NHSN 2023 Long Term Care Facility *Clostridioides difficile* Infection (CDI) External Validation Toolkit

Version 3.1 – Updated February 2025

Contents

About the 2023 Long-term Care Facility *Clostridioides difficile* External Validation Toolkit

The 2023 National Healthcare Safety Network (NHSN) External Validation Toolkit (EVT) for use in Long-term Care Facilities (LTCFs) provides guidance for validation of *Clostridioides difficile* infection (CDI) laboratory-identified (LabID) events in the eligible settings of nursing homes and skilled nursing facilities. The purpose of validation is to improve quality of surveillance data through accountability and by identifying, understanding, and correcting reporting problems. This document focuses on external validation of facility-reported NHSN surveillance data conducted by state health departments or other oversight agencies. Facilities that seek to conduct internal validation (data quality check) of their own NHSN data can find a separate guidance document available at https://www.cdc.gov/nhsn/pdfs/ltc/data-quality-check-guidance-508.pdf. NHSN-specified external validation standards are intended to ensure reported surveillance outcomes meet NHSN surveillance definitions and methods, as determined and documented by trained validators. Survey tools assess reporter knowledge and facility practices required to conduct adequate surveillance.

Comments and Feedback Welcome

NHSN validation approaches are a work-in-progress and will improve more quickly with the generous input and feedback of those implementing the methods. Please direct any comments or suggestions for improvement to the NHSN Helpdesk: *NHSN@cdc.gov* with the subject line "LTCF External Validation Toolkit" or by logging into the Secure Access Management Services (SAMS) and submitting a ticket through the ServiceNow portal and selecting "Other" for Component and "External Validation" for Category.

Acknowledgment and Thanks

Many aspects of this document were adapted from jurisdictions conducting validation. In addition, many experts from state and local health departments and healthcare facilities collaborated to develop, review, and contribute to this document. The contributions of these individuals are gratefully acknowledged. However, the Guidance and Toolkit recommendations are the sole responsibility of the Centers for Disease Control and Prevention (CDC) and should not be regarded as having received the endorsement of any individuals or organizations outside of CDC.

Abbreviations, Terms, and Acronyms

ACUTE CARE TRANSFER-LONG-TERM CARE FACILITY-ONSET (ACT-LO)*	(NHSN) LTCF-onset (LO) LabID event with date specimen collected 4 weeks or less following the date of last transfer from an acute care facility (specifically, a hospital, long-term acute care hospital, or acute inpatient rehabilitation facility) to the LTCF. Event date >=4 days after current admission date and resident has a transfer from an acute care facility <= 4 weeks prior to event.
ADT	A core facility data system for capturing admissions, discharges, and transfers.
CCN	CMS Certification Number, that is, a facility identifier
CDC	Centers for Disease Control and Prevention
CDI	*Clostridioides difficile* infection
CDI Laboratory-identified (LabID) Event*	*C. difficile* positive laboratory assay collected while resident is under the care of the reporting LTCF, which includes residents physically housed and cared for in in the reporting LTCCF, as well as residents being cared for during a brief outpatient visit in which the resident returns to the reporting LTCF on the day of the outpatient visit or the following calendar day.
C. difficile* positive laboratory assay	(1) An unformed/loose stool that tests positive for *C. difficile* toxin A and/or B. This includes molecular assays (PCR) and/or toxin assays; or (2) A toxin-producing *C. difficile* organism detected din an unformed/loose stool sample by culture or other laboratory means.
CEO	Chief executive officer
CMS	Centers for Medicare & Medicaid Services
C-SUITE	Office for senior executives such as Chief Executive Officer (CEO) or Chief Medical Officer (CMO) of a healthcare facility.
DOB	Date of birth
DOE *	(NHSN) Date of event. The first element used to meet an NHSN site-specific infection criterion occurs for the first time within the seven-day infection window period.
DOH	Department of health
DUPLICATE CDI LABID EVENT*	(NHSN) Any CDI LabID event submitted by the reporting LTCF for the same resident in the facility following a previous CDI LabID event within the past two weeks (<15 days).
ED	Emergency department
EMR	Electronic medical record
EPISODE OF CARE	All medical services provided to a patient within a specific time period within a facility. For surveillance of HAIs, this term is used to indicate a single inpatient admission and includes the ED visit leading to admission.
EVENT DATE*	Date the specimen used to meet LabID Event Criteria was collected.
EXTERNAL VALIDATION	Survey and record review process performed by an external agency to ensure quality of NHSN surveillance and reporting.

FacWideIN*	(NHSN) Facility-Wide Inpatient; all resident care locations in the facility.
HAI*	(NHSN) Healthcare-associated infection. An infection is considered an HAI if the DOE occurs on or after the 3rd calendar day of admission to the facility (the day of admission to an inpatient location is calendar day 1). All elements used to meet site-specific infection criteria must occur during the Infection Window Period.
INCIDENT CDI LABID EVENT*	(NHSN) Either the first CDI LabID event ever submitted by the reporting LTCF for an individual resident in the facility, or a subsequent CDI LabID event submitted more than 56 days (8 weeks) after the most recent CDI LabID event reported by the LTCF for the individual resident.
INFECTION WINDOW PERIOD*	(NHSN) Seven days during which all site-specific infection criteria must be met. It includes the collection date of the first positive diagnostic test that is used as an element of the site-specific infection criterion, the 3 calendar days before and the 3 calendar days after.
INTERNAL VALIDATION	Active efforts by a facility to ensure completeness and accuracy of NHSN data.
IP	Infection preventionist or infection prevention department
IT	Information technology
Laboratory-identified (LabID) Event*	(NHSN) A measure developed for easy electronic infection surveillance using laboratory results without the requirement for extensive clinical documentation.
LONG-TERM CARE FACILITY-ONSET (LO) LABID EVENT*	(NHSN) LabID event (specifically, specimen collection date) occurs 3 calendar days after the date of current admission to the reporting long-term care facility (for example, day 4 or after).
LOS	Length of stay (in days)
MEDICAL RECORD	A record systematically documenting a single patient's medical history and care across time within a healthcare provider's jurisdiction. For sampling, a medical record (which over time could include many healthcare encounters) refers to a single facility inpatient admission.
MRN	Medical record number
MSSA	Methicillin-susceptible *Staphylococcus aureus*
NICU	Neonatal intensive care unit
NHSN	National Healthcare Safety Network
OrgID*	(NHSN) Organization ID. NSHN facility identifier
POA*	(NHSN) Present on admission. An infection is POA if the DOE occurs on the day of admission, during the two days before, or on the day after admission. POA infections should not be reported as HAIs. POA is not used for SSI, VAE, or LabID Events.
QIO	Quality Improvement Organization
RECURRENT CDI LABID EVENT*	(NHSN) Any CDI LabID event submitted by the reporting LTCF more than 14 days (2 weeks) and less than 57 days (8 weeks) after the most recent CDI LabID event submitted by the reporting LTCF for an individual resident.

REPORTER	Infection Preventionist or other designated NHSN user inputting a facility's reportable HAI events into the NHSN database.
RESIDENT — DAYS*	(NHSN) The number of residents housed in a facility during the designated counting time each day and summed for a monthly denominator report for urinary tract infections (UTI) and LabID Events.
RIN	Resident Identification Number
SIR*	(NHSN) Standardized infection ratio
VALIDATION	Process to ensure that reported NHSN surveillance data meet pre-determined specifications and quality standards.
VALIDATOR	Member of external agency that reviews a facility's surveillance determinations and methods to evaluate surveillance program quality, data completeness, and reporting accuracy.

*(NHSN) indicates a term used and defined by NHSN.

Chapter 1: Purpose and Goals of External Validation

Validation can be defined as confirming or ensuring that data meet pre-determined specifications and quality standards. NHSN external validation ensures high quality data across three healthcare-associated infection (HAI) reporting domains: denominators, numerators, and risk adjustment variables.

Why validate?

NHSN was launched in 2006 as a voluntary, confidential HAI reporting system for facilities conducting surveillance, benchmarking, and quality improvement for HAIs. Since its establishment, state and federal agencies also use NHSN data for public reporting purposes and to incentivize quality improvement through payment mechanisms. In 2012, NHSN launched the long-term care facility (LTCF) component for use by nursing homes and skilled nursing facilities. LTCF boards, administrators, and clinical leadership need to trust their facility's data to assess performance, manage change in their facilities, and to know that other facilities are held to the same high standards when reporting. Consumers seeking to make informed decisions about their healthcare expect that publicly reported data are valid. These requirements are challenging because NHSN definitions are complex and may involve tracking and linking information from multiple facility information systems (e.g., laboratory, admissions, and clinical data), coordinated data collection and interpretation, and data entry by multiple staff members. All of these attributes introduce opportunities for variation and make it difficult to meet stakeholders' needs without taking additional steps to ensure data quality. The NHSN reporting landscape will continue to change over time as surveillance methods evolve and reporting requirements expand.

What is External Validation?

External validation is a survey and review process conducted by an agency outside the reporting facility (e.g., state health department). One or more trained validators who work for or on behalf of the external agency review the facility's surveillance determinations and methods to evaluate surveillance program quality, data completeness, and reporting accuracy. Facilities can use findings from external validation to correct reporter misconceptions about NHSN definitions, criteria, and data requirements. External validation can help ensure adherence to NHSN's specifications for HAI reporting by identifying and correcting shortcomings that would be difficult to address through internal validation alone. Understanding what led to reporting errors enhances reporting going forward. Validators should help reporters identify incorrectly reported data, and document and discuss common errors and challenging cases with reporters, providing education and feedback to improve future reporting.

Goals of NHSN External Validation

Evaluate **NHSN LTCF CDI LabID Event surveillance practices:**

- Assess staff understanding of the Event Protocol
- Assess data collection and reporting methods
- Identify common barriers to complete and accurate data collection and reporting

Educate **facility staff on NHSN CDI LabID Event Surveillance**:

- Improve staff understanding of the methods and definitions in the Event Protocol
- Improve staff data collection and reporting practices
- Increase staff awareness of reporting resources

Assess **and** ***improve*** **the quality of CDI LabID Event data reported to NHSN:**

- Identify under- and over-reported events and provide instructions for correcting these events in NHSN
- Identify systematic and recurrent errors that may require correction to data beyond the specific feedback provided
- Suggest strategies to improve facility data collection and reporting practices

Provide ***feedback*** **to CDC to support continuous improvement of public resources in order to:**

- Improve this Toolkit and the corresponding documents
- Develop optimal and standardized data evaluation methods
- Improve existing NHSN CDI LabID event surveillance and reporting resources, such as training materials, reporting instructions, and frequently asked questions (FAQs) to address common areas of confusion

Chapter 2: Overview for Conducting 2023 NHSN External Validation

The data validation activities in this toolkit include a survey of the facility staff's surveillance knowledge and practices, and a review of medical records to assess concordance of facility reported data with validators' determinations of reportable NHSN data. These activities may be performed together or individually, depending on the scope and goals of your data quality validation project. All tools required to implement the validation project, as outlined in this document, are included in template form so they can be easily customized to your organization and specific project parameters.

Because of advances in electronic medical records (EMRs) and telecommunication, many validation elements can now be performed either on- or off-site. However, this toolkit recommends on-site medical record reviews by trained validators using a medical record abstraction tool (MRAT) that follows 2023 NHSN methods and definitions, *when feasible*. On-site validation provides optimal opportunity for validators to gain full access to any documented information used by reporters when conducting surveillance, and to strengthen relationships with reporting facilities through transparency. In addition, site visits encourage interaction, education, and understanding of the overall HAI surveillance program. Use of EMR systems that are made available at a distance to validators is a feasible, alternate way to review medical records. NHSN discourages remote review of copied medical records for external validation program methodology, as copied material lacks complete data access and the interactivity that facilitates program capacity building**.** Ideally, validators will be either employed or contracted by agencies that have oversight responsibilities for patient/resident safety and public health in the validated healthcare facilities, and across the continuum of healthcare. Regardless of whether validation activities are conducted on-site or remotely, it should be noted that LTCFs may not have the most up-to-date EMR technology, may utilize paper medical records, or use a combination of electronic and paper records. Be sure to discuss the type of medical record system used with facilities so that proper accommodations can be made.

CDC Recommended Validation Elements and Preferred Approach

Validation Element	Off-site	On- or Off-site
Validator training and assessment	X	
Facility selection, request for line listings	X	
Medical Record Selection, NHSN data download, and arrangements for site visit	X	
Facility surveillance practices survey		X
Review of facility location mapping, bed size		X
Medical Record Reviews (MRATs)		X
Post-review conference with IP re: surveillance practices and medical records review discrepancies		X
Administration of additional denominator counting surveys, as needed		X
Review of facility results, strengths, and weaknesses		X
Follow-up corrections and report to IP and administration	X	

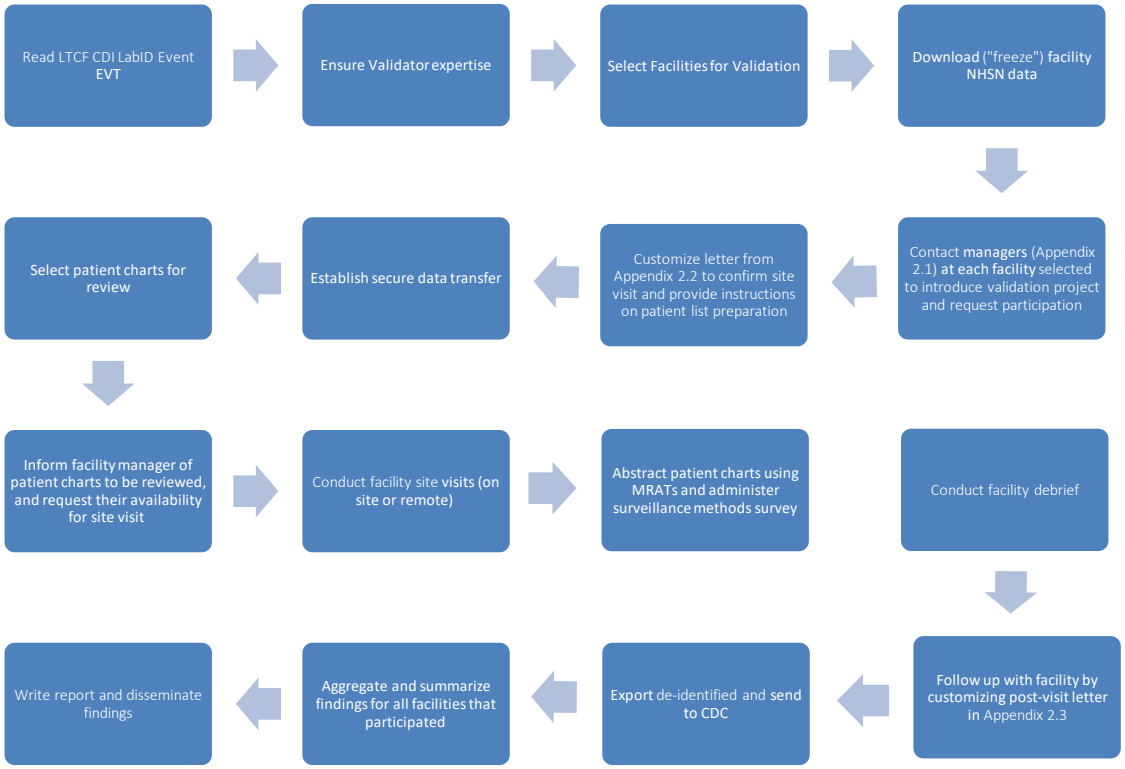
Project Timeline

This timeline is an example and should be used as a guide, as it may vary for your jurisdiction, and duration of each step will depend upon the scope of your organization's validation project and the number of participating facilities. Refer to the table below for the suggested duration of these steps; several activities may occur concurrently. Consider your project's scope and available resources and use the right-hand column to create a timeline more specific to your project.

External Validation Project Steps Total estimated duration ~26 weeks	**Project Duration**
1) Preparation (estimated duration 4 weeks) ☐ Read the 2023 LTCF CDI External Validation Toolkit in its entirety. ☐ Train project staff on NHSN CDI LabID Event Surveillance and on the use of validation tools and resources. ☐ Determine the validation timeframe (which months of NHSN data will be validated). ☐ Determine when validation (on-site or remote) will occur. ☐ Select facilities to be included in the validation project. ☐ Download ("freeze") facility NHSN data. ☐ Customize Template Letters 1 and 2 (Appendix 2) for your organization and project parameters. ☐ Optional: Consider hosting webinar for jurisdiction/selected facilities to describe validation process and its benefits.	
2) Solicit Facility Participation (estimated duration 4 weeks) ☐ Contact Facility Manager, using Template Letter 1 (Appendix 2.1), to introduce the validation project and invite them to participate. ☐ Establish mechanism of secure data transfer between facility and external validation agency. ☐ Document facilities that decline to participate and reasons why.	
3) Confirm Site Visits (estimated duration 2 weeks) ☐ Send Template Letter 2 (Appendix 2.2) to Facility Manager confirming site visit and requesting line listings. ☐ Use facility-provided line listings to select which medical records will be validated. ☐ Inform Facility Manager of selected medical records, and request for these records to be available on the day of the site visit. ☐ Optional: Send denominator collection and surveillance methods surveys to facilities to complete prior to site visit – may be included with Template Letter 2. Surveys may also be completed during or after site visit.	
4) Prepare for Each Site Visit, on-site or remote (estimated duration 1 day per site) ☐ Have extra materials (e.g., calendar, pens, etc.) ready. ☐ If abstracting directly into REDCap medical record abstraction tool (MRAT), have a laptop/device with internet access available and bring device's charger; OR if abstracting manually on paper, be sure to print enough copies of the MRAT for the selected medical records. ☐ Contact Facility Manager a few days before the site visit to confirm. Ensure that space and computer access is ready (if performing validation on-site), selected medical	

records will be available, staff will be available for survey administration and intermittent questions throughout day, and arrange meeting time.	
5) Conduct Site Visits, on-site or remote (estimated duration 6-12 weeks) ☐ Conduct greetings and introductions. ☐ Request documentation of current NHSN reporter training. ☐ Conduct chart review/abstraction and enter data into REDCap (if applicable) MRAT. ☐ Administer surveys, if not yet completed. ☐ Conduct Facility Debrief to discuss survey findings and chart review findings.	
6) Post-site Visits: Facility follow-up and Data Summary and Dissemination (estimated duration 4 - 8 weeks) ☐ Summarize findings and customize Template Letter 3 (Appendix 2.3) and send to Facility Manager. ☐ Follow-up ~4 weeks post-site visit to ensure any identified errors were corrected. ☐ Export deidentified data from REDcap (if applicable) and send to CDC. ☐ Aggregate and summarize findings for all facilities that participated in the project. ☐ Write a state/jurisdiction summary report, disseminate findings to key stakeholders (e.g., participating facilities, CDC).	

Flowchart of Validation Activities



Chapter 3: Pre-Validation Activities

Ensure Project Staff Expertise

Surveillance and validation require rigorous adherence to standard NHSN protocols, surveillance methods, and definitions as written. Project staff conducting validation should be familiar with NHSN LTCF CDI LabID event surveillance definition and reporting instructions and remain up to date when changes are made. In addition to reporter training resources, validator training resources are available on the NHSN LTCF Training website. These trainings are listed below in the recommended order of review for validators:

Type of NHSN Training	Recommended Validator Standard	Symbol Key for Online NHSN Training Types (Examples as below)
Interactive Online Multimedia Instruction Modules	Ensure that all 2023 validators successfully complete these courses for any NHSN component they will validate, and provide copies of the certificates of completion	 Self-paced, interactive trainings used to gain in-depth knowledge of NHSN HAI definitions
Slide sets	Highly recommended: Slide presentations include case-studies to help validators implement the basic content presented in HAI training webinars	 Presentations and case studies used to walk through difficult cases to learn to apply the NHSN HAI definitions accurately
Webinars & Podcasts	Basic prerequisite for prospective validators; Basic training in HAI and LabID event surveillance	 Webinars and podcasts used to provide basic information on NHSN HAI and LabID event definitions and surveillance protocols

Other opportunities for training include:

- CDC-sponsored trainings
- NHSN blast emails, external partner calls, the quarterly NHSN newsletter, and the NHSN Manual, updated prior to each January with any changes to methods and definitions

Even after training, willingness to seek help when needed from NHSN on definitions and criteria is important when cases are challenging. If facilities and validators cannot agree on case-determination using documented information and the NHSN case-definition as a gold standard, the case should be referred to CDC for adjudication. Forms for tracking cases that result in discrepancies and that require adjudication are found in Appendix 1.

Data Review Time Period

Determine the data validation time period, which includes the months that NHSN LTCF CDI LabID event surveillance data will be reviewed for this project. Note that some facilities do not report their data into NHSN until the CMS deadline, which is three months after the end of the quarter (e.g., October through December 2023 data are due by March 31, 2024). It is also critical that the time period chosen be identical across all participating facilities. A period of no less than 6 consecutive months during the same calendar year is recommended.

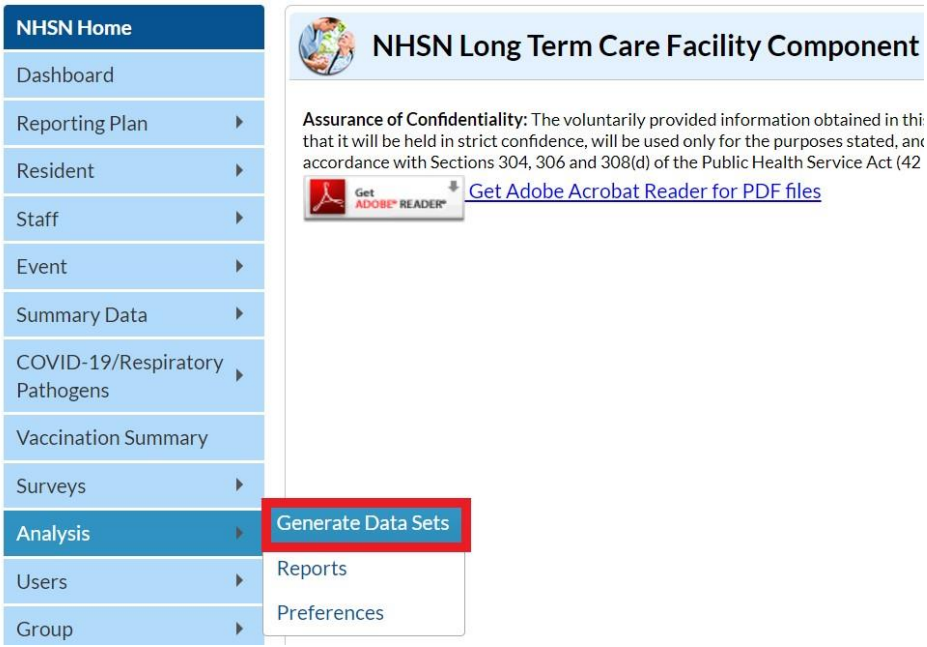
Facility Selection

Selection of LTCFs for participation can be accomplished through different methods to meet the jurisdiction's validation goals. This toolkit primarily recommends the selection of 1) a random representative sample of facilities, or when a random sample is not feasible, 2) a convenience sample of facilities (e.g. a sample of volunteer facilities). To make the most of available resources and project goals, organizations are encouraged to determine how many facilities can participate in the project and decide which of these two methods for facility selection is most appropriate for their jurisdiction. See sample letter, Appendix 2.1, inviting facilities to participate in the validation project.

Since all facilities should be accountable for accurate reporting of CDI LabID Event data to NHSN, using a random sample to select facilities for participation is preferred and will provide representative data for the jurisdiction. See below for instructions on how to generate and select a random sample of facilities.

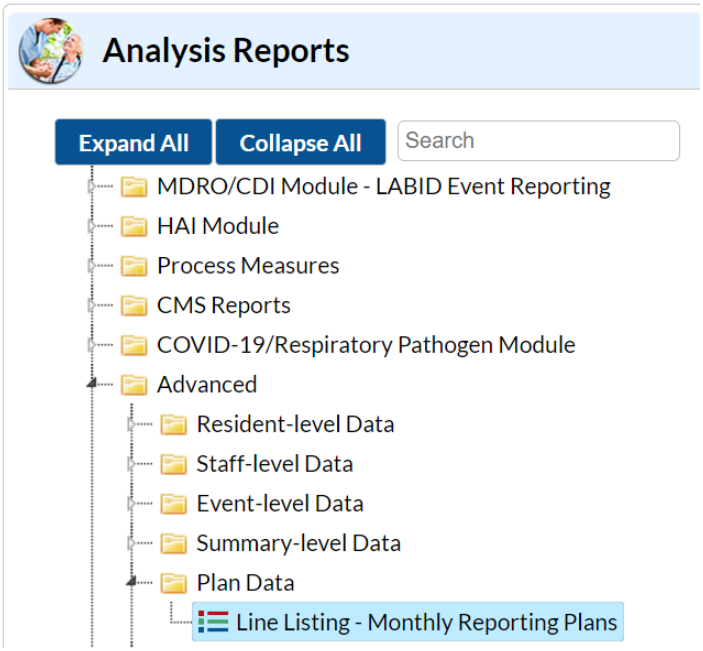
How to Select Facilities – Random Sampling

1) Log into NHSN application and select the Long-Term Care Facility component and the appropriate state/jurisdiction Users' Group from the drop-down menu on the landing page. Generate new datasets to ensure any data updates are included for analysis by selecting the Analysis tab and click Generate Data Sets. Click the Generate Reporting Data Sets button and allow the generation process to complete; you can leave NHSN during the generation process.

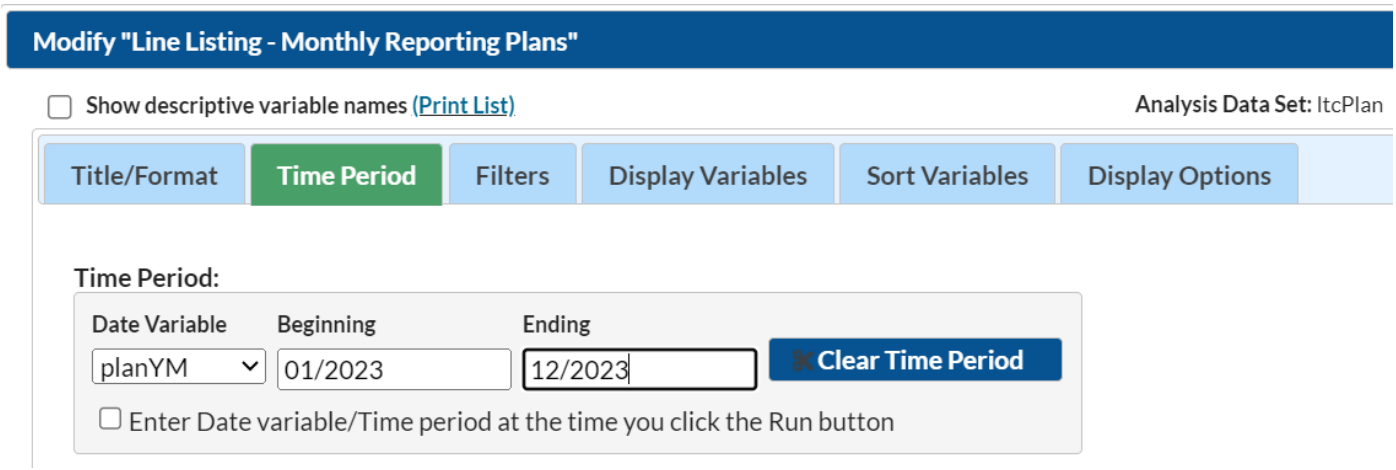


2) After successful dataset generation, navigate to Analysis → Reports to display the tree view list of all analysis reports available within NHSN's analysis tool.

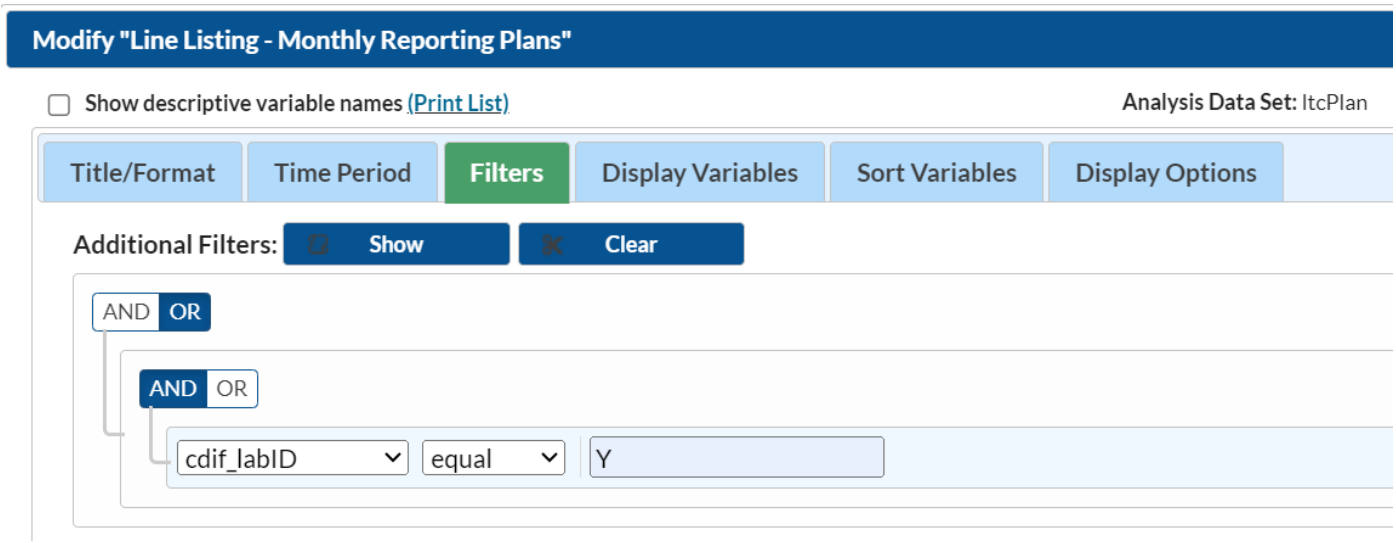
3) From Reports, select Advanced → Plan Data → Line Listing – Monthly Reporting Plans. Click the Modify Report button to proceed to the modification screen.



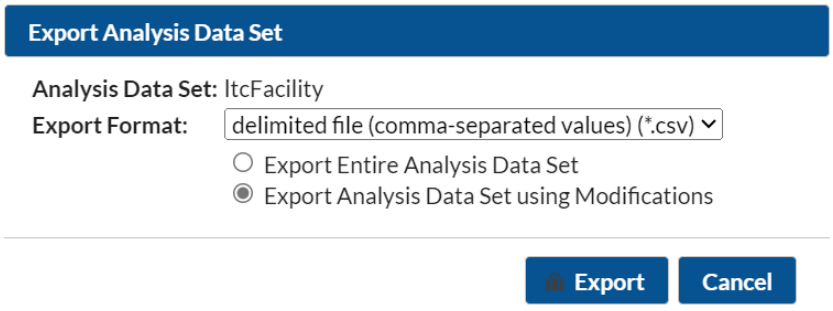
4) In the modification window, go to the Title/Format tab and select xls format. Then navigate to the Time Period tab and select the Date Variable "planYM." For Beginning, enter 01/2023 and for Ending, enter 12/2023, or other dates corresponding with the time frame being validated.



5) Go to the Filters tab – in the drop-down lists, select "cdif_labID," then "equal," and then enter "Y."



6) Scroll to the bottom of the modification window and click the Export button. When the Export Analysis Data Set window appears, use the default file format (.csv) and select the bullet "Export Analysis Data Set using Modifications." Click on the Export button in the Export Analysis Data Set window to export the modified data.



7) De-duplicate the orgID column so that there is only one orgID listed per facility. Assign each facility a random number using one of the methods outlined in Table 1 below.

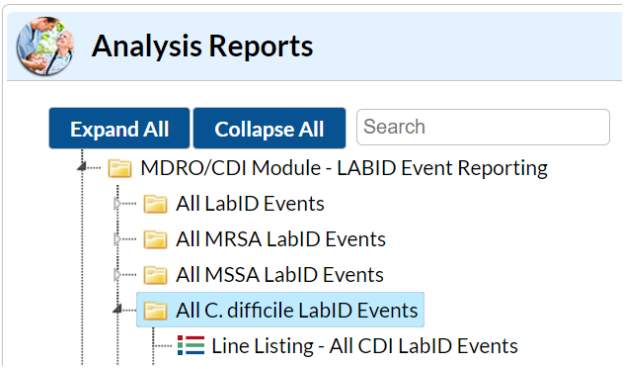
8) Sort facilities in ascending order by the random number assigned and select the first 30 as your sample.

9) Before contacting the facility, be sure to download, or "freeze", the facilities' data. Once the final list of 30 sampled facilities is complete, contact the selected facilities to request participation. If any facility declines to participate, document the reason(s) why and select additional facilities from the list sorted by lowest random number.

Download ("freeze") the facility's reported data from NHSN

Prior to selecting the medical records sample, use NHSN Analysis Reports and the modifications described below to "freeze" (take a snapshot of) the data and export the facility's reported CDI LabID events. Freeze the data for each facility selected for validation.

To "freeze" data, log in to NHSN and select the Analysis tab in the left-hand navigation bar, and then Reports. Select the MDRO/CDI Module – LABID Event Reporting folder, All C. difficile LabID Events, and then Line listing of all C. difficile LabID Events, and then click Modify Report.



Suggested Modifications:

1) Under the Title/Format tab, select xls as the format. You may also change the title of the report (e.g. <Facility ID > <Freeze Date> NHSN CDI LabID Events Line List).
2) Under the Time Period tab, go to the Date Variable drop-down and select "eventDateYr." For both Beginning and Ending, enter 2023, or different dates corresponding to the year of data to be validated.
3) Under the Filters tab, click the green Add Rule button. In the row of drop-down boxes, select "orgID," "equal," and enter the facility's orgID number.
    a. Optional: Export single report with all facilities, sort by "orgID," and copy/paste each facility's data into its own spreadsheet. Save each line list in a secure location.
4) Click on the "Export" button. Keep the format as-is (.csv) and select the "Export Analysis Data Set using Modifications" radio button. This will generate the line listing in Excel.
5) Save the line listing to a secure location.

Notification of Facilities and Line List Requests

For chosen facilities, contact the manager inviting them to participate in the validation project (Appendix 2.1), including the likely scope of validation and its importance to data quality improvement. Emphasize that external validation is not related to any regulatory surveys and highlight the benefits of external validation to the facility.

As facility managers agree to participate in the data validation project, send a letter confirming the details of the on-site/remote visit and preparation of line listings (Appendix 2.2). Describe the request for *C. difficile* - positive line listings (with structures described below). Ask about the lead-time for the facility to generate the required line listings and how much lead-time the medical records department will need to arrange for medical record access. Ask how resident medical records can best be accessed onsite, or remotely, and how they are organized; this can affect the time required to abstract the records. Discuss the anticipated number of days and reviewers needed to complete validation, based on experience or the guidance to follow.

Structure and Content of Laboratory Line Listings

For CDI LabID Events, resident medical records are selected from *C. difficile*-positive stool specimen line listings. From each selected facility, obtain a complete list of final *C. difficile* PCR-positive laboratory results collected in 2023 for residents facility-wide. Laboratories may conduct one-, two-, or three-step testing for toxigenic *C. difficile* on unformed stool specimens; regardless of testing approach, only final positive results indicating the presence of *C. difficile* should be included. The line listings should be sortable and searchable (e.g., .csv, Excel) files, and should include facility information such as facility name, CCN (CMS Certification Number) and NHSN orgID, contact name, contact phone, contact email, date of report, and timeframe of laboratory results. NHSN encourages facilities to develop capacity to generate these lists electronically, because recurring need for this task is expected, and creation of manual line listings presents an excessive burden.

Validators need to be able to identify NHSN-reported CDI LabID events on laboratory line listings. Facilities should be reporting CDI LabID events to NHSN using the resident identification number (RIN) and may also use resident name. In most cases, matching of reported CDI LabID events will be based on RIN, sex, date of birth, and date of event. In some situations, more information may be needed from the facility manager about reported NHSN events to identify reported CDI LabID events on the laboratory line listing, for example, a request for additional personal identifiers of residents with NHSN-reported CDI LabID events that can be linked to laboratory reports.

Note: Facilities should report positive laboratory tests according to date of specimen collection, not date of result reporting.

To ensure completeness of the laboratory line listings, facilities may need to request laboratory data directly from the laboratory information management system if required information is not included in vendor software (such as data-mining programs) reports. However, if evidence exists that vendor software can provide complete laboratory data, vendor systems may provide convenient linkage to admission/discharge/transfer (ADT) data that would otherwise need to be created manually. This issue may need to be explored through individual discussions with facilities and by facilities with their vendors.

Consider a mutually agreeable due date for the laboratory line listings, dates for the medical record request, and proposed date(s) for the validation. For the validation, request arrangements for medical records access including workspace, computer systems, terminals, and passwords and (eventually) specific medical records, if conducting validation on-site. For remote validation, ensure electronic access to medical records. This could include temporary access to the EMR system, or secure remote review via screensharing. If a facility does not have an EMR system, you will need to discuss other methods for chart review (e.g. entire records scanned or faxed).

LTCFs may not have the capability to test specimens on-site and may send them out for testing at outside laboratories. Be sure to specify that all positive specimens, tested on-site or at an outside laboratory, are included in the line list. The line list should also include ED/OP visits when the date of return to the facility is the same calendar day or the next calendar day (no change in current admission date).

For positive CDI LabID Event, facility-wide, inpatient/RIN, facility current admission date, stool specimen number, specimen collection date, result of CDI test, resident location, sex, and date of birth are required data. Additional resident identifiers such as resident name may be helpful. Sort the line list by RIN and facility admission date, which together characterize unique eligible admissions/episodes of care with possible CDI LabID Event.

Template positive *C. difficile* assay (* indicates required data)

*RIN Resident ID	*Facility Current Admission Date	*Laboratory Stool Specimen Number	*Specimen Collection Date	*Result of CDI Test	*Specific NHSN Location, include ED/OP	Sex	*Date of Birth	First Name	Last Name

Establish Mechanism for Secure Data Transfer

To determine which resident charts will be reviewed, your organization will need to request specific resident line lists from each participating facility, which will include protected health information (e.g., resident identification numbers, resident names, etc.). Therefore, it is necessary for your organization to establish a mechanism for secure data transfer and determine how those data will be secured upon receipt. Some agencies have established secure file transfer (for example, encrypted email, secure file transfer protocol [FTP] site, or encrypted file by courier or snail mail) for transfer of these sensitive data. Consider existing systems for secure data transfer and how to secure these data flow in both directions (to send line listings to develop the sampling frame and to respond with the sample of medical records for review).

Medical Record Selection

For sampling, a medical record refers to the record of a single facility inpatient admission, also referred to as an episode of care (EoC). A sample size of up to 30 medical records per facility is recommended. You will sample the 30 medical records from 3 facility-provided resident lists:

1) Line list of residents with at least one positive *C. difficile* result during the validation timeframe.
2) List of residents that left the facility for an outpatient visit (Emergency Department visit/ clinic visit/ outpatient) during the validation timeframe.
3) List of all residents in the facility during the validation timeframe.

How to Select Medical Records

1) Starting with list #1, assign a random number to each positive *C. difficile* result on the facility-provided line list. Refer to Table 1 for three methods of random number assignment. Sort the list by random number and select the first 15 records for validation. If multiple records are selected for the same resident, replace the duplicate record(s) with the next random number in the list. If this list has less than 15 unique resident records, review all.
2) Repeat step 1 for list #2: assign a random number to each resident that left the facility for an outpatient visit. Sort by random number and select the first 15 records. Replace any duplicate records with the next random number from the sorted list. If this list has less than 15 unique resident records, review all.
3) If there are fewer than 30 records after sampling from lists #1 and #2, randomly select additional records from list #3, using the same random number assignment method and removing duplicates, to reach a total of 30 sampled records.

Note: If there is not a total of 30 unique records among these 3 lists, all unique records should be reviewed.

Table 1. Random number assignment methods	
Option 1: Excel	1. Using the facility list created above, or an HAI line list, insert the command =ROUND(RAND()*1000000,0) into column B and drag to paste this command for each row of the facility list. This will generate a random number for each orgID. 2. Select and copy the values from column B and use the Paste Special (Paste Values) feature to paste the number values into column C. Note: any edit made to the Excel sheet will cause the numbers in column B to recalculate. This is normal and can be ignored if you have an iteration copied. 3. Delete column B so the columns shift left and column C becomes column B. 4. Sort by column B, making sure column A is included in the sort (click on "Expand selection" if a dialog box appears). This is your final list that has been assigned and sorted by a random number.
Option 2: Random Number Generator Website + Excel	1. Identify the total number of facilities from the list created above, or the number of records on HAI line list. 2. Go to https://www.random.org/sequences/ 3. Input 1 as the smallest value, and the total number of facilities/records as the largest value and click "Get Sequence." 4. Copy the sequence created and paste it into column B of your spreadsheet. 5. Sort by column B, making sure column A is included in the sort (click on "Expand selection" if a dialog box appears). This is your final list that has been assigned and sorted by a random number.
Option 3: SAS Codes	1. Enter the appropriate file path where prompted in the code. 2. For medical record random number generation, determine if you need/want the program to create an 'EoC' number. If yes, run code as written. If no, delete the lines of code as specified in the program, then run code. 3. The final list, assigned and sorted by a random number, will be exported to the same folder specified in step 1.

Request Selected Medical Records

When the medical record selection process is complete, inform the facility manager of the selected records and submit the medical records request to the facility prior to the site visit in a secure fashion so they can arrange for access to the information for your review.

Chapter 4: Conducting Validation Activities

Checklist for NHSN LTCF CDI LabID Event Validation Site Visits (On-site or remote)

- ☐ 2023 NHSN LTCF Manual
  - Before visit: Tag/highlight case definitions
  - Tag/highlight location descriptions for patient location mapping
- ☐ Information about the facility:
  - List of medical records requested for review
  - Confidential list of CDI LabID Events reported by facility to NHSN (ensure that validators are blinded until after review is completed)
- ☐ It is recommended that validation data are directly entered into the REDCap MRAT. However, if conducting abstractions on paper, be sure to have multiple copies of blank MRATs found in Appendix 4**.**
- ☐ Validation discrepancies reports
- ☐ Methods Surveys and form to collect contact information

Please note that some of the listed tools are templates that should be adapted to the facility and state before use.

Following introductions, validators should reiterate the project goals, stressing the educational nature of the validation activities. Reporting staff may be worried that an unfavorable evaluation may lead to sanctions by their supervisors which may bias answers to survey questions. Every effort should be made to make participating staff feel comfortable providing honest feedback.

Validators can choose to begin by administering the Survey to Assess NHSN LTCF CDI LabID Event Surveillance (Appendix 3) or by initiating the patient chart review process. If multiple validators are present, these activities can occur concurrently.

Request Documentation of Current NHSN Reporter Training

NHSN reporters should have documentation, such as a certificate, of successful completion of the most recent online, self-paced multimedia training modules for HAIs they oversee. This is an opportunity to establish or reinforce state expectations for this annual update. Consider recording the results in the LTCF CDI Survey in Appendix 3.

Structured Medical Records Review

Validator Blinding, Review, and Consultation

Validator blinding as to HAI status is recommended as much as feasible for jurisdiction resources. It is normally accomplished by mixing and reviewing the selected medical records before determining which have been reported to NHSN as an HAI event. Medical records should be reviewed using 2023 Medical Records Abstraction Tool (MRAT) templates (Appendix 4). This tool includes algorithms and logic designed to establish the presence or absence of required criteria for case definitions and to provide support to avoid common errors.

If working on paper, bring enough copies of the MRAT to complete a separate form for each medical record, however, it is recommended that these data are collected electronically through the REDCap MRAT. After all medical records have been abstracted by validators, events reported to NHSN should be revealed and a meeting arranged with NHSN reporters to discuss any discrepancies between validator outcomes and reported outcomes, while medical records are readily available.

Staff Surveillance Practices and Denominator Collection Methods Surveys

Surveillance Practices Survey

The surveillance practices survey (Appendix 3) should be administered to the primary person or people responsible for all aspects of NHSN surveillance and reporting – CDI LabID event determination, denominator collection, data entry into NHSN, and data analysis. If multiple people perform these roles, please include them in the survey.

The survey is designed to assess the facility's surveillance and reporting practices, and the staff understanding of the CDI LabID protocol. The questions are both open-ended and multiple choice. Some of the questions are scenario-based. Some have follow-up questions to elicit more information. Throughout the survey there are "Notes to Interviewer" – these notes provide information that can be shared with the interviewees for educational purposes during the survey.

The survey contains 4 sections:

A. Facility Information and NHSN

This section gathers information on the staff involved in CDI LabID event reporting and how they use NHSN.

B. Admission Dates and Denominator Data Collection

The questions in this section assess staff understanding of CDI LabID event denominator definitions and the facility's denominator collection practices.

C. CDI LabID Events

The questions in this section assess staff understanding of CDI LabID event definitions and the facility's case surveillance practices.

D. Additional Questions to Identify Areas of NHSN Improvement - opportunity for users to provide feedback to NHSN

Denominator Methods and Documentation Review

"FacWideIN" surveillance data includes all resident days counted at the same time each day for residents housed in a bedded location. This information is often collected electronically. Manual counts should be within 5% of the referent (usual) electronic counts, or an evaluation of why they differ should be conducted. Electronic ADT data often are found to be more accurate than electronic billing data in this regard. This internal validation process can be conducted by facilities when requested or required.

Depending on time and availability of staff, surveillance methods and denominator data collection surveys (Appendix 5) may be completed before, during, or after the visit.

Facility Debrief

Debrief the Facility Manager and any staff involved in NHSN reporting of the findings from the chart review and survey administration, using the report template in Appendix 6 or the corresponding SAS code, located on the NHSN External Validation webpage under 'Statistical Tools.' This provides an opportunity to discuss your findings in general terms, address any outstanding questions, commend staff for excellent processes and/or progress, and suggest improvements. It may also be necessary to develop a process improvement plan if serious deficiencies are found. Leave a copy of expected changes to NHSN data with the Facility Manager and mutually agree upon a deadline for changes to be made. Thank the Facility Manager and staff for their participation.

Post-visit

Facility Follow-up

A follow-up letter to the manager and facility leadership (e.g., director of nursing, medical director, NHSN facility administrator, etc.) will close the communication loop and provide valuable feedback. Send a letter thanking them, recognizing all participants in the validation project, and documenting results, necessary corrections, and recommendations. When appropriate, identify systematic strengths as well as problems with resources and support for surveillance, data collection, and reporting (Appendix 2.3).

If the facility was required to change data in NHSN or to re-review information due to systematic errors, follow-up with the facility and ensure corrections are made by the agreed upon deadline.

Aggregate, Summarize, and Disseminate Findings

Following the completion of all facility site visits, medical chart reviews, and entering of data into the REDCap MRAT instrument, deidentified data should be exported out of REDCap and sent to CDC. See the How To Guide for step-by-step instructions for exporting and sending deidentified data. Identify opportunities to share your findings with key stakeholders; this should include CDC and all participating facilities. If your jurisdiction is not using REDCap to collect abstracted data, contact the NHSN Validation team by logging into SAMS and submitting a case through the ServiceNow portal, or by emailing nhsn@cdc.gov, with "External Validation Toolkit" as the subject, for alternate methods of data transfer.

Analyze aggregated data from all facilities that participated in the project – these data should be used to write and publish a state/jurisdiction summary report and be disseminated to key stakeholders.

Data collected through the course of the validation project will be used to inform future CDC data quality improvement efforts, including the development of:

- Trainings to address common reporting errors
- Frequently Asked Questions
- Updates to this document

Appendix 1: (Optional) Template for CDI LabID Event Validation Discrepancies Discussion with Facilities

Please feel free to adapt these templates to meet your jurisdiction's needs to discuss discordant outcomes and request changes.

***Instructions**: For each CDI LabID Event with a discordant outcome between facility reporters and validators, record what was reported to NHSN by the facility and the validator's determination. Use the Comment area to document reasons for discrepancy. Many jurisdictions have examined this type of data to identify common errors and direct future education and training. Keep a copy for your records and leave a copy with the facility.*

Summary Findings from Evaluation of NHSN CDI LabID Event Reporting between _____/___/_____ and ___/___/_____

Facility Name: _____ # Resident Charts Reviewed:_____ Date of Site Visit: ___/___/_____

Res ID	CDI LabID Event identified				This CDI LabID event was determined to be:			Comments/notes
	No	Yes	Identified during evaluation site visit	Reported to NHSN by facility staff	*Correctly reported*	*Under reported*	*Over* reported	

Appendix 2: Letter Templates

Appendix 2.1 Introduction/Invitation Letter

<<Insert Date >>
<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>

Dear *<<Name of Facility Manager>>*:

I am inviting you to participate in a data quality evaluation of Long-term Care Facility (LTCF) *Clostridioides difficile* Infection Laboratory Identified (CDI LabID) Event data that are reported to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). This validation is being conducted by *<<agency/jurisdiction conducting validation>>* to learn how NHSN CDI LabID Event surveillance data collection procedures are understood and carried out in LTCFs, as well as to identify and address barriers to reporting complete and accurate data.

We are contacting you because your facility is among a subset of LTCFs within *<<Jurisdiction/state/area>>* that has been selected as part of a *<<random/convenience sample>>.* Please be assured that this validation is NOT related to any regulatory surveys. No observations of infection control practices or other aspects of patient care will be made during the site visit. Moreover, the identities of participating facilities will remain confidential, and all patient identifiable information will be maintained securely and remain confidential. All on-site visits will be scheduled prior to visit; there will be no unannounced visits.

To conduct the evaluation, staff from *<<agency/jurisdiction conducting validation>>* will be visiting several LTCFs in *<<geographic area>>* during *<<time period month(s)/year of visits>>*. If an on-site visit is not feasible for your facility, the activities may be done remotely. These site visits include three main activities:

1. A standardized interview with facility staff involved in NHSN CDI LabID Event data collection or reporting to evaluate surveillance practices within your facility.
2. A review of pre-selected resident medical records, including both paper charts and any electronic records, to assess the completeness and accuracy of the data reported to NHSN.
3. Education for facility staff about CDI LabID Event surveillance, use of the NHSN system, and common reporting omissions and errors and their causes.

It is anticipated the visit will be completed in *<<number of days>>*, and the staff interview (in person or virtual) will take no longer than an hour. On the day of the visit, <<*agency/jurisdiction conducting validation*>> staff will need a space to review resident charts and access the facility's electronic medical records systems. If the chart review is being done remotely, it may be conducted over a predetermined period of time and the method of patient chart access <<*agency/jurisdiction conducting validation*>> staff will use is at the discretion of your facility. This includes methods such as securely emailing or faxing the complete patient records or by letting staff members access your electronic health record system directly.

Validation of the data is critical to ensure they are complete and accurate. The findings from this validation will be used to identify, correct, and prevent common reporting errors. Your participation is vital to these surveillance support and data

quality improvement efforts.

In return for your facility's participation, you will have the following opportunities:

- Obtain confidential feedback about your facility's NHSN reporting,
- Interact one-on-one with an CDI LabID Event surveillance expert who can address any questions you may have about reporting, and
- Provide feedback about your experience with CDI LabID Event data collection and reporting that will be used to help inform changes that will improve future reporting efforts.

Please confirm your interest in participation by contacting me with available dates for a site visit during the months of <<*site visit time period*>>. Once you confirm your participation, we will schedule a mutually agreeable date for the visit and ask you to prepare some information on the residents at your facility during <<*validation period*>>. If you opt for a remote visit, we will discuss your preferred method for us to review patient charts and schedule time to meet with the pertinent staff from your facility.

I am happy to answer any questions you have or provide further information. I can be reached at <<*phone*>> or via email at <<*email address*>>.

Thank you for your assistance to evaluate and improve the quality of NHSN CDI LabID Event Surveillance data and reporting.

Sincerely,

<<*Primary Contact's Name*>>
<<*Primary Contact's Title*>>
<<*Agency/Jurisdiction's Contact Information*>>

Appendix 2.2 Confirm Site Visit Letter

<<Insert Date >>

<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>

Dear *<<Name of Facility Manager>>*:

Thank you again for agreeing to participate in our evaluation of NHSN *Clostridioides difficile* Infection Laboratory Identification (CDI LabID) Event data and reporting. Without your participation, this valuable project would not be possible.

As discussed, we will be visiting your facility on *<<date of visit>>*. *<<Names of persons who will be conducting validation>>* from *<<name of agency>>* will arrive at approximately *<<time of arrival>>*.

Preparation before the site visit

To prepare for the chart reviews, we need you to provide the lists of residents outlined below. Each list should include a resident identification number, date of birth, first and last name (optional). Send these lists to the attention of *<<Name>>* via secure/encrypted email at *<<email address>>* by *<<deadline date>>.*

1. All residents who had any *C. difficile* positive laboratory assay results between *<<month year to month year – the validation timeframe>>*. This might require contacting the laboratory routinely used by your facility for *C. difficile* specimen testing.
2. List of residents that left the facility for an outpatient visit (Emergency Department visit/ clinic visit/ outpatient) *<<month year to month year – the validation timeframe>>*.
3. All residents in your facility between *<<month year to month year – the evaluation timeframe>>*.

Facilities must provide the resident lists in an Excel format. A template of the required information is provided in the table below. These lists will be maintained securely by us to protect the release of any resident identifiers. Using the lists provided, we will preselect resident charts for us to review during the site visit. The list of resident charts for review will be provided to you in advance of the site visit.

Template positive C. difficile assay line listing. (*indicates required data):

***Resident ID**	***Date of current admission to the facility**	***Laboratory Specimen Number**	***Specimen Collection Date**	***Result of CDI Toxin Test**	***Location of resident at time of specimen collection**	***Date of Birth**	**First Name**	**Last Name**

What to expect during the site visit

When we arrive, we will need assistance to obtain the preselected resident charts. For the chart review, we will require a workspace and access to your facility's medical records. You do not need to stay with us during our review, but we may need your assistance to answer intermittent questions throughout the day.

When it is most convenient for you, we will interview the facility staff involved in NHSN data collection or entry, which takes about one (1) hour. The group interview is meant to be interactive and provides on-the-spot feedback about NHSN surveillance practices and is a valuable learning opportunity for staff. Before we conclude, we will summarize our findings and review them with you, as well as address any outstanding questions from you or your staff.

Please confirm your receipt of this information and contact me if you have any questions about preparing the lists or the site visit itself.

Thank you,

<<Primary Contact's Name>>
<<Primary Contact's Title>>
<<Agency/Jurisdiction's Contact Information>>

Appendix 2.3 Post Site Visit Letter

<<Insert Date >>

<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>
Date of site visit: _____/_____/_____

Dear *<<Name of Facility Manager>>*:

Thank you for participating in the validation of facility surveillance practices and the *Clostridioides difficile* Infection Laboratory Identification (CDI LabID) Event data reported to the National Healthcare Safety Network (NHSN). We appreciate you taking time from your schedule to work with us. The valuable information you provided will enable us to improve the quality of the data reported to NHSN and identify focus areas for education and training of NHSN users.

During our visit, *<<number>>* resident charts were reviewed. The documentation from these charts was used to identify CDI LabID Events correctly reported to NHSN. Here is a summary of our findings:

- *<<Number>>* of CDI LabID Events found in charts by our staff
  - *<<Number>>* of these events found in charts that were correctly reported to NHSN
  - *<<Number>>* of these events found in charts that were incorrectly reported to NHSN
  - *<<Number>>* of these events reported to NHSN, but were not found in charts

A summary of our findings can be found in the attached report *<<run the LTCF CDI LabID Events SAS code, or otherwise generate a summary report of validation results to attach>>*. **We would like you to perform the following steps to correct data discrepancies that were identified**:

1. Report to NHSN the events listed below as "under-reported." These are events that were not reported to NHSN by your facility staff, but should have been.
2. Delete or edit the NHSN records of the events listed below as "over-reported." These are events that were reported to NHSN by your facility staff, but should not have been.

Please make these corrections by *<<deadline>>*. Please contact us with any questions or concerns you have about making these changes.

<u>Denominators for LTCF Form</u>
From the information obtained during the survey, it appears the monthly denominator data/patient census data *<<is/is not>>* being reported correctly on the Denominators for LTCF form. Please *<<begin/continue>>* to report using the NHSN LabID Event Protocol for LTCF "Denominator" instructions and the "Instructions for Completion of the MDRO and CDI Monthly Monitoring for Long-term Care Facility" form.

In addition, it is recommended that you and your staff involved in reporting review the NHSN CDI LabID Event Protocol for LTCF, noting the following common reporting issues found at your facility:

- *<<Highlight up to 3 main issues that were discovered during the validation process. Include excerpt(s) of the NHSN CDI LabID Event Protocol for LTCF that pertain to those issues. If data validation (quality checks) is not being performed, please highlight this as an issue and provide guidance on the importance of performing data quality checks on a routine basis (at least quarterly prior to CMS submission deadlines).>>*
- *<<Issue 2>>*
- *<<Issue 3>>*

Thank you for work with regards to improving the quality of NHSN LTCF CDI LabID Event surveillance data. We recognize the time and effort that you have committed. We also appreciate your willingness to participate in these important quality improvement activities. We hope the experience was also helpful to you. Please do not hesitate to contact us with any remaining questions or concerns you may have.

Sincerely,

<<Primary Contact's Name>>
<<Primary Contact's Title>>
<<Agency/Jurisdiction's Contact Information>>

Appendix 3: Long Term Care CDI LabID Event Survey

NHSN Long-term Care Facilities (LTCFs) 2023 CDI LabID Event Surveillance Practices Survey

INTERVIEWER INSTRUCTIONS

Prior to interview:
Identify the primary person who does NHSN CDI LabID Event data collection and reporting at the facility to interview. If other staff perform NHSN activities such as data entry or analysis, it is ideal for them also to be included.

During Interview:
This interview is a tool to evaluate and improve NHSN CDI LabID Event data collection and reporting. If data collection or reporting errors are identified through this evaluation of practices, the interviewer should provide education and information to help correct errors and ensure that staff report data correctly to NHSN. Refer to the "*Note to Interviewer*" boxes for reference information.

Note to Interviewer –

If there is a correct answer to a question, the correct answer is **bolded**.

SECTION A: FACILITY INFORMATION AND NHSN

Facility Name: _____ NHSN Org ID: _____

Interviewer Name: _____ Interview Date: _____

1. Are any NHSN CDI LabID Event data collected or reported by persons that do not work directly within this facility (e.g., IP consultant, quality improvement partner, hospital/corporate partner) Yes No
    a. If yes, specify who and what data:_____
    _____

2. Please list all staff involved in NHSN CDI LabID Event Surveillance and their involvement:

	Interviewee 1	Interviewee 2	Interviewee 3
Name(s)			
Job Title(s)			
Background/Degree(s)			
Collects NHSN CDI LabID Event data?	Yes No	Yes No	Yes No
Collects NHSN CDI LabID denominator data?	Yes No	Yes No	Yes No
Has access to NHSN?	Yes No	Yes No	Yes No
Does NHSN data entry?	Yes No	Yes No	Yes No
Creates reports/uses NHSN analysis?	Yes No	Yes No	Yes No
Has read the NHSN CDI LabID Event Protocol?	Yes No	Yes No	Yes No
Has completed NHSN CDI LabID Event Surveillance reporting training?	Yes No	Yes No	Yes No

3. For staff that completed NHSN CDI LabID Event Reporting Training, what kind of training did they do?
    (Check all that apply)
    - ☐ Online NHSN CDI LabID Event Surveillance Protocol training
    - ☐ Webinar, presented by a CDC trainer
    - ☐ In person, by a non-CDC trainer (e.g., State Health Department or Quality Innovation Network-Quality Improvement Organization (QIN-QIO))
    - ☐ Webinar, by a non-CDC trainer (e.g., State Health Department or QIN- QIO)
    - ☐ Other, specify: _____

4. What have you done if you had a question about how or what to report to NHSN?

    (Check all that apply)
    - ☐ Read the NHSN CDI LabID Event Protocol
    - ☐ Visit the NHSN CDI LabID Event website (https://www.cdc.gov/nhsn/ltc/cdiff-mrsa/index.html)
    - ☐ Contact the NHSN Helpdesk (nhsn@cdc.gov or ServiceNow Portal)
    - ☐ Contact Hospital/Corporate Partner
    - ☐ Contact QIN-QIO
    - ☐ Contact IP Consultant
    - ☐ Contact State Health Department
    - ☐ Other, specify: _____
    - ☐ Never had a question
    - ☐ Never sought an answer

5. Once data are reported to NHSN, does anyone from your facility go back and review the reported data to make sure it is correct? Yes No
    a. If yes, specify who: _____
    b. If yes, specify how often: _____

6. Does anyone from your facility use the NHSN analysis reports (also called "output options")?
   Yes No
   a. If yes, which ones?
   (Check all that apply)
      - ☐ Line Listing – All CDI LabID Events
      - ☐ Rate Tables for CDI LabID Event Data
      - ☐ Line Listing – All Events
      - ☐ Line Listing – All Summary Data
      - ☐ Line Listing – Monthly Reporting Plan
      - ☐ Other, specify: _____

   b. If yes, for what are the reports used?
   (Check all that apply)
      - ☐ Checking that reported data are correct (data quality checks)
      - ☐ Shared at quality improvement meetings
      - ☐ Communicating to leadership about event rates
      - ☐ Communicating to frontline staff about event rates
      - ☐ Performing root cause analysis of infections
      - ☐ Informing prevention activities
      - ☐ Other, specify: _____

SECTION B: ADMISSION DATES AND DENOMINATOR DATA COLLECTION

7. The date of first admission to the facility is the date the resident first entered the facility.
   a. If a resident transfers from your facility to a hospital on June 1 and returns to your facility on June 4, does the first admission date change? Yes **No**
   b. If a resident transfers from your facility to a hospital on June 1, then goes to an inpatient rehab facility, and finally returns to your facility on July 10, does the first admission date change? **Yes** No
   c. If yes, what is the new date of first admission? _____ (answer: July 10)

8. The date of current admission is the most recent date the resident entered the facility.
   a. If a resident transfers from your facility to a hospital on June 1 and returns June 4, does the current admission date change? **Yes** No
   b. If yes, what is the new current admission date? _____ (answer: June 4)
   c. If the same resident goes to the ED for an evaluation on June 12 and returns on June 13, does the current admission date change? Yes **No**

9. In your facility, how do you count residents to obtain the monthly denominator data for number of residents?

   _____
   _____

10. In your facility, how do you count the number of admissions for the month?

    _____
    _____

11. In your facility, how do you count the number of admissions on *C. difficile* treatment for the month?

    _____
    _____

Note to Interviewer – Protocol instructions for admission dates and denominator data collection:

- Date of first admission to facility: If the resident leaves the facility for < 30 consecutive days, the date remains the same. If the resident leaves the facility for > 30 consecutive days, the date of first admission should be updated to the date of return to the facility.
- Date of current admission to facility: If the resident leaves the facility for > 2 calendar days (the day the resident left the facility = day 1) and returns, the date of current admission should be updated to the date of return to the facility. If the resident has not left for > 2 calendar days, then the date of current admission should not be changed.
- Number of residents: For each day of the month, record the number of residents present in the facility at the same time each day. The aggregate count for the calendar month should be entered as the total Resident Days. Do not include residents for whom a bed is being held but who are not actually in the facility.
- Number of admissions: For each day of the month, count and record the number of residents admitted to the facility. The aggregate count for the calendar month should be entered as the total Resident Admissions. Include both new admissions and re-admissions when a resident was out of the facility for >2 calendar days (that is, change to the Current Admission Date).
- Number of admissions on *C. difficile* treatment: For each day of the month, count and record the number of residents who are receiving antibiotic therapy for *C. difficile* infection at the time of admission. The aggregate count for the calendar month should be entered as the total Number of Admissions on *C. difficile* Treatment. Include both new admissions and re-admissions when a resident was out of the facility for > 2 calendar days (that is, change to the Current Admission Date).

12. What sources are used to determine your denominator data (number of residents, number of admissions, and number of admissions on *C. difficile* treatment) for the "Denominators for LTCF" form? (*Check all that apply*)
    - ☐ From a computer generated report (specify types of reports)
      _____
      _____
    - ☐ By performing resident chart reviews
    - ☐ By observation and counting residents
    - ☐ Other methods used, specify: _____

13. Has anyone at your facility checked the accuracy of the denominator data or reviewed the denominator data method to identify errors?
    Yes No
14. If not using NHSN denominator criteria, summarize below how denominator data is determined at this facility:

_____

_____

_____

SECTION C: CDI LABID EVENTS

The following questions are designed to assess the interviewee's ability to correctly identify CDI LabID Events.

15. Only results from unformed/loose stool specimens that conform to the shape of the container should be included in CDI LabID Event reporting. **True** False

16. Mr. A is a long-term resident in your facility. On December 31, he developed diarrhea and abdominal pain. On January 1, a loose stool specimen was collected and tested positive for *C. difficile* toxin. This is the first time Mr. A. has tested positive for *C. difficile* in your facility. Is this event reportable? **Yes** No
    If yes, what is the date of the event? _____ (answer: January 1, the date of specimen collection)

17. Mr. A was started on treatment for *C. difficile*, and over the next few days his symptoms resolved. On January 13, he had several more episodes of diarrhea, and another loose stool specimen was collected that tested positive for *C. difficile*. Is this event reportable? Yes **No**
    (since this is a duplicate specimen, collected < 15 days from the first specimen, it is not reportable to NHSN)

18. On January 20, Mr. A had another positive *C. difficile* toxin result. Is this event reportable? Yes **No**
    (while it has been more than 14 calendar days since the most recent CDI LabID Event was entered into the NHSN on January 1, it has not been more than 14 calendar days since his most recent *C. difficile* positive laboratory assay on January 13; therefore, this is considered a duplicate event)

19. On February 10, Mr. A had another positive *C. difficile* toxin result. Is this event reportable? **Yes** No
    (since it has been more than 14 calendar days since his most recent *C. difficile* positive laboratory assay on January 20, this specimen is entered into NHSN as a CDI LabID Event)

20. Mrs. X is a resident in your facility. She does not have a history of *C. difficile*. On March 1, she was transferred to the local emergency department (ED) for evaluation of diarrhea. While in the ED, a loose stool specimen was collected and tested positive for *C. difficile*. She given IV fluids in the ED, and transferred back to your facility on March 2. Is this event reportable into NHSN by your facility? **Yes** No
    (when a specimen is collected from an outpatient setting, such as an emergency department or clinic and the resident returns back to the LTCF on the same calendar day of the outpatient visit or the very next calendar day, the specimen collected from the outpatient location should be reported by the LTCF as if the resident never left the LTCF)

21. Mrs. X continues to have diarrhea and is transferred back to the ED on March 4. She is admitted to the acute care facility where she has a positive *C. difficile* toxin result on March 5. She returns to your facility on March 10 and is receiving antibiotic treatment for *C. difficile*.
    a. Is the positive *C. difficile* toxin result on March 5 reportable by your facility? Yes **No**
       (laboratory results obtained during an admission in another facility are excluded from the LTCF LabID Event reporting)
    b. Is Mrs. X counted as an admission on *C. difficile* treatment for denominator data? **Yes** No
       (since she left the facility for > 2 days, her current admission date changes, and she is considered a re-admission for denominator data counting)

22. On March 13, Mrs. X has another positive *C. difficile* toxin result at your facility. Is this reportable? Yes **No** (since it has been < 15 calendar days since her most recent positive *C. difficile* positive laboratory assay reported for this facility on March 1, it is not reportable to NHSN; the 14 calendar days between specimens crosses current admissions)

23. On April 1, Mr. C. a long-term care resident in your facility, is admitted to the local hospital for treatment of acute diarrhea. During his hospital admission, a stool specimen was collected on April 1 and tested positive for *C. difficile* toxin. After receiving care in the acute care facility for several days, he returned to your facility on April 5. His diarrhea returned on April 7 and a loose stool specimen was collected and tested positive for *C. difficile* toxin. Is the April 7 event reportable by your facility? **Yes** No (since he had not had a *C. difficile* positive laboratory assay while receiving care in your facility; specimens collected during an admission to another healthcare facility are not reported by the LTCF nor are they counted when considering duplicate events)

Note to Interviewer – Protocol definitions for CDI LabID Events:

- Date of event: The date of specimen collection.
- *C. difficile* positive laboratory assay: An unformed/loose stool that tests positive for *C. difficile* toxin A and/or B (includes molecular assays [PCR] and/or toxin assays)

  OR
  A toxin-producing *C. difficile* organism detected in an unformed/loose stool sample by culture or other laboratory means.
- Duplicate *C. difficile* positive laboratory assay: Any CDI LabID event submitted by the reporting LTCF for the same resident in the facility following a previous CDI LabID Event within the past two weeks.
    - **Note**: As of 2020 NHSN will categorize duplicate lab assays. ALL positive LabID Events from specimens collected while the resident was receiving care within the LTCF must be submitted to NHSN.

24. When a resident has been transferred from an acute care facility, how do you determine if he/she was receiving treatment for *C. difficile*?
    - ☐ Review hospital discharge summary
    - ☐ Review admission/transfer medication list
    - ☐ Review hospital medication administration record
    - ☐ Ask the resident's physician
    - ☐ Other, specify: _____

25.

a. What data sources do you use to help you find CDI LabID Events?	
Daily direct observation of residents	☐
Resident chart reviews	☐

Review computer generated reports	☐
If used computer reports, specify the type(s):	

Staff discussion	☐
Pharmacy records	☐
Positive laboratory reports	☐
Hospitalization records	☐
Administrative (billing or discharge) codes	☐
Other data sources, specify:	
How frequently is case finding performed (e.g., daily, weekly, monthly, quarterly)?	
b. Once you have identified a resident with a CDI LabID Event, what process do you use to keep track of them before they are entered into NHSN?	
Keep a line listing (e.g., a log) of events	☐
Fill out a paper NHSN CDI LabID Event form	☐
Flag events in Electronic Medical Record	☐
Other, specify:	

26. Does your facility keep track of all resident hospitalizations and outpatient visits? Yes No

27. After residents return to your facility following a hospitalization or outpatient visit, does your facility request a copy of your residents' medical records? Yes No

a. Are records requested for <u>every</u> hospitalization and outpatient visit? Yes No

b. Is there a standard process to request records (e.g., a request form)? Yes No

c. Does your facility have a follow-up system in place to ensure all requested records are received? Yes No

If yes, please describe the process:

_____

_____

_____

d. Please specify the type of records requested for all resident hospitalizations or outpatient visits:

(Check all that apply)

- ☐ Admission history and physical
- ☐ Microbiology laboratory reports
- ☐ Pharmacy/drug administration records/logs
- ☐ Discharge summary
- ☐ The complete record
- ☐ Other, specify: _____

28. If a resident develops diarrhea that is concerning for *C. difficile*, when does your facility usually start treatment with antibiotics? (*Check all that apply*)

- ☐ Treatment is started **without** sending a stool specimen for *C. difficile* testing for residents who have any history of *C. difficile* anytime in the past
- ☐ Treatment is started **without** sending a stool specimen for *C. difficile* testing only for residents who have a recent history of *C. difficile* (within the past 4 weeks)
- ☐ For all residents with or without a history of *C. difficile*, treatment is started immediately and a specimen is sent for *C. difficile* testing; if the test results are negative then treatment is discontinued
- ☐ For all residents with or without a history of *C. difficile*, a specimen is always sent for *C. difficile* testing, and treatment is only started if the result is positive
- ☐ Other (please specify): _____

SECTION D: ADDITIONAL QUESTIONS TO IDENTIFY AREAS OF NHSN IMPROVEMENT

29. What two things would be most helpful to improve NHSN data collection and/or reporting?

_____

_____

30. What are the two main challenges to NHSN reporting?

_____

_____

31. Do you have any other questions or comments about NHSN?

_____

Appendix 4: Medical Record Abstraction Tool

Instructions: This form is a tool to review a long-term care facility resident chart and collect NHSN LTCF CDI LabID Event Surveillance information to determine whether data were correctly reported. Chart reviewers must be familiar with the NHSN LTCF CDI LabID Events Protocol instructions and definitions prior to chart review.

Section 1. Patient Information and Medical Identifiers			
Facility (NHSN) OrgID:	Date of Review: ___ / ___ / ___	Review Start Time:	Review End Time:
Patient ID:	Patient DOB: ___ / ___ / ___	Reviewer Initials:	

Section 2: Positive *C. difficile* Specimens

Enter the selected positive *C. difficile* specimen (PCS) in the first row, then review the 14 days prior to the selected PCS to determine if additional PCS were collected for this resident, as defined by the NHSN LTCF CDI LabID Event Surveillance Protocol. If additional specimens are identified, enter them into the table in reverse chronological order and review the next 14-day period from the earliest collection date identified to find additional PCS results. Repeat this until no additional specimens are identified. Work across the row to determine if the PCSs were reportable to NHSN. Include all PCSs obtained while the resident is receiving care from the LTCF, including specimens collected from an emergency department (ED) or outpatient (OP) setting during a resident's current admission.

Current Admission Date	**Date of PCS Collection**	**Location of PCS Collection**	**# Days since last PCS collection**	**Was this a "duplicate specimen" (collected < 15 days since the last PCS)?***	**Should this PCS be reported to NHSN?**
		LTCF ED OP	_____ days	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No

*Note: The LabID Event algorithm for determining duplicate events (<15 calendar days between positive specimens) applies across current admissions. The NHSN application will make the determination of duplicate, incident, or recurrent event. ALL *C. difficile* positive laboratory assays should be reported to NHSN.

Section 3. Case Classification: Determine the appropriate classification for the selected *C. difficile* positive specimen.
☐ **Correctly Reported or Correctly Not Reported HAI** ☐ **Over Reported HAI** ☐ **Under Reported HAI**
Section 4. Misclassification Reason: If the selected specimen was misclassified by the facility, select the most applicable reason for misclassification.
1. Lab ID definition misapplication 2. Duplicate reporting (≤14 days since the last CDI positive specimen) 3. Missed case finding/failure to review positive specimen 4. Did not review previous inpatient episode 5. Used outdated criteria 6. Other (specify): _____

Appendix 5: LabID Event Facility-Wide Inpatient (FacWideIN) Denominator Validation Template

Please feel free to adapt this template to meet your state's needs

Electronically collected CDI FacWideIN denominators

"FacWideIN" surveillance data includes all admissions (new and re-admissions) and resident days counted at the same time each day for residents housed in a bedded location. This information may be collected electronically. Manual counts should be within 5% of the referent (usual) electronic counts, or an evaluation of why they differ should be conducted. Electronic ADT data often are found to be more accurate than electronic billing data in this regard. This internal validation process can be conducted by facilities when requested or required.

Number of Admissions on C. difficile treatment

For each day of the month, count and record the number of residents who are receiving antibiotic therapy for *C. difficile* infection at the time of admission to the facility. Include both new admissions and re-admissions when a resident was out of the facility more than 2 calendar days (specifically, change to the Current Admission Date).

NOTE: A resident admitted on CDI treatment should be included in this count even if he/she does not have a CDI LabID event for the LTCF.

CDI LabID Event Denominator Validation									
	Month of Validation *(specify)*	Admissions			Resident Days			Number of Admissions on C. diff Treatment:	
		Usual Count	5% Tolerance interval†	Manual Count	Usual Count	5% Tolerance interval†	Manual Count	Reported by facility	Identified during validation
†Equation for 5% tolerance interval is: Usual Count ± (Usual Count * 0.05). Example calculations where Usual Count = 164 and Manual Count = 178: Eligible 5% tolerance interval = [164±(164*0.05)]=155.8 to 172.2 Manual Count 178 falls outside the tolerance interval, suggesting that Usual Count is inaccurate and should be investigated.								The most common medications used to treat CDI are oral (PO) vancomycin, oral (PO) metronidazole (Flagyl), and fidaxomicin	

Appendix 6: CDI LabID Event Validation Summary

***required **conditionally required**

Facility Validation Overview	
*Facility ID:	
*Facility Type:	☐ Nursing home ☐ Skilled nursing facility ☐ Assisted living facility
*Facility sampling method:	☐ Random Sampling ☐ Convenience Sampling
Reason facility was sampled:	☐ All facilities were validated ☐ Randomly selected facility ☐Facility volunteered to participate

Numerator Validation

***Sampling information for numerator validation at this facility:**

Event	Sampling Frame Elements	Sampling Frame (# episodes eligible for review for timeframe)	Total # events from facility reported to NHSN for timeframe (before validation)
CDI LabID event	Inpatient^ stools positive for C. difficile	_____	_____

*** CDI LabID Event Validation Results:**

Event Determination	Validation: Yes – CDI test reported as LabID event	Validation: No – CDI test NOT reported LabID event
Facility: Yes - Date-matched CDI test reported as LabID event	a. _____	b. _____
Facility: No - Date-matched CDI test NOT reported as LabID event	c. _____	d. _____

^Inpatient includes residents physically housed and cared for in the reporting LTCF, as well as brief outpatient encounters (e.g. emergency department or outpatient clinic) where the resident returns the to LTCF on the same or next calendar day.

Denominator Validation	
**Has this facility completed any internal validation of LabID event denominator data counting?	☐ Yes ☐ No

Note: Validation of denominator data counting requires concurrent patient level denominator counting (reference) vs. standard electronic data for ≥1 month; validated data should fall within 5% of the reference standard.

**If yes, provide the following information for all months validated:

Location of validation	Month of validation	Admissions		Resident Days	
		Usual count	Manual count	Usual count	Manual count

NHSN Inpatient Location Validation: MAPPING

**Do any inpatient locations require mapping or re-mapping within NHSN?	☐ Yes ☐ No

**If yes, indicate which locations need to be mapped/re-mapped and recommendations:

Location	Current CDC location code designation	Current bed count	Recommended CDC location code designation	Recommended bed count
Add rows as needed.				

**How does this facility obtain inpatient admissions data?	☐ Electronic from billing ☐ Electronic from vendor system ☐ Electronic from ADT ☐ Other (specify): _____
**How does this facility obtain inpatient patient days data?	☐ Electronic from billing ☐ Electronic from vendor system ☐ Electronic from ADT ☐ Other (specify): _____

Risk Adjustment Variable Validation	
*Facility bed size	
Facility bed size reported on 2023 NHSN Annual Facility Survey:	
Validated bed size:	

Comments