
New Jersey Department of Health

Electronic Laboratory Reporting

On-Boarding Manual

Version 1.5

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Revision History

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On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

		<p>compliance.</p> <p>Added ISO OID request within lab list</p> <p>Added guidance on what should be tested in phase 1</p> <p>Added case IDs may be provided in place of hard copies in phase 2</p>	
6-May-2019	1.5	<p>Updated link for NJDOH Validation Service</p>	

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

Table of Contents

1. Introduction	5
1.1 Purpose	5
1.2 Scope	5
1.3 Definitions, Acronyms and Abbreviations	6
1.4 References	7
1.5 Overview	8
1.6 Enrollment	8
1.6.1 Responsible parties /contact list	9
1.6.2 LOINC, SNOMED lists	9
1.6.3 List of laboratories	9
1.6.4 Establish electronic transmission mechanism	10
1.7 Test Phase 1:	12
1.8 Test Phase 2:	13
1.9 Production phase:	14

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

NJDOH Electronic Laboratory Reporting

1. Introduction

In an effort toward improving disease surveillance and timely notification of communicable disease reports for public health intervention, the New Jersey Department of Health (NJDOH) mandated electronic reporting of laboratory test results from all licensed state, commercial and hospital laboratories. Electronic laboratory reports (ELR) are critical for an effective public health response both for routinely reportable diseases as well as potential bioterrorism (BT) agents.

Currently the NJDOH Electronic Laboratory Reporting System (ELRS) acts as the data repository of all laboratory results and is designed to accept ELR in the CDC-recommended, PHIN-compliant and meaningful use ready format of Health Level 7 (HL7). The ELRS facilitates conveyance of these results to program areas via several downstream systems such as the Communicable Disease Reporting and Surveillance System (CDRSS), Enhanced HIV/AIDS Reporting System (eHARS), LeadTrax, as well as other government agencies.

1.1 Purpose

This document serves to guide an interface implementer through the steps involved in producing, validating, and delivering HL7 messages to the NJDOH ELRS and its associated downstream systems. The intent of this document is to provide a succinct ELR implementation guide to facilitate a rewarding partnership with the NJDOH.

1.2 Scope

Detailed within are processes to obtain authorization for communicating ELR to the NJDOH, producing acceptable HL7 messages and validating these messages for structure and vocabulary constraints. In order to meet the NJDOH requirements, the messages may be in HL7 2.3z, 2.3.1 or 2.5.1 ELR to Public Health format. This document will not serve to re-iterate fundamental HL7 standards and specifications unless such items have been further constrained by this implementation guide. In addition, adherence to an implementation guide(s) contained here-in grant nor imply certification by Meaningful Use standards. This document serves to facilitate the communication of data in a standard format for the consumption of NJDOH and its associated downstream systems only. It is assumed that the reader has background knowledge of, and access to the version of HL7 specifications, on which they wish to build a message. NJDOH may provide some guidance with regard to base HL7 specifications, but cannot be relied upon as the sole

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

authority for which all decisions are based.

1.3 Definitions, Acronyms and Abbreviations

CDRSS - <http://www.state.nj.us/health/cd/cdrss.shtml> : (Communicable Disease Reporting and Surveillance System) An electronic, web-enabled system where public health partners statewide can instantly report and track incidences of communicable diseases. The CDRSS facilitates timely reporting and immediate sharing of pertinent data, thus supporting appropriate public health responses, be they isolated incidences or multi-state outbreaks. Direct line feeds from commercial laboratories and acute care hospitals electronically load laboratory results into the system overnight, while the manual keying in of information takes place on a daily basis as hundreds of trained users enter data. The CDRSS is available 24 hours a day, 7 days a week and weekly transmissions to the Centers for Disease Control and Prevention (CDC) support national as well as statewide surveillance.

ELRP : (Electronic laboratory reporting partner) An entity conveying data directly or indirectly to the public health department.

ELRS : (Electronic Laboratory Reporting System) A system of applications and databases designed to extract, validate, transform, and load laboratory data, facilitating its warehousing and propagation to program areas and government entities.

HL7- <http://hl7.org> : Health Level Seven International is one of several American National Standards Institute -accredited Standards Developing Organizations operating in the healthcare arena and the global authority on standards for interoperability of health information technology with members in over 55 countries.

LOINC - <http://loinc.org> : Logical Observation Identifiers Names and Codes identify the laboratory observation. LOINC applies universal code names and identifiers to medical terminology related to the electronic health record. The purpose is to assist in the electronic exchange and gathering of clinical results (e.g. laboratory tests, clinical observations, outcomes management, research). The LOINC database is developed and maintained by the Regenstrief Institute.

NIST ELR Validation Suite - <http://hl7v2-elr-testing.nist.gov> : The NIST Electronic Lab Reporting (ELR) Validation Suite is intended for certifying 2014 Edition Meaningful Use EHR technology. The validation suite provides functionality to test EHR senders. The ELR test tool covers the *§170.314(f)(4) Inpatient setting only – transmission of reportable laboratory tests and values/results* Test Procedure.

NJDOH validation service – https://cdrs.doh.state.nj.us/cdrss/main/file_test: This service provides a partner the ability to test their messages directly against NJ’s HL7 validation engine.

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

PHIN VADS - <https://phinvads.cdc.gov/vads> : The Public Health Information Network Vocabulary Access and Distribution is a vocabulary repository and server which allows CDC's public health partners to browse, search and download vocabulary concepts required for PHIN messaging and applications.

SNOMED : A system of standardized medical terminology developed by the College of American Pathologists. It can be described as comprehensive clinical terminology covering diseases, clinical findings, and procedures that allow for a consistent way of indexing, storing, retrieving and aggregating clinical data across specialties and sites of care. SNOMED helps provide structure and computerize the medical record, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research.

The following link provided points to a maintained subset of SNOMED codes identified for their applicability to reportable conditions, also known as the Reportable Condition Mapping Table (RCMT).

<https://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.114222.4.5.274&code=RCMT>

1.4 References

- NJAC 8:57 Communicable Diseases Regulations
 - <http://www.lexisnexis.com/hottopics/njcode/>
- HL7 Specifications and implementation guides
 - **HL7 2.3z** : Health Level Seven Specifications for Electronic Laboratory-Based Reporting of Public Health Information (CDC, 1997)
 - **HL7 2.3.1** : Implementation Guide for Transmission of Laboratory-Based Reporting of Public Health Information using Version 2.3.1 of the Health Level Seven (HL7) (CDC, 2005)
 - **HL7 2.5.1** Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (electronic version in PDF) with errata (HL7, 2010)

NOTE: The aforementioned guides, and standards upon which they are based, are available free of charge through the CDC or HL7.org.

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

1.5 Overview

Initiating contact with the NJDOH is the first step in being able to craft an HL7 message for the purpose of communicating electronic laboratory reports. Once the request to establish an HL7 2.x feed with the department is filed and approved, the ELRP will be directed to the NJDOH Data Connect group to facilitate a connection over which data will be conveyed.

A partner will pass through two test phases, during which they will build their messages, test them externally until error free, followed by transmission to the NJDOH for further structural and content review. Once all issues are resolved, the partner will be given permission to report within the production system.

1.6 Enrollment

To begin the process of becoming an ELRP, entities will first need to complete an online enrollment form. This form serves to kick-off the interface process by collecting pertinent information such as the type of feed, initial contact information, entities involved, as well a statement of authorization to act on behalf of reporting entities. Upon approval, NJDOH staff will begin communication with the primary contact to facilitate the process as well as provide further NJDOH technical staff contact information.

- 1. Complete online enrollment form**
- 2. Supply comprehensive contact list**
- 3. Compile LOINC & SNOMED list**
- 4. Supply list of laboratories** (vendors, health systems, reference laboratories only)
- 5. Establish electronic communication mechanism**

Following these preliminary steps, an ELRP may begin test phases 1 and 2, concluding with production approval and migration.

NOTE: All lists are required within 45 days of enrollment, prior to proceeding with the establishment of an electronic communication mechanism. Applicants unable to fulfill these requirements within this time frame will be disenrolled.

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

1.6.1 Responsible parties /contact list

All partners will need to provide a contact list containing the name, title, email, phone and contact type (content, IT, vendor) to facilitate communication when issues arise. An email distribution list may also accompany this information to facilitate communication with larger teams. It is recommended that the ELRP indicate primary and secondary contacts.

1.6.2 LOINC, SNOMED lists

As per CDC-recommended industry standards, all HL7 messages will include Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine (SNOMED) codes, where applicable, to describe the tests and organisms found. A complete compilation of tests, in terms of LOINC's and SNOMED's, which they intend to communicate, must be submitted.

NOTE: In order to standardize results, free text may not be used to describe tests, LOINC's must be used. In addition, free text cannot be used for results of a SNOMED dependent LOINC, as in the case of cultures and its organisms.

In terms of HL7, the OBX-2 (Value type) field's data type used to describe OBX-5 (Observation value) must not be of a text data type if the OBX-3 (Observation identifier) contains a test which would describe an organism. OBX-3 (Observation identifier) requires a LOINC. OBX-5 (Observation result) data types shall be dictated by the LOINC's type of scale, which describes the result as quantitative, ordinal, etc.

In addition, for more specific information which cannot be listed in HL7 fields, please use the associated observation group's NTE segments to report such items.

1.6.3 List of laboratories

This section applies only to vendors, health systems, and reference laboratories, handling transmissions for multiple entities.

A list of referring entities whose data will be transmitted must be submitted prior to the receipt of any messages into the NJDOH test environment. These lists help systems downstream of NJDOH's ELRS to easily identify new feed additions, facilitating data review and reporting.

Vendors and health systems may convey data for multiple sites within a single batch utilizing FHS, BHS and MSH fields as described within the NJDOH implementation guide. In summary, the FHS and BHS 4 (Sending facility) fields would reflect the health system name and ISO OID, with MSH-4

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

listing the laboratory name and CLIA/ISO OID.

The list must include:

- **Vendors / Health Systems:**

1. The exact spelling of the health system name as it will be sent in FHS/BHS-4.1 (Sending Facility Namespace ID).
2. The ISO OID as it will be sent in FHS/BHS -4.2
3. The exact spelling of the name as it will be sent in MSH-4.1 (Sending Facility Namespace ID).
4. The CLIA or ISO OID as it will be sent in MSH-4.2

- **Reference Laboratories**

1. The exact spelling of the name as it will be sent in ZLR-2.1/ORC 21.1 (Ordering Facility Namespace ID).

NOTE: All name, CLIA, and OID changes **must** be communicated to the NJDOH prior to implementation.

1.6.4 Establish electronic transmission mechanism

After enrolling to instantiate an interface with the NJDOH, the ELRP will receive the Data Connect group's contact information and processes for establishing electronic communication. Any communication with the Data Connect group must reference "ELR" within the subject to facilitate any request.

The primary method of file transmission is SFTP. Alternate methods must be negotiated with the NJDOH Data Connect group on a case by case basis.

SFTP Directories:

When transmitting via SFTP, an account is created for the partner within which two folders, "TEST" and "PROD" will reside. Files deposited within either of these directories will be propagated to the testing or production environments automatically; during which time a notification email may be sent to the sending partner should they elect to receive one.

Transmission frequency:

Files may be transmitted as often as the partner deems necessary.

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

File names:

File names must be unique, no duplicates may be sent. All transmitted HL7 files must be denoted using the “.hl7” file extension, unless otherwise permitted.

NOTE: Files placed within the SFTP account’s root directory will not be processed automatically unless alternate rules have been agreed upon. Partners unable to differentiate between folders in test and production environments may be permitted to denote test files with the “.test” file extension.

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

1.7 Test Phase 1:

The ELRP may begin building their HL7 messages as per the guidelines set within this document, HL7 implementation guide and associated specifications. Once the HL7 structural build is complete, the ELRP must use the NJDOH's validation service for all accepted message types. If MU compliance is sought, the ELRP must also validate their messages against NIST's ELR Validation Suite. Validating messages against NIST's ELR Validation Suite, then NJDOH's validation service will help facilitate a successful interface implementation. A comprehensive test bank encompassing a large variety of reports the ELRP intends submit to the NJDOH, if not all, should be verified. **All validation issues should be resolved prior to the submission of message batches via the connection provided by the Data Connect group.**

Once all external validation issues have been addressed, the ELRP will notify the NJDOH and may begin sending message batches of test data via the established connection. Received batches will undergo further review for issues such as, but not withstanding, invalid vocabulary and conditional rules. Given the resolution of all issues, the ELRP will send at least three additional batches, depending on batch volume. Should no new issues arise, the ELRP will be moved on to the second test phase.

Step summary:

- 1. Build messages**
- 2. Validate messages online**
- 3. Submit messages for manual review**
- 4. Receive feedback**

NOTE: The NJDOH reserves the right to require additional changes to an interface in order to comply with revised state statutes, regulations, and/or HL7 specifications. All validations performed against the NJDOH validation service are based on the absolute minimum NJDOH requirements to assimilate a message successfully, and are not designed to imply HL7 or Meaningful Use compliance. Partners' messages will be validated against the [NIST ELR Validation Suite](#) for purposes of HL7 specification adherence, and asked to continue to update their interface to comply with its standards should errors be identified.

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

1.8 Test Phase 2:

This phase includes placing production data into a test environment as well as providing hard copies of all test results (as they appear at the physicians' office) to public health staff. Partners already submitting data electronically may provide references to production case IDs to facilitate reconciliation. During this phase, intense quality testing and assurance will be conducted to verify that all information on the hard copy result is captured accurately in the electronic transmission. Once all issues are resolved, the ELRP shall continue to send batches until approximately 10 (volume dependent) successive batches are conveyed without error.

Upon completion of the test phase, an ELRP will be notified when public health staff has cleared the interface for migration to the production environment.

Step summary:

- 1. Schedule message submissions via communication mechanism**
- 2. Submit result hard copies**
- 3. Data reviewed by public health staff**
- 4. Receive feedback**

On-boarding Manual	Version: 1.5
Electronic Laboratory Reporting	Date: 6-May-19

1.9 Production phase:

Once authorization to move to production with a vetted interface is established, public health and ELRP staff will determine a go-live date from which future batches will be sent to the production environment. In addition, the ELRP must designate an individual(s) who will own the process of entering tests into downstream systems (as per NJ regulations) which fail to be electronically reported, or are void of required demographic and/or contact information. Hard copies of results may still be requested by public health staff, but may be discontinued upon agreement by both parties. Any changes to the production interface must be communicated to public health staff and vetted in the test environment before any changes are committed.

With SFTP serving as the communication mechanism, sending to the production environment will mean a partner shall begin placing files within the "PROD" directory on their SFTP account's root. The continued submission of test files to the "TEST" folder may continue only in the case that further testing is being performed and a future change to the production interface is forthcoming.

Step summary:

- 1. Determine go-live date**
- 2. Designate report administrator (as per by NJ regulations)**
- 3. Begin submission of files to production environment**
- 4. Cessation of test files submissions**