Critical incident reporting – assisted reproductive technology practice and storage licensed facilities

1. Purpose

This mandatory operational policy outlines the Licence Supervisors responsibilities to report and manage critical incidents *(other than Reportable Serious Adverse Events)* as per the mandatory requirements of the *Human Reproduction Technology Directions 2021.*

For further information on Reportable Serious Adverse Event classifications and guidelines refer to Department of Health ART-Serious-adverse-events-notification-guidelines (1).pdf. Adverse Events must be reported separately via ART Serious Adverse Event Notification - Part 1 (health.wa.gov.au)

2. Definitions

2.1 Reportable Critical Incident

Any incident *(other than a clinical incident*) that poses a serious risk to the life, health, or safety of an individual who is receiving services from a licensed facility, including any incident that causes disruptions to normal service delivery.

3. Applicability

This policy is applicable to all facilities licensed under the *Human Reproductive Technology Act 1991*. This policy does not supersede other legislative or agency reporting requirements.

4. Reportable critical incidents

Critical incidents are rare but impactful, persistent, repeated, or unresolved in nature and require a risk mitigation strategy to be implemented.

Examples of critical incidents include fire, reportable outbreak of infection, serious criminal acts, building or other structural damage or collapse, serious equipment failure, serious environmental hazard (e.g., chemical spillage) and major cyber/security breach.

The 'Other' incident category stated on the Critical Incident Form refers to issues such as the inability to comply with staffing quotas; events where extraordinary actions are required to address a rare failure or non-compliances; breaches with licensed hours or operations and dispensations/conditions as they apply to the license; and an event that may pose a significant risk to patients, staff, and visitors.

4.1 Timeframes for notification

All licensed facilities are required to report **critical** incidents to LARU **within 48 hours** of the event/s occurring.

4.2 Incident management

All licensed practice and storage units are required to have written protocols for managing critical incidents which include but are not limited to:

- Business Continuity Plan

- Policies and procedures that clearly delineate what actions are to be followed and by whom and identifies lines of responsibility for documenting, reporting, investigating, implementing, and evaluating any identified measures to prevent similar incidents.
- Relevant committees are in place where Serious Adverse Events (SAEs) and Critical incidents are tabled, reviewed, and risked assessed to ensure similar incidents are prevented.

At a minimum (where relevant), committees with oversight are to include:

- Medical Advisory Committee; and
- Executive Management Committee (however titled).

4.3 Method of notification

A completed **Critical Incident Report Form** is to be forwarded to the Licensing and Accreditation Regulatory Unit via email: LARUCompliance@health.wa.gov.au within the timeframes indicated above.

5. Review

This **mandatory policy** will be reviewed as required to determine effectiveness, relevance, and currency. At a minimum it will be reviewed at least every three years.

Version	Effective from	Effective to	Amendment(s)
V1	12 March 2024	March 2027	Original version
V2			
V3			

The review table indicates previous versions of the mandatory policy and any significant changes.

6. Approval

Approval by	Vanessa Macdonald, Manager, Licensing and Accreditation Regulatory Unit
Approval date	11 March 2024

This document can be made available in alternative formats on request for a person with a disability.