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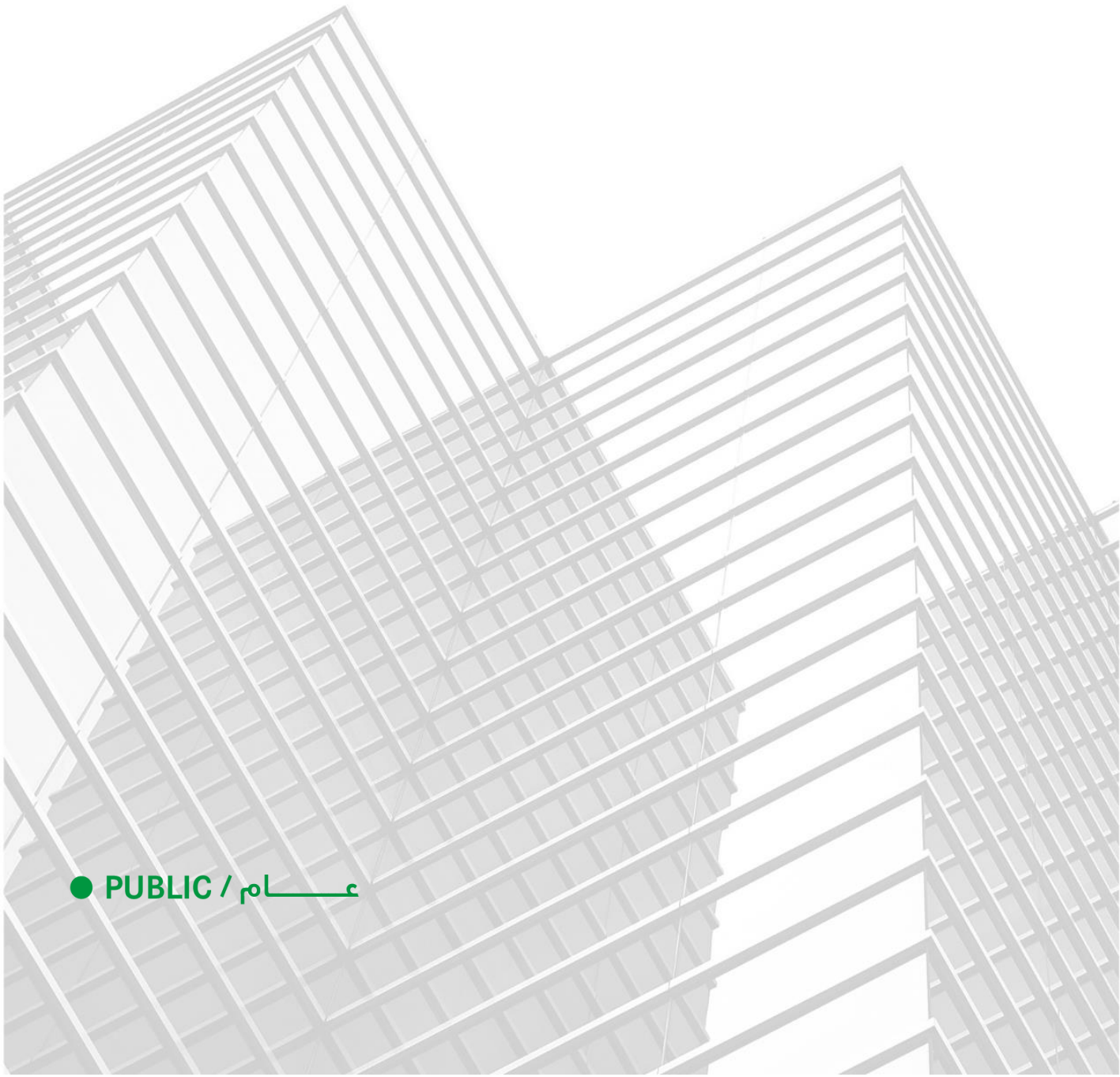
DEPARTMENT OF HEALTH

Incident Reporting and Management Standard



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1.Standard Scope and Purpose

1.1 The scope:

1.1.1 Applies to all DoH licensed healthcare providers (licensed healthcare professionals and facilities) and all staff employed by healthcare facilities.

1.1.2 Involves the recognition, investigation, response, and learning from all types of incidents, including hazards, near misses, adverse events, and sentinel events. It encompasses incidents involving patients, staff, visitors, contractors, equipment, property, or services, at all levels and types. The standard outlines the subsequent courses of action to address these incidents effectively.

1.1.3 This standard sets the minimum requirements for identifying, internal investigation, reporting, and managing of a sentinel event within a healthcare facility, also a subsequent submission of Root Cause Analysis (RCA) and Corrective Action Plan (CAP) to DoH.

1.2 The purpose:

1.2.1 To clarify the types of incidents that may occur and clarify the process of reporting and classification of incident type and severity (level of harm),

1.2.2 To mandate the requirement to develop and implement a management and reporting system for all types of incidents defined in this standard; and

1.2.3 To specify the criteria for information collection and DoH notification on sentinel events as defined by this standard.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Adverse Event	An injury caused by medical management, rather than by the underlying condition / disease, which may prolong hospitalization, produces a disability at the time of discharge, or both.
2.2	Adverse Event Following Immunization (AEFI)	Is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.
2.3	Authorized Person	The guardian or other individual(s) having the legally recognized ability to consent on behalf of the minor.
2.4	Corrective Action Plan (CAP)	Structured approach to achieve targeted outcomes for resolution of identified errors to identify the most effective actions that can be implemented to correct error causes, develop and implement a plan of action to improve processes so that outcomes are more effective and efficient. The goal is to achieve measurable improvement in the

		highest priority areas, eliminate repeated deficient practices and ensure sustainability to prevent resources.
2.5	Healthcare Facility	Facilities that provide healthcare services. They include, but are not limited to hospitals, clinics, outpatient care centers, primary healthcare centers, and specialized care centers.
2.6	DoH	Department of Health – Abu Dhabi
2.7	Healthcare Facility Leader/Director	The designated individual who has the responsibility to oversee effective functioning of processes within a defined scope of services.
2.8	Incapacitated Patient	An adult individual who lacks the ability to meet essential requirements for physical health, safety, or self-care and /or unable to receive / evaluate information or make/communicate decisions.
2.9	Invasive Procedure	Any procedure in which skin or mucous membranes and/or connective tissue are incised or punctured, an instrument is introduced through a natural body orifice, or foreign material is inserted into the body for diagnostic or treatment-related purposes.
2.10	Medication Error	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.
2.11	Just Culture	A culture in which frontline personnel feel comfortable disclosing errors including their own while maintaining professional accountability. A just culture recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, "routine rule violations"), but has zero tolerance for reckless behavior.
2.12	Minor	Any person or patient who is less than 18 years of age.
2.13	Near Miss	Circumstances or events that had the capacity to cause an adverse event, but which did not reach the patient.
2.14	Root Cause Analysis (RCA)	A comprehensive and systematic analysis method using tools that focus on systems and processes for identifying the causal and contributing factors that resulted in the event.
2.15	Second Victim	A health care practitioner involved in an unanticipated adverse patient event, a medical error, and/or a patient-related injury who

		becomes victimized in the sense that the practitioner is traumatized by the event.
2.16	Sentinel Event	Any unanticipated adverse event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not arising from the natural course of the patient's illness.
2.17	Severe Temporary Harm	Defined as critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care/monitoring for a prolonged period, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition [(1)].
2.18	Vascular Air Embolism	The entrainment of air (or exogenously delivered gas) from the operative field or other communication with the environment into the venous or arterial vasculature, producing systemic effects.
2.19	Safety Incident	An event, incident, or condition that could have resulted or did result in harm to a patient. A patient safety incident can be, but is not necessarily, the result of a defective system or process design, a system breakdown, equipment failure, or human error. Patient safety incident also include adverse events, no-harm events, near misses, hazardous conditions and sentinel event which are defined as follows: • An adverse event • A No-harm event • A near miss (or close call) • A hazardous (or "unsafe") condition(s)
2.20	Incident	Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation.
2.21	Harm	Any adverse event, injury, or unintended consequence that occurs to a patient during the course of their medical care or treatment.
2.22	Root Cause Analysis	Systematic process for identifying the root causes of problems or events, and for determining the appropriate solutions to prevent recurrence.
2.23	Patient	Person who receives medical attention, care, or treatment from a healthcare provider, such as a doctor, nurse, or other medical professional. The patient is the recipient of the healthcare services

		and is typically someone who is seeking diagnosis, treatment, or management of a medical condition or illness.
2.24	Measures Of Success	Specific indicators used to evaluate the achievement or progress of a particular goal, project, or initiative. These measures provide a way to quantify and assess the outcomes, impacts, or effectiveness of an undertaking.
2.25	Severe Harm	An event or condition that reaches the individual, resulting in life-threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring and/or surgery, invasive procedure, or treatment to resolve the condition.
2.26	Permanent Harm	An event or condition that reaches the individual, resulting in any level of harm that permanently alters and/or affects an individual's baseline health.

3.Standard Requirements and Specifications

3.1 A healthcare facility should encourage reporting and investigation of incident reports in a timely manner for any event that is not consistent with the standard operations of the healthcare facility or standard care of a particular patient, visitor, or employee.

3.2 The first action to be taken in the case of an incident occurrence is ensuring a safe environment for all those involved including patients, staff, and bystanders. All items involved in the incident (e.g. medical equipment, etc.) are preserved so that they may be used as evidence or as a starting point for future investigation.

3.3 All employees shall report any incident, which can negatively affect (or has the potential to negatively affect), the care of patients, employees, visitors or the facility using the facility's electronic safety incident reporting system.

3.4 An employee who witnesses or is made aware of an incident is mandated to report it through electronic safety incident reporting system adopted by the facility and will be held accountable for failure to report the event within twenty-four hours from the date of discovery.

3.5 Incident reporting will not result in disciplinary proceedings, except in the most exceptional circumstances, for example, where there has been a breach of law, gross negligence or professional misconduct.

3.6 Safety incident must not be used to calculate practitioner error rate reports and are not to be used for internal or external comparison purposes.

3.7 Submitted incidents must be assessed, analyzed, and managed by authorized staff, according to the level of incident as described in clause 3.19.

3.8 Reporting mechanisms:

3.8.1 Adverse Drug Reaction (ADR) and Adverse Event following Immunization (AEFI) shall be reported as per DoH Standard on Reporting Suspected Adverse Drug Reactions and Adverse Events Following Immunization.

3.8.2 Medication errors shall be reported as per DoH Standard on Reporting Medication Errors & Suspected Quality Problems Related to Medicinal Products and Dietary Supplements.

3.8.3 Medical devices incidents shall be reported as per DoH Standard on Medical Device Reporting (MDR).

3.9 Healthcare facility shall notify DoH of Occupation Health and Safety (OSH) incidents related to their employees and contractors and injuries to other persons such as visitors as per the requirements of Mechanism 11.0 – Incident Notification, Investigation and Reporting.

3.10 The incident reports cannot be altered (e.g. Date, Time, description) after they have been submitted on facility's incident reporting system, however, amendments can be made in certain aspects (e.g. type of event, harm level, classification).

3.11 Employees must refrain from disclosure or dissemination of incident report information.

3.12 Disclosure of incident information to the patient/family members must follow the healthcare process outlined in the facility disclosure policy of patient safety events.

3.13 The healthcare facility should provide appropriate support to the staff (Second Victims) involved in sentinel events. If staff members feel that they need to discuss the incidents involved with a counsellor, the facility should take the appropriate measures to see that the staff members' needs are addressed.

3.14 Any intentional unsafe act must be handled through administrative disciplinary lines of authority, for appropriate action.

3.15 Healthcare facilities shall allow anonymous reporting for all incidents reporting.

3.16 Each facility must maintain an incident reporting database that will help the facility monitor action plans, conduct necessary analysis for the data and share lessons learned.

3.17 Table 1 describes the types, descriptions and investigations of reported safety incidents.

Table 1: Reported Safety Incidents

Incident level	Description	Example	Investigation Required
Level One	A reportable incident in which there was significant potential for harm, but no incident occurred	• Busy intensive care unit remaining grossly understaffed for an entire shift. • Taking a defibrillator to an emergency and discovered that it does not work although it was not needed	These incidents generally require minimum investigation that can be undertaken adequately by the ward/departmental manager. However, they must be monitored regularly to identify patterns or trends and, when necessary, develop and implement actions. It is acceptable for the ward/departmental manager to close such incidents following investigation and recording of findings and lessons learned on electronic reporting system database. Investigation of this grade of incident should normally be completed and closed within 5 working days
Level	A near miss is an incident	Unit of blood being	These incidents generally require minimum

Two	that did not reach the patient.	connected to the wrong patient's intravenous line, but the error was detected before the infusion started.	multidisciplinary investigation that can be undertaken adequately by the ward/departmental manager. However, they must be monitored regularly to identify patterns or trends and, when necessary, develop and implement actions. It is acceptable for the ward/departmental manager to close such incidents following investigation and recording of findings and lessons learned on electronic reporting system database. Investigation of this grade of incident should normally be completed and closed within 10 working days.
Level Three	A no harm incident is one in which an event reached a patient, but no discernable harm resulted.	If the unit of blood was infused but was not incompatible.	The degree of seriousness of these incidents may require multidisciplinary or independent investigation. The Head of Service/General Manager for the area where incident occurred is responsible for ensuring an appropriate level of investigation is conducted, formal recording and dissemination of findings, actions taken, lessons learned and closure of these incidents. Where necessary advice can be taken from the Quality Manager. Investigation of this grade of incident should normally be completed and closed within 14 working days.
Level Four	A harmful incident (adverse event) is an incident that results in harm to a patient. Including sentinel event.	• Injury • Fracture • Laceration • Wound	The Hospital/Facility leadership is responsible for ensuring that a thorough investigation is undertaken. The Facility Director will agree with the Director Quality and patient safety whether a Root Cause Analysis is required and will appoint a lead investigating officer (who is appropriately trained). Investigation of this grade of incident should, when possible, be completed within 14 working days except in sentinel event should follow the below process. Closure or down-grading of incidents requires

			approval by the Quality Department, who, in conjunction with the Risk Management, will review investigation/closure of incidents monthly.

3.18 A just culture approach must be applied to provide a fair and productive alternative to the "punitive culture" or "blame-free culture".

3.19 All sentinel event information submitted to DoH is considered private and confidential. Sentinel events data will be observed for trends and used anonymously for the purpose of disseminating lessons learned.

3.20 **Sentinel Event Reporting and Management within Healthcare Facilities:**

3.20.1 ***Reporting of Sentinel Events***

3.20.1.1 Upon the occurrence of an incident suspected to be a sentinel event (as per categories and definitions stated in this standard), healthcare facilities must notify DoH HCFSQPS@DoH.gov.ae within 48 hours from the date of becoming aware of the sentinel / suspected sentinel event using the sentinel event notification form.

3.20.1.2 In case a healthcare facility is uncertain whether an incident qualifies as a sentinel event, the healthcare facility must provide the event details to DoH HCFSQPS@DoH.gov.ae**.** Based on available information received about the event, DoH will determine whether an event meets the definition of sentinel event.

3.20.2 ***Healthcare facility response following a Sentinel Event***

3.20.2.1 Once the responsible facility department is informed about any adverse event or incident that is suspected to be a sentinel event, it is expected that the facility department in coordination with the designated team within the healthcare facility, promptly reviews, verifies, and compares the incident with the sentinel event categories outlined and specified in this standard.

3.20.2.1.1 The healthcare facility leader/director shall appoint a Root Cause Analysis (RCA) team in charge of managing the event within (24) hours of the time of identifying of the event.

3.20.2.1.2 Ideally, the RCA team shall include a Subject Matter Expert in the event under investigation, a staff who is not familiar with the incident under investigation, an experienced Root Cause Analysis (RCA) facilitator, and frontline staff.

3.20.2.2 The RCA team may also include managers and supervisors as per the event scope. It is not advised to include any staff who are directly involved in the event, or supervisors/managers of the department where the event occurred in the RCA team, to avoid any potential conflict of interest.

3.20.2.3 The assigned RCA team is responsible for the following:

3.20.2.3.1 Provide support to the staff involved in the event.

3.20.2.3.2 Initiate the investigation process.

3.20.2.3.3 Interview of patient/family, if applicable, and staff who were directly involved in the event.

3.20.2.3.4 Conduct a credible and comprehensive Root Cause Analysis (RCA) for

identifying the root causes and contributory factors, using the tools specified in this standard.

3.20.2.3.5 Recommend a Corrective Action Plan (CAP), with assigned responsibilities and the timeline for implementation.

3.20.2.3.6 Submit the Root Cause Analysis (RCA) and Corrective Action Plan (CAP), after review and approval of the healthcare facility leader/director, to DoH.

3.20.2.3.7 Because of the nature and sensitivity of these events, every healthcare facility is obliged to have a disclosure process of patient safety events to patients and their families.

3.20.3 **Conducting a Root Cause Analysis (RCA)**

Following the reporting of a sentinel event, the assigned RCA team is responsible for completing the RCA template (Appendix II).

3.20.4 **Corrective Action Plan**

The RCA team is to develop a Corrective Action Plan (CAP) after identifying the root causes and contributing factors to the event (Appendix II). The CAP should identify what needs to be done to prevent similar events from occurring in the future. Actions might differ in their strength to control or eliminate system hazards as classified by the Action Hierarchy (Appendix III) into strong actions, intermediate actions, or weak actions.

3.20.4.1 The team may identify more than one corrective action for each root cause and contributing factor; it is recommended to identify at least one stronger or intermediate strength action for each contributing factor to the event occurrence. To ensure the Corrective Action Plan's implementation, the team shall assign actions to the responsible individuals with target date(s) for completion.

3.20.4.2 Before submission of the CAP to DoH, the healthcare facility leader/director must make sure that the plan includes the following:

3.20.4.2.1 Well identified contributing factors.

3.20.4.2.2 A causal statement/root cause for each contributing factor.

3.20.4.2.3 Corrective Action(s) for each causal statement, that includes at least one stronger or intermediate strength.

3.20.4.2.4 Responsible person for the implementation of each action.

3.20.4.2.5 The target date for completion of each action.

3.20.4.3 One of the effective tools that can be used by the sentinel event analysis and management team for monitoring and controlling the timeliness of the implementation of the action plan is the Gantt Chart. Use of the Gantt Chart is recommended as an effective tool to monitor and control the action plan timeliness of implementation.

3.21 Sentinel Event Reporting and Management Process for the Healthcare Facility

The facility Quality and patient safety department shall submit the completed sentinel event reporting form with the RCA and CAP section (Appendix I, II) to DOH "Quality and Patient Safety" HCFSQPS@DoH.gov.ae within Forty-five calendar days from the date of notification of the event, considering confirmation day 1.

3.22 **Process Post Submission of the Sentinel Event, RCA, and CAP to DoH**

3.22.1 Upon submission of the Sentinel Event, RCA, and CAP to DoH, the assigned DoH employee will review the event with all its related documents to ensure that the RCA is comprehensive and focuses on the system, not individuals, and the CAP has assigned responsibility with timelines. In case of any inquiries, the assigned DoH employee shall communicate with the healthcare facility's Quality and patient safety department representative (See Table 2).

3.22.2 After reviewing RCA and CAP by DoH, feedback will be sent to healthcare facility's Quality and patient safety department informing them if it's accepted or not. If it is not accepted, the healthcare facility must amend the RCA and CAP within fifteen calendar days and send it back to DoH.

3.22.3 The responsible team in DoH shall review and analyze the contributing factors and the root causes of all reported events. Based on the analysis, DoH shall prepare a quarterly report that identifies trends and lessons learned to be presented for review and approval by the Quality and Patient Safety Committee. An annual report shall be submitted to the Abu Dhabi Quality and Patient Safety Committee.

3.22.4 Healthcare facilities are required to send CAP progress Report MOS "Measures of Success" with supportive evidence for each action item submitted. Failure to submit will consider CAP not incomplete.

Table 2: List of Reportable events that are considered a sentinel event that require a review, include but are not limited to:

No.	Type of sentinel event	Definition	Inclusion	Exclusion
1	Abduction of any patient receiving care within a healthcare facility.	This event is intended to capture all instances when patients of any age are abducted from a healthcare facility.	Abduction cases for any patients, whether under care or receiving care of any age group and health conditions (i.e., regardless of a patient's health condition) within a healthcare facility's premises/campus.	• Areas outside of the premises/campus of a healthcare facility. • Healthcare facility visitors and patients' companions. • Patients present within the premises/campus of a healthcare facility but not yet under care.
2	Discharge of an infant to the wrong family.	This event is intended to capture all cases where an infant was discharged to the wrong parent/legal guardian.	All incidents where an infant is discharged to the wrong parent/legal guardian.	• None.
3	Discharge of a Minor or Incapacitated Patient to an unauthorized person.	This event is intended to capture all cases where a minor or incapacitated patient was discharged to an unauthorized parent/legal guardian.	All incidents due to the failure to double-check and/or identify the correct family, parents, or legal guardian before discharge.	• None.
4	Maternal death and Severe maternal morbidity (leading to permanent harm or severe harm)	This event is intended to capture death, permanent harm, or severe harm cases of women while pregnant or within 42 days of the termination of pregnancy.	• Any cause related to or aggravated by the pregnancy or its management. • Severe maternal morbidity is defined as a patient safety event that occurs intrapartum through immediate postpartum period (24 hours), that requires the transfusion of 4 or more units of packed red blood cells and/ or admission to the intensive care unit (ICU).	• Cases that were not related to the birth process. • Accidental or incidental causes.
5	Suicide, attempted suicide, or self-harm that results in severe temporary harm, permanent harm, or death while being cared for in a healthcare setting or within 7 days of discharge, including the emergency department.	This event is intended to capture all cases of suicide, attempted suicide, or self-harm while being under care in any healthcare facility.	Death caused by self-inflicted injurious behavior if any of the following apply: • While in a health care setting. • Within 7 days of discharge from inpatient services. • Within 7 days of discharge from emergency department (ED). • While receiving or within 7 days of discharge following behavioral health care.	Patients present within a healthcare-facility but not yet under care, e.g., attempts suicide in the healthcare facility restroom prior to checking in for care.
6	Surgery/invasive procedures performed at the wrong site, on the wrong patient, or the wrong procedure.	This event is intended to capture all surgical/invasive procedures performed on the wrong patients, wrong site, or wrong procedure regardless of whether death, permanent harm, or severe, temporary harm has occurred or not.	• Any surgical/invasive procedure performed on the wrong patient, wrong site, or wrong procedure. • Dental procedures involving wrong teeth extraction.	• None.

No.	Type of sentinel event	Definition	Inclusion	Exclusion
7	Administration of incompatible ABO, Non-ABO of blood/ blood products, or transplantation of incompatible organs resulting in death, permeant harm or sever harm.	This event is intended to capture cases involving administration of blood or blood products having unintended ABO and non-ABO (Rh, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusion resulting in death, permanent harm, or severe harm.	• All cases involving the administration of incompatible blood/blood products or organs.	• None.
8	Unintended retention of a foreign object in a patient after surgical/invasive procedure.	This event is intended to capture all cases involving the unintended retention of a foreign object in a patient after surgery or other invasive procedure regardless of whether death, permanent harm, or severe, temporary harm occurred or not.	• All cases involving the unintended retention of a foreign object in a patient, regardless of whether the retained object was discovered within a healthcare facility during hospitalization post-procedure or post-discharge. • Any item is subject to a formal counting/checking process at the start of a surgical/invasive procedure and before completing the procedure, such as and not limited to swabs, needles, instruments, and guidewires.	• Any object left for medical reasons in a patient, e.g., sutures, stents, implants, and medical devices. • Objects that are known to be missing before completion of the procedure and may be inside the patient but action to locate and/or retrieve them is impossible or more damaging than retention (eg screw fragments, drill bits)
9	Unanticipated death of a “full- term” infant	This event is intended to capture all unanticipated death cases of a “full-term” infant.	• All cases include the unanticipated death of a “full- term” infant. • All term pregnancies, according to the definition of the International Classification of Diseases delivered between 37 weeks 0 days and 41 weeks 6 days.	• The death of a “full-term” infant was related to congenital abnormalities. • Pregnancies resulting in fetal demise before 37 weeks of gestation. • Terminations of pregnancy for life-limiting fetal anomalies, or inductions of labor for previable premature rupture of membranes.
10	Transmission of disease as a result of using contaminated instruments or equipment provided by the healthcare facility	This event is intended to capture all cases of disease transmission after using contaminated devices, instruments, or equipment regardless of the source of contamination	• All cases of disease/infection transmission. • Inpatients and Ambulatory care services	• None.
11	Physical Assault leading to death, permanent harm, or severe harm, or homicide of a patient, staff member, licensed independent practitioner, visitor, or vendor while on-site at the healthcare facility	This event is intended to capture all physical assault and homicide cases for patients, staff members, visitors, or vendors within the premises/campus of a healthcare facility that led to death, permanent harm, or severe harm or homicide cases.	• All physical assault and homicide cases within the premises/campus of a healthcare facility that led to death, permanent harm, or severe harm.	• physical assault with minor harm.

No.	Type of sentinel event	Definition	Inclusion	Exclusion
12	Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the health care facility.	This event is intended to capture all fire, flame, unanticipated smoke, or flashes that caused by equipment which is used at the time of the event; staff do not need to be present.	All fire, flame, unanticipated smoke, or flashes that occur within a healthcare facility because of using equipment.	• None.
13	Unauthorized departure of the patient (within 72 hours Elopement) leading from healthcare facility that resulted in death, permanent harm, or severe temporary harm	This event is intended to capture all death, permanent harm, or severe temporary harm cases associated with a patient leaving a healthcare facility without the knowledge/authorization of the healthcare facility staff.	• All patients who leave a healthcare facility (including emergency care) while being cared for without the healthcare facility staff's knowledge/authorization.	• None.
14	Medication error leading to death, permanent, or severe temporary harm	This event is intended to capture all medication error cases resulting in death, permanent harm, or severe temporary harm, such as errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong preparation, or wrong route of administration.	• Medication errors include, but are not limited to, death, permanent or severe temporary harm associated with: *Administration of the wrong dose, including over or under-dosing. *Administration of a medication to a patient with a known allergy to the drug or one of its components, the failure to check/review the patient's allergies before administration, or the failure to record/retrieve a patient's allergy information before administration. *Drug interactions or contraindications with known potential risk. *Failure to administer prescribed medications, e.g., missed doses or missed medication. *Wrong route of administration.	• Medication errors related to unknown allergies.
15	Patient death, permanent, or severe temporary harm associated with intravascular air embolism	This event is intended to capture all cases where patient death, permanent harm, or severe temporary harm was associated with air embolism.	• High-risk procedures, including but not limited to procedures involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation. • Low-risk procedures, including those related to the placement of infusion lines in a vascular space.	• Neurosurgical procedures, where surgery was performed in a position that puts the head above the heart to reduce venous pressure, e.g., suboccipital craniotomy.

No.	Type of sentinel event	Definition	Inclusion	Exclusion
16	Patient death, permanent, or severe temporary harm as a result of medical device breakdown or failure when in use	This event is intended to capture all cases of death, permanent or severe temporary harm as result of medical devices failure within healthcare facilities	• All medical devices.	• None.
17	The unexpected collapse of any building within a healthcare facility	This event is intended to capture all cases of unexpected building or construction collapse within the premises/campus of a healthcare facility regardless of whether death, permanent or severe temporary harm occurred or not.	• All buildings within the premises/campus of a healthcare facility, including structures under renovation or construction.	• None.
18	Transfusing/transplantation of contaminated blood, blood products, organ or tissue	This event is intended to capture all cases of disease transmission associated with the infusion of contaminated blood, blood products, organs, or tissues.	• All cases of transfusing/transplantation of contaminated blood, blood products, organs, or tissues.	• Any case of transfusion/transplantation related to emergency case/lifesaving circumstances.
19	Death or serious disability associated with failure to manage/identify severe neonatal hyperbilirubinemia.	This event is intended to capture all cases with severe neonatal hyperbilirubinemia "bilirubin>30mg/Deciliter".	• All cases resulted from failure to identify/re-assess or manage neonatal hyperbilirubinemia.	• None.
20	Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or > 25% above the planned radiotherapy dose	This event is intended to capture all cases where radiotherapy dose was delivered to wrong patient, wrong body region, unintended procedure, or > 25% above the planned radiotherapy dose.	• This event includes radioisotope therapy and radiation producing machines.	• None.
21	Any (stage 3, 4 or unstageable) healthcare facility- acquired pressure injury (ulcer)	This event is intended to capture any stage 3, 4, or unstageable pressure injury acquired after patient admission.	• All stage 3, 4, or unstageable pressure injury cases acquired after patients' admission. • This includes the following stages: * Stage 3 Pressure Injury: Full-thickness skin loss. * Stage 4 Pressure Injury: Full-thickness skin and tissue loss. * Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss.	• Progression from stage 2 to stage 3, if stage 2 was recognized upon admission.
22	Unexpected death, permanent or severe temporary harm associated with transport/transfer of patients	This event is intended to capture all death, permanent, or severe temporary harm associated with the transport or transfer of patients.	• All cases of transport or transfer inside or outside the healthcare facility premises, where healthcare facility protocols were not followed.	• None.

No.	Type of sentinel event	Definition	Inclusion	Exclusion
23	Patient death, permanent harm, or severe temporary harm as a result of patient fall	This event is intended to capture patient falls while being cared for within a healthcare facility resulting in any of the following: • Any fracture. • Surgery, casting, or traction. • Required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury. • A patient with coagulopathy who receives blood products as a result of the fall • Death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)	• Patients admitted within a healthcare facility, including day surgery and emergency department. • Cases due to the failure of performing patient fall's risk assessment/identification. • Failure to monitor/manage patients identified as “at fall risk.”	• None.
24	Patient death, permanent harm, or severe temporary harm associated with wrong administration/connection of medical gas	This event is intended to capture all death, permanent harm, or severe temporary harm cases associated with the administration/connection of the wrong medical gas.	• Incidents where systems designated to deliver medical gas to a patient contain no gas or the wrong gas.	• None.
25	Death, permanent, or severe temporary harm associated with the use of incorrectly positioned Oro – or Nasogastric tube	This event is intended to capture all instances of death, permanent harm, or severe temporary harm associated with the use of a misplaced naso- or orogastric tube.	• All cases where a naso- or orogastric tube is accidentally inserted into the pleura or respiratory tract and not detected before starting a feed, flush, or medication administration and resulted in death, permanent harm, or severe temporary harm.	• None.
26	Fluoroscopy resulting in permanent tissue injury	This event is intended to capture all Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed.	• All cases resulted were clinical and technical optimization not implemented and/or recognized practice parameters were not followed.	• None.

27	Accidental burn of second degree and above during patient care	This event is intended to capture all cases of second-degree burns or above that occur during patient care.	• Inpatient and ambulatory care accidental burn of second degree or higher due to, but not limited to, heat, electrical discharge, friction, chemicals, and radiation. • The following classification of burns based on the American Burn Association: * Second Degree (Partial Thickness): Skin may be red, blistered, swollen. Very painful. * Third Degree (Full Thickness): Whitish, charred, or translucent, with no pinprick sensation in a burned area.	• This event does not include burns due to a patients' personal use of room facilities/equipment such as the kitchen and shower.
28	Sexual abuse/assault of any patient (receiving care, treatment and service), staff member, visitor, or vendor while on site at the health care facility or while providing care or supervision to patients.	This event is intended to capture all Sexual abuse/assault cases for patients, staff members, visitors, or vendors within the premises/campus of a healthcare facility.	Sexual abuse includes but is not limited to the following: • Unwanted intimate touching of any kind, especially of the breasts, buttocks, or perineal area • All types of sexual assault or battery, such as rape, sodomy, and coerced nudity (partial or complete) • Forced observation of masturbation and/or sexually explicit images, including pornography, texts, or social media. • Taking sexually explicit photographs and/or audio/video recordings of an individual and maintaining and/or distributing them (for example, posting on social media); this would include but is not limited to nudity, fondling, and/or intercourse involving an individual.	• None.

4.Key stakeholder Roles and Responsibilities

DoH licensed healthcare facilities and all healthcare professionals should comply with the above-mentioned requirements.

5.Monitoring and Evaluation

DoH monitoring and evaluation framework is applied to evaluate the effectiveness, quality outcomes, and impact of this Standard, and where necessary revise the Standard to ensure it remains fit for purpose and responsive to the new developments in healthcare sciences, emerging technologies, medical practices, models of care, research, and healthcare education and training.

Indicator Number:

- QI001: Rate of sentinel events (unexpected occurrence involving death or serious physical or psychological injury) per 1000 inpatient days
- QI003: Rate of selected reported Adverse Incidents (level 1-3) per 1000 inpatient days
- QI013: Rate of hospital associated or worsening pressure injury (Stage II and above) per 1000 inpatient days

6.Enforcement and Sanctions

DoH may impose sanctions in relation to any breach of requirements under this Standard in accordance with the disciplinary regulation of the healthcare sector.

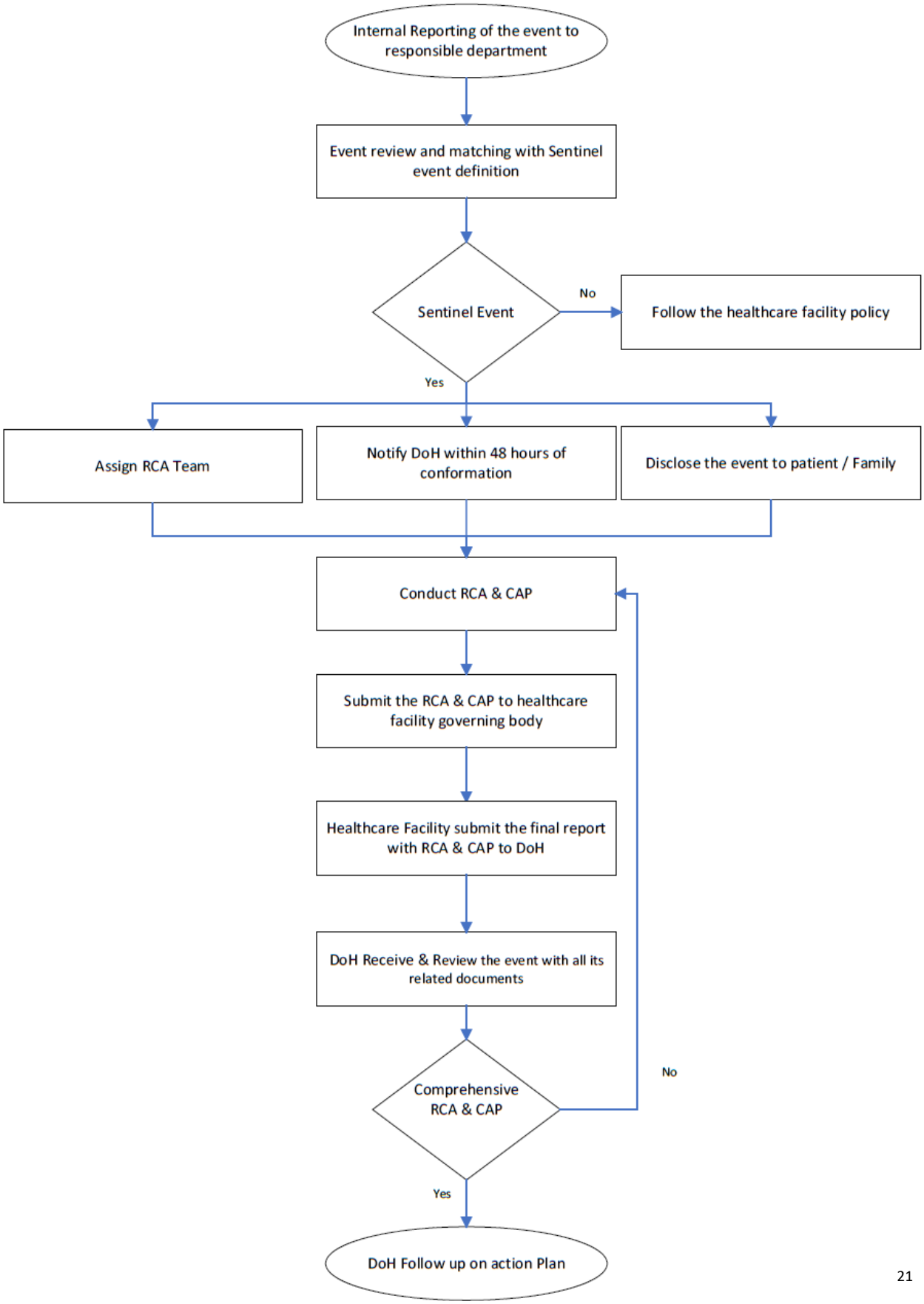
7. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	2020	JCI	Joint Commission International (JCI), "Joint Commission International Accreditation Standards for Hospitals," Oak Brook, 2020. https://store.jointcommissioninternational.org/assets/1/7/JCIH20_sample_pages_3_6_20.pdf
2		WHO	World Health Organization (WHO), "Maternal and perinatal health," Geneva. https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/maternal-health/maternal-and-perinatal-death-surveillance-and-response
3	2011	NQF	National Quality Forum (NQF), "List of Serious Reportable Events (aka SRE or "Never Events")," Washington, 2011. https://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx
4	2015	CPSI	Canadian Patient Safety Institute (CPSI), "Never Events for Hospital Care in Canada Safer Care for Patients," 2015. https://psnet.ahrq.gov/issue/never-events-hospital-care-canada-safer-care-patients
5	2002	AAFP	M. L. Porter and B. L. Dennis, "Hyperbilirubinemia in the Term Newborn," 2002 https://www.aafp.org/pubs/afp/issues/2002/0215/p599.pdf
6	2019	NPIAP	National Pressure Injury Advisory Panel (NPIAP), "Prevention and Treatment of Pressure Ulcers/Injuries: Quick Reference," European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP) and Pan Pacific Pressure Injury Alliance (PPPIA), 2019. https://npiap.com/page/InternationalGuidelines

7	2016	MOHAP	Medical liability legislation https://mohap.gov.ae/assets/c0ff95b5/Federal%20Decree-
8	2021	SPSC	Saudi Patient Safety Center (2021). Saudi Healthcare Sentinel Event Manual https://www.spsc.gov.sa/English/PublishingImages/Pages/R
19	2019	Classification of Burn Injury	P. L. Rice and D. P. Orgill, "UpToDate," 2019. [Online]. Available: https://www.uptodate.com/contents/assessment-and-classification-of-burn-injury#H4218372011. [Accessed 09 December 2020]. https://www.uptodate.com/contents/assessment-and-classification-of-burn-injury#H4218372011.%20[Accessed%2009%20December%202020
10	2017	DoH Health Care Providers Manual	https://www.DoH.gov.ae/en/resources/policies
11	2024	Accreditation Standards for Healthcare Facilities (Hospitals)	https://www.DoH.gov.ae/en/resources/standards
12	2024	Standard On Reporting Suspected Adverse Drug Reactions And Adverse Events Following Immunization	https://www.DoH.gov.ae/en/resources/standards

13	2020	Reporting Adverse Events Following Immunization (AEFI)	https://www.DoH.gov.ae/en/resources/Circulars
14		JAWDA Quarterly Guidelines for (Specialized and General Hospitals)	https://www.DoH.gov.ae/en/programs-initiatives/muashir/jawda-indicators-submission-guidelines
15	July 2016	Abu Dhabi Occupational Safety and Health System Framework (OSHAD-SF) Mechanisms	https://www.adphc.gov.ae/-/media/Project/ADPHC/ADPHC/PDF/OSHAD-SF/Mechanisms/11---Incident-Notification-Eng.pdf

Appendix I. Sentinel Event Reporting Process



Appendix II. Sentinel Event Notification Form

Sentinel event notification form

To be submitted within 48 hours from the date of becoming aware of the sentinel / suspected sentinel:
DoH Quality and Patients Safety " HCFSQPS@DoH.gov.ae"

I.EVENT DEMOGRAPHICS:

Name of Healthcare Facility:	**Healthcare Facility MF Number:**
Patient MRN Number:	**Gender:**
Patient EID:	**Date of Birth:**
Patient Nationality:	**Physical Location of Patient when SE Occurred:**
SE Occurrence date and time:	**Date of detection of SE:**

II.SENTINEL EVENT TYPE:

No.	Type of sentinel event	No.	Type of sentinel event	No.	Type of sentinel event
1	Abduction of any patient receiving care within a healthcare facility.	2	Discharge of an infant to the wrong family.	3	Discharge of a Minor or Incapacitated Patient to an unauthorized person.
4	Maternal death and Severe maternal morbidity (leading to permanent harm or severe harm)	5	Suicide, attempted suicide, or self-harm that results in severe temporary harm, permanent harm, or death while being cared for in a healthcare setting or within 7 days of discharge, including the emergency department.	6	Surgery/invasive procedures performed at the wrong site, on the wrong patient, or the wrong procedure.
7	Administration of incompatible ABO, Non-ABO of blood/ blood products, or transplantation of incompatible organs resulting in death, permeant harm or sever harm.	8	Unintended retention of a foreign object in a patient after surgical/invasive procedure.	9	Unanticipated death of a "full-term" infant
10	Rape of a patient, staff member, licensed independent practitioner, visitor, or vendor while on-site at the healthcare facility	11	Physical Assault leading to death, permanent harm, or severe harm, or homicide of a patient, staff member, licensed independent practitioner, visitor, or vendor while on-site at the healthcare facility	12	Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the health care Facility.
13	Unauthorized departure of the patient (within 72 hours Elopement) leading from healthcare facility that resulted in	14	Medication error leading to death, permanent, or severe temporary harm	15	Patient death, permanent, or severe temporary harm associated with intravascular air embolism

	death, permanent harm, or severe temporary harm				
16	Patient death, permanent, or severe temporary harm as a result of medical device breakdown or failure when in use	17	The unexpected collapse of any building within a healthcare facility	18	Transfusing/transplantation of contaminated blood, blood products, organ or tissue
19	Death or serious disability associated with failure to manage/identify severe neonatal hyperbilirubinemia.	20	Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or > 25% above the planned radiotherapy dose	21	Any (stage 3, 4 or unstageable) healthcare facility- acquired pressure injury (ulcer)
22	Unexpected death, permanent or severe temporary harm associated with transport/transfer of patients	23	Patient death, permanent harm, or severe temporary harm as a result of patient fall	24	Patient death, permanent harm, or severe temporary harm associated with wrong administration/connection of medical gas
25	Death, permanent, or severe temporary harm associated with the use of incorrectly positioned Oro – or Nasogastric tube	26	Fluoroscopy resulting in permanent tissue injury	27	Accidental burn of second degree and above during patient care
28	Sexual abuse/assault of any patient (receiving care, treatment and service), staff member, visitor, or vendor while on site at the health care Facility or while providing care or supervision to patients.				

III.DEGREE OF IMPACT:

Harm – death	☐	Harm – permanent loss of functioning	☐
Harm – permanent reduction in	☐	Harm – temporary loss of functioning	☐
Harm – temporary reduction in	☐	Harm – but no loss/reduction in	☐
Harm – significantly inconvenienced	☐	No harm	☐
Unknown	☐		

Provide a de-identified summary of the event:

[maximum 100 words]

Describe any actions taken immediately following the event to eliminate the risk of recurrence:

Appendix III. RCA and Corrective Action Plan (RAC) Report

ROOT CAUSE ANALYSIS AND CORRECTIVE ACTION PLAN (RAC) REPORT

*To be submitted within **Forty-five** (**45**) Calendar days from the date of notification of the event to:*
DOH Quality and Patients Safety " HCFSQPS@DoH.gov.ae"

I.EVENT DEMOGRAPHICS:

Name of Healthcare Facility:	**Healthcare Facility MF Number:**
Patient MRN Number:	**Gender:**
Patient Insurance Type:	**Date of Birth:**
Patient Nationality:	**Physical Location of Patient when SE Occurred:**
Patient EID:	**Sentinel Event Type:**
SE Occurrence date and time:	**Date of detection of SE:**
Was the patient referred from another facility ☐ Yes ☐ No *If yes, please indicate the name of the facility:*	

Source (as applicable):

- ☐ Incident Reporting
- ☐ Complaint
- ☐ Media
- ☐ DoH
- ☐ Others (Specify): _____

II.ROOT CAUSE ANALYSIS TEAM

<table>
<tr><td rowspan="11">RCA team (including titles and specialties)</td><td colspan="3">RCA Team Leader</td></tr>
<tr><td>Name</td><td>Specialty</td><td>Email</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td colspan="3">RCA Team Facilitator</td></tr>
<tr><td>Name</td><td>Specialty</td><td>Email</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td colspan="3">Other RCA Team Members</td></tr>
<tr><td colspan="3">Specialty</td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td>Date RCA initiated:</td><td colspan="3"></td></tr>
<tr><td>Date RCA completed:</td><td colspan="3"></td></tr>
</table>

III. ROOT CAUSE ANALYSIS EXECUTIVE SUMMARY

Brief case description and consequences (High level) *Note: A summary of the RCA should ideally be provided here. Not to repeat the preliminary assessment report (This summary will ideally be more accurate and comprehensive as it is provided after the entire event has been thoroughly investigated).	
Patient status at the time the RCA report is generated	☐ Transferred to another facility ☐ Hospitalized ☐ Discharged ☐ Deceased ☐ Others (Specify):
Was a debriefing conducted?	☐ No ☐ Yes Date: By whom: Specialty:

Has such an event occurred in the past? **If YES, please elaborate**	
After analysis, was this event considered to be	☐ Preventable ☐ Unpreventable
Lessons learned to share for enhanced patient safety	
Was the event disclosed to the patient/family?	☐ No ☐ Yes Date: By whom: specialty:

IV. FULL ROOT CAUSE ANALYSIS REPORT

Section 1: Chronology of Events

**Note: Please note that times are approximate and may reflect a delay in documentation under busy circumstances. Please avoid using names of involved clinicians. No 'Copy and Paste' of the entire medical record, kindly only document events that are of relevance to the SE.*

Date	Time	Description of Events	Source (ex: medical record, staff interview, patient interview)

Insert a process Flowchart here. (If applicable)

Section 2: Causality Analysis and Contributing Factors

S.NO	Analysis Question	Findings	Causal factor Type	Causal factor details	RC,CF,IF
1	*Insert questions as per Table 1 (24 Analysis Questions)*	*Describe findings using causal statements and follow "5 rules of causation" (*). Enter each individual finding using a separate row. You may use multiple rows for the same question. (Refer to RCA)*	*Refer to Table 2 (Causal Factor Types & Details)*	*Refer to Table 2 Table 1 (Causal Factor Types & Details)*	*RC, CF,IF (**)*
2...					
24					

Important Notes:

Analysis Question:

01) What was the intended process flow

02) Were there any steps in the process that did not occur as intended

03) What human factors were relevant to the outcome?

04) How did the equipment performance affect the outcome?

05) What controllable environmental factors affected the outcome?

06) What uncontrollable external factors influenced the outcome?

07) Were there any other factors that directly influenced this outcome?

08) What are the other areas in the health care Facility where this could happen?

09) Was staff properly qualified and currently competent for their responsibilities?

10) How did the actual setting compare with ideal level?

11) What is the plan for dealing with staffing contingencies?

12) Were such contingencies a factor in this event?

13) Did staff performance during the event meet expectations?

14) To what degree was all the necessary information available when needed? Accurate? Complete?

15) To what degree is communication among participants adequate?

16) Was this the appropriate physical environment for the processes being carried out?

17) What systems are in place to identify environmental risks?

18) What emergency and failure mode responses have been planned and tested?

19) How does the healthcare Facility's culture support risk reduction?

20) What are the barriers to communication of potential risk factors?

21) How does leadership address the continuum of patient safety events, including close calls, adverse events, and unsafe, hazardous conditions?

22) How can orientation and in-service training be improved?

23) Was available technology used as intended?

24) How might technology be introduced or redesigned to reduce risks in the future?

Casual factors Type:

1.Communication factors

2.Enviornmental factors

3.Equipment/Device/Supply/healthcare IT Factors

4.Task/process factors

5.Staff performance factors

6.Team Factors

7.Management/Supervisory/workforce factors

8.Organizational Factor/Leadership

NA

Casual factors Details:

1.1. Communication breakdown between and among teams, staff, and providers

1.2. Communication during handoff, transition of care

1.3. Language or literacy

1.4. Availability of Information

1.5. Misinterpretation of Information

1.6. Presentation of Information

2.1. Noise, lighting, flooring conditions etc.

2.2. Space availability, designs, location, storage

2.3. Maintenance, housekeeping

3.1. Equipment, device, or product supplies problems or availability

3.2. Health information technology issues such as display/interface issues, system interoperability

3.3. Availability of Information

3.4. Malfunction, incorrect selection, misconnection

3.5. Labelling instructions, missing

3.6. Alarms silenced, disabled, overridden

4.1 Lack of process or redundancies, interruptions, or lack of decision support

4.2. Lack of error recovery

4.3. Workflow insufficient or complex

5.1. Fatigue, inattention, distraction or workload

5.2. Staff knowledge deficit or competency

5.3. Criminal or intentionally unsafe act

6.1. Speaking up or disruptive behavior, lack or shared mental model

6.2. Lack of empowerment

6.3. Failure to engage patient

7.1. Disruptive or intimidating behavior

7.2. Staff Training

7.3. Appropriate rules/policies/procedure or lack thereof

7.4. Failure to provide appropriate staffing or correct a known problem

7.5. Failure to provide necessary information

8.1. Organizational - level failure to correct a known problem and or provide resource support including staffing

8.2. Workplace climate/institutional culture

8.3. Leadership commitment to patient safety

NA

(*) The 5 Rules of Causation

Rule 1. Clearly show the "cause and effect" relationship.

Rule 2. Use specific and accurate descriptors for what occurred, rather than negative and vague words. (Avoid negative descriptors such as: Poor; Inadequate; Wrong; Bad; Failed; Careless.)

Rule 3. Human errors must have a preceding cause.

Rule 4. Violations of procedure are not root causes, but must have a preceding cause.

Rule 5. Failure to act is only causal when there is a pre-existing duty to act.

(**)

RC - Root Cause: The underlying weaknesses ultimately leading to an incident or the existence of a hazard.

Identifying the root cause may be accomplished by asking three questions:

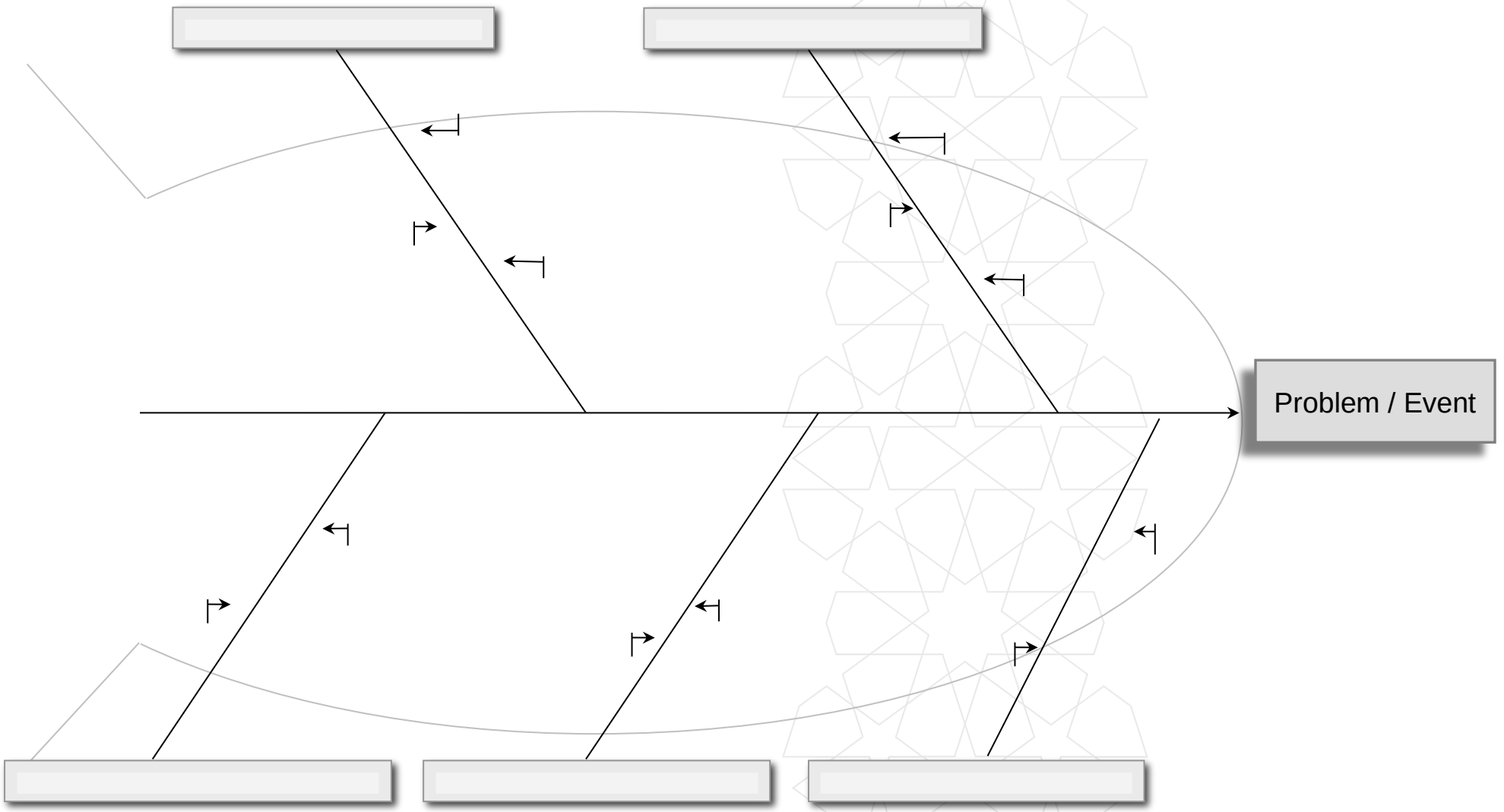
1. *Would the problem have occurred if the cause had not been present?*
2. *Will the problem recur due to the same causal factor if the cause is corrected or eliminated?*
3. *Will correction or elimination of the cause lead to similar events?*

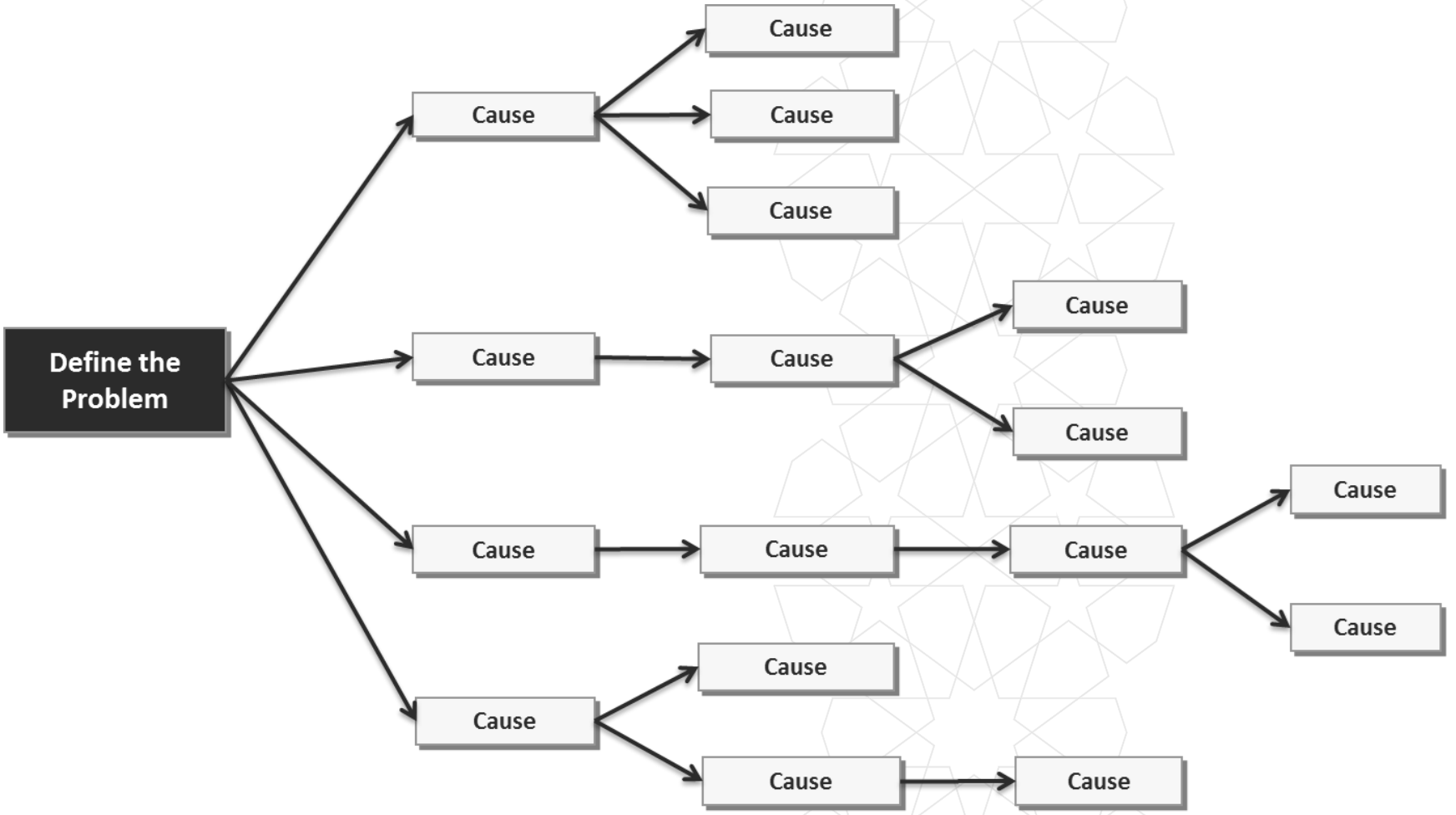
If the answer to each question is "No," then the team has identified the root cause.

CF – Contributing Factor: Conditions or actions that, if removed, would likely prevent the incident or hazard from happening, or reduce the severity of its consequences.

IF – Incidental Finding: Occurring or likely to occur as unpredictable or minor consequences.

Section 3: Cause and Effect / Logic Tree Diagram(s)




Define the Problem
Cause
Cause
Cause
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Cause

Section 4: Action Plan for Improvements and Risk Reduction Strategies

Root Cause (s):

Findings (Causal Statements)	Existing Controls	Recommended Actions	Department	Responsibility of	Effectiveness Measure	Targeted Completion Date	Status

Other Contributing Factor(s):

Findings (Causal Statements)	Existing Controls	Recommended Actions	Department	Responsibility of	Effectiveness Measure	Targeted Completion Date	Status

Appendix IV. Action Hierarchy

Action Strength	Action Category	Example
Stronger Actions (These tasks require less reliance on humans to remember to perform the task correctly)	Architectural/physical plant changes	Replace revolving doors at the main patient entrance into the building with powered sliding or swinging doors to reduce patient falls.
	New devices with usability testing	Perform heuristic tests of outpatient blood glucose meters and test strips and select the most appropriate for the patient population being served.
	Engineering control (forcing function)	Eliminate the use of universal adaptors and peripheral devices for medical equipment and use tubing/fittings that can only be connected the correct way (e.g., IV tubing and connectors that cannot physically be connected to sequential compression devices [SCDs]).
	Simplify process	Remove unnecessary steps in a process.
	Standardize on equipment or process	Standardize the make and model of medication pumps used throughout the institution. Use bar coding for medication administration.
	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff; support the RCA[2] process (root cause analysis and action); purchase needed equipment; ensure staffing and workload are balanced.
Intermediate Actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
	Software enhancements, modifications	Use computer alerts for drug-drug interactions.
	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps
	Education using simulation-based training, with periodic refresher sessions and observations	Conduct patient handoffs in a simulation lab/environment, with after action critiques and debriefing.
	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms. Use a checklist when reprocessing flexible fiber optic endoscopes.
	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the unit medication room
	Standardized communication tools	Use read-back for all critical lab values. Use read-back or repeat-back for all verbal medication orders. Use a standardized patient handoff format.
	Enhanced documentation, communication	Highlight medication name and dose on IV bags.
Weaker Actions (these tasks require more reliance on humans to remember to perform the task correctly)	Double checks	One person calculates dosage, another person reviews their calculation.
	Warnings	Add audible alarms or caution labels
	New procedure/ memorandum/policy	Remember to check IV sites every 2 hours.
	Training	Demonstrate correct usage of hard-to-use medical equipment.