 Regulatory Compliance	Title: Missing Specimen Escalation Policy (Man Overboard)	
	SOP: Laboratory Policies	Version: 1.2
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Approved by:

Medical Director

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_____ (Name) _____ (Signature)

_____ (Initials) _____ (Date)

Section Director


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_____ (Name) _____ (Signature)

_____ (Initials) _____ (Date)

Revision Record

Revision No.	Date	Responsible Person	Description of Change
1	7/26/2017	wht	Changed email group names, added Client Services responsibility, modified "two full shifts", further defined irreplaceable specimens.
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Archival Date:	Department Supervisor/Manager :
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Biennial Review

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Purpose

Establish a policy to provide direction to manage missing specimens at BBPL.

Scope

This policy establishes guidelines for escalating the management of missing specimens. There are two distinct tiers of missing specimens. The first tier represents certain critical, irreplaceable specimens. Additionally the presumption of a large number of missing specimens falls under the first tier (i.e. an entire bag / volume of specimens from a single customer). The second tier represents replaceable specimens.


Responsibility

- Each department is responsible for developing a department-specific SOP. The SOP must define search protocols appropriate to the department, including detailed instructions.
- Supervisors and managers are the front line of notification. You are expected to communicate the contents of the notification to your staff immediately.
- Everyone should conduct a quick search of their area for any unidentified specimens or packages. Should the search prove to be unsuccessful, all staff should be reminded of the significance of the event, and should continue to look. Question everything.
- Extensive resources are committed to a *Man Overboard*. A thorough investigation and accurate determination of events must be completed before triggering an alert.

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.

Irreplaceable Specimen – is any specimen where it would be impossible, or very difficult to obtain another sample. Tissue (histology), cytology/MDX (fine needle aspirate, vaginal swab) , kidney stones, CSF, body fluids, bone marrow, genetic specimens, paternity specimens, and blood cultures are irreplaceable specimens .

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Replaceable Specimen – is any specimen where - although inconvenient - another sample can be obtained. Serum, plasma, whole blood, stool and urine are replaceable specimens.

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.

Process


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. Pending work lists should be checked frequently to avoid long delays before recognizing a specimen is missing. Each department will set the interval to check the pending list and be responsible for maintaining that frequency.

Several steps must be taken before triggering the *Man Overboard* alert.

1. 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 BBPL Processing Department with the requisition/order. This includes confirming the appropriate specimen type.
3. The testing department and the Processing Department will coordinate with each other during the investigation. Associated paperwork (requisition) and any inquiry notes should be reviewed. 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. 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 your immediate supervisor.
2. Review all paperwork and manifests.

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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 *Man Overboard* is initiated, time initiated, departments involved, specimen(s) type (first tier or second tier) and client. Also confirm that department *Man Overboard* SOP is being followed.
5. Notify supervisors and managers by email using the **CentralMOB** email group. Include information listed in 4. 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*.

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. 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*: A first tier *Man Overboard* requires each department, upon completion of a department search, to make available a specialist or detective. This person should be someone with significant BBPL experience. Several detectives working together greatly improve the likelihood of a quick resolution. 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.

Continuity of communication: There should never be a communication dark period during a *Man Overboard*. Every department is required to provide clear communication to staff during a *Man Overboard* event. This would include shift change. 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

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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).

- Client Services (or any other BBPL department receiving the contact) should alert the testing department and the Processing department.
- The investigation must include positive confirmation that an order and a requisition were received.
- Thoroughly search Processing and testing departments and investigate the specimen trail.
- If following this investigation a lost specimen is still presumed the *Man Overboard* alert should be triggered.
- 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.

References

NA