NEMSIS v3.4.0 Compliance

April 2, 2015

Resources

Pre-Testing Package: http://nemsis.org/v3/becomingCompliant/complianceProcess.html

Software in Compliance Testing: http://nemsis.org/v3/compliantSoftware.html

NEMSIS TAC Validator Web Service: https://www.nemsis.org/NemsisV3Validator4/NemsisWsService?wsdl

NEMSIS TAC Compliance Web

Service: https://www.nemsis.org/NemsisV3ComplianceTest4/NemsisWsService?wsdl

Overview

Products seeking NEMSIS v3 compliance must be in final form, ready-for-market, installation ready, and versioned. The NEMSIS TAC may install a product on a test server, request administrative rights to a web application, or (if necessary) travel to test a more complex application. The NEMSIS v3 compliance encompasses 2 processes called "Collect Data" and "Receive and Process Data".

General Requirements for Collect Data. (Reference the Collect Data section in this document for specifics)

- Data entry for the Demographic dataset & EMS dataset
- Receive and process the CAD dataset & Medical Device dataset
- Schematron and XSD validation when a record is finalized for the Demographic dataset & EMS dataset
- Dataset submission via webservice for Demographic dataset & EMS dataset
- Modification of Demographics triggers a Demographic dataset submission
- Custom elements implemented in the user interface and dataset submission for the Demographic Dataset & EMS Dataset

General Requirements for **Receive and Process Data**. (Reference the <u>Receive and Process Data</u> section in this document for specifics)

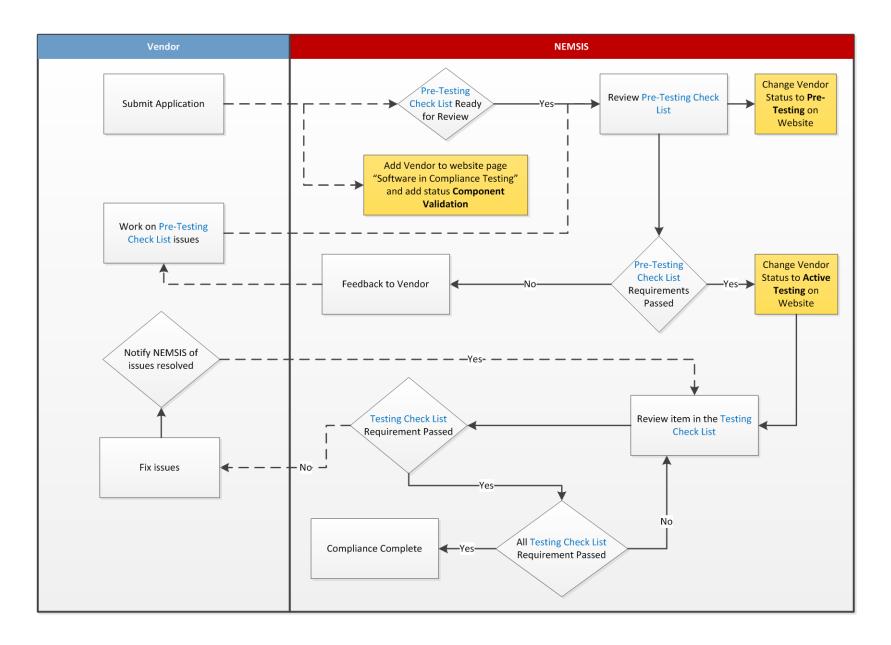
- Dataset submission via webservice for Demographic dataset & EMS dataset
- Receive and process the Demographic dataset & EMS dataset
- Receive and Send the Demographic dataset & EMS dataset via web service

Receiving the Demographic dataset triggers a Demographic dataset submission

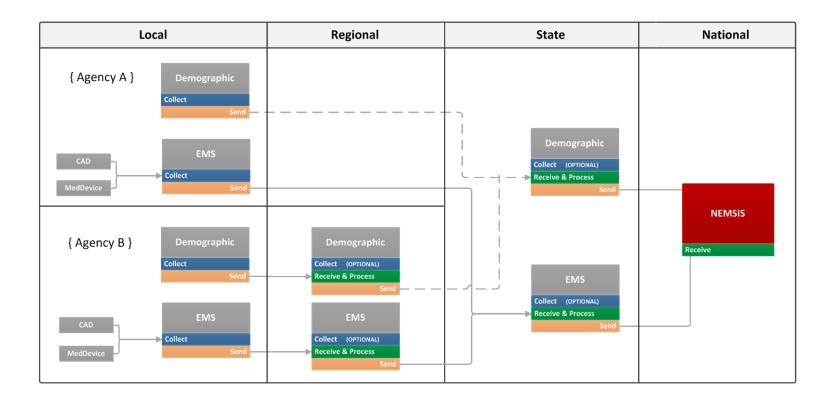
As a vendor proceeds with becoming compliant their progress and status will be updated as different mile stones are achieved. The status of a vendor can be found on the web page "Software in Compliance Testing" as referenced in the <u>Resources</u> section. Mile stone requirements for each status are as follows:

- Component Validation: Working with NEMSIS TAC to validate Pre-Testing requirements.
- **Pre-Testing**: Ensuring components are properly implemented.
 - o Pre-Testing cases (entered by vendor), software interface, schematron implementation, and other items will be reviewed by the NEMSIS TAC and Vendor via webinar.
- Active Testing: Actively evaluating and validating test cases results.
 - o Test cases (entered by vendor), import of CAD and MED, schematron, data export, and other items will be reviewed by the NEMSIS TAC and Vendor via webinar.

Compliance Process



Data Flow



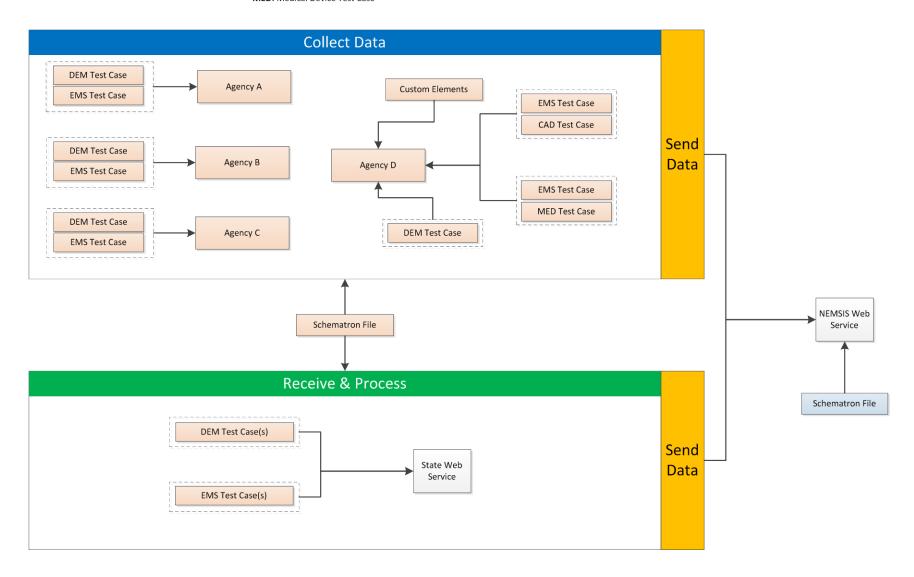
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Pre-Testing Process

☐ To be completed by the NEMSIS TAC☐ To be completed by the applicant

EMS: EMS Test Case
DEM: Demographic Test Case
CAD: CAD Test Case

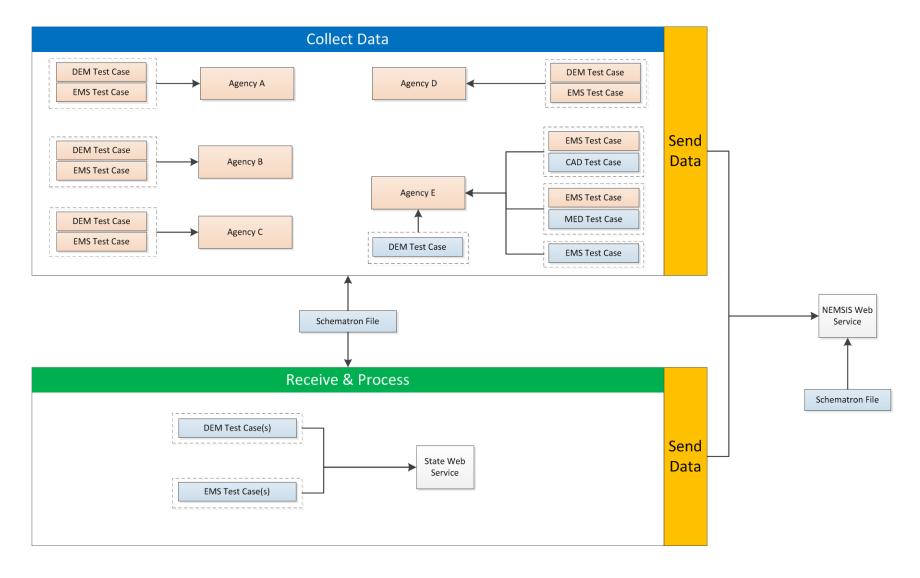
MED: Medical Device Test Case



☐ To be completed by the NEMSIS TAC☐ To be completed by the applicant

EMS: EMS Test Case
DEM: Demographic Test Case
CAD: CAD Test Case

MED: Medical Device Test Case



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Collect Data

Products that **Collect Data** must demonstrate the implementation of all NEMSIS v3 Demographic and EMS dataset elements, processing a CAD and MedDevice dataset, implementation of custom elements, application of business logic at record finalization, and XML representation of the Demographic and EMS dataset.

Overview of Requirements

- 1. The full NEMSIS v3 Demographic standard is implemented in the user interface.
- 2. The full NEMSIS v3 EMS standard is implemented in the user interface.
- 3. The implementation of custom elements as provided in the test cases.
- 4. The implementation of Schematron for business logic.
- 5. The ability to process multiple Schematron files.
- 6. The use of Schematron for business rules when a Demographic record is finalized.
- 7. The use of Schematron for business rules when an EMS record is finalized.
- 8. The processing of a NEMSIS v3 CAD & MED dataset populates the EMS event.
- 9. The client is able to properly submit data in accordance to the NEMSIS v3 Web Service standard. Reference the Web Service Communication section for details.

Pre-Testing Check List

Use the **Pre-Testing** test package as referenced in the <u>Resources</u> section at the beginning of this document to complete the following items:

- 1. **Software Access:** The NEMSIS TAC must have access to the software so they may enter clinical test cases. Steps to meet this requirement are as follows:
 - a. If software needs to be installed by the NEMSIS TAC, provide the NEMSIS TAC with hardware requirements of the software.
 - b. If software needs to be installed by the NEMSIS TAC, provide the NEMSIS TAC with all packages required to install the software, including licenses.
- 2. **Custom Element Implementation**: The software must export custom elements specified by the NEMSIS TAC. Steps to meet this requirement are as follows:
 - a. Implement all custom elements defined in the "CollectData\CustomElements" directory of the Pre-Testing Package. There are three (3) files containing total of five (5) custom elements.
 - b. Custom elements must be included in the XML export of the software.
- 3. **Schematron Rules**: The software must allow for dynamically adding a set of Schematron rules. Steps to meet this requirement are as follows:
 - a. Implement the ability to dynamically import a Schematron rules file. The rules file to be imported is contained in the "Schematron" directory of the Pre-Testing Package, however it must be loaded dynamically and not built into the software.
 - b. Provide the NEMSIS TAC with instructions on how to import a Schematron rules file.
 - c. Implement the ability to import multiple schematron files.

- 4. **DEM and EMS Test Cases**: All EMS and DEM test cases must be entered into the system by the applicant and available to the NEMSIS TAC for review. Steps to meet this requirement are as follows:
 - a. Implement all EMS and DEM data set elements in the software user interface.
 - b. Provide the NEMSIS TAC with instructions on how to locate elements within the interface. The instructions may be by section as opposed to element by element.
 - c. Enter the test cases for DEM and EMS data sets manually as follows:
 - Step 1. Use the test case "CollectData\Agency-A\DEM\ DEMDataset-ElementsRepeat-1.html" to create **Agency A**.
 - Step 2. Use the test case "CollectData\Agency-B\EMS\ EMSDataset-ElementsRepeat-1.html" to create a PCR assigned to Agency A.
 - Step 3. Use the test case "CollectData\Agency-C\DEM\ DEMDataset-Nils-2.html" to create Agency C.
 - Step 4. Use the test case "CollectData\Agency-C\EMS\ EMSDataset-Nils-2.html" to create a PCR assigned to Agency C.
 - Step 5. Use the test case "CollectData\Agency-D\DEM\ DEMDataset-NoRepeat-3.html" to create **Agency D**.
 - Step 6. Use the test case "CollectData\Agency-D\EMS\ EMSDataset-NoRepeat-3.html" to create a PCR assigned to Agency D.
 - Step 7. Use the test case "CollectData\Agency-B\DEM\ DEMDataset-PNs-4.html" to create Agency B.
 - Step 8. Use the test case "CollectData\Agency-B\EMS\ EMSDataset-PNs-4.html" to create a PCR assigned to Agency B.
 - d. Each test case must remain in the system for verification by the NEMSIS TAC.
- 5. **CAD Test Cases**: All CAD test cases must be entered into the system by the applicant and available to the NEMSIS TAC for review. Steps to meet this requirement are as follows:
 - a. Implement the dynamic import of CAD data set XML files into the software interface.
 - b. Enter the test cases for CAD data sets as follows:
 - Step 1. Use the test case "CollectData\Agency-D\CAD\EMSDataset-NoRepeat-1.html" to create a partial PCR assigned to Agency D (see 4. DEM and EMS Test Cases above).
 - Step 2. Import the test case "CollectData\Agency-D\CAD\CADDataSet-NoRepeat-1.xml" into the PCR from step 1.
 - c. Each test case must remain in the system for verification by the NEMSIS TAC.
- 6. **MedDevice Test Cases:** All MEDDevice test cases must be entered into the system by the applicant and available to the NEMSIS TAC for review. Steps to meet this requirement are as follows:
 - a. Implement the dynamic import of MedDevice data set XML files into the software interface.
 - b. Enter the test cases for MedDevice data sets as follows:
 - Step 1. Use the test case "CollectData\Agency-D\MED\EMSDataset-NoRepeat-1.html" to create a partial PCR assigned to **Agency D** (see 4. **DEM and EMS Test Cases** above).
 - Step 2. Import the test case "CollectData\Agency-D\MED\MEDDataSet-NoRepeat-1.xml" into the PCR from step 1.
 - c. Each test case must remain in the system for verification by the NEMSIS TAC.

7. Additional Requirements:

- a. See the <u>Send Data</u> section for additional requirements
- b. Reference the <u>Demographic Updates (Collect Data)</u> section for additional requirements.

An active testing package with instructions will be provided once the Pre-Testing check list is complete and has been reviewed by the NEMSIS TAC.

The following items will need to be completed by the applicant:

- 1. **DEM and EMS Test Cases**: All EMS and DEM test cases must be entered into the system by the applicant and available to the NEMSIS TAC for review. Steps to meet this requirement are as follows:
 - a. Implement all EMS and DEM data set elements in the software user interface.
 - b. The NEMSIS TAC will provide instructions and test cases during the Active Testing phase.
 - c. Each test case must remain in the system for verification by the NEMSIS TAC.
- 2. **CAD Test Cases**: All CAD test cases must be imported into the system by the applicant and available to the NEMSIS TAC for review. Steps to meet this requirement are as follows:
 - a. Implement the dynamic import of CAD data set XML files into the software interface.
 - b. The NEMSIS TAC will provide instructions and test cases during the Active Testing phase.
 - c. Each test case must remain in the system for verification by the NEMSIS TAC.
- 3. **MedDevice Test Cases:** All MedDevice test cases must be imported into the system by the applicant and available to the NEMSIS TAC for review. Steps to meet this requirement are as follows:
 - a. Implement the dynamic import of MedDevice data set XML files into the software interface.
 - b. The NEMSIS TAC will provide instructions and test cases during the Active Testing phase.
 - c. Each test case must remain in the system for verification by the NEMSIS TAC.

The following items will be completed by the NEMSIS TAC:

- 1. **Schematron Rules:** The NEMSIS TAC will apply a schematron file.
- 2. **Demographic and EMS Test Cases:** The NEMSIS TAC will enter the information for DEM test case for **Agency-E** and assign all clinical EMS test cases to that agency.
- 3. **Custom Elements**: The NEMSIS TAC will verify the implementation of custom elements when entering clinical test cases. Clinical test cases will contain data that will be entered into the various custom elements.
- 4. CAD and Medical Device: The NEMSIS TAC will import all CAD & MED test case files for the partially completed EMS test cases for MedDevice Test Cases and CAD Test Cases from items 2 & 3 completed by applicant.

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Receive and Process Data

Products that **Receive and Process Data** must demonstrate the capability of receiving and processing the NEMSIS v3 Demographic and EMS dataset. Processing a dataset includes structure validation and business rules validation of a dataset received. A sample test package will be provided prior to testing.

Overview of Requirements

- 1. The client is able to properly interoperate the status codes in NEMSIS v3 Web Service standard. Reference the <u>Web Service Communication</u> section for details.
- 2. The ability to receive Demographic and EMS data.
- 3. The ability to send Demographic and EMS data.
- 4. The implementation of Schematron for business logic.
- 5. The ability to process multiple Schematron files.

Pre-Testing Check List

Use the **Pre-Testing** test package as referenced in the <u>Resources</u> section at the beginning of this document for the following items:

- 1. **Schematron Rules**: The software must allow for dynamically adding a set of Schematron rules. Steps to meet this requirement are as follows:
 - a. Implement the ability to dynamically import a Schematron rules file. The rules file to be imported is contained in the "Schematron" directory of the Pre-Testing Package; however it must be loaded dynamically and not built into the software.
 - b. Provide the NEMSIS TAC with instructions on how to import a Schematron rules file.
 - c. Implement the ability to import multiple schematron files.
- 2. **Web Service Account:** Provide the NEMSIS TAC with the web service URL and an account. Steps to meet this requirement are as follows:
 - a. Provide the NEMSIS TAC with all necessary information to access the software's web service.
- 3. **Test Case Submission:** Submit Demographic and EMS test cases to the application's web service. Review the section <u>Demographic Submission (Receive and Process)</u> section for handling modifications to a previous Demographic submission. Steps to meet this requirement are as follows:
 - a. Test cases directory overview:
 - i. **DEM** contains xml files that pass XSD and schematron validation.
 - ii. **Fail** contains xml files that fail XSD validation. This directory also contains xml files that pass XSD validation and fail schematron.
 - b. Agency-A Test Cases (Directory: Receive&Process\DEM):
 - i. Submit the DEM file DEMDataset-ElementsRepeat-1.xml, which contains 1 DEM test case, to the software's web service.
 - ii. Submit the DEM file DEMDataset-Nils-2.xml, which contains 1 DEM test case, to the software's web service.

- iii. Submit the EMS file DEMDataset-NoRepeat-3.xml, which contains 1 PCR, to the software's web service.
- iv. Submit the EMS file DEMDataset-PNS-4.xml, which contains 1 PCR, to the software's web service.
- v. Submit the EMS file DEMDataset-5.xml, which contains 4 Demographic Records, to the software's web service.
- c. Agency-B Test Cases (Directory: Receive&Process\EMS):
 - i. Submit the EMS file EMSDataset-ElementsRepeat-1.xml, which contains 1 PCR, to the software's web service.
 - ii. Submit the EMS file EMSDataset-Nils-2.xml, which contains 1 PCR, to the software's web service.
 - iii. Submit the EMS file EMSDataset-NoRepeat-3.xml, which contains 1 PCR, to the software's web service.
 - iv. Submit the EMS file EMSDataset-PNS-4.xml, which contains 1 PCR, to the software's web service.
 - v. Submit the EMS file EMSDataset-ElementsRepeat-5.xml, which contains 10 PCRs, to the software's web service.
 - vi. Submit the EMS file EMSDataset-Nils-6.xml, which contains 10 PCRs, to the software's web service.
 - vii. Submit the EMS file EMSDataset-PNS-7.xml, which contains 10 PCRs, to the software's web service.

 Submit the EMS file EMSDataset-NoRepeat-8.xml, which contains 10 PCRs, to the
 - submit the EMS file EMSDataset-NoRepeat-8.xml, which contains 10 PCRs, to the software's web service.
- d. Agency-H Test Cases (Directory: Receive&Process\Fail):
 - i. Submit the DEM file DEMDataset-failXSD.xml, which contains 1 DEM test case, to the software's web service.
 - ii. Submit the EMS test case EMSDataset-failXSD.xml, which contains 1 PCR, to the software's web service.
 - iii. Submit the DEM file DEMDataset-failSchematron.xml, which contains 1 DEM test case, to the software's web service.
 - iv. Submit the EMS test case EMSDataset- failSchematron.xml, which contains 1 PCR, to the software's web service.

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4. Additional Requirements:

- a. Reference the Send Data section for additional requirements
- b. Reference the <u>Demographic Updates (Receive and Process Data)</u> section for additional requirements.

^{*}Note: These test cases are expected to fail xml validation

An active testing test package will be provided once the Pre-Testing check list is complete and has been reviewed by the NEMSIS TAC. The following items will be completed by the NEMSIS TAC

- 1. **Schematron Rules:** The NEMSIS TAC will apply a schematron file.
- 2. **Test Case Submission:** The NEMSIS TAC will submit Demographic and EMS test cases to the application's web service for review of <u>Web Service Communication</u> requirements. The NEMSIS TAC is at **discretion** to submit as many test cases as they see fit.
- 3. **Sending Data**: The NEMSIS TAC will complete the <u>Send Data</u> testing process

Send Data

Products that **Send Data** must demonstrate the capability of sending the NEMSIS v3 Demographic and EMS datasets. State level products must also demonstrate the capability of submitting a NEMSIS v3 Demographic and EMS dataset that contains National elements only.

Overview of Requirements

- 1. The Demographic export from <u>Collect Data</u> or <u>Receive and Process Data</u> process is a valid XML file and submits to the NEMSIS v3 web service.
- 2. The EMS export from <u>Collect Data</u> or <u>Receive and Process Data</u> process is a valid XML file and submits to the NEMSIS v3 web service.
- 3. If the Product functions at the state level, the submission of National only elements is also implemented for the Demographic and EMS dataset.
- 4. The client is able to properly interoperate the status codes in NEMSIS v3 Web Service standard. Reference the <u>Web Service Communication</u> section for details.
- 5. Review <u>Demographic Submission (Collect Data)</u> or <u>Demographic Updates (Receive and Process Data)</u> section for additional items.

Pre-Testing Check List

- 1. **Prerequisites**: Complete the <u>Collect Data</u> or <u>Receive and Process Data</u> process because these test cases will be used in this process. Steps to meet this requirement are as follows:
 - a. Test cases from <u>Collect Data</u> or <u>Receive and Process Data</u> process have been successfully submitted to the NEMSIS TAC's web service, passed XSD validation, and schematron validation.
- 2. **Demographic and EMS Submissions:** Provide a mechanism to the NEMSIS TAC for submitting test cases to the NEMSIS TAC's compliance web service. If the Product functions at the state level, the NEMSIS TAC will also verify the Product's implementation for submitting the Demographic and EMS dataset that contains National elements only. Steps to meet this requirement are as follows:
 - a. Submit data to the NEMSIS TAC's web service, see <u>Resources</u> at the beginning of this document, to from the <u>Collect Data</u> or <u>Receive and Process Data</u> process.
 - b. If the software is being tested for <u>Receive and Process Data</u> submit all test cases with National Elements only.
- 3. **Demographic and EMS Submission Validation:** Validate the test cases entered by comparing the Product's export to the expected XML output files. Steps to meet this requirement are as follows:
 - a. Use the NEMSIS TAC's web service, see <u>Resources</u> at the beginning of this document, to validate data from the <u>Collect Data</u> or <u>Receive and Process Data</u> process.

4. Additional Requirements:

c. Reference the Web Service Communication section for additional requirements.

The test cases from <u>Collect Data</u> or <u>Receive and Process Data</u> will be used for testing of this section. The following items will be completed by the NEMSIS TAC:

- 1. **Test Case Submission:** The NEMSIS TAC will submit Demographic and EMS test cases, from <u>Collect Data</u> or <u>Receive and Process Data</u> process to the NEMSIS TAC's web service for comparison of files.
- 2. **National Elements Only:** If the software is being tested for <u>Receive and Process Data</u> the NEMSIS TAC will export an additional set of test cases from the vendor's software to test for the export of National elements only

Web Service Communication

Products receiving and processing data must implement the NEMSIS v3 Web Service standard. The web service must implement HTTPS communication channel, SOAP protocol, and status codes listed in the table below. A sample test package will be provided prior to testing.

Category	Status Code	Meaning
PrivilegeErrorCodes	-1	Invalid username and/or password
	-2	Permission denied to the client for the operation
	-3	Permission denied to the client for that organization
SubmitDataProcessCodes	-12	XML file failed XML Schema validation
	-13	XML file failed schematron rule(s) validation
	1	XML file passed XML Schema and Schematron validation
ResultPendingCode	0	Process is not finished for an attempted operation
QueryLimitCodes	51	Successful operation of QueryLimit

Overview of Requirements

- 1. HTTPS communication channel and SOAP protocol is implemented.
- 2. A "PrivilegeErrorCode" is returned when the account (username, password, and organization) is not allowed access to the service and the "requestHandle" is null.
- 3. The "SubmitData" function is implemented .
 - a. The server responds with a unique "requestHandle" and "statusCode"
- 4. The "RetrieveStatus" function is implemented.
 - a. The server echos the "requestHandle" and a "statusCode" of -12, -13, 1, or 0
- 5. The "QueryLimit" function is implemented.
 - a. The server returns the "limit" in kilobytes and a "statusCode" of 51 or 0

Pre-Testing Check List

- 5. **Web Service Account:** Provide the NEMSIS TAC with the web service URL and an account. Steps to meet this requirement are as follows:
 - a. Provide the NEMSIS TAC with all necessary information to the software's web service.
- 6. **Request Validation:** The following submit a "QueryLimit", "Submitdata", "RetrieveStatus" request to the Product's web service. Steps to meet this requirement are as follows:
 - a. Submit a "QueryLimit" request to the software's web service.

- b. Submit a "Submitdata" request to the software's web service using test cases in the Pre-Testing package.
- c. Submit a "RetrieveStatus" request to the software's web service from test cases submitted.

The NEMSIS TAC will be submitting numerous test cases to the software's web service to test the following:

- 1. A "PrivilegeErrorCode" is returned when the account (username, password, and organization) is not allowed access to the service and the "requestHandle" is null.
- 2. The "SubmitData" function is implemented.
 - a. The server responds with a unique "requestHandle" and "statusCode"
- 3. The "RetrieveStatus" function is implemented.
 - a. The server echos the "requestHandle" and a "statusCode" of -12, -13, 1, or 0
- 4. The "QueryLimit" function is implemented.
 - a. The server returns the "limit" in kilobytes and a "statusCode" of 51 or 0 $\,$

Demographic Submission (Collect Data)

Products that **Collect Data** must demonstrate submission, within 24 hours, of the Demographic dataset when a new demographic record is entered or when an element listed as "mandatory" or "required" is modified.

Overview of Requirements

- 1. A process is triggered for submitting the Demographic dataset when a demographic element is entered or updated.
- 2. This process occurs for elements listed as "mandatory" or "required".
- 3. The process exports the Demographic dataset within 24 hours of being triggered.
- 4. The attribute "timestamp" is populated with the date and time the demographic dataset was generated.

Pre-Testing Check List

- 1. Prerequisites: Complete the Collect Data process
- 2. **Demographic Updates:** A demographic element that is "mandatory" or "required" submits the Demographic dataset to the NEMSIS v3 Compliance Web Service. Steps to meet this requirement are as follows:
 - a. Use DEM test case from the <u>Collect Data</u> process and modify a national element. This action triggers a DEM submission to the NEMSIS TAC's web service with the updated DEM information.

Testing Process

The NEMSIS TAC will randomly select and change the data for an element that is "mandatory" or "required" and test the following:

1. **Demographic Updates:** The NEMSIS TAC will test that the modified demographic information has been submitted within a 24 hour time period and will compare the demographic submission to an expected output file.

Demographic Submission (Receive and Process Data)

Products that **Receive and Process Data** must demonstrate submission, within 24 hours, of the Demographic dataset when a new demographic record is entered or when an element listed as "mandatory" or "required" is modified.

Overview of Requirements

- 1. A process is triggered for submitting the Demographic dataset when a demographic dataset is received with new demographic records or changes to a demographic current record.
- 2. This process occurs for elements listed as "mandatory" or "required".
- 3. The process exports the Demographic dataset within 24 hours of being triggered.

Pre-Testing Check List

- 1. **Prerequisites**: Complete the <u>Receive and Process Data</u> process
- 3. **Demographic Updates:** The NEMSIS TAC will update a demographic element that is "mandatory" or "required" and verify the submission of the Demographic dataset to the NEMSIS v3 Compliance Web Service. Steps to meet this requirement are as follows:
 - a. Use DEM test case from the <u>Receive and Process Data</u> process and modify a national element. Submit this modified DEM test case and submit this to the software's web service. This must trigger a DEM submission to the NEMSIS TAC's web service with the updated DEM information.

Testing Process

The NEMSIS TAC will randomly select and change the data for an element that is "mandatory" or "required" and test the following:

1. **Demographic Updates:** The NEMSIS TAC will test that the modified demographic information has been submitted within a 24 hour time period and will compare the demographic submission to an expected output file.

Software Updates/Upgrades

Software is considered compliant only for the version being tested. Any version changes require reevaluation by the NEMSIS TAC. All software changes (e.g. release notes, bug fixes, etc) must be provided to the NEMSIS TAC to determine what components need testing to certify the new release of software as compliant.