CONTINUITY OF OPERATIONS PLAN TOOLKIT





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GLOSSARY & ABBREVIATIONS

AFB	Acid-Fast Bacilli; acid-fast is a descriptive term to describe the bacilli that do not decolorize with acid alcohol because the bacilli contain mycolic acids
After-action reports	Analysis or summary of a past event that is used to re-assess decisions and identify areas for improvement and/or possible alternatives for future scenarios (1)
BACTEC™ MGIT™	Mycobacterium Growth Indicator Tube; commercial non-radiometric broth-based mycobacterial culture system by Becton Dickinson and Co.
BACTEC™ MGIT™ 320/960	Instrument that is a fully automated system using the fluorescence of an oxygen sensor to detect growth of mycobacteria in culture
Clients	Tuberculosis Programs, tuberculosis clinics, or referring laboratories that submit specimens or isolates for mycobacteriology testing to the state public health laboratory; also referred to as healthcare submitters or providers
Contingency plan	Policies to maintain or restore operations
СООР	Continuity of Operations Plan; plan that ensures continued performance of essential functions under a broad range of circumstances (2, 3)
Culture	Solid or liquid media that have been inoculated with a diagnostic specimen or microorganism and kept under controlled laboratory conditions such as an incubator
Direct detection	Detection of pathogens directly from clinical specimens; examples include microscopy or nucleic acid amplification testing performed directly on a clinical specimen
DST	Drug Susceptibility Testing; inoculation of bacteria in/on media containing a particular drug for determination of susceptibility or resistance based on growth of the organism
Formal agreement	Official agreement that has been accepted and signed by all involved parties
Hot wash	Quick review after an operation, exercise, or event to determine the level of success; used to establish lessons learned that can be implemented to improve the outcome for similar future events
ID	Identification
ISE	Interruption of Service Event; can include natural disasters, planned maintenance, facility issues, equipment failures, pandemics, and other unexpected events
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
МТВС	Mycobacterium tuberculosis complex; aerobic, slow-growing, intracellular acid-fast bacilli; consists of M. tuberculosis, M. bovis, M. bovis BCG, M. caprae, M. microti, M. africanum, M. canettii, M. pinnipedii, and M. mungi
NAAT	Nucleic Acid Amplification Test; molecular methods that can be used for direct detection of MTBC in clinical specimens
PHL	Public Health Laboratory
Referral laboratory	Laboratory that performs testing services for another laboratory
Submitter	Hospital, local/county public health, or referring laboratory that submits specimens or isolates for mycobacteriology testing to the state public health laboratory; also referred to as healthcare providers or clients
TAT	Turnaround Time
ТВ	Tuberculosis

INTRODUCTION, OBJECTIVES, & AUDIENCE

Many public health laboratories (PHL) have experienced situations with the potential to disrupt testing services, including pandemics, natural disasters, and laboratory-related facility or maintenance issues. These types of interruption of service events (ISEs) may result in a temporary inability to use equipment or laboratory space, compromise staffing and infrastructure, preclude maintenance or calibration of equipment, and prevent or require extensive disinfection and decontamination. A continuity of operations plan (COOP) allows for the development of specific processes and procedures to minimize interruptions to laboratory testing when an ISE occurs.

This *Continuity of Operations Plan Toolkit for Public Health Mycobacteriology Laboratories* was developed after public health mycobacteriology laboratorians responded to a questionnaire and participated in focus groups regarding their experiences in preparing for ISEs. The toolkit focuses specifically on COOPs for mycobacteriology testing and continuity of testing services for the diagnosis of tuberculosis (TB) for both public health and clinical importance. Processes for creating, modifying, or implementing mycobacteriology COOPs, including considerations for leveraging partnerships are included.

The toolkit's primary audience is microbiology laboratory managers, mycobacteriology laboratory supervisors and technologists, and other leadership and preparedness staff within a PHL.

Objectives for this COOP Toolkit for Public Health Mycobacteriology Laboratories include:

- Describe pandemic, natural disaster, and other ISEs that have or may affect PHL testing services
- Summarize the importance of preparedness for ISEs and the availability of COOPs for the mycobacteriology laboratory
- Identify the necessary actions for advanced preparation of ISEs, planned or forecasted ISEs, and activated and inactivated mycobacteriology laboratory COOPs
- Recognize the importance of identifying a referral laboratory within a COOP for mycobacteriology testing services
- Encourage mycobacteriology personnel to create or revise mycobacteriology laboratory COOPs based on information provided in this toolkit

This toolkit also includes various templates and checklists which can be adapted to meet specific local needs.

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

TYPES OF INTERRUPTION OF SERVICE EVENTS (ISEs)

There are many different types of ISEs that can impact testing services within a PHL. Equipment failure, maintenance, and facility issues are the most common ISEs that affect PHLs, and the testing services provided. A list of potential ISEs is listed below:

Pandemics

Disease epidemics that spread across large regions, for instance multiple continents or worldwide, that will ultimately have an impact on workforce, small and large businesses, healthcare and testing, and daily lives

Natural disasters

Events resulting from natural processes that may unexpectedly impact PHL infrastructure and testing, such as:

- > Flood
- > Hurricane
- > Earthquake
- > Tornado
- > Wildfire
- > Winter/ice Storm

Facility issues

Events resulting from failures in laboratory infrastructure or local environment that impact PHL testing, such as:

- > Electrical power failure
- > Water supply issue
- > Hazardous materials
- > IT systems failure/cyber attacks
- Loss of negative air pressure in biosafety level 3 (BSL-3) laboratory
- Large scale spill/laboratory decontamination

Equipment failures

Sudden or unexpected interruptions in laboratory equipment that may impact PHL testing, such as:

- Broken or damaged test equipment or instrument (e.g., centrifuge, slide warmer, thermocycler, etc.)
- Incubator failing to maintain temperature or CO2 level
- Biological safety cabinet (BSC) failing to maintain appropriate airflow

• Equipment/facility maintenances

Planned interruptions for laboratory equipment or facilities that may impact PHL testing, such as:

- Service of laboratory equipment (e.g., repairs, cleaning, maintenance, etc.)
- > Rebalancing air handling systems
- Installation/relocation of laboratory equipment

Other events

That may impact testing, such as:

- > Terroristic threats/terrorism
- > Civil disturbance
- > Reagent/supply backorder/shortage
- > Limited testing personnel
- Damage to municipal infrastructure preventing laboratory access
- > Sequestration/spending cuts

IMPORTANCE OF A CONTINUITY OF OPERATIONS PLAN (COOP)

A COOP is defined as a documented comprehensive plan that describes the procedures, policies, and essential functions necessary for an organization or laboratory to respond quickly and effectively to a wide variety of possible disruptions or threats and ensures that critical operations can be continued if an event were to affect normal operations. This plan should be a living document or set of documents that is reviewed periodically and updated as needed. In some instances, activation of a COOP may be required for ISEs that impact the PHL for more than a day or two.

The advantages to having an effective COOP include (2, 3):

- · Continuance of essential functions
- · Minimization of danger, damage, or loss of life
- Delegation of authority with succession planning of key leadership
- · Continuity of communications
- · Reduction in operational disruptions
- Protection of essential assets
- · Timely recovery

There is no standard method for the development of a COOP. The plan should be specific to the needs of the laboratory/organization for which it is being written. COOP resources and templates exist that can be utilized to assist in the development of a COOP (2, 3).

Although PHLs may have an overarching COOP in place, it is important for the mycobacteriology laboratory to also have a specific plan. The plan should address continuity of mission critical functions including availability of testing personnel, specimen receipt, testing of specimens, cultures, or isolates, referral testing, biosafety, equipment, infrastructure, and other key activities.

The information described below should be considered when developing or updating a mycobacteriology laboratory COOP. Persons involved in preparing the mycobacteriology laboratory COOP should minimally include the mycobacteriology laboratory supervisor, PHL director, mycobacteriology testing personnel, biosafety officer, and the quality assurance manager. Representatives from the jurisdictional TB Program should also be included.

DEVELOPMENT OF A MYCOBACTERIOLOGY LAB COOP

A COOP allows the mycobacteriology laboratory to shift efficiently from its regular structure to a structure that enables timely continuation of services. This is critical for mycobacteriology laboratories timely testing and result reporting. The mycobacteriology COOP should align with the larger PHL COOP.

A mycobacteriology laboratory COOP should include:

- A. Organization and Point(s) of Contact
- **B.** Introduction
- C. Purpose
- D. Scope
- E. Objectives
- F. Types of ISEs
- G. Critical Functions of the Mycobacteriology Laboratory
- H. Personnel and Responsibilities
- I. Critical Records and IT Infrastructure
- J. Critical Communications
- K. Referral Laboratory
- L. Referral Testing Timeline Considerations
- M. Mycobacteriology Laboratory Best Practice Considerations
- N. Annual Review of the Mycobacteriology Laboratory COOP
- O. Mycobacteriology Laboratory COOP Training and Exercises

Included as part of this toolkit is a Mycobacteriology Laboratory COOP Template, which includes each of the topic areas listed above. The next section will be used to guide you in developing content for each of the topic areas to draft a mycobacteriology COOP.



MYCOBACTERIOLOGY LABORATORY COOP TOPICS

Include this information in your laboratory's COOP, whether already in place or in the Mycobacteriology Laboratory COOP Template within this toolkit.

A. Organization and Point(s) of Contact

Provide the name of both the PHL and mycobacteriology laboratory and the points of contact within the mycobacteriology laboratory (e.g., names, telephone numbers, and email addresses). Include the date this document was finalized and any revision dates.

A table for Organization and Point(s) of Contact is included as part of the Mycobacteriology Laboratory COOP Template within this toolkit.

B. Introduction

Provide an introduction describing why a COOP specific to the mycobacteriology laboratory is needed.

C. Purpose

Provide a purpose describing what the mycobacteriology laboratory COOP will be used for.

D. Scope

Provide a scope describing specific plans of action if the mycobacteriology laboratory COOP were to be activated.

E. Objectives

Describe objectives for the mycobacteriology laboratory COOP such as:

- Recognize the importance of mycobacteriology testing services during an ISE
- Establish mycobacteriology laboratory testing plans for advanced preparation of ISEs, planned or forecasted ISEs, and mycobacteriology COOP activation and inactivation
- Identify mycobacteriology laboratory personnel responsible for leading COOP activities in the event of an ISE
- Implement plans for referral testing of mycobacteriology specimens, cultures, or isolates through formal agreements
- Detail communication strategies with submitters, clients, TB Program, and partners

F. Types of ISEs

Planned, forecasted, or unanticipated ISE's may occur due to pandemics, natural disasters, and laboratory-related facility or maintenance issues. Include a list of potential ISEs that may affect the mycobacteriology laboratory.

A table of Types of Interruption of Service Events is included as part of the Mycobacteriology Laboratory COOP Template within this toolkit and may be helpful to mycobacteriology laboratories.

G. Critical Functions of the Mycobacteriology Laboratory

Describe the critical mycobacteriology testing performed in the PHL and the need for its continuance. Include a visual testing algorithm for reference.

H. Personnel and Responsibilities

List mycobacteriology personnel, contact information, and their responsibilities. Include any other relevant personnel from the PHL such as the laboratory director or biosafety officer.

A Laboratory Personnel Contact List template is included in this toolkit.

I. Critical Records and IT Infrastructure

Define how mycobacteriology critical records and IT infrastructure, as part of the broader PHL COOP, will be protected and how data will be saved and accessed during an ISE.

J. Critical Communications

Detail how and when the mycobacteriology laboratory supervisor(s) or responsible officials (e.g., technical supervisor, manager, laboratory director, etc.) will communicate to personnel, submitters, clients, jurisdictional TB Program, partners, and referral laboratory(s) (if applicable) through various methods including telephone, text, email, mail, and/or electronic systems (e.g., Ready OP, etc.). Specific information regarding critical communications can be listed here; included templates and checklists provide specific logistics and awareness communication examples and may be helpful for mycobacteriology laboratories.

A Laboratory Submitter/Client Contact List and a Laboratory Vendor Contact List template are included in this toolkit.

K. Referral Laboratory

Consider the following aspects when discussing referral laboratory testing needs. Specific information regarding the selection of a referral laboratory can be listed here; included templates and checklists provide specific examples and may be helpful for mycobacteriology laboratories.

Early in the process of determining a potential referral laboratory:

- Select a primary and secondary referral laboratory and identify a tertiary, or back-up, referral laboratory to send specimens/cultures/isolates to if the primary or secondary referral laboratory impacted by the ISE or is unable to test additional specimens/cultures/isolates at the time requested. Consider that some ISEs may be local, while other ISEs may be regional therefore impacting potential referral laboratories in neighboring states.
- Determine if mycobacteriology workload volume could be undertaken by a single referral laboratory or if more than one referral laboratory may be needed. Higher volume PHLs may require more than one referral laboratory in the event of an ISE.
- Reach out to potential referral laboratories to determine if they have the workload capacity including personnel and instrumentation for this additional testing.
 - Determine if the referral laboratory can accept cultures (i.e., inoculated or incubating media) or referred isolates.
- Compare testing methods, algorithms, and turnaround times with the referral laboratory
 - Consider the ability of the referral laboratory to perform or access molecular testing (i.e., NAAT) and second-line drug susceptibility testing (DST)
 - > Consider how referral for genotyping will take place

- Discuss costs with the referral laboratory performing mycobacteriology testing and how these costs might be covered (e.g., billing, formal contract, or in-kind supply replacement) for the duration of the ISE
- Discuss and/or develop an MOU or MOA with the selected referral laboratory
- Determine how specimen test requisition will be conducted and what forms will be used
 - Determine the specimen/patient information required for the specimen or isolate to be tested at the referral laboratory; laboratories may have specimen/patient information requirements that if not completed, the submission will be rejected
 - Determine submission criteria for the specimen, culture, or isolate to be submitted to the referral laboratory; laboratories may have minimum acceptance criteria (i.e., time from specimen collection, storage, stability in each medium or sample matrix, transport temperatures, etc.)
- Determine how specimens, cultures, and isolates, if applicable, will be transported to the referral laboratory for testing—courier, private shipping company (i.e., FedEx, UPS), or postal service
 - Determine if specimens/isolates will be shipped directly from the submitter to the referral laboratory, shipped from the referring PHL to the referral laboratory, or if another process will be used
 - > Determine a submission tracking process
- Decide how test results will be reported to the submitter; by reporting system, fax, or secure portal and whether there are any IT requirements
 - Discuss if the referral laboratory will provide results directly to the submitter or if the referral laboratory will provide results to the referring laboratory to provide results to the submitter
 - Compare reporting language used by the referral laboratory to that of the PHL mycobacteriology laboratory; if the language will be different, inform submitters of these differences
 - Verify with submitters receipt of test results during implementation of a COOP reporting process to ensure that results are being transmitted effectively
- Monitor result turnaround times (TAT) if referral testing is performed
- Communicate with the referral laboratory, submitters, clients, and partners to keep all parties aware of updated plans, testing methods, TAT, etc.
- Maintain communication with the referral laboratory when the COOP is implemented

A Laboratory Submitter/Client Contact List and a Laboratory Vendor Contact List template are included in this toolkit.

L. Referral Testing Timeline Considerations

Consider developing a referral testing timeline in such cases where the mycobacteriology laboratory COOP must be activated due to laboratory closure. Timelines can be defined by hours, days, months, and are contingent upon time of repair for the laboratory and equipment as well as availability of trained mycobacteriology testing personnel. Any such timeline could be estimated with input from responsible official(s) and communicated to all partners involved, including:

- PHL leadership
- Mycobacteriology testing personnel
- · Submitters and clients
- TB Program
- Referral laboratory(s)
- Centers for Disease Control and Prevention (CDC)
- Association of Public Health Laboratories (APHL)

A Referral Testing Timeline table is included as part of the Mycobacteriology Laboratory COOP Template within this toolkit.

M. Mycobacteriology Laboratory Best Practices Considerations

Specific information regarding mycobacteriology laboratory best practice considerations for advanced preparation of the mycobacteriology laboratory for any type of ISE, when an ISE is planned or forecasted, and when a mycobacteriology COOP is activated or inactivated can be listed here.

Checklists for Advanced Preparation of ISEs, Planned or Forecasted ISEs, and Mycobacteriology COOP Activation and Inactivation are included in this toolkit and provide specific examples that may be helpful for mycobacteriology laboratories.

N. Annual Review of the Mycobacteriology Laboratory COOP

Mycobacteriology laboratory COOPs should be reviewed and updated annually. This is important even when an ISE has not occurred since changes to external partners or practices may have occurred. PHLs should also consider any suggestions or feedback given in recent after-action reports and update COOPs appropriately with these changes.

An After-Action Report Template is included in this toolkit.

Be sure to hold annual COOP reviews when laboratories are typically less impacted by work or before seasonally recurring ISEs. If an ISE occurs, then the mycobacteriology laboratory may want to consider reviewing their COOP sooner.

O. Mycobacteriology Laboratory COOP Training Exercises

The effectiveness of activating and operating a COOP depends on the readiness and competence of laboratory personnel. In addition to annual COOP reviews, PHLs and mycobacteriology supervisors should provide annual refresher COOP trainings for all new and existing personnel within the mycobacteriology laboratory. This is particularly important following major revisions or updates made to the laboratory's COOP. Readiness exercises or simulations should be performed to reinforce laboratory personnel roles and identify areas for improvement.

TEMPLATES

The templates in this section can be modified for local use and can be included in the mycobacteriology COOP.

- Mycobacteriology Laboratory COOP
- Laboratory Personnel Contact List
- Laboratory Submitter/Client Contact List
- Laboratory Vendor Contact List
- Referral Laboratory Identification Form
- Referral Specimen Test Requisition Form
- After-Action Report



MYCOBACTERIOLOGY LABORATORY COOP

A. Organization and Point(s) of Contact

Laboratory Name	
Department	
Point(s) of Contact and Contact Information	
Date Finalized	
Reviewed	

B. Introduction

Public health laboratories (PHLs) and the core testing services provided are vulnerable to external and internal unforeseen events as well as planned or tracked events. Most laboratory organizations have an overall continuity of operations plan (COOP) to ensure core services within the laboratory can be continued if an interruption of service event (ISE) occurs. ISEs may occur internally (i.e., facility issues such as disruptions in heating, ventilation, and air conditioning [HVAC], negative pressure, or biological safety cabinets [BSCs] and equipment maintenance issues) or due to external sources (i.e., hurricanes, tornadoes, winter/ice storms, wildfires, or pandemics). It is imperative that the mycobacteriology laboratory within the greater laboratory organization be prepared for ISEs by having a written mycobacteriology laboratory COOP. This COOP allows the laboratory to shift efficiently from its regular structure to a structure that enables timely continuation of services. The ability to make this rapid shift without delay is critical specifically for mycobacteriology laboratories regarding timely testing and result reporting.

C. Purpose

The purpose of this COOP is to document processes, procedures, and activities that must be completed within the mycobacteriology laboratory prior to, during, or after an ISE. This plan will allow the mycobacteriology laboratory to consider how best to efficiently resume services or plan for the referral of testing services.

D. Scope

The has a responsibility to provide testing services for submitters/clients with limited delays.

The testing involves specialized instrumentation, biosafety level (BSL)-2 and BSL-3 specific features, and electronic reporting systems which all must be available for testing to continue. This mycobacteriology laboratory COOP document will provide specific plans of action for time periods prior to, during, and after ISEs, responsible mycobacteriology personnel, and the availability of a referral testing plan, if applicable.

E. Objectives

- Recognize the importance of mycobacteriology testing services during an ISE
- Establish mycobacteriology laboratory testing plans for advanced preparation of ISEs, planned or forecasted ISEs, and mycobacteriology COOP activation and inactivation
- Identify mycobacteriology laboratory personnel responsible for leading COOP activities in the event of an ISE
- Implement plans for referral testing of mycobacteriology specimens, cultures, and isolates through formal agreements
- Detail communication strategies with submitters, clients, TB Program, and partners

F. Types of ISEs

Civil Disturbance	Other Natural Disaster
Earthquake	Other (Unspecified Event)
Electrical Power Failure	Pandemic
Equipment/Facility Maintenance	Reagents/Supplies Backordered or Shortage
Equipment Failure	Sequestration/Spending Cuts
Facility Issue	Terroristic Threat/Terrorism
Flooding	Testing Personnel Unavailable
Hazardous Materials	Tornado
Hurricane	Water Supply Issue
Infrastructure Damage	Wildfire
IT Systems Failure	Winter/Ice Storm
Large Scale Spills/Laboratory Decontamination	

G. Critical Functions of the Mycobacteriology Laboratory

The supports critical mycobacteriology testing for the . The laboratory is responsible for testing specimens and isolates submitted for tuberculosis/mycobacterial testing. Laboratory methods include specimen processing, acid-fast bacillus (AFB) smear, nucleic acid amplification testing (NAAT), culture growth isolation, identification of *Mycobacterium tuberculosis* complex (MTBC), drug susceptibility testing (DST) for anti-tuberculosis treatment, and submission for genotyping. These timely test results are pertinent for the patient and provider for treatment initiation and cure.

A visual testing algorithm/workflow diagram is attached.

H. Personnel and Responsibilities

In the event of an ISE, the responsible official(s) and mycobacteriology personnel should be named on the Laboratory Personnel Contact List.

A Laboratory Personnel Contact List template is attached.

Responsible individual(s) will communicate the status and mycobacteriology testing services plan with personnel, submitters, clients, TB Program, partners, and referral laboratory(s) (if applicable). This individual(s) will oversee the activities prior to, during, and after the ISE.

I. Critical Records and IT Infrastructure

The , in response to a potential ISE threat, will protect, save, and allow access to all testing protocols, specimen tracking documents, and patient test results. This will occur using an electronic system (i.e., laboratory information management system or laboratory management system) or a paper-based system. Uninterruptible power supply (UPS) systems will be used to backup data.

J. Critical Communications

Mycobacteriology laboratory supervisor or responsible officials will communicate with personnel, submitters, clients, TB Program, partners, and referral laboratory(s) (if applicable) through various methods including telephone, text, email, mail, and/or electronic systems (e.g., Ready OP, etc.). These channels should be established prior to any ISE. The will use established contact lists to communicate critical communications to the above listed individuals.

A Laboratory Submitter/Client Contact List is attached.

A Laboratory Vendor Contact List is attached.

K. Referral Laboratory

In the event the Ample A

reporting, and turnaround time (TAT) of results will be discussed and agreed upon. This MOU or

MOA agreement may be attached as an appendix, or a Referral Laboratory Identification Form is included to assist in preparing an MOU or MOA.

A Referral Laboratory Identification Form is attached.

A Referral Specimen Test Requisition Form is attached.

L. Referral Testing Timeline Considerations

The	has defined a timeline for m	ycobacteriology testing
referral practices if an ISE were to occur.		

24-48 hours	
3-5 days	
6-14 days	
>14 days	
≥1 month	
≥3 months	
≥6 months	
Additional time periods	

M. Best Practice Considerations

Advanced preparation of the mycobacteriology laboratory for any type of ISE:

The can prepare the mycobacteriology laboratory for ISEs by taking the following actions and ensuring the specifics of items are included in their mycobacteriology laboratory COOP:

Review Checklist: Advanced Preparation of the Mycobacteriology Laboratory for Any Type of ISE.

Considerations when an ISE is planned or forecasted:

» If the were to learn of a planned ISE or becomes aware of an impending or forecasted ISE, the following actions should take place:

Review Checklist: Considerations When an ISE is Planned or Forecasted.

Considerations when a mycobacteriology COOP is activated:

> When the experiences an ISE and the mycobacteriology COOP is activated, the following actions should take place:

Review Checklist: Considerations When a Mycobacteriology COOP is Activated.

Considerations when a mycobacteriology COOP is inactivated:

After the experiences an ISE and the mycobacteriology COOP is inactivated, the following actions should take place:

Review Checklist: Considerations After a Mycobacteriology COOP is Inactivated.

N. Annual Review of the Mycobacteriology Laboratory COOP

The will annually review and update the mycobacteriology laboratory COOP. The should consider any suggestions or feedback given in after-action reports from various internal personnel, submitters, referral laboratories, and external partners.

An After-Action Report is attached.

O. Mycobacteriology Laboratory COOP Training and Exercises:

The will offer training opportunities for preparedness of ISEs. These may be part of training offered by the or specific to the . Training topics will be offered and will include topics pertaining to . In addition to training, the will hold training exercises (e.g., seminars, tabletop or readiness exercises, or simulations) to familiarize mycobacteriology personnel with ISE preparedness and continuity of operations plans. Training will include the roles of mycobacteriology personnel, communication plans, testing processes if an ISE were to occur, referral laboratory testing, , etc.

LABORATORY PERSONNEL CONTACT LIST

Last Name	First Name	Position Title	Responsibilities	Office Phone	Cell Phone	Home Phone	Email	Home Address

LABORATORY SUBMITTER/CLIENT CONTACT LIST

Submitter/Client	Address/Location	Point of Contact	Title	Office Phone	Cell Phone	Email

LABORATORY VENDOR CONTACT LIST

Supply/Reagent/ Media	Vendor Name	Point of Contact	Address/Location	Office Phone	Cell Phone	Email

REFERRAL LABORATORY IDENTIFICATION FORM

The purpose of this Referral Laboratory Identification Form is to identify primary, secondary, and

tertia	ary referral laboratories fo	or the ,
if the	-	experiences an Interruption of Service Event (ISE).
		ogy specimens, cultures, or isolates will be tested at the specified referral
	ratory through a	. Through this
_	·	y, testing algorithm, costs, specimen requirements, transport means,
resu	lt reporting, and turnarou	nd time (TAT) of results will be outlined and agreed upon.
A. P	rimary Referral Laborato	ory
	Laboratory Name	
	Point(s) of Contact & Contact Information	
	Written MOU or MOA	
_		
	Expiration Date	
	Overall Agreement	
	Agreed Upon Elements of	Communication
	Agreed Upon Elements of	Specimen Transport
	Agreed Upon Elements of	Testing
_		
	Agreed Upon Elements of	Reporting
_		
	Other Considerations	

B. Secondary Referral Laboratory

Laboratory Name	
Point(s) of Contact & Contact Information	
Written MOU or MOA	
Expiration Date	
Overall Agreement	
Agreed Upon Elements of 0	Communication
Agreed Upon Elements of S	Specimen Transport
Agreed Upon Elements of	[esting
Agreed Upon Elements of I	Reporting
Other Considerations	

C. Tertiary Referral Laboratory

Laboratory Name	
Point(s) of Contact & Contact Information	
Written MOU or MOA	
Expiration Date	
Overall Agreement	
Agreed Upon Elements of	Communication
Agreed Upon Elements of S	Specimen Transport
Agreed Upon Elements of	Testing Testing
Agreed Upon Elements of I	Reporting
Other Considerations	

D. Applicable Personnel

I have read and understood this COOP Referral Laboratory Identification Form and hereby attest that the information provided here was provided on to identify an appropriate referral laboratory if

experiences an ISE. This information will be updated one year following the date below to ensure accurate information and cooperation with primary, secondary, and tertiary referral laboratories.

Name	Title	Signature	Date	
port Approval	·	·	·	
Approved by:			Date:	
Approved by:			Date:	
Approved by:			Date:	

REFERRAL SPECIMEN TEST REQUISITION FORM

Submitting/Referring Laboratory Information	Referral/Recipient Laboratory Information		
Facility Name:	Facility Name:		
Street Address:	Street Address:		
City, State, Zip:	City, State, Zip:		
Facility Phone:	Facility Phone:		
Facility Fax:	Facility Fax:		
Submitter/Referring Laboratory Specimen Information	Referral/Recipient Laboratory Specimen Information		
Specimen ID#:	Date Received at Referral Lab:		
Date Collected:	Time Received at Referral Lab:		
Time Collected:	Referral Lab Specimen Accession#:		
Date Received:	Visible Contamination? Yes No		
Time Received:			
Visible Contamination? Yes No			
Additional Category of Information			

Patient Information	Specimen Type	
Loot Name	Blood	Sputum
Last Name: First Name:	Body Fluid	Stool *not ideal specimen to test for TB
Date of Birth:	Bronchial Wash	Tissue
Age:	Bronchoalveolar Lavage (BAL)	Urine
Street Address:	Gastric Aspirate	Wound
	Isolate	Other
City, State, Zip:	-	
Phone:	_	

Gender and Race/Ethnicity		Patient History/Clinical Information		
Gender:	Male	Female	Clinical Diagnosis: _	
	Non-Binary	Other	Date of Onset:	
Race/Ethnicity:	Asian	Unknown		Surveillance
	African American	White		Disease Determination
	Hispanic/Latino	Native Hawaiian/ Pacific Islander	Date of	
	Native American	Other	Death: _	

Mycobacteriology Test Requested

AFB Isolate for Identification

TB Genotyping Send Out

TB MDDR Send Out

TB MDDR Send Out

TB Pyrosequencing

TB Targeted Next Generation Sequencing/
Whole Genome Sequencing

TB Drug Susceptibility

Other

TB Drug Susceptibility — 2nd Line

AFTER-ACTION REPORT

A. Purpose

The pu	urpose of this Afte	r-Action Report is to describe the	
on	, at the	and	

Response to this Interruption of Service Event (ISE), challenges and/or obstacles encountered while responding to this ISE, and recommended changes to the mycobacteriology laboratory COOP.

B. Select the Type(s) of ISE(s) that Affected the Public Health Laboratory (PHL):

Civil Disturbance	Other Natural Disaster
Earthquake	Other (Unspecified Event)
Electrical Power Failure	Pandemic
Equipment/Facility Maintenance	Reagents/Supplies Backordered or Shortage
Equipment Failure	Sequestration/Spending Cuts
Facility Issue	Terroristic Threat/Terrorism
Flooding	Testing Personnel Unavailable
Hazardous Materials	Tornado
Hurricane	Water Supply Issue
Infrastructure	Wildfire
IT Systems Failure	Winter/Ice Storm
Large Scale Spills/Laboratory Decontamination	
	I .

C. Describe the ISE that affected the PHL. Be sure to include relevant information about the type of ISE (e.g., natural disaster, facility/equipment failures, etc.), in what way(s) the ISE impacted mycobacteriology laboratory testing, how long the ISE affected the laboratory, and any other information to describe this event.

D. Describe how the mycobacteriology labora	tory responded to the ISE described above.
Be sure to include relevant information ab	out pauses in normal laboratory operations,
specimen referrals, specimen/culture/isola	ate workflow or testing algorithm modifications,
communications to external partners/refer	ral laboratory, or any other adjustments the
laboratory had to make in response to the	ISE.

E. Dsescribe any challenges or obstacles encountered by the mycobacteriology laboratory because of the ISE or modifications to the mycobacteriology laboratory's normal testing process. These challenges may include IT/network problems, personnel challenges, supply/reagent shortages, equipment failures, communication lapses, and any other challenges experienced by the laboratory during the ISE response efforts.

F. Describe any recommended changes to the mycobacteriology laboratory COOP or lessons learned resulting from the experiences described in this report. Recommendations should include those from internal partners (e.g., laboratory leadership, laboratory testing personnel, laboratory support staff, etc.) and external partners (e.g., specimen/isolate submitters/clients, COOP referral laboratories [if applicable], TB Program, etc.).

G. I have read and understood this After-Action Report and hereby attest that the information reported here accurately describes the ISE that affected the . Further, I have provided feedback to the Mycobacteriology Unit Supervisor to support our laboratory's efforts to update the COOP and to minimize challenges/obstacles we may encounter during the next ISE.

Name	Title	Signature	Date	
eport Approval				
Approved by:			Date:	
Approved by:			Date:	
Approved by:			Date:	
			1	

CHECKLISTS

The checklists in this section can be modified for local use and can be printed or referred to for quick access.

- Advanced Preparation of the Mycobacteriology Laboratory for Any Type of ISE
- Considerations When an ISE is Planned or Forecasted
- Considerations When a Mycobacteriology COOP is Activated
- Considerations After a Mycobacteriology COOP is Inactivated



Advanced Preparation of the Mycobacteriology Laboratory for Any Type of ISE

The can prepare the mycobacteriology laboratory for ISEs by taking the following actions and ensuring the specifics of items are included in their mycobacteriology laboratory COOP:

Topic	Checklist Item	Additional Considerations
Laboratory Preparati	on	
Prepare facilities, mycobacteriology	Ensure availability of a generator	Install mitigation measures for anticipated ISEs (e.g., flood clearance pallets, bolting
laboratory space(s), and equipment	Have a back-up plan for each piece of equipment in the event of equipment failure or damage	bookshelves to walls, secure objects from falling, etc.)
Personnel Support		
Personnel support	Create/maintain mycobacteriology personnel contact list information	Assess mycobacteriology personnel proximity to laboratory and, if allowable, willingness to travel to the laboratory during and/or after ISE
	Cross-train personnel in all aspects of mycobacteriology (if possible)	Provide COOP refresher training annually when PHL/mycobacteriology laboratory typically less impacted by work or prior to seasonally recurring ISEs
	Provide COOP training to new and existing laboratory personnel annually	Hold annual COOP review by managemen
	Schedule and execute readiness exercises/drills to reinforce training modules	
Testing Status		
	Assess anticipated ISE and determine which specific events may result in temporary testing suspension, laboratory closure, or potential referral of specimens/cultures/isolates	Discuss the threshold of time in which it is acceptable for specimens/cultures/ isolates to remain in the laboratory (e.g., in refrigerator, incubator, BACTEC™ MGIT™ 320/960, etc.)
Evaluate anticipated ISE and ability to perform mycobacteriology testing	Determine if pending testing should be completed before a laboratory closure	Determine if a laboratorian is willing and/ or able to monitor the specimens/cultures/ isolates due to their proximity to the laboratory
	Create a plan for cultures already inoculated and incubating	Determine when the mycobacteriology laboratory will begin to consider referral of testing of specimens/cultures/isolates
	Consider a timeline for mycobacteriology testing according to how long the mycobacteriology laboratory may be unable to perform testing	

Торіс	Checklist Item	Additional Considerations
Referral Laboratory		
	Speak with the referral laboratory established through MOU or MOA and review specifics of referral mycobacteriology testing	Select a primary and secondary referral laboratory and identify a tertiary, or backup, referral laboratory to send specimens/ cultures/isolates to if the primary or secondary referral laboratory is impacted by the ISE or is unable to test additional specimens/cultures/isolates at the time requested
	Discuss the cost of referral testing and how to cover these costs	Compare testing methods, algorithms, and turnaround times with the referral laboratory
Coordinate with a referral laboratory	Determine referral laboratory's workload capacity, personnel, instrumentation, and ability to perform additional testing	Determine the specimen/patient information required for the specimen, culture, or isolate to be tested at the referral laboratory; laboratories may have specimen/patient information requirements that if not completed, submission will be rejected
	Determine how specimen test requisition will be conducted and what forms will be used	Determine a submission tracking process
	Determine if the referral laboratory can accept cultures (i.e., inoculated/ incubating media)	Decide how test results will be reported to the submitter
	Determine how specimens/cultures/ isolates, if applicable, will be transported to the referral laboratory	
	Decide how test results will be reported to the submitter	
	Maintain communication	
Laboratory Supplies and	Reagents	
Assess status of supplies	Create/maintain a list of vendor contact information to confirm product shipments and potential product backorders or supply shortages	ldentify alternative supplies, reagents, and consumables available to the laboratory if supply chains are interrupted
and reagents	Create/maintain a back-up plan for potential product backorders or supply shortages	
Communication		
Contacting submitters and clients	Create/maintain submitter and client contact list information	Identify possible contingencies/ strategies for communicating results if IT infrastructure is lost or impeded due to the ISE
	Review the current list of TB Program staff and their contact information	

Considerations When an ISE is Planned or Forecasted

If the were to learn of a planned ISE or becomes aware of an impending or forecasted ISE, the following actions should take place:

Topic	Checklist Item	Additional Considerations	
Laboratory Preparation			
	Complete an immediate assessment of the physical mycobacteriology laboratory space(s) to ensure personnel, specimens/ cultures/isolates, and equipment/ instruments will be safe and secure during the ISE	Prepare for equipment failures; have a back-up plan for each piece of critical equipment in case damage occurs	
	Secure equipment to prevent falling from countertops, shelves, etc.	General reasons for COOP activation include:	
A	Cover equipment for protection from leaks or debris	PHL has implemented COOP affecting all test sections	
Assess facilities, mycobacteriology laboratory space(s), and equipment	Move items off the floor	Equipment has sustained damage and must be repaired or serviced prior to operation	
	Ensure availability of a generator	ISE has impaired the ability for mycobacteriology testing personnel to perform normal	
	Secure and ensure biosafety and biosecurity of specimens/cultures/isolates	testing activities (e.g., travel to mycobacteriology laboratory is not possible, personnel sustained	
	Determine if the mycobacteriology laboratory COOP should be activated	injuries due to the ISE, laboratory does not have electricity or water, unable to maintain negative pressure in BSL-3 laboratory, etc.)	
Personnel Support			
Personnel support	Ensure communication with personnel to assess safety when an ISE occurs during work hours and after	Assess mycobacteriology personnel proximity to laboratory and, if allowable, willingness to travel to the laboratory during and/or after ISE	
Testing Status			
Evaluate the ISE and ability to perform mycobacteriology testing	Assess the anticipated ISE and estimated (with input from responsible official) amount of time the mycobacteriology laboratory may not be available to preform testing given a variety of circumstances	Establish the threshold of time in whi it is acceptable for specimens/culture isolates to remain in the laboratory (e in refrigerator, incubator, BACTEC™ MGIT™ 320/960, etc.)	

	Determine if the mycobacteriology laboratory will be able to accept specimens/cultures/isolates for testing	Identify a laboratorian that is willing and/or able to monitor the specimens/ cultures/isolates due to their proximity to the laboratory
Evaluate the ISE	Determine if pending testing could be completed before a laboratory closure	Determine when the mycobacteriology laboratory will begin to consider referral of testing of specimens/cultures/isolates
and ability to perform mycobacteriology testing	Inventory cultures already inoculating and incubating to determine if testing can be completed in-house or should be referred	
	Finalize a timeline for mycobacteriology testing according to how long the mycobacteriology laboratory may be unable to perform testing	
Laboratory Supplies and R	eagents	
Assess status of supplies and reagents	Determine the status of supplies in transit and possible delays caused by ISE	Ensure alternative supplies, reagents, and consumables are available to the mycobacteriology laboratory if supply chains are interrupted
supplies and reagents	Confirm your backup plan for product backorders or supply shortages	
Communication		
	Communicate with submitters, clients, and partners of any changes to testing or possible laboratory closures and provide an estimated (with input from responsible official) timeframe	Confirm contingencies/strategies for communicating results if IT infrastructure is lost or impeded due to the ISE
	Determine the status of each submitter regarding specimen submission and implement a plan for each regarding future specimen/isolate testing	
Contact submitters, clients, TB Program,	Track any specimens/isolates in route to the mycobacteriology laboratory	
and other partners	Communicate with TB Program of decisions made by the PHL/ mycobacteriology laboratory so they can communicate information to clinics and other submitters/clients	
	Contact partners with ISE status updates (e.g., CDC, APHL, etc.)	
	Discuss with submitters, clients, and partners that the TAT of test results may be increased due to referral testing	

Referral Laboratory			
Coordinate with a referral laboratory	Determine the possible length of the closure and necessity for referring mycobacteriology testing to another laboratory Refer to the mycobacteriology laboratory's MOU or MOA		
	Communicate with the referral laboratory established through MOU or MOA and review specifics or referral mycobacteriology testing		
	Determine specifics for specimen test requisition form use and specimen transport		
	Finalize with the referral laboratory how test results will be reported		

Considerations When a Mycobacteriology COOP is Activated

When the experiences an ISE and the mycobacteriology COOP is activated, the following actions should take place:

Topic	Checklist Item	Additional Considerations	
Laboratory Preparation			
	Assess the laboratory's operational capacity; check the structural integrity of BSL-3 testing spaces to ensure proper safety protocols, containment, and maintained negative pressure, and mycobacteriology testing requirement (e.g., BSCs, centrifuges, MGIT instruments, etc.) are fully operational and not damaged	I I	
Assess mycobacteriology laboratory operational capacity	Once the mycobacteriology COOP is activated and normal operation is not possible, responsible officials (e.g., technical supervisor, manager, laboratory director, etc.) should estimate a timeline for laboratory closure, referral of specimens/cultures/isolates for testing and/or resuming testing services, if known	I I	
	Secure and ensure biosafety and biosecurity of specimens/cultures/isolates		
Personnel Support			
Personnel support	Ensure communication to determine personnel safety when an ISE occurs during and after work hours	Communicate local hazards or PHL closures to laboratory personnel	
	Verify mycobacteriology personnel proximity to laboratory and, if allowable, willingness to travel to the laboratory during and/or after ISE	Establish periodic check-ins to communicate status and any update:	

Testing Status					
			Follow the timeline for mycobacteriology testing according to how long the laboratory may be unable to perform testing:		
		Determine if pending testing should be completed before a laboratory closure			Apply the threshold of time in which it is acceptable for specimens/cultures/isolates to remain in the laboratory (e.g., in refrigerator, incubator, BACTEC™ MGIT™ 320/960, etc.)
Determine mycobacteriology laboratory testing status		Execute the plan for cultures already inoculated and incubating			Communicate with the laboratorian that is willing and/ or able to monitor specimens/ cultures/isolates due to their proximity to the laboratory
					Implement plan for referral of testing of specimens/cultures/ isolates, as applicable

Referral Laboratory	
	Activate formal MOU and MOA referral testing agreements and discuss anticipated closure timeline Provide submitters with specimen submission and test ordering/referral laboratory instructions (if applicable)
	Communicate with the referral laboratory to ensure they have not been affected by the same ISE and discuss specimen/culture/isolate referral Follow DOT/IATA shipping requirements when sending mycobacteriology specimens/cultures/ isolates to referral laboratory (if applicable)
Communicate with referral laboratory	Identify local courier or shippers (e.g., FedEx, UPS, etc.) available to transport specimens/cultures/ isolates to referral laboratories and following appropriate specimen packaging, shipping, and cold chain transport requirements Communicate frequently with referral laboratory to ensure results reporting meets appropriate TAT as much as possible
	Determine if specimens/isolates will be shipped directly from the submitter to the referral laboratory, shipped from the referring PHL to the referral laboratory, or if another process will be used Establish periodic check-in calls to communicate status and any updates
	Discuss tracking of referred test volume and completion of tests by the referral laboratory
	Notify referral laboratory of any specimens/cultures/isolates that will be immediately referred by the PHL for testing
	Use the agreed upon specimen test requisition form
	Establish result reporting processes with the referral laboratory and submitters of specimens/isolates based on availability of LIS/LIMS interfaces, internet service, or need for use of secure fax. NOTE: it is important to verify the receipt of test results with submitters after implementation of a COOP reporting process to ensure that results are being transmitted effectively

Status of supplies and reagents	Determine the status of supplies in transit and possible delays caused by ISE	
Communication		
Communicate with submitters, clients, TB Program, and other partners	Communicate with the referral laboratory to ensure they have not been affected by the same ISE and discuss specimen/culture/isolate referral	Establish periodic check-ins to communicate status and any updates
	Contact the local/state TB Program to provide an assessment of the affected PHL's/mycobacteriology laboratory's capacity	Encourage open lines of communication with submitters during referral period (if applicable)
	Communicate with submitters, clients, and partners of any changes to testing or laboratory closures and provide an estimated (with input from responsible official) timeframe	Resubmit supply orders impacted by ISE or cancel pending orders if PHL cannot receive supplies or store appropriately
	Track any specimens/isolates or supply shipments in route to the mycobacteriology laboratory	
	Contact partners with ISE and COOP activation status updates or assistance requests (e.g., CDC, APHL, etc.)	
	Discuss with submitters, clients, and partners that the TAT of test results may be increased due to referral testing	

Considerations After a Mycobacteriology COOP is Inactivated

After the experiences an ISE and the mycobacteriology COOP is inactivated, the following actions should take place:

Topic	Checklist Item Additional Considerations	
Communication		
Communicate with submitters, clients, TB Program, and other partners	Communicate with mycobacteriology laboratory personnel on plans for re- opening of the laboratory	Notification to submitters should describe which mycobacteriology tests are available (e.g., full testing menu or only some tests) and the earliest date specimens/isolates can be received by the PHL
	Notify the referral laboratory when the mycobacteriology laboratory will resume normal operations and referral specimens/cultures/isolates will no longer be sent	Submitter notification may also serve as an opportunity to check in with submitter and clients to ensure that tests reports have been received for any referred specimens/isolates
	Allow the referral laboratory to finalize any/all remaining test reports for referred specimens/cultures/isolates	Coordinate with fiscal services to discuss compensation for referral testing services performed (e.g., contracted funds, supplies, reagents, etc.), as applicable
	Notify submitters and clients when the PHL can resume receiving specimens/ isolates for mycobacteriology testing	
	Notify the TB Program and any other external partners (e.g., CDC/APHL, etc. when the PHL and mycobacteriology laboratory will resume normal testing operations	
Personnel Support		
Personnel support	Provide COOP training to new and existing laboratory personnel annually	Provide refresher training annually when PHL/mycobacteriology laboratory typically less impacted by work or prior to seasonally recurring ISEs
	Schedule and execute readiness exercises/drills to reinforce training modules	
Post-ISE Feedback		
Seek feedback after the ISE		Organize "hot wash" debriefs or request informal feedback during and immediately following an ISE
	Provide COOP training to new and existing laboratory personnel annually	Schedule time shortly after the mycobacteriology laboratory returns to normal operations for personnel to provide feedback for the after-action report (i.e., gather feedback from partners using surveys, emails, or phone calls)

After Action-Reports		
	Prepare after-action reports to identify areas for improvement, lessons learned, and incorporate feedback from laboratory personnel and external partners including submitters and the jurisdictional TB Program. After-action reports should include:	Integrate necessary changes identified in after-action report
	Detailed descriptions of the ISE	Update any changes to referral laboratory mycobacteriology testing algorithm or reporting practices
	How the ISE impacted mycobacteriology testing services	Incorporate personnel, submitter, client, and partner feedback collected following ISE
Prepare an after-action report and update mycobacteriology	Duration mycobacteriology testing was impacted	
laboratory COOP as necessary	How the PHL/Mycobacteriology laboratory responded to the ISE	
	Workload volume and TATs of the referral laboratory, as applicable	
	Successes and challenges associated with the specimen/ culture/isolate referral, as applicable	
	Challenges and obstacles encountered by the PHL/ mycobacteriology laboratory	
	Recommend changes to the COOP based on ISE experiences	
After-Action to the Mycob	acteriology Laboratory COOP	
Update the mycobacteriology laboratory COOP	Incorporate personnel, submitter, client, and partner feedback collected in the after-action report into an updated mycobacteriology laboratory COOP	Update any changes to referral laboratory mycobacteriology testing algorithm or reporting practices

RESOURCES

COOP resources and templates exist that can be utilized to assist in the development of a COOP for a laboratory/organization. Helpful resources include:

- > CDC Laboratory Continuity of Operations (COOP) Planning Course. http://www.cdc.gov/labtraining
- > Guidelines for the Public Health Laboratory Continuity of Operations Plan (COOP). 2021. Association of Public Health Laboratories. https://www.aphl.org/programs/preparedness/ Pages/default.aspx,

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CONTRIBUTORS

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- > Kentucky Department of Public Health, Division of Laboratory Services
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