SERIOUS REPORTABLE EVENTS LIST

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ABBREVIATIONS

SRE	Serious reportable event
ASA	American Society of Anesthesiologists
WHO	World Health Organization
ACOG	American College of Obstetricians and Gynecologists
CT	Computed Tomography
MRI	Magnetic Resonance Imaging

GLOSSARY

Patient	A person who is a recipient of healthcare from any healthcare facility in Maldives, irrespective of age, gender, ethnicity or nationality
Healthcare facility	Any healthcare facility in Maldives that is registered in Ministry of Health and possess an active operational license and registration license
Healthcare professional	All professionals who are registered under Maldives Medical & Dental Council, Maldives Nursing & Midwifery Council & Maldives Allied health professional and possess an active practicing license
Healthcare service staff	Any staff working in any healthcare facility in Maldives that is registered in Ministry of Health and possess an active operational license and registration license
Patient safety incident	Refers to any unintended &/or unanticipated incident which that could have resulted or did result in harm to a patient while in the care of a healthcare facility. These include adverse events, no harm incident & near miss.
Adverse event	A negative consequence of care that resulted in unintended harm to a patient which may or may not have been preventable in a healthcare facility.
Serious injury	Any injury that can result in death, loss of a body part, disability, loss of bodily function or require major intervention (e.g. higher level of care, surgery, etc.) or a substantial change in the individual's long-term risk status such that care or monitoring is required when it was not required before the adverse event occurring.
Serious reportable events	Any adverse event that has the potential to result in death, loss of a body part, disability, loss of bodily function or require major intervention for correction. Also considered as an "adverse event that should never be allowed to happen" or never events which are largely preventable.

INTRODUCTION

Patient safety initiatives have gained significant momentum globally, especially over the past 2 decades of the 21st century. Responding to the global imperative, Maldives has also undertaken efforts to participate in the patient safety movement. One of the the key initiatives that showcase Maldives' commitment to patient safety is the development of the National Patient Safety Framework by the Quality Assurance & Regulations Division (QARD) of the Ministry of Health in collaboration with WHO Maldives. This framework serves as comprehensive a guide for the improvement of patient safety by defining strategic objectives and action plan for implementation of the objectives. One of the strategic objectives in this framework is the establishment of a patient safety event reporting system. Currently there is no system for incidence surveillance, reporting and learning at the National and Atoll level. Most of the health facilities lack institutional arrangement to review adverse events & near misses. To fulfill the objective and as per the action plan in the National Patient Safety Framework, QARD has embarked on the development of a web-based patient safety incident surveillance system. Recognizing the urgency of surveillance of serious reportable events even before the full system is operational, QARD has compiled a preliminary list of serious reportable events to be utilized in the interim.

GENERAL CONSIDERATIONS

- Serious reportable events are applicable to all the grades of facilities and both government and private health facilities. This includes health centers, atoll hospitals, regional hospitals, tertiary hospitals, private hospitals and clinics.
- All the serious reportable events mentioned in Table 1 must be notified to Quality Assurance & Regulation Division of Ministry of Health immediately or within 24 hours of event discovery by the healthcare facility.
- The below mentioned information must be compiled and reported within 3 working days via email to qa_review@health.gov.mv. QARD will request any further information deemed necessary from the health facility.
    - Information to be included
        - Health facility name.
        - Victim's details: Name, national identity card, age & gender.
        - Victim's encounter: Inpatient, outpatient, visitor, healthcare. professional, healthcare service staff.
        - Event reporter's details: Name, designation, national identity card, age, gender & role in the incident
        - Location of event, event date & time.
        - Concerned specialty if applicable. Final diagnosis if applicable.
        - Event discovery/reported date & time.
        - Date of confirmation of serious reportable event.
        - How was the event reported? What is the adverse outcome of the event?
        - Event description
        - Immediate action taken regarding the event (E.g. Incident review initiated etc.)

OVERVIEW OF SERIOUS REPORTABLE EVENTS

1. SURGICAL OR INVASIVE PROCEDURE EVENTS

- 1A. Surgery or other invasive procedure performed on the wrong site by a healthcare service provider
- 1B. Surgery or other invasive procedure performed on the wrong patient by a healthcare service provider
- 1C. Wrong surgical or other invasive procedure performed on a patient by a healthcare service provider
- 1D. Wrong implant/ prosthesis/invasive device inserted into a patient by a healthcare service provider
- 1E. Unintended retention of a foreign object in a patient after surgery or other invasive procedure by a healthcare service provider
- 1F. Intraoperative or immediately postoperative/post procedure unexpected death occurring after surgery or other invasive procedure performed by a healthcare service provider

2. PRODUCT OR DEVICE EVENTS

- 2A. Patient death or serious injury associated with the use of contaminated drugs, devices, equipment provided by the healthcare facility
- 2B. Patient death or serious injury or disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended or anticipated in the care of a patient provided by a healthcare service provider
- 2C. Patient death or serious injury or disability associated with intravascular air embolism that occurs while being cared for in a healthcare setting

3. PATIENT PROTECTION EVENTS

- 3A. Discharge of minor or incapacitated patient from a healthcare facility to an unauthorized parent/ legal guardian
- 3B. Patient death or serious injury or disability associated with patient absconding from a healthcare facility
- 3C. Suicide, attempted suicide, or self-harm that results in serious injury, of a person who is receiving inpatient care in a healthcare facility or within 72hrs of discharge

4. CARE MANAGEMENT EVENTS

- 4A. Patient death or serious injury associated with a medication error
- 4B. Patient death or serious injury or risk thereof associated with unsafe administration of blood or blood products
- 4C. Maternal death or serious injury associated with pregnancy or delivery
- 4D. Death or serious injury of a term or preterm (>28 weeks) neonate associated with labor or delivery.
- 4E. Patient death or serious injury associated with a fall while being cared for in healthcare facility
- 4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission to a healthcare facility
- 4G. Any assisted human reproductive technology which has or, may have, resulted in insemination with wrong sperm or wrong egg or transfer of wrong embryo
- 4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
- 4I. Patient death or serious injury resulting from failure to follow up or communicate clinical test results

5. ENVIRONMENTAL EVENTS

- 5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare facility
- 5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances
- 5C. Patient or staff death or serious injury associated with a burn incurred from any source, in the course of a patient care process in a healthcare facility
- 5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare facility
- 5E. Patient death or serious injury associated with an unexpected collapse of any building structure within a healthcare facility

6. RADIOLOGIC EVENTS

- 6A. Death or serious injury of a patient or staff associated with the introduction of a ferromagnetic object into the MRI area
- 6B. Errors involving administration of radiation therapy (to the wrong body site, to the wrong patient, with a wrong dose) by a healthcare professional
- 6C. Radiological procedure performed on wrong patient, site or a wrong ionising radiological procedure performed on a patient
- 6D. Ionising radiological procedure performed on a pregnant patient
- 6E. Radiopharmaceutical and contrast media administered to wrong patient, through a wrong route or with a wrong type or dose

7. POTENTIAL CRIMINAL EVENTS

- 7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- 7B. Abduction of a patient/resident of any age while being cared for in healthcare facility
- 7C. Rape /sexual injury /sexual assault of a patient or staff member within or on the grounds of a healthcare facility
- 7D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility

APPENDIX 1

1. SURGICAL OR INVASIVE PROCEDURE EVENTS

1A. Surgery or other invasive procedure performed on the wrong site by a healthcare service provider		
Definition	**Specification**	**Implementation guidance**
• Defined as any surgery or other invasive procedure performed on a body part or site that is not consistent with correctly documented informed consent for that patient.	• Surgery or other invasive procedure includes all major & minor surgeries, interventions that are considered to be surgical but may be done outside a surgical environment such as interventional radiology procedure, cardiology procedure, drain insertion and line insertion, endoscopies. • The incident is detected at any time after the start of the procedure.	**Inclusions but not limited to:** • Surgery or other invasive procedure on the correct body part but on wrong location/site: Left/right organ, steroid injection into wrong knee. • Surgery or invasive procedure performed on wrong body site even if it was corrected during the procedure/intraoperatively. **Exclusions** • Changes in plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk or burden of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g. adhesions, spine level/extra vertebrae)

1B. Surgery or other invasive procedure performed on the wrong patient by a healthcare service provider		
Definition	**Specification**	**Implementation guidance**
• Defined as any surgery or other invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient.	• Surgery or other invasive procedure includes all major & minor surgeries, interventions that are surgical but may be done outside a surgical environment such as interventional radiology procedure, cardiology procedure, drain insertion and line insertion, endoscopies. • The incident is detected at any time after the start of the procedure.	**Examples include but not limited to:** • Surgery or invasive procedure that has begun on one patient but was intended for a different patient.

1C. Wrong surgical or other invasive procedure performed on a patient by a healthcare service provider		
Definition	**Specification**	**Implementation guidance**
• Defined as any surgery or other invasive procedure performed that is not consistent with correctly documented informed consent for that patient.	• Surgery or other invasive procedure includes all major & minor surgeries, interventions that are considered to be surgical but may be done outside a surgical environment such as interventional radiology procedure, cardiology procedure, drain insertion and line insertion, endoscopies.	**Inclusions but not limited to:** • A surgery or procedure that is not consistent with the informed consent documented for that patient. **Exclusions** • Changes in procedural plan upon entry into the patient

	• The incident is detected at any time after the start of the procedure.	with discovery of pathology in close proximity to the intended body site where the risk of a second surgery or procedure outweighs benefit of patient consultation or unusual physical configuration (e.g. adhesions, spine level/extra vertebrae).

1D. Wrong implant/ prosthesis/invasive device inserted into a patient by a healthcare service provider		
Definition	**Specification**	**Implementation guidance**
• Wrong implant/prosthesis/ invasive device inserted" means the placement of an implant/prosthesis/i nvasive device into a patient that is other than the implant/prosthesis/i nvasive device specified in the procedural plan either before or during the procedure.	• "Implant/prosthesis/inva sive device" include but is not limited to intraocular lens, coronary stents and orthopedic screws, plates, rods, joint replacements, artificial spinal discs, central venous lines and dialysis catheters. • The incident is detected at any time after the implant/prosthesis/ invasive device is inserted.	**Examples include but not limited to:** • The insertion of the wrong implant/prosthesis/invasive device into the correct body site stated in the procedural plan. **Exclusions but not limited to:** • Intended changes to the implant/prosthesis/invasive device from the implant/prosthesis/invasive device specified in the procedural plan, based on clinical judgement at the time of the procedure.

1E. Unintended retention of a foreign object in a patient after surgery or other invasive procedure by a healthcare service provider		
Definition	**Specification**	**Implementation guidance**
• Defined as an event whereby a foreign object is introduced into the body of a patient during surgery or other invasive procedure but is not removed before the end of the surgery or other invasive procedure; and that the failure to remove the foreign object was not intentional.	• "Foreign object" includes but is not limited to wound packing material, sponges, catheter tips, trocars and guidewires • The incident is detected at any time after the surgery or invasive procedure.	**Exclusions but not limited to:** • Foreign objects that are already present in the body of the patient prior to the surgery or other invasive procedure that are intentionally left in place after the said surgery or other invasive procedure. • Foreign objects that are intentionally implanted in the patient as part of a planned intervention E.g. sutures, stents, implants and medical devices. • Foreign objects that were introduced into the patient's body but removed within the same sitting, and not requiring patient to undergo unnecessary procedures.

1F. Intraoperative or immediately postoperative/post procedure unexpected death occurring after surgery or other invasive procedure performed by a healthcare service provider		
Definition	**Specification**	**Implementation guidance**
• "Immediately postoperative/post-procedure death" means a death that occurs within 48 hours after surgery or other invasive procedure. • Intraoperative: considered as the time between shifting the patient to operating room until they are shifted out from operating room to postoperative recovery room. • Unexpected death: considered as death occurring in ASA class 1 patients (normal, healthy person) and in patients with comorbidities in whom risk of potential complications such as death was not anticipated or expected by treating doctors prior to procedure/surgery.	• Surgery or other invasive procedure includes all major & minor surgeries, interventions that are considered to be surgical but may be done outside a surgical environment such as interventional radiology procedure, cardiology procedure, drain insertion and line insertion, endoscopies.	**Inclusions but not limited to:** • Unexpected deaths associated with the administration of anesthesia, whether the planned surgical procedure was carried out or not. • Intraoperative or immediately post-operative/post procedure unexpected deaths, whether or planned procedure was carried out or not.

2. PRODUCT OR DEVICE EVENTS

2A. Patient death or serious injury associated with the use of contaminated drugs, medical devices, equipment provided by the healthcare facility		
Definition	**Specification**	**Implementation guidance**
• "Drugs "are defined as pharmaceuticals regardless of route of administration. (Eg: vaccine, IV drugs, oral drugs) • "Devices" are defined as instruments /apparatus used for diagnosis, treatment or prevention of disease {Pacemaker, implant) • Equipment are defined as tools used in surgery or other invasive procedures (Eg. scalpel, scopes)	• "Contaminated" includes contaminations that can be seen with the naked eye, with the use of detection machines of general use, or with the use of more specialized testing mechanisms (e.g. cultures, nucleic acid testing, mass spectrometry and tests that signal changes in Ph or glucose levels). • Also includes contaminations that cannot be detected by any of the foregoing but can be inferred from circumstances of the event and potentially changes the risk status for life (e.g. a needle or syringe that has been used to administer medication to a patient by injection or via connection to a patient's intravenous infusion bag or administration set or hemodialysis can be inferred as being contaminated).	**Inclusions but not limited to:** • Administration of contaminated vaccine or medication (Eg: Intramuscular antibiotic) • Serious infection from contaminated drug or device used in surgery or an invasive procedure (Eg. scalpel)

2B. Patient death or serious injury or disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended or anticipated in the care of a patient provided by a healthcare service provider		
Definitions	**Specification**	**Implementation guidance**
	• "Medical devices" include but are not limited to catheters, drains and other specialized tubes, infusion pumps, endoscopes, ventilators and procedural and monitoring equipment.	

2C. Patient death or serious injury or disability associated with intravascular air embolism that occurs while being cared for in a healthcare setting		
Definition	**Specification**	**Implementation guidance**
	• While being cared for in a healthcare setting implies patient's receiving inpatient care in a healthcare.	**Exclusions but not limited to:** • Death, serious injury or disability associated with certain neurosurgical procedures or cardiac procedures known to present high risk of intravascular air embolism (Eg. Left ventricular assist device insertions that have a small but known & recognized risk of air embolism).

3. PATIENT PROTECTION EVENTS

3A. Discharge of minor or incapacitated patient from a healthcare facility to an unauthorized parent/ legal guardian		
Definition	**Specification**	**Implementation guidance**
• Minors are defined as patients under age 18 years as stated in Chapter 4 of Health service Act of Maldives (29/2015). • Incapacitated patients are defined as patients that cannot give informed consent as stated in Chapter 4 of Health Service Act of Maldives (29/2015).		**Inclusions but not limited to:** • All incidents due to the failure to double-check and/or identify the correct family, parents, or legal guardian before discharge.

3B. Patient death or serious injury or disability associated with patient absconding from a healthcare facility		
Definition	**Specification**	**Implementation guidance**
• Absconding can be defined as the unauthorized absence of an admitted patient from the boundaries of the care unit without the	This event relates to instances including but not limited to: • Failure to screen for elopement risk. • Failure to take precaution/measures for patients identified as	**Exclusions but not limited to:** • Death or serious injury occurring to adults as with mental capacity to give consent (defined by Health Service Act of Maldives), that decides to leave the

knowledge/authorization or the healthcare facility staff.	being at risk for elopement.	health facility against medical advice. • Death or serious injury to patients that have absconded but whose death, serious injury or disability is not related to the reason patient was seeking care they absconded from (Eg: patient treated for respiratory infection absconding and dying due to road traffic accident.)

3C. Suicide, attempted suicide, or self-harm that results in serious injury, of a person who is receiving inpatient care in a healthcare facility or within 72 hours of discharge		
Definition	**Specification**	**Implementation guidance**
• Suicide: Defined as self-inflicted death with implicit or explicit evidence that the person intended to die (Kaplan and Sadock's Comprehensive Textbook of Psychiatry)	This event relates to instances where: • Failure to screen for suicidal ideations or thoughts in a patient with prior history of suicide or self-harm upon admission or prior to discharge • Failure to make a safety plan during admission, prior to discharge • Failure to inform guardian/caretaker regarding presence of suicidal ideations and	**Inclusions but not limited to:** • All inpatients regardless of the medical discipline they are receiving care under. **Exclusions but not limited to:** • Excludes deaths resulting from self-inflicted injuries and/or attempted suicide that were the reason for admission to the healthcare facility.

	educate them about suicidal precautions during admission and prior to discharge or LAMA (leave against medical advice) • Failure to provide early follow-ups for identified patients with severe risk of suicide • Failure to refer complex psychiatric cases to specialists	• Death or serious injury to the patient after the patient had absconded from the prescribed healthcare facility. • Death or serious injury to the patients leaving against medical advice from healthcare facility.

4. CARE MANAGEMENT EVENTS

4A. Patient death or serious injury associated with a medication error		
Definition	**Specification**	**Implementation guidance**
	• Harm, death or serious injury to the patient that occurs at any stage of the medication management process (e.g. prescribing, preparation, dispensing, administration, and therapeutic monitoring) is included in this SRE.	**Inclusions but not limited to:** • Where there is erroneous, absent, or inappropriate prescription of the drug. • Where the wrong drug was administered. • Where the wrong dosage was administered. • Where the drug was administered to the wrong patient. • Where the drug was administered at the wrong time. • Where the drug was administered at the wrong rate.

		• When the administered drug was wrongly prepared. • Where the drug was administered through the wrong route or with the wrong/poor technique • Where the indicated drug was omitted from being administered. • Where an expired drug was administered. • The administration of a drug to a patient where the patient has a known allergy or serious contraindication to the said drug. • Failure to inquire regarding allergies prior to prescribing • The administration of drugs to a patient causing a drug-drug interaction or polypharmacy in the patient for which there is a known potential for death or serious injury • Improper use of single-dose/ single-use and multi-dose medication vials and containers for a patient resulting in dose adjustment problems to the patient. **Exclusions but not limited to:** • Death or serious injury related to unknown allergies.

4B. Patient death or serious injury or risk thereof associated with unsafe administration of blood or blood products		
Definition	**Specification**	**Implementation guidance**
		Inclusions but not limited to: • Administering blood or blood products to the wrong patient • Administering blood or blood products to a patient that is of a blood type that does not correspond to the blood type of that patient • Administering blood or blood product that have been improperly stored or handled • Administering blood where the Rhesus Status, Antibody, Cross-Matching and ABO matching screenings were not done adequately. **Exclusions but not limited to:** • Patient death or disability when the incompatibility is not detectable by routine screening. • Administration of unmatched blood or blood products in a life-threatening emergency as a last resort.

4C. Maternal death or serious injury associated with pregnancy or delivery		
Definition	**Specification**	**Implementation guidance**
	• Includes maternal death or serious injuries that occur within 42 days post-delivery. • Pregnancy or delivery includes all pregnancies or deliveries regardless of risk.	**Inclusions but not limited to:** • Any cause related or aggravated by the pregnancy or it's management.

4D. Death or serious injury of a term or preterm (>28 weeks) neonate associated with labor or delivery		
Definition	**Specification**	**Implementation guidance**

	• As specified by ACOG, term pregnancies include
	  • early term (37 0/7 weeks of gestation through 38 6/7 weeks of gestation)
	  • Full term (39 0/7 weeks of gestation through 40 6/7 weeks of gestation)
	  • Late term (41 0/7 weeks of gestation through 41 6/7 weeks of gestation)
	• Preterm: Weeks of gestation through 28 weeks – 37 weeks.
		Inclusions but not limited to:
		• All death irrespective of location of delivery.
		Exclusions but not limited to:
		• Death of "term" infant related to congenital abnormalities

4E. Patient death or serious injury associated with a fall while being cared for in a healthcare facility		
Definition	**Specification**	**Implementation guidance**
	• Intended to capture failure of identifying and monitoring patient's "at fall risk" adequately.	

4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission to a healthcare facility		
Definition	**Specification**	**Implementation guidance**
	• Stage 3: Full thickness skin loss, full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. • Stage 4: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of wound bed. • Unstageable pressure ulcer: Depth unknown, full thickness tissue loss in which base of ulcer is covered by slough &/or eschar in wound bed.	**Inclusions but not limited to:** • Applicable to all patients regardless of discipline in which care was received.

4G. Any assisted human reproductive technology which has or, may have, resulted in insemination with wrong sperm or wrong egg or transfer of wrong embryo		
Definition	**Specification**	**Implementation guidance**
• Wrong egg is defined as situations where the egg used does not belong to the recipient patient. • Wrong sperm is defined as situations where the sperm used does not belong to the husband of the recipient. • Wrong embryo is defined as situations where an embryo that is not intended for the recipient is used.	• Assisted reproductive technology includes Intrauterine insemination, Invitro fertilization & Intracytoplasmic sperm injection. • This SRE captures the breeches in care in the criteria outlined under "Couple and sample identification, Documentation in the" National Standard for Assisted Reproductive Technology in the Maldives"	

4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen		
Definition	**Specification**	**Implementation guidance**
• "Irretrievable loss of a biological specimen" refers to the loss of a biological specimen where it is not possible to secure a replacement, or a repeat/separate surgery or procedure is required to be carried out on the patient to replace the lost biological specimen.	• "Death or serious injury" includes the changing of the patient's risk status for life (because of an undiagnosed disease or threat of disease), requiring monitoring that was not needed before the event.	**Inclusions but not limited to:** • Death or serious injury to the Patient where biological specimens are misidentified, analyzed with the wrong diagnostic test, and discarded before the correct procedure can be carried out • Death or serious injury to the Patient resulting from the loss of a biological specimen and another procedure cannot be done to produce a similar specimen;

4I. Patient death or serious injury resulting from failure to follow up or communicate clinical test results		
Definition	**Specification**	**Implementation guidance**
	• "Death or serious injury" includes the new diagnosis of an advancing stage or worsening of an existing diagnosis (e.g. cancer). • "Failure to follow up or communicate" includes both communication	**Inclusions but not limited to:** • Clinical tests include but not limited to all laboratory, pathology, radiology, ECG, pulmonary function tests, sleep

	between healthcare staff and communication with the either the patient or patient party.	studies, endoscopy, audiometry exam, psychiatric diagnostic assessments etc.

5. ENVIRONMENTAL EVENTS

5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare facility		
Definition	**Specification**	**Implementation guidance**
	• Patient death or serious injury involving unintended electric shock during the course of treatment. • Staff death or injury associated with unintended electric shock at a healthcare facility.	**Exclusions but not limited to:** • Events involving planned treatments such as cardioversion or electroconvulsive therapies. • Injury to staff who are not involved in patient care

5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances		
Definition	**Specification**	**Implementation guidance**
		Inclusions but not limited to: • Anesthetic gases

5C. Patient or staff death or serious injury associated with a burn incurred from any source, in the course of a patient care process in a healthcare facility		
Definition	**Specification**	**Implementation guidance**

	• All cases involving burns coming under the classification of American burn association as second degree and above.
	• 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
		Inclusions but not limited to:
		• Burns that occur during care process such as:
		  • Due to oxygen fires,
		  • Unintended burns occurring during surgery
		  • Heat or cold burns from assisted bathing
		  • Use of hot or cold packs
		  • Due to friction, chemicals, radiation or electrical discharge.
		Exclusions but not limited to:
		• Burns due to a patients' personal use of room facilities/equipment such as the kitchen and shower.

5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare facility		
Definition	**Specification**	**Implementation guidance**
• Physical restraint can be defined as any manual method or physical or mechanical device, material or equipment		**Inclusions but not limited to:** • Deaths or serious injury where the restraints implicated (Eg. Strangulation, entrapments, asphyxiation)

attached or adjacent to the resident's body that the individual cannot easily remove that restricts freedom of movement or normal access to one's body.		

5E. Patient death or serious injury associated with an unexpected collapse of any building structure within a healthcare facility		
Definition	**Specification**	**Implementation guidance**
		Inclusions but not limited to: • Patients receiving inpatient and outpatient care in healthcare facility.

6. RADIOLOGIC EVENTS

6A. Death or serious injury of a patient or staff associated with the introduction of a ferromagnetic object into the MRI area		
Definition	**Specification**	**Implementation guidance**
	• Involves incident related to material inside patient's body or projectiles outside the patient's body.	**Inclusions but not limited to:** • Retained foreign objects • External projectiles • Pacemakers

6B. Errors involving administration of radiation therapy (to the wrong body site, to the wrong patient, with a wrong dose) by a healthcare professional		
Definition	**Specification**	**Implementation guidance**
• "Delivered to wrong body site "means that radiation therapy is carried out on a body site that is not consistent with the correctly documented informed consent for that patient. • "Delivered to the wrong patient" means that the radiation therapy is carried out on a patient who is not the patient who gave the correctly documented informed consent to undergo the procedure. • "Wrong dose" means that the radiation therapy is carried out with a radiation dose different from the dose intended for the patient.		

6C. Radiological procedure performed on wrong patient, site or a wrong radiological procedure performed on a patient		
Definition	**Specification**	**Implementation guidance**
• Wrong patient is defined as patient who has not given properly documented informed consent to undergo the procedure. • Wrong site means procedure carried out on body site that is not consistent with the properly documented informed consent for that patient. • Wrong radiological procedure means that the procedure performed on a patient is not consistent with the correctly documented informed consent for that patient.	• Radiological procedure includes, but is not limited to, X-Ray, CT scans, ultrasounds, MRIs etc.	**Inclusions but not limited to:** • Radiological procedures initiated on one patient when it is intended for a different patient • Radiological procedures initiated on the wrong location/site on the body. • Wrong radiological procedure initiated on the intended patient.

6D. Ionizing radiological procedure performed on a pregnant patient		
Definition	**Specification**	**Implementation guidance**
	• Intended to capture any ionizing radiological procedure that may result in unintended delivery of radiation to the fetus in a pregnant patient, as may occur due to failure to confirm the pregnancy status of the patient before carrying out the procedure; or the failure to adequately and appropriately shield the patient for the procedure. • Ionizing Radiological procedure" includes, but is not limited to, X-Ray, CT scans etc.	**Exclusions but not limited to:** • Emergent situations where the benefit of performing the procedure outweighs the risk of radiation to the fetus due to the procedure. • Ionizing radiological procedure performed on a pregnant woman with adequate shielding.

6E. Radiopharmaceutical and contrast media administered to wrong patient, through a wrong route or with a wrong type or dose		
Definition	**Specification**	**Implementation guidance**
• Wrong patient is defined as a patient who is not the patient that gave correctly documented informed consent to undergo the procedure.		

• Wrong route, type or dose means that the radiopharmaceutical and contrast media is administered through a route, or with a type or dose different from that intended for the patient.		

7. POTENTIAL CRIMINAL EVENTS

7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider		
	Specification	**Implementation guidance**
		Inclusions but not limited to: • Individuals without practicing license from respective councils, Maldives Medical and Dental Council, Maldives Nursing and Midwifery council, Maldives Allied Health Council • Individuals with practicing license from respective councils, Maldives Medical and Dental Council, Maldives Nursing and Midwifery council, Maldives Allied Health Council acting beyond the scope of practice set by the respective council.

		Exclusions but not limited to: • Healthcare providers who are practicing within the scope of their license on whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider.

7B. Abduction of a patient/resident of any age while being cared for in healthcare facility.		
Definition	**Specification**	**Implementation guidance**
• Abduction means the taking away of a person by persuasion, by fraud, or by open force or violence.	• All cases of abduction whether death or serious injury occurred or not.	**Exclusions but not limited to:** • Abduction occurring in 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.

7C. Rape /sexual injury /sexual assault of a patient or staff member within or on the grounds of a healthcare facility.		
Definition	**Specification**	**Implementation guidance**
• Rape is defined as the insertion, however minute, of a person's sexual organ into a sexual organ or an organ which is not a sexual organ of another person without consent. • Sexual injury is defined as the insertion of any part of a person's body into a sexual organ or an organ which is not a sexual organ of another person without consent, and in a manner, which would not constitute it a rape. Or it is the insertion by a person of an object into a sexual organ or an organ which is not a sexual organ of another person without consent. • Sexual assault is defined as touching of a sexual organ of a person, with or without a sexual intent by another person, with or without the use of an object or a tool, without consent, and in a manner, which would not constitute it a Rape or Sexual Injury.	• Patient: Includes patients receiving inpatient and outpatient care from a healthcare facility.	**Exclusions but not limited to:** • Sexual assault or rape of patient or staff member occurring outside the premises of the healthcare facility.

Or it is forcing a person to reveal his sexual organ without his consent. Or causing an injury to a person's sexual organ without his consent. Or causing any other degrading act on the sexual organ of a person's sexual organ without his consent.		

7D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of a healthcare facility		
Definition	**Specification**	**Implementation guidance**
According to Penal Code of Maldives Chapter 120 (Assault, endangerment and threat offenses), Section 120 – Assault • Assault: A person commits an offense if he, without the consent of another person (1) touches or injures such person or (2) puts such person in fear of imminent bodily injury.	• Patient: Includes patients receiving inpatient and outpatient care from a healthcare facility.	**Exclusions but not limited to:** Physical assault of patient or staff member occurring outside the premises of the healthcare facility.

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