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PURPOSE:

Establish a procedure to discover and manage missing specimens in a timely manner.

SCOPE:

Essential to the management of missing specimens is timely awareness of the possible loss of a sample. Each testing department is expected to manage orders and pending work lists specific to their respective departments.

Processing monitors the Unreceived Pending list daily to avoid long delays before recognizing a specimen is missing.

This procedure establishes guidelines for the Processing Department to expediently discover and search for missing specimens and defines further steps to take in order to escalate the process as needed in accordance with the general Laboratory Policy titled “Missing Specimen Escalation Policy”.

RESPONSIBILITY:

The Medical or Section Director is responsible for ensuring that the procedure is in compliance with CAP and CLIA regulations. The Director must review and approve this procedure at appropriate intervals. The Medical Director may delegate some of the responsibilities to other CLIA/CAP qualified personnel.

The Processing Supervisor/Manager will have the overall responsibility for implementing this procedure. The supervisor/manager is responsible for ensuring that the procedure is followed accurately and that competency documentation is appropriate.

All processors performing this procedure are required to have appropriate training and competency approved. They are responsible for reading, understanding and competently performing this procedure without deviation.

DEFINITIONS:

Man Overboard - is the common terminology used across BBPL. The terminology is designed to be easily recognizable and should direct all personnel to react immediately.

First tier alert - Irreplaceable Specimen – is any specimen where it would be impossible, or very difficult to obtain another sample. Examples are tissue (histology), cytology, kidney stones, CSF, body fluids, bone marrow, genetic specimens, paternity specimens, and blood cultures.

Second tier alert - Replaceable Specimen – is any specimen where - although inconvenient - another sample can be obtained. Examples are serum, plasma, whole blood, and urine.


Lost at Sea – is the culmination of a full *Man Overboard* investigation concluding that a specimen was received by BBPL and is a lost. Testing has not been and can't be completed. The client must be informed of the lost specimen.

EQUIPMENT/SUPPLIES:

Lablink Access
Antrim Access
Key to Large Shred Bin
Instrument Manager Access
Manager/Coordinator access to email
GML Access

PROCEDURE:

1. The following Processing staff members are responsible for management of the Unreceived Pending List, calling up and reviewing the list at the times designated below for discovery of a potential *Man Overboard* and for immediately informing the appropriate Processing Coordinator, Supervisor, Manager, House Supervisor or lead/senior technologist in Core Lab when it appears that a specimen is missing:
 - **Monday-Friday - Processing Coordinator/Manager monitor specimens unreceived for >24 hours from order**
 - **Weekends- Processor monitors specimens unreceived for >24 hours from order**
 - **Send outs (weekday/weekend) – Monitors queue list and pending to track missing specimens**
2. All Processors are responsible for conducting a daily search of their area for any unidentified specimens, missing specimens, or unidentified packages
3. The Processing coordinator, manager, or supervisor on shift will initiate the MOB and coordinate with all departments regarding the missing specimen.
4. The Processing coordinator, manager or supervisor on shift is responsible for initiating the Man Overboard Alert and all email communication following per this procedure.
 - **NOTE:** Extensive resources are committed to a *Man Overboard*. A thorough investigation and accurate determination of events must be completed before triggering an alert.
5. **The Processing supervisor or Manager on shift is responsible for following through with the process, leading and advising staff, and logging the event in the QA system with the appropriate CAPA assigned.**

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INITIAL STEPS WHEN SUSPECTED MISSING SPECIMEN

1. Often, another department will begin the process by bringing an issue of a missing specimen to Processing.
 - a. A pending order for a test (department or testing area) is confirmed and no specimen found in the department or testing area.
2. Confirm that a specimen was received in the Processing Department with the requisition/order. This includes confirming the appropriate specimen type.
 - a. Check bags from that route
 - b. Check pod shred bins
 - c. Check all pods/areas specimens might be processed
 - d. Check centrifuges in Core Lab and Processing
 - e. Check Exception bin
 - f. Check Extra bin
3. The testing department and the Processing Department will coordinate with each other during the investigation
 - a. Associated paperwork (requisition) and any inquiry notes should be reviewed.
 - b. Immediate and complete search of both the testing department or area and the Processing department will be implemented and completed.
4. Many specimens are managed by Modular Pre-Analytics (MPA) in the Core Laboratory and subsequently archived.
 - a. Check to make sure the specimen has not been archived either inadvertently, as an “extra” specimen, or following testing.
5. If the search is non-productive and a loss is still presumed the first *Man Overboard* alert must be triggered.


FIRST MAN OVERBOARD ALERT:

1. Inform the Manager during the day shift and the House Supervisor during the evening and night shifts. On the weekends, call the Processing Manager
2. Review all paperwork and manifests.
3. Secure and suspend all trash pickup (notify facilities management). No trash pickup should occur within the facility or externally until these sources can be positively eliminated as a potential discovery point.
4. Notify the Executive team by email using the **ManOverboard** email group. Include that
 - a. *Man Overboard* is initiated
 - b. Date and time initiated
 - c. Departments involved (including any potentially impacted)
 - d. Accession number
 - e. Patient name
 - f. Specimen(s) type (first tier or second tier)
 - g. Client
 - h. Also confirm that Processing *Man Overboard* SOP is being followed.
5. Notify supervisors and managers by email using the **CentralMOB** email group. Include
 - a. *Man Overboard* is initiated
 - b. Date and time initiated
 - c. Departments involved (including any potentially impacted)
 - d. Accession number
 - e. Patient name
 - f. Specimen(s) type (first tier or second tier)
 - g. Client
 - h. Also confirm that Processing *Man Overboard* SOP is being followed.

6. Notify Client Services by phone with the information listed in 4. Client Services will be responsible for calling specific departments to confirm the department has been alerted to the *Man Overboard*.
7. Search Processing department thoroughly again. Include
 - a. Extra bin
 - b. Exception bin
 - c. Sendout area
 - d. Pods
 - e. Floors
 - f. Under counters and desks
 - g. Under shelving
 - h. Pod shred bins
 - i. Unlock and check large shred bin
8. The Executive team must receive a status update **within two hours**, with updates via email for two full shifts (16 hours) **from the time the specimen arrived** in the building.
 - a. If the problem is resolved sooner an “**All Clear**” (cancellation) can be issued. A significant commitment of resources occurs when the *Man Overboard* alert is triggered. Communication is essential to insure resources are not used unnecessarily.

ESCALATION OF FIRST TIER *MAN OVERBOARD*

1. A first tier *Man Overboard* requires each department, upon completion of a department search, to make available a specialist or detective.
 - a. This person should be someone with significant BBPL experience.
 - b. Several detectives working together greatly improve the likelihood of a quick resolution.
 - c. The supervisor or manager of the department triggering the *Man Overboard* alert should coordinate the detectives and include progress in email updates provided to the Executive team.

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CONTINUITY OF COMMUNICATION

1. There should never be a communication dark period during a *Man Overboard*.
2. Every department is required to provide clear communication to staff during a *Man Overboard* event. This would include shift change.
3. Should a department have operational hours less than two shifts the supervisor or manager should coordinate with the supervisor or manager of the department issuing the *Man Overboard* alert before end of shift.

EXTERNAL NOTIFICATIONS OF POTENTIAL LOSS

1. Situations may arise when a client of BBPL contacts Client Services to request the status of testing that should be complete. This may be the first notification that a specimen was lost (or not received).
2. Client Services (or any other BBPL department receiving the contact) should alert the testing department and the Processing department .
3. The investigation must include positive confirmation that an order and a requisition were received.
4. Thoroughly search Processing and testing departments and investigate the specimen trail.
5. If following this investigation a lost specimen is still presumed the *Man Overboard* alert should be triggered.
6. Communicate essential information once the alert is triggered. This should include how many hours or days since the order received, specimen type (tier one or tier two), and any other information relevant to the order and specimen.

CLIENT NOTIFICATION

If the *Man Overboard* investigation concludes with *Lost at Sea* the Client Services department will coordinate with the account representative (Sales), sales director, director or manager of the testing department and if necessary a pathologist to determine how the client will be notified.

DOCUMENTATION

A root cause analysis will be performed for each event. The event will be logged in the QA system with the appropriate CAPA assigned. The Processing Manager is responsible for this task.

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REFERENCES : NA

RELATED DOCUMENTS:

Missing Specimen Escalation Policy (Man Overboard) Version 1.2 Regulatory Compliance Department
Laboratory Policies Manual

APPENDICES: NA