Agency receives this State Integration Guide and a zip file, *ORA DX Contracted Inspection with Attachments State Integration Package Rel 11.1 Schema 11.2.zip*, containing the following files:
 - Contracted Attachments-related files
 - SIG_ContractInsp_Attach.docx

- SIG_Suppl_ContractInsp_Attach.docx
- Attachment Data Elements Business Rules.xlsx
- 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
- Common Files
 - NFSDX Schema v11.2.zip
 - NfsdxService11.2.WSDL file
 - ReferenceDataSTATES.xml

The WSDL file describes the NFSDX synchronous web service for both the Pre-Production and Production environments. Other supporting files, NFSDX Schema v11.2.zip, Attachments Data Elements Business Rules.xlsx, and ReferenceDataSTATES.xml, are described in detail in [Appendix B: Attachment Operations Schema and Reference Data](#) and [Appendix D: Business Rules and Error Messages](#).

SOAP requests and response examples for adding Attachment operations to the Contracted Inspection results will be provided upon request.

Contracted Inspection - related files are described in detail in the State Integration Guide for Submission of Contracted Inspection.

1.5 GLOSSARY OF TERMS

Definitions of abbreviated terms and acronyms used within this document are listed in [Appendix A: Glossary 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.

2.0 ATTACHMENT OPERATIONS INTERFACE DETAILS

2.1 STATES-NFSDX INTERFACE OVERVIEW

The States–NFSDX interface allows States to perform Attachment operations for the Contracted

Inspection results in 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 – Submits one of the Attachment operations requests (Upload Attachment/Delete Attachment/Retrieve Attachment List) for the Contracted Inspection results
- NFSDX – Processes the Attachment operations request (Upload Attachment/Delete Attachment/Retrieve Attachment List) to send it to the FDA system of record for validation, data retrieval, deletion, or storage through exposed web service endpoints

2.2 STATES-NFSDX BUSINESS FLOW: UPLOAD ATTACHMENT

The States–NFSDX interface allows NFSDX to upload Attachments to the existing Contracted Inspection from participating States and route the data to the FDA system of record. NFSDX provides XML-based standards for States to upload Attachments to the existing inspection data, and supports Attachment virus scan of the uploaded Attachment and auditing capabilities by storing transactional data such as calling system, organization, etc. The XML schema defined in [Appendix B: Attachment Operations Schema and Reference Data](#) is used to upload Attachments to the existing Contracted Inspection. The NFSDX business flow covers the following processes: 1) State user authentication, 2) Attachment virus scan, 3) State upload of Attachment to the existing Contracted Inspection results in FDA, and 4) State notification of upload process outcome.

The diagram in **Exhibit 1** provides an illustration of the business process flow for uploading Attachments to the existing Contracted Inspection results in NFSDX.

The NFSDX business flow is summarized as follows:

1. NFSDX receives an Attachment submission to the existing Contracted Inspection 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 Attachment submission request is processed in XML format from the State.
2. NFSDX validates the Attachment upload request data against the ORA XML schema. If the submitted XML file fails schema validation, NFSDX sends notification back to the State that validation failed.
3. In the case of successful XML validation, the uploaded Attachment is scanned for viruses. Depending on the outcome of the virus scan, the notification of successful or unsuccessful virus scan is sent back to the State. If the uploaded Attachment passes the virus scan, it goes through business rules validation.
4. If the uploaded Attachment passes business rules validation, the Attachment is stored in the FDA system of record.
5. Once the Attachment 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.

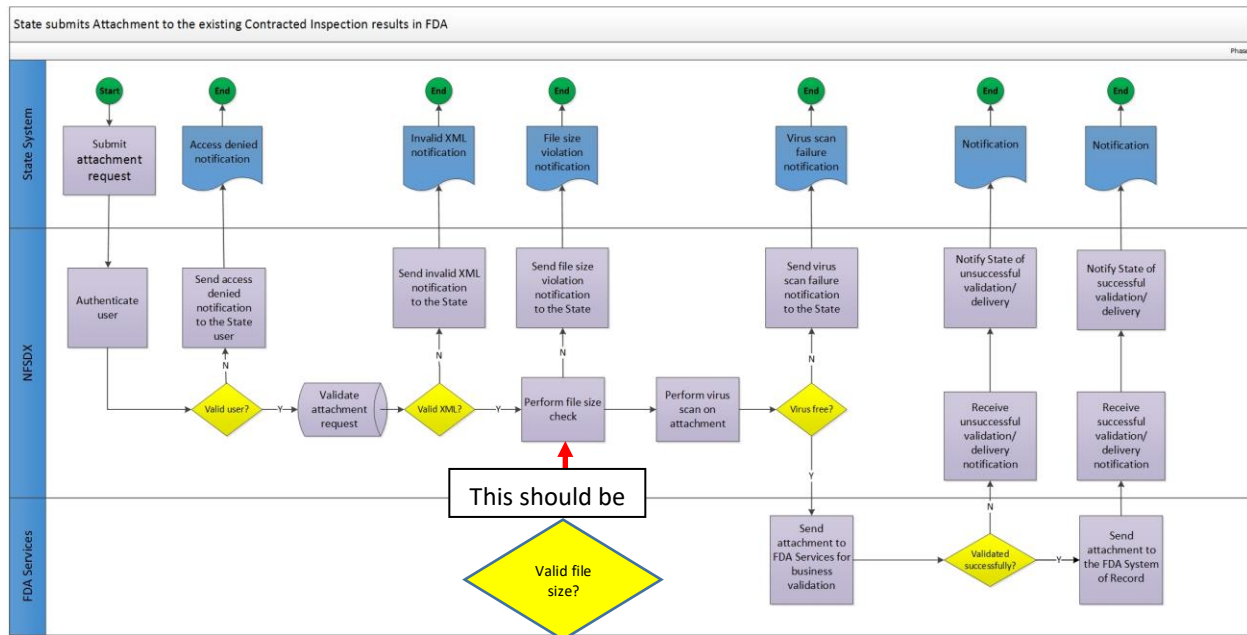


Exhibit 1: Business Flow for States Uploading an Attachment for the Existing Contracted Inspection via NFSDX

2.3 STATES-NFSDX BUSINESS FLOW: DELETE ATTACHMENT(S)

The States–NFSDX interface allows the State to request deleting Attachment(s) from the existing Contracted Inspection via NFSDX. NFSDX provides XML-based standards for States to delete Attachment(s) from the existing inspection data, and supports XML schema validation and auditing capabilities by storing transactional data such as calling system, organization, etc. The XML schema defined in [Appendix B: Attachment Operations Schema and Reference Data](#) is used to delete Attachment(s) from the existing Contracted Inspection. The NFSDX business flow covers the following processes: 1) State user authentication, 2) State request for Attachment(s) deletion from the existing Contracted Inspection and 3) State notification of Attachment(s) deletion process outcome.

The diagram in **Exhibit 2** provides an illustration of the business process flow for deleting Attachment(s) from the existing Contracted Inspection via NFSDX.

The NFSDX business flow is summarized as follows:

1. NFSDX receives the State’s request to delete Attachment(s) from the existing Contracted Inspection and authenticates the State user. In the case of invalid State credentials, NFSDX rejects the request and notifies the State that access was denied. In the case of successful authentication, the Attachment deletion request is processed in XML format.
2. NFSDX validates the Attachment(s) deletion request data against the ORA XML schema. If the submitted XML file fails schema validation, NFSDX sends notification back to the

State that validation failed.

3. In the case of successful XML validation, the Attachment(s) deletion request goes through business rules validation.
4. If the Attachment(s) deletion request passes business rules validation, the Attachment(s) is/are deleted from the Contracted Inspection.
5. Once the Attachment(s) deletion request is processed, depending on the outcome, the notification of successful or unsuccessful processing/failed business validation is sent back to the State. Every transaction is recorded in the NFSDX audit log.

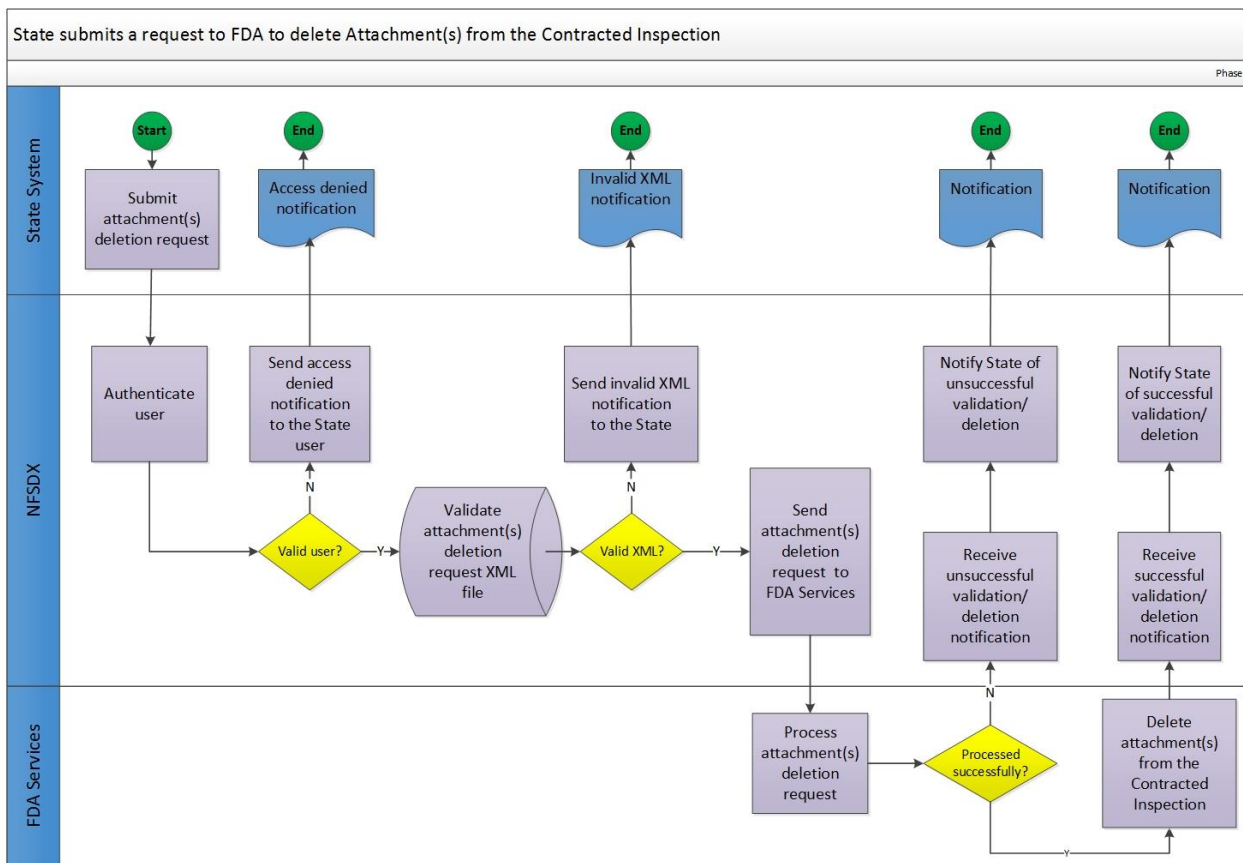


Exhibit 2: Business Flow for States Requesting to Delete Attachment(s) from the Existing Contracted Inspection via NSFDX

2.4 STATES-NFSDX BUSINESS FLOW: RETRIEVE ATTACHMENT LIST

The States–NFSDX interface allows users to request retrieving an Attachment(s) list from the existing Contracted Inspection via NFSDX. NFSDX provides XML-based standards for States to request an Attachment(s) list for the existing inspection data, and supports XML schema validation and auditing capabilities by storing transactional data such as calling system, organization, etc. The XML schema defined in [Appendix B: Attachment Operations Schema and Reference Data](#) is used to request the Attachment(s) list for the existing Contracted Inspection. The NFSDX business flow covers the following processes: 1) State user authentication, 2) State

request for Attachment(s) list for the existing Contracted Inspection, and 3) State reception of Attachment(s) list for the existing Contracted Inspection. Note that the Attachment(s) list for the existing Contracted Inspection doesn't contain the actual Attachment(s) but the list of attributes (metadata) associated with each file (e.g., file name, file type, document type, etc.).

The diagram in **Exhibit 3** provides a visual illustration of the business process flow for requesting an Attachment(s) list for the existing Contracted Inspection via NFSDX.

The NFSDX business flow is summarized as follows:

1. NFSDX receives the State's request to retrieve an Attachment(s) list for the existing Contracted Inspection and authenticates the State user. In the case of invalid State credentials, NFSDX rejects the request and notifies the State that access was denied. In the case of successful authentication, the Attachment(s) list retrieval request is processed in XML format.
2. NFSDX validates the Attachment(s) list retrieval request data against the ORA XML schema. If the submitted XML file fails schema validation, NFSDX sends notification back to the State that validation failed.
3. In the case of successful XML validation, the Attachment(s) list retrieval request goes through business rules validation.
4. If the Attachment(s) list retrieval request passes business rules validation, it is sent to FDA for processing.
5. Once the Attachment(s) list retrieval request is processed, depending on the outcome, the notification of successful or unsuccessful processing is sent back to the State. In the case of successful processing, the Attachment(s) list is sent back to the State or, in the case of unsuccessful processing/failed business validation, notification of the failed transaction is sent back to the State. Every transaction is recorded in the NFSDX audit log.

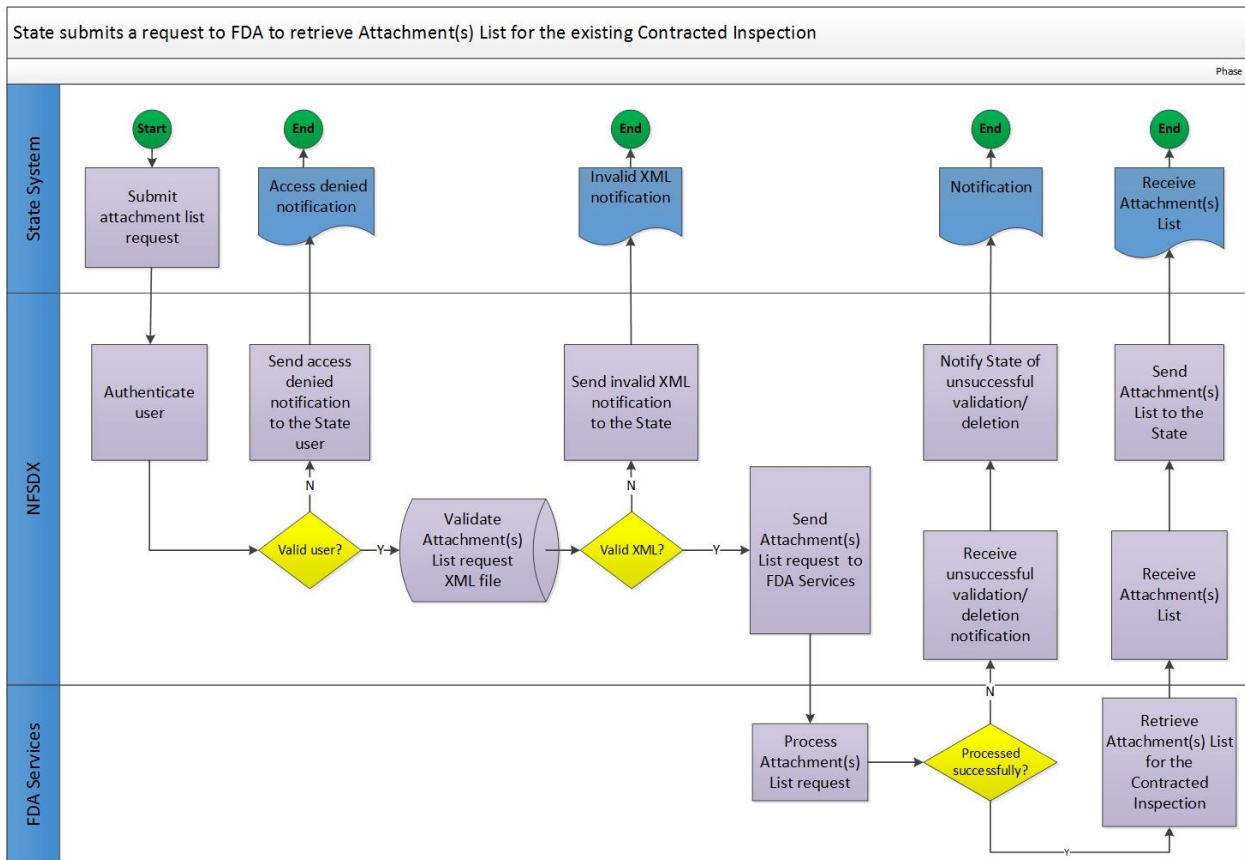


Exhibit 3: Business Flow for States Requesting Retrieval of Attachment(s) List for the Existing Contracted Inspection via NFSDX

2.5 NFSDX WEB SERVICE ENDPOINTS

The NFSDX system will provide web service endpoints for the States to perform Attachment operations.

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

The Web Services Description Language (WSDL) file and associated XML schema files describing the NFSDX web service will be provided.

Example SOAP/XML requests and responses for adding Attachment operations to Contracted Inspections will be provided upon request.

2.6 SUPPORTED OPERATIONS

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

Client / Server	Operation	Inputs	Outputs	Description
STATE → NFSDX	UploadInspectionAttachmentOperation	Attachment and Attachment Metadata	Response Message	State submits Attachment to the existing Contracted Inspection to the FDA system of record via NFSDX.
STATE → NFSDX	DeleteInspectionAttachmentOperation	Attachment Deletion request	Response Message	State submits a request to delete Attachment(s) from the existing Contracted Inspection in the FDA system of record via NFSDX.
STATE → NFSDX	RetrieveInspectionAttachmentOperation	Attachment Retrieval request	Response Message, Attachment(s) List	State submits a request to retrieve a list of Attachment(s) (metadata only) associated with the existing Contracted Inspection in the FDA system of record via NFSDX.

2.7 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
Upload Attachment Operation						
State	NFSDX	Web Service	Real-time	XML	SOAP / HTTPS	Submit Attachment request message. Refer to Appendix B: Attachment Operations Schema and Reference Data for the Attachment Operations schema.
NFSDX	State	Web Service	Real-time	XML	SOAP / HTTPS	Send Attachment response message. Refer to Appendix B: Attachment Operations Schema and Reference Data for the Attachment Operations schema.
Delete Attachment(s) Operation						
State	NFSDX	Web Service	Real-time	XML	SOAP / HTTPS	Submit Delete Attachment(s) request message. Refer to Appendix B: Attachment Operations Schema and Reference Data for the Attachment Operations schema.

Interface From	Interface To	Interface Type	Frequency	Data Format	Protocol	Data Transferred
NFSDX	State	Web Service	Real-time	XML	SOAP / HTTPS	Send Delete Attachment(s) response message. Refer to Appendix B: Attachment Operations Schema and Reference Data for the Attachment Operations schema.
Retrieve Attachment List Operation						
State	NFSDX	Web Service	Real-time	XML	SOAP / HTTPS	Submit Request Attachment(s) List request message. Refer to Appendix B: Attachment Operations Schema and Reference Data for the Attachment Operations schema.
NFSDX	State	Web Service	Real-time	XML	SOAP / HTTPS	Send Attachment(s) List response message and, in the case of successful request, an Attachment(s) List. Refer to Appendix B: Attachment Operations Schema and Reference Data for the Attachment Operations schema.

2.8 STATES-NFSDX INTEGRATION STEPS FOR PERFORMING ATTACHMENT OPERATIONS

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 3.5](#) for details about SOAP header security requirements)
 - A SOAP header which includes the transaction type ‘inspection11.2’
 - A SOAP header which includes the Application ID
 - A SOAP payload which includes transaction header elements and Attachment operation elements. (Please refer to [Appendix B: Attachment Operations Schema and Reference Data](#) for a list of the Attachment operations 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

- NFSDX authenticates State client credentials.
- NFSDX validates the SOAP message payload against the XSD schema listed in [Appendix B: Attachment Operations Schema and Reference Data](#).
- NFSDX passes the Attachment operation request to the FDA system of record for business validation and processing, captures a response message and requested data, if applicable, and forwards the response back to the State. In the case of Upload Attachment, the Attachment is also stored in the FDA system of record.
- When an error occurs in the NFSDX system, a “Failure” response message will be constructed in NFSDX and sent to the State.

2.9 STATE UPLOADS ATTACHMENT TO THE EXISTING CONTRACTED INSPECTION

The table below shows the Upload Attachment operation supported by the States–NFSDX interface.

Client / Server	Operation	Inputs	Outputs	Description
STATE → NFSDX	UploadInspectionAttachmentOperation	Attachment upload request: AssignmentID OperationID StateCD StateAgency Attachment data Attachment	Response Message	Submit Attachment for the existing Contracted Inspection via NFSDX.

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

- SOAP Header – The mandatory fields for the SOAP header are username, 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">XXX</info:ApplicationID>
```

 where XXX is the Application ID assigned to the State system
- Transaction Header – The mandatory fields for the Transaction header are ApplicationID, TransactionID, and TransactionTimeStamp.

3. **Payload** – Attachment data submitted to the existing contracted inspection is expected in the Payload section. For the list of required and optional Submit Attachment Operation data payload elements, please refer to the *Attachment Data Elements Business Rules.xlsx* spreadsheet in [Appendix B: Attachment Operations Schema and Reference Data](#).

The table below describes the States' Upload Attachment 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.
TransactionType	SOAP Header	The transaction type: inspection.
ApplicationID	SOAP Header	The NFSDX team will provide each State or State system with an ApplicationID.
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.
OraSchemaVersion	Transaction Header	Schema Version number used for by the request provided by the NFSDX team and set by the client system.
Submit Attachment Operation Data Elements	Payload Section	Payload section is provided by the client system. For a detailed list of Submit Attachment Operation Data Elements data elements, see the spreadsheet <i>Attachment Data Elements Business Rules.xlsx</i> in Appendix B: Attachment Operations Schema and Reference Data .

The Upload Attachment operation uses SOAP Message Transmission Optimization Mechanism/XML-binary Optimized Packaging (MTOM/XOP).

SOAP MTOM/XOP defines a method for optimizing the transmission of XML data of type `xs:base64Binary` or `xs:hexBinary` in SOAP messages. When the transport protocol is HTTP, MIME Attachments are used to carry that data while at the same time allowing both the sender and the receiver direct access to the XML data in the SOAP message without having to be aware that any MIME artifacts were used to marshal the `base64Binary` or `hexBinary` data.

For NFSDX Upload Attachments, the DocumentContent is defined in the XSD as:

```
<xsd:element name="DocumentContent" type="xsd:base64Binary" minOccurs="0"
xmlns:ns1="http://www.w3.org/2005/05/xmlmime"/>
```

When MTOM/XOP is used to optimize a SOAP message, it is serialized into a MIME Multipart/Related message using XOP processing. The base64Binary data is extracted from the SOAP message and packaged as separate binary Attachments within the MIME message, in a manner similar to e-mail Attachments.

The size of the base64Binary data is significantly reduced because the Attachments are encoded in binary format. The XML in the SOAP message is then converted to XOP format by replacing the base64Binary data with a special <xop:include> element that references the relevant MIME Attachment using a URI.

The modified SOAP message is called the XOP document, and forms the root document within the message. The XOP document and binary Attachments together form the XOP package. When applied to the SOAP MTOM specification, the XOP package is a MIME message in MTOM format.

The binary data optimization process involves the following steps: 1) encode the binary data, 2) remove the binary data from the SOAP envelope, 3) compress the binary data, 4) attach the binary data to the MIME package, and 5) add references to the MIME package in the SOAP envelope.

To call the NFSDX MTOM/XOP enabled service, the client should enable MTOM as appropriate for the technology used (Java, .net, etc.)

2.9.1 Upload Attachment Success Response Message

For a request that results in successful delivery of the Attachment to the existing Contracted Inspection, the message will contain *Status* and *Message* in the *Status Response* location, with the *Status* set to *Success*, as indicated in the table below.

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.
SourceApplicationID	Transaction Header	The NFSDX system will provide the original value of SourceApplicationID 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.
TransactionID	Transaction Header	Unique identifier of a transaction generated by the NFSDX system. It is unique for each request/operation. (Example: 900001)

Element Name	Location	Description
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").
DocumentId	Status Response Payload	ID of the Document that has been successfully deleted.
DocumentFileName	Status Response Payload	Name of the document, including extension, that has been successfully deleted.
DocumentUploadStatus	Status Response Payload	Success or Failure

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

2.9.2 Upload Attachment 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.

Please note that the Failure response will be similar for all three Attachment operations: Upload Attachment, Delete Attachment, and Retrieve Attachment List.

Element Name	Location	Description
ApplicationID	Transaction Header	Unique Identifier of the application initiating the transaction. This is a pre-assigned ID for 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 provide the original value of SrcTransactionID 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).

Element Name	Location	Description
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.

An 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: Attachment Operations Schema and Reference Data](#).

2.10 State Requests Deleting Attachment(s) from the Existing Contracted Inspection

States may use this operation to delete Attachment(s) data from the existing Contracted Inspection. The table below shows the Delete Attachment(s) operation supported by the States–NFSDX interface.

Client / Server	Operation	Inputs	Outputs	Description
STATE → NFSDX	DeleteInspection AttachmentOperation	Attachment Deletion request: AssignmentID OperationID StateCD StateAgency Document ID(s)	Response Message	Delete Attachment(s) from the existing Contracted Inspection

A Delete Attachment(s) operation can be performed when an Attachment is no longer needed. An example of the SOAP request to delete an Attachment from the existing Contracted Inspection will be made available to 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, 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">XXX</info:ApplicationID>
```

where XXX is the Application ID assigned to the State system

2. Transaction Header – The mandatory fields for the Transaction header are ApplicationID, TransactionID, and TransactionTimeStamp.
3. Payload – The Payload contains Attachment Delete request data elements. For the list of required and optional Attachment Delete payload elements, please refer to the *Attachment Data Elements Business Rules.xlsx* spreadsheet in [Appendix B: Attachment Operations Schema and Reference Data](#).

The table below describes the States' Attachment Delete 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	SOAP Header	The NFSDX team will provide each State or State system with an ApplicationID.
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.
Delete Attachment request	Payload Section	Payload section is provided by the client system. For a detailed list of the Delete Attachment request data elements, see the spreadsheet <i>Attachment Data Elements Business Rules.xlsx</i> in Appendix B: Attachment Operations Schema and Reference Data .

2.10.1 Attachment Delete Success Response Message

For a request that results in successful deletion of the Contracted Inspection Attachment, the message will contain *Status* and *Message* in the *Status Response* location, with the *Status* set to *Success*, as indicated in the table below.

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.

Element Name	Location	Description
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 SrcTransactionID 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.
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").
DocumentId	Status Response Payload	ID of the Document that has been successfully deleted.
DocumentFileName	Status Response Payload	Name of the document, including extension, that has been successfully deleted.
DocumentDeleted	Status Response Payload	State (True or False) of the document being deleted.

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

2.10.2 Attachment Delete 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.

Please note that the Failure response will be similar for all three Attachment operations: Submit Attachment, Delete Attachment, and Retrieve Attachment List.

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 SrcTransactionID as provided by the client system in the

Element Name	Location	Description
		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.

An 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: Attachment Operations Schema and Reference Data](#).

2.11 STATE RETRIEVES A LIST OF ATTACHMENT(S) FOR THE EXISTING CONTRACTED INSPECTION

States may use this operation to retrieve a list of Attachment(s) (metadata only) for the existing Contracted Inspection.

The table below shows the Retrieve Attachment(s) List operation supported by the States–NFSDX interface.

Client / Server	Operation	Inputs	Outputs	Description
STATE à NFSDX	RetrieveInspectionAttachmentOperation	Attachment retrieval request: AssignmentID OperationID StateCD StateAgency	Response Message, List of Attachment IDs	Retrieve a List of Attachments(s) (metadata only) associated with the existing Contracted Inspection

An example of code to retrieve an Attachment(s) list for the existing Contracted Inspection will be made available to the 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, 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">XXX</info:ApplicationID>
```

where XXX is the Application ID assigned to the State system

2. Transaction Header – The mandatory fields for the Transaction header are ApplicationID, TransactionID, and TransactionTimeStamp.
3. Payload –The Payload contains Attachment(s) List Retrieve request data elements. For the list of payload elements, please refer to the *Attachment Data Elements Business Rules.xlsx* spreadsheet in [Appendix B: Attachment Operations Schema and Reference Data](#).

The table below describes the States’ Retrieve Attachment 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	SOAP Header	The NFSDX team will provide each State or State system with an ApplicationID.
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.
Payload	Payload Section	Payload section is provided by the client system. For a detailed list of the Retrieve Attachment request data elements, see the spreadsheet <i>Attachment Data Elements Business Rules.xlsx</i> in Appendix B: Attachment Operations Schema and Reference Data .

2.11.1 Requests a List of Attachments Success Response Message

For a request that results in successful delivery of the List of Attachments, the message will contain *Status* and *Message* in the *Status Response* location, with the *Status* set to *Success*, as indicated in the table below, with the payload containing a list of Attachment(s) data elements.

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 provide the original value of SrcTransactionID 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.
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.
List of Attachment(s)	Payload	The List of Attachment(s) data set. For a detailed description of the Retrieve Attachment request data elements, see the spreadsheet <i>Attachment Data Elements Business Rules.xlsx</i> in Appendix B: Attachment Operations Schema and Reference Data .

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 Requests a List of Attachments 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

Element Name	Location	Description
ApplicationID	Transaction Header	Unique Identifier of the application initiating the transaction. This is a pre-assigned ID for NFSDX system.

Element Name	Location	Description
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 SrcTransactionID 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.

An 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: Attachment Operations Schema and Reference Data.

2.12 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 username 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.

Error Condition	Recovery
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 suggestion to retry the request or contact system administrator is returned to the client.

3.0 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 STATE 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 an Attachment operation. The State will receive a fault message for the failed authorization due to the unauthorized State calling to perform an Attachment operation. An 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 NFSDX ERROR HANDLING FOR XML SCHEMA VALIDATION ERRORS

Currently all Oracle Service Bus (OSB) schema-level validation errors return SOAP fault messages that are intended for the technical team. 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., entering a character instead of a digit), incorrect length (e.g., 10 digits provided instead of allowable 6 digits), etc.

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

3.5 SECURITY HEADER

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

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
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
ID	Identifier
IFSS	Integrated Food Safety System
NFSDX	National Food Safety Data Exchange
ORA	Office of Regulatory Affairs
SOAP	Simple Object Access Protocol
SSL	Secure Sockets Layer
TLS	Transport Layer Security
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: ATTACHMENT OPERATIONS 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 State Integration package.

A second Attachment to this guide includes the *Attachments Data Elements Business Rules.xlsx* spreadsheet.

The spreadsheet will also map the data element to the Attachment business rule(s) that apply to that data element and includes a list of Attachment file types allowed for upload.

When submitting Attachment operations 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 the reference code lists may be updated on an ad hoc basis, as a result 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 Attachment operation XML elements’ predefined values and will guide the States in determining whether to provide either the code or description when submitting a request for an Attachment operation.

Domain	XML Element Name	State to Share Code or Description?
Attachments - Upload	InspectionAttachmentDocumentType	Description

APPENDIX C: NFSDX ERROR MESSAGES

All available error messages and error codes produced by NFSDX and then captured and forwarded to States 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-110	Invalid Operational Status provided in the inspection results.
NFSDX-ERR-115	Invalid State Code provided in the inspection results.
NFSDX-ERR-119	The Document Type for the Attachment is not valid. Select a valid Document Type and try again.
NFSDX-ERR-120	The Attachment file type is not supported. Select a valid file type and try again.
NFSDX-ERR-121	The Attachment file type is missing. Provide a valid file type and try again.
NFSDX-ERR-122	The Attachment is missing. Include Attachment in the submission and try again.
NFSDX-ERR-960	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-970	A virus was detected. Remove any viruses from the Attachment and try again.
NFSDX-ERR-980	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-990	The Attachment file size exceeds the 250MB limit. Reduce the Attachment file size and try again.
NFSDX-ERR-995	The submission contains more than one Attachment. Only one Attachment per submission is allowed. Remove the additional Attachment(s) and resubmit.

APPENDIX D: BUSINESS RULES AND ERROR MESSAGES

The Attachment Operations business rules, corresponding error codes, and error messages produced by FDA, as captured and forwarded to State agencies by NFSDX, are described on the second tab, *ContrInspAtt Business Rules List*, in the Excel spreadsheet *Attachment Data Elements Business Rules.xlsx* provided as part of the State Integration package.

The parameter values with curly brackets { } represent (where applicable) data element value(s) replaced with values submitted in the Attachments operation 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).