HAZARD REPORTS AND SAFETY ALERTS

1. Site Applicability

VCH, FHA, PHC, PHSA

2. Purpose

2.1.1 Procedure Objective: Risk Management – (CESOP, Objective 7.9):

- To minimize device-related risk to patients and staff and on the financial, physical resources and reputation of the organization.

2.1.2 LMBME interpretation of Policy Objective **2.1.1**:

- To minimize device-related risk to:
  - Staff of LMBME.
  - Patients and staff of related groups.
  - The financial and physical resources of LMBME.
  - The reputation of LMBME.

2.1.3 **Procedure Guideline:** Hazard Reports and Safety Alerts – (CESOP, **Requirement 7.9.1**):

- The service is involved in processes for managing medical device related hazard reports, alerts, and recalls received by the organization.
- This includes notifying relevant staff of action required and organizing service follow-up to confirm that proper actions are taken.

3. Definitions

Acronym or Word	Definition
Asset	Any equipment managed in TMS.
Hazard Reports, Alerts, and Recalls	*CESOP Terminology* Communications received by LMBME identifying a hazard related to a medical device that may include specific information and actions related to LMBME risk management.
Alert Log Work Order	Master tracking work order that is created for Alerts that receive intake into LMBME's Hazard Reports and Safety Alerts process.
Alert Log	Log of all Alert Log Work Orders. The Alert Log is maintained in TMS and is located in VCH's segment.
RM work-order	Risk management work-order. TMS work-order that describes corrective actions required for a specific asset in relation to an alert for the specific asset.

ECRI	Emergency Care Research Institute
Alert Group	A procedure specific team.
Alert Chair	A procedure specific role.
Alert Coordinator	A procedure specific role.
Alert Clerk	A procedure specific role.
Alert DBA	A procedure specific role.
Team Supervisor	A role within LMBME.
Consumable	Any item used in conjunction with a medical device to deliver care to a patient that is generally used once-only and/or is reprocessed under strict Reprocessing Guidelines.
Alerts Meeting	Weekly meeting where Alert Group reviews new alerts, assigns Alert Coordinators and reviews alerts requiring follow-up.
LMBME	Lower Mainland Biomedical Engineering
VCH	Vancouver Coastal Health
PHC	Providence Healthcare
FHA	Fraser Health Authority
PHSA	Provincial Health Services Authority
Supported Groups	VCH, PHC, FHA, PHSA

4. Scope

4.1 Included:

4.1.1 Process: Hazard Reports and Safety Alerts (CESOP Requirement 7.9.1).

4.2 Excluded:

4.2.1 Provincial Alert Process:

- Monitors ECRI for new alerts.
- Determines if alerts affect biomedical engineering.
- Assigns potential alerts to LMBME.

5. Guidelines and Protocols

5.1 Procedural Roles

5.1.1 The following roles execute this standard operating procedure:

- Alerts Group – A group composed of:
  - Alerts Chair.
  - Alerts Clerk.
  - Alert Coordinators.
  - Alerts DBA.

  - LMBME Supervisors.
  - LMBME Directors.

- Alerts Chair –
  - An LMBME Engineer.
  - Directs the activities of the Alert Group.
  - Maintains the alert logs.

- Alerts Clerk –
  - An LMBME Clerk.
  - Supports alerts process documentation.

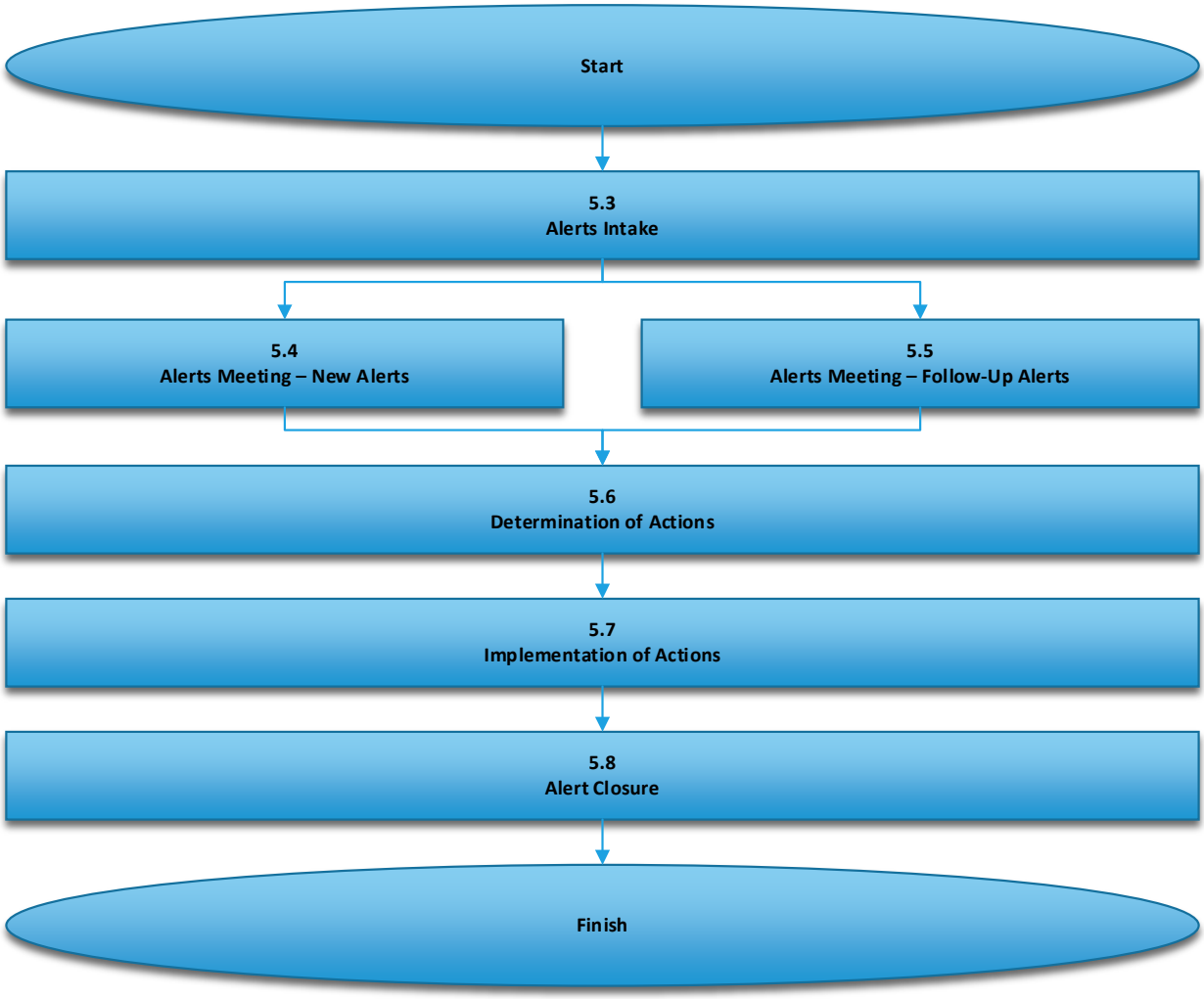
- Alert Coordinator –
  - Temporary assignment for specific Alert
  - An LMBME Director, Manager, Engineer, Supervisor or Technologist
  - Assess alerts, determine corrections, and complete reports.

- Alerts DBA –
  - An LMBME DBM Team member.
  - Supports TMS related activities.

- Supervisors/Technologists –
  - Discovers alerts, identifies affected inventory, and implements corrective actions.

- Directors –
  - Support process as required.

5.2 Process Flow Chart



5.3 Alerts Intake

5.3.1 Flow Chart for Intake of Potential Alerts:

5.3.2 If an LMBME Team receives a vendor letter, the **Supervisor/Technologist**:

- Informs the **Alerts Clerk** that vendor letter was received.
- Provides the vendor letter to the **Alerts Clerk**.
- Acknowledges (informs the vendor of) the receipt of the vendor letter.

5.3.3 LMBME Teams *may* proactively identify an alert through monitoring sources such as:

- FDA, Health Canada, ECRI, Health Information Sharing and Analysis Center.

5.3.3.1 An alert should be proactively identified by LMBME Team if the hazard or external alert:

- Affects their team.
- Affects another team.
- Affects a common model.

5.3.4 If an LMBME Team proactively identifies an alert, the **Supervisor/Technologist**:

- Informs the **Alerts Clerk** that an alert was identified.
- Provides the alert document or document reference to the **Alerts Clerk**.

5.3.5 The provincial alert process discovers alerts from sources such as ECRI, Health Canada, vendors and assigns alerts to LMBME.

5.3.6 If the **Alerts Clerk** receives a vendor letter, alert identified by LMBME Teams or alerts assigned to LMBME by the provincial process:

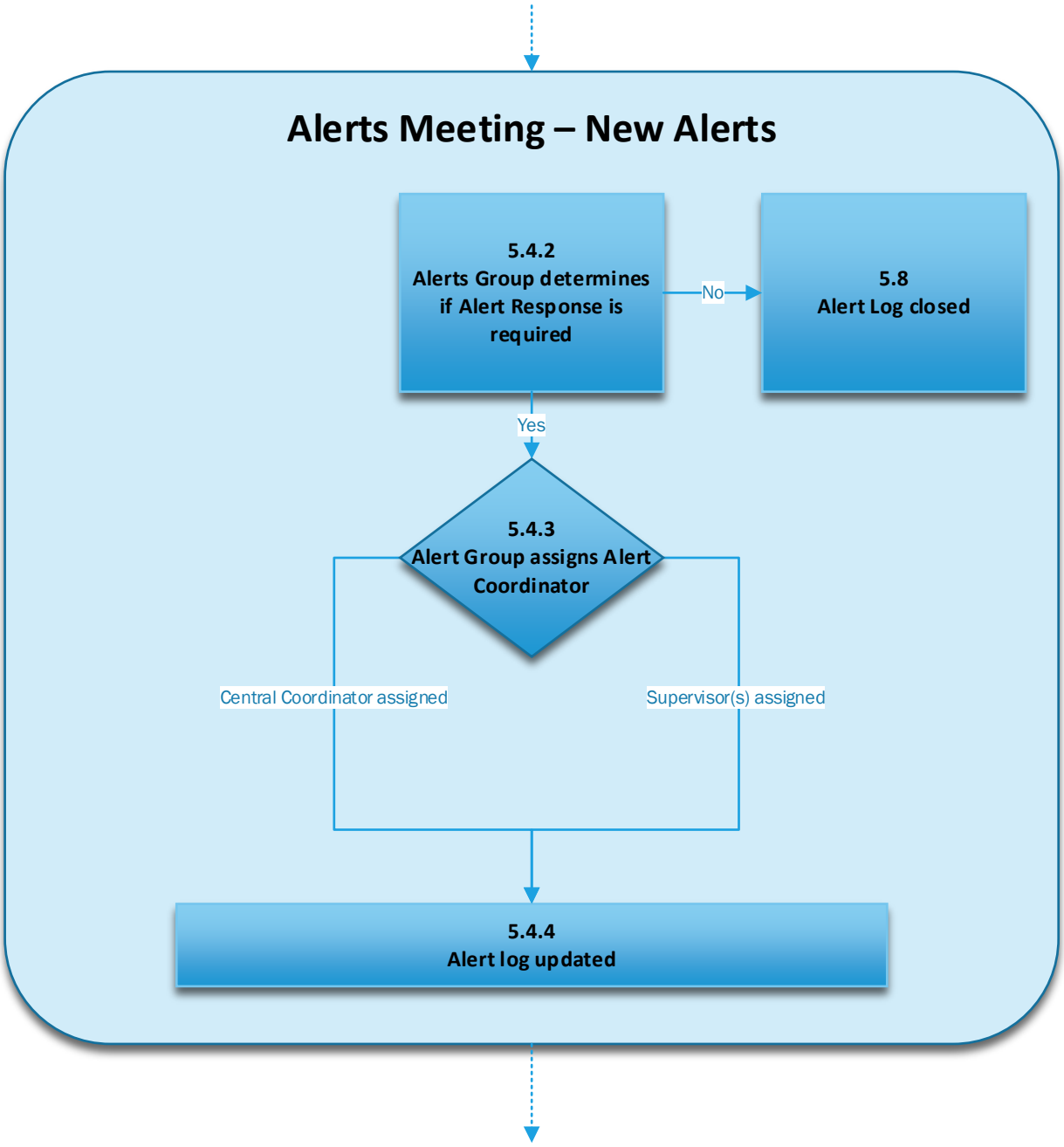
- The **Alerts Clerk** creates a work order in the alert log and populates the appropriate fields.
- The Alerts Clerk attaches the alert or vendor letter to the work order.

5.3.7 <u>For all alerts entered into the alert log</u>, the **Alerts DBA**:

- Performs a TMS query to identify affected assets and attaches the list to the alert log.
- Updates appropriate fields in alert log.

5.4 Alerts Meeting – New Alerts

5.4.1 Flow Chart for Alerts Meeting – New Alerts:



5.4.2 For all new alerts, the **Alerts Group** convenes weekly and determines if an LMBME alert response is needed.

5.4.2.1 An LMBME alert response is required for the following:

- The alert is related to medical equipment which LMBME services for VCH, PHC, PHSA, or FHA.
- The alert is related to a consumable which is used with medical equipment which LMBME manages for VCH, PHC, PHSA, or FHA.

5.4.2.2 An LMBME alert response is not needed if LMBME assets do not meet detailed alert criteria such as:

- Manufacture date.
- Geographic region.
- Firmware version.
- Specific circumstances and use-cases that do not occur.

5.4.2.3 An LMBME alert response is not needed if the consumable alert:

- Does not affect the related device's hazards.

5.4.3 If an LMBME alert response is needed, the **Alert Group**:

- Assigns an **Alert Coordinator** to the alert.

5.4.3.1 The **Alert Coordinator** must be a person qualified to assess the alert:

- Knowledgeable in the clinical use of the device.
- Knowledgeable in the design of the device.
- Experienced with risk assessment.

5.4.3.2 The **Alert Coordinator** may seek the expert opinion to support gaps in knowledge.

5.4.3.3 The **Alerts Group** may assign the **Supervisor** of each affected team as the **Alert Coordinator** for a given alert.

- This would be appropriate if the alert difficulty is low and the **Supervisor** does not need further support from the central process.
- Each **Alert Coordinator** would use RMWO to document their alert related activity.

5.4.3.4 The **Alerts Group** may assign a central coordinator as the **Alert Coordinator** for a given alert.

- This would be appropriate if the alert difficulty is high, actions are unclear or if Supervisors would benefit from support from the central process. This could include alerts with potential actions that:
    - Will significantly disrupt patient care delivery.

- Will incur significant cost in parts and labour.
- Involve communication with related groups.
- Should be consistent across teams.

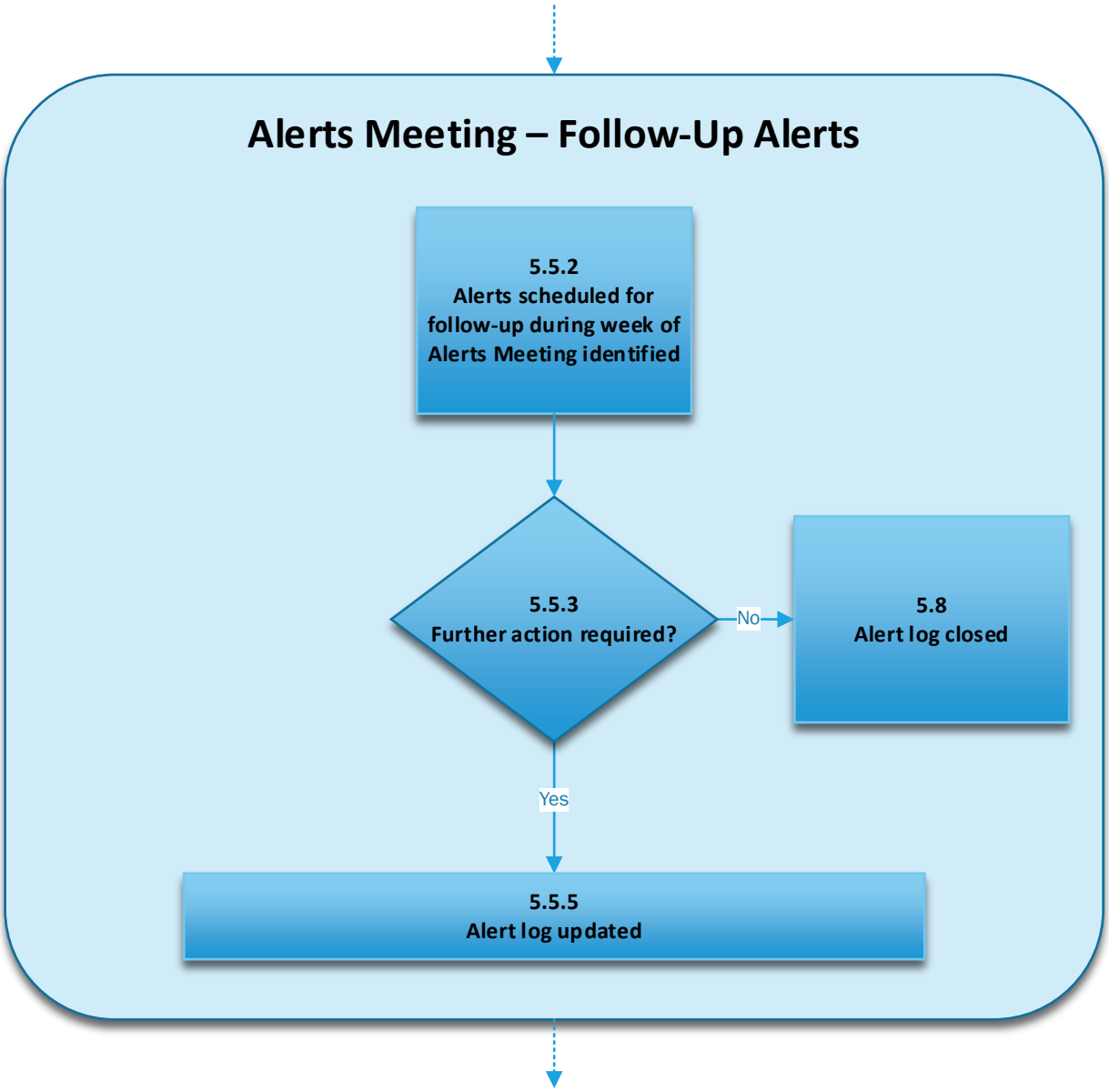
5.4.4 The **Alerts Chair** updates the Alert Log including assignment of a follow-up date for the alert.

5.4.5 If an alert response is not needed, the **Alert Chair**:

- Completes the Alert Log Work Order justifying why no response is needed.
- Notifies PHSA Supply Chain that LMBME is not responding to the alert.
- Closes the alert per section **5.8**.

5.5 Alerts Meeting – Follow-Up Alerts

5.5.1 Flow Chart for Alerts Meeting – Follow-Up Alerts:



5.5.2 The **Alerts Chair** identifies alerts scheduled for follow-up during week of Alerts Meeting.

5.5.3 The **Alert Coordinator(s)** provide an update on the alert to the **Alerts Group** and indicates if further action is required.

5.5.4 If further action is required, the **Alerts Chair**:

- Updates the Alert Log including assignment of a follow-up date for the alert.

5.5.5 If no further action is required, the **Alerts Chair**:

- Closes the alert per section **5.8**.

5.6 Alerts Assessment

5.6.1 The **Alert Coordinator** assesses risk related to the alert in the context of LMBME.

5.6.2 The **Alert Coordinator** completes the following information to the Alert Log Work Order:

- Risk Assessment – LMBME's assessment of risk.

5.6.2.1 The Alert Description and Risk Assessment are recorded to any of the following locations:

- Alert Log Work Order – Requestor Details.
- An attachment to the Alert Log Work Order.

5.6.2.2 The original alert *may* be referenced instead of interpreted.

5.6.2.3 The original alert risk assessment *may* be accepted as stated and is considered the default risk assessment.

5.6.3 The **Alert Coordinator** determines corrective actions within 5 business days of the weekly Alerts meeting including:

- Determines appropriate corrective actions on a team or site basis.
- Communicates with the manufacturer to arrange manufacturer support.
- Establishes mile-stone targets for medium and long term actions.

5.6.4 The **Alert Coordinator** documents corrective actions in the Alert Log Work Order.

5.6.4.1 The Corrective Actions are recorded to the any of the following locations:

- Alert Log Work Order – Requestor Details.
- An attachment to the Alert Log Work Order.

5.6.5 If corrective actions are not needed, the **Alert Coordinator**:

- Completes the Alert Log Work Order justifying why no action is needed.
- Requests the Alerts Chair to close the alert per section **5.8**.

5.7 Implementation of Corrective Actions

5.7.1 If corrective actions are not needed, section **5.7** does not apply.

5.7.2 The **Alerts Chair** or **Alert Coordinator** distributes internal communications as per the corrective action plan.

5.7.3 The **Supervisor**, **Alerts DBA** or **Alerts Clerk** creates Risk Management work-orders including:

- Creating TMS RM work-orders for each individual asset affected within their LMBME team and site.

5.7.4 **Supervisors** control the completion of RM work-orders including:

- Assigning RM work-orders to **Technologists**.
- Notifying **Technologists** that RM work-orders have been assigned.
- Ensuring **Technologists** update RM work-order Completion Comments including any issues faced with completing the work-order.
- Monitoring RM work-order progress and ensuring RM work-orders are completed as planned.

5.7.5 The **Alert Coordinator or Alerts Chair** monitors completion of RM work-orders including:

- Detecting RM work-orders not closed as planned.
- Monitoring mile-stone targets for medium and long term actions.

5.7.6 The **Alert Coordinator or Alerts Chair** reviews the Alert Log to confirm the alert response is complete including:

- Verify that all RM work-orders are completed satisfactorily.

5.7.7 Once the corrective actions are complete, the **Alert Coordinator** requests the **Alerts Chair** to close the alert as per section **5.8**.

5.8 Alert Closure

5.8.1 If the alert response is complete, the **Alerts Chair**:

- Updates the Alert Log to state that the alert response is closed.

6. Reference Documents

The Canadian Medical and Biological Engineering Society. Clinical Standards of Practice for Canada (3rd Edition)
Policy ABCD-14-16-40003 – Hazard Reports and Safety Alerts

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	1.0	21-OCT-2013	Draft	Engineers
	1.1	24-DEC-2013	Review	Engineer
	1.2	08-JAN-2014	Review, Active	Executive Director
	1.3	03-MAY-2014	Added Appendix B – Weekly Alerts Procedure	Director
	1.4	27-JAN-2019	Pilot Version 1 Major Revision	Alerts Working Group
	1.5	18-JUL-2019	Revisions following pilot	Engineer