LICENCE CONDITIONS FOR

SERIOUS REPORTABLE EVENT

IMPOSED UNDER
SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1. Application

1.1. These licence conditions ("**LCs**") apply to all persons licensed under the Healthcare Services Act 2020 ("**HCSA**") that are required to appoint at least one Serious Reportable Event QAC ("**Licensees**") under the HCSA and the Healthcare Services (General) Regulations 2021 (such persons referred to as "**Licensees**").

1.2. The defined terms used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.

1.3. A breach of these LCs may result in regulatory action being taken against the Licensee under section 20 of the HCSA, including but not limited to –

a) suspension or revocation of the Licensee's licence(s);
b) shortening the term of the Licensee's licence(s);
c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
d) a direction requiring the Licensee to pay a financial penalty.

1.4. For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2. DEFINITION OF KEY TERMS

2.1. In these LCs, unless otherwise specified:

a) "**abscondment**" refers to a situation where a patient who is cognitively, physically, mentally, emotionally and/or chemically impaired wanders, walks, runs away, escapes or, otherwise leaves the approved permanent

premises where the patient was receiving care at, unsupervised, unnoticed and/or prior to the patient's scheduled discharge;

b) "**adverse event**" refers to a negative consequence of care that resulted in harm to a patient;

c) "**associated with**" means that it is reasonable to assume that the adverse event was due whether in whole or in part to a licensable healthcare service;

d) "**authorised person**" refers to the surrogate, guardian or other individual(s) having the legally recognised ability to consent on behalf of a minor, an incapacitated individual or a person designated by the surrogate to release or give consent for the patient;

e) "**PSQI**" refers to the Patient Safety and Quality Improvement Branch of MOH;

f) "**error**" refers to the failure to carry out a planned action as intended or the application of an incorrect plan;

g) "**harm**" refers to temporary or permanent impairment of the physical structure, biological and psychological functions of the body and/or any deleterious effect(s) arising from there, including death[1];

h) "**low-risk pregnancy**" refers to a woman aged 18 to 39 (both ages inclusive), with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes or other previously documented condition that poses a high risk of poor pregnancy outcome;

i) "**medical device**" refers to any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific

[1] Adapted from the definition in '*The WHO Conceptual Framework for the International Classification for Patient Safety (v.1.1). Final Technical Report 2009*' by the World Health Organisation (WHO)

purposes of:

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;
(iv) supporting or sustaining life;
(v) control of conception;
(vi) disinfection of medical devices; or
(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its intended function by such means;

j) "**MOH**" refers to the Government of the Republic of Singapore as represented by the Ministry of Health;

k) "**NQAS**" refers to the online reporting system known as the National Quality Assurance System at https://elis.moh.gov.sg/NQAS/login/login.action;

l) "**patient safety incident**" refers to an unintended or unexpected incident, including but not limited to an adverse event, which is associated with, could have, or did, lead to harm to a patient;

m) "**preventable**" refers to an adverse event that could have been anticipated and prepared for by the Licensee but which occurred because of a human error, or a system error or failure;

n) "**root cause analysis**" **or** "**RCA**" refers to the systematic process whereby a serious reportable event is reviewed to determine the errors, systems failures and underlying cause(s) so that measures can be taken to prevent similar events from occurring or recurring within that approved permanent premises;

o) "**serious injury**" refers to harm that substantially limits one or more of the major life activities of an individual, whether in the short term or otherwise,

and which may or may not become a disability if extended into the long term. It includes but is not limited to harm (i) that results in death; (ii) that results in the loss of a body part; (iii) that results in disability; (iv) that results in the loss of a bodily function; (v) that requires major intervention such as a higher level of care or surgery; or (vi) that results in 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 event that caused the harm;

p) "**significant learning value**" refers to the benefit derived by healthcare systems and professionals from raising the awareness of a serious reportable event with: -

(i) potentially wide systemic risk;
(ii) high probability of occurrence; and
(iii) any one of the following: -
  (A) serious impact on patient(s); or
  (B) widespread impact across the approved permanent premises or across Singapore;

q) "**surgery**" refers to an invasive operative procedure during which skin or mucous membranes and connective tissue are incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgeries include minimally invasive procedures (including but not limited to biopsy or the placement of probes or catheters requiring the entry into a body cavity through a needle or trocar), minimally invasive dermatological procedures (including but not limited biopsy, excision and deep cryotherapy for malignant lesions), as well as those performed in relation to vaginal birth or Caesarean delivery to extensive multi-organ transplantation. It does not include the use of such things as otoscopes or drawing blood. Surgery begins, regardless of setting, at the point of surgical incision, tissue puncture or the insertion of instrument into tissues, cavities or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, devices such as probes or instruments have been removed and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room;

r) "**systems failure**" refers to a fault, breakdown or dysfunction in the operational methods, processes or infrastructure of the Licensee;

s) "**QAC**" refers to a quality assurance committee; and

t) **"working day"** refers to a day which is not a Saturday, Sunday or public holiday in Singapore.

3. SERIOUS REPORTABLE EVENTS

3.1. The serious reportable events are set out in Table 1 below (see Appendix 1 for the detailed specifications of each serious reportable event).

Table 1: Serious Reportable Events

I.	**Surgical or Other Invasive Procedure**
1.	Surgical or other invasive procedure performed on the wrong body site
2.	Surgical or other invasive procedure performed on the wrong patient
3.	Wrong surgical or other invasive procedure performed on a patient
4.	Wrong implant/prosthesis/invasive device inserted into a patient
5.	Unintended retention of a foreign object in a patient after surgical or other invasive procedure
6.	Intraoperative or immediately post-operative/post-procedure death in an American Society of Anesthesiologists (ASA) Class I patient, according to the American Society of Anesthesiologists Physical Status Classification System
II.	**Product or Medical Device**
7.	Patient death or serious injury associated with the use of contaminated drugs, medical devices or biologics provided by the Licensee
8.	Patient death or serious injury associated with the use or function of a medical device in patient care
9.	Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in the approved permanent premises
III.	**Patient Protection**
10.	Unauthorised discharge or release of an infant, a child or any person who lacks capacity, as referred to in section 4(1) of the Mental Capacity Act 2008

11.	Patient death or serious injury associated with patient abscondment
12.	Patient suicide, attempted suicide or self-harm that results in patient death or serious injury, while being cared for in the approved permanent premises
IV.	**Environmental**
13.	Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas or are contaminated by toxic substances
14.	Patient death or serious injury associated with a burn incurred while being cared for in the approved permanent premises
15.	Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in the approved permanent premises
V.	**Care Management**
16.	Patient harm, death or serious injury associated with a medication error falling within Categories E to I of Appendix 2
17.	Patient death or serious injury or risk thereof associated with the unsafe administration of blood or blood products
18.	Transmission of communicable diseases following blood transfusion or organ/tissue transplant
19.	Maternal death or serious injury associated with pregnancy or delivery
20.	Infant death or serious injury associated with labour or delivery in a low-risk pregnancy
21.	Patient death or serious injury resulting from the irretrievable loss of a biological specimen
22.	Patient death or serious injury resulting from failure to follow up or communicate clinical test results
23.	Unexpected death[2] or serious injury as a result of lack of treatment or delay in treatment which could have been preventable otherwise
24.	Unexpected death[2] or serious injury as a result of medical intervention which could have been preventable otherwise
25.	Any assisted human reproductive procedure which has or, may have, resulted

[2] Category 3 mortality, see Appendix 3

	in insemination of wrong gamete or transfer of wrong embryo
VI.	**Radiological**
26.	Ionising radiological procedure performed on (i) a wrong patient, (ii) on a wrong site, or (iii) a wrong ionising radiological procedure performed on a patient
27.	Ionising radiological procedure performed on a pregnant patient
28.	Radiopharmaceutical and contrast media administered (i) to a wrong patient; (ii) through a wrong route; (iii) with a wrong type; or (iv) with a wrong dose
29.	Radiation therapy delivered (i) to a wrong body site; (ii) to a wrong patient; or (iii) with a wrong dose
30.	Death or serious injury of a patient associated with the introduction of a metallic object into the magnetic resonance imaging (MRI) area
VII.	**Patient Safety**
31.	Unintended harm or risk of unintended harm to a patient while being cared for in the approved permanent premises

4. GENERAL REQUIREMENTS FOR SERIOUS REPORTABLE EVENTS AND SERIOUS REPORTABLE EVENT QAC

4.1. The Licensee:

a) shall establish at least one Serious Reportable Event QAC to identify, monitor, evaluate and review serious reportable events occurring within the approved permanent premises of the Licensee that occurs in the course of providing a licensable healthcare service by the Licensee;

b) shall ensure that the quality, safety standards and clinical appropriateness of the licensable healthcare service by the Licensee are monitored and evaluated regularly by a Serious Reportable Event QAC;

c) shall ensure the timely implementation of recommendations by a Serious Reportable Event QAC to improve the quality and safety standards of the licensable healthcare service by the Licensee;

d) shall establish a system to collect information on serious reportable events occurring within the approved permanent premises of the Licensee;

e) shall ensure that timely and appropriate training is provided to all Serious Reportable Event QAC members, and that all Serious Reportable Event QAC members have a working knowledge of these LCs and the root cause analysis review methodology;

f) shall appoint a QAC supervisor for each Serious Reportable Event QAC;

g) shall ensure that a QAC supervisor is a fully registered medical practitioner holding a position of Consultant and above at the approved permanent premises. The following individuals may be appointed as a QAC supervisor: -

(i) the chief executive officer or equivalent of the approved permanent premises;
(ii) the medical director or, equivalent of the approved permanent premises;
(iii) any other person on the medical board and/or clinical governance staff of the approved permanent premises; or
(iv) any other person;

h) shall ensure that a QAC supervisor carries out the following: -

(i) reviews the activities and effectiveness of the Serious Reportable Event QAC based on periodic reports of the activities, findings and recommendations submitted by the Serious Reportable Event QAC;
(ii) assesses the effectiveness of the previous recommendations by the Serious Reportable Event QAC to protect patients from a patient safety incident, by monitoring the number of serious reportable events reported and the recurrence of similar events, if any;
(iii) provides the necessary resources to support the effective functioning of the Serious Reportable Event QAC; and
(iv) ensures that the recommendations of the Serious Reportable Event QAC are implemented by the Licensee;

i) shall maintain written documentation of each review conducted by the Serious Reportable Event QAC, including but not limited to the following:

(i) objective of the review conducted by the Serious Reportable Event QAC;
(ii) relevant statutory provisions under which the review was conducted by the Serious Reportable Event QAC;
(iii) composition of the Serious Reportable Event QAC;
(iv) terms of reference of the Serious Reportable Event QAC;
(v) time that the Serious Reportable Event QAC took to complete the review;
(vi) number of times the Serious Reportable Event QAC met;
(vii) review process adopted by the Serious Reportable Event QAC; and
(viii) report documenting findings and follow-up of recommendations of the Serious Reportable Event QAC;

j) shall ensure that compliance with the obligations set out in this paragraph 4.1 is reviewed and updated regularly to ensure the effectiveness of the Serious Reportable Event QAC; and

k) shall ensure that the Serious Reportable Event QAC complies with the directives issued by the Director-General of Health to the Licensee.

5. IDENTIFICATION AND NOTIFICATION OF SERIOUS REPORTABLE EVENTS

5.1. Upon identification of a serious reportable event, the Licensee shall ensure that the following are carried out:

a) immediately carry out a preliminary assessment to determine if the harm arising from the serious reportable event has the potential to spread and affect a large number of people, whether within or outside of the approved permanent premises. If it does have such potential, the Licensee shall immediately implement interim measures to contain the harm or risk of harm arising from the serious reportable event while waiting for more conclusive findings from the Serious Reportable Event QAC. A serious reportable event with such potential includes but is not limited to the use of contaminated drugs, medical devices or biologics resulting in the widespread transmission of blood-borne diseases;

b) notify PSQI within **two (2) working days** of the date that the serious reportable event was identified:

(i) on the NQAS, in the provided form titled '*SRE Notification Form*'; or

(ii) in the event of network connection or technical issues, via electronic mail to moh_nqas@moh.gov.sg or such other address as may be prescribed, in the form of the '*SRE Notification Form*' as set out in Annex A of Appendix 4;

and to include in the said notification:

A. the date the serious reportable event occurred;
B. the date the serious reportable event was identified;
C. the location in which the serious reportable event occurred;
D. a short summary of the serious reportable event;
E. a description of any interim measures implemented by the Licensee pursuant to paragraph 5.1a; and
F. any additional information requested by the MOH; and

c) direct the Serious Reportable Event QAC to monitor, evaluate and review the serious reportable event in accordance with the requirements set out in these LCs.

5.2. Where more than one Licensee and/or person are directly and/or indirectly involved in a serious reportable event, each Licensee so involved shall ensure that paragraphs 5.1a to 5.1c above are carried out. In addition, each Licensee, shall ensure that the other Licensees so involved are immediately notified of the serious reportable event. For the avoidance of doubt, a Licensee or persons shall be deemed to be involved in a serious reportable event, if that Licensee or person: -

a) identified the serious reportable event; or
b) provided services and/or care to the patient involved in the serious reportable event, any time during the period commencing on the date the serious reportable event occurred and ending on the date the serious reportable event was notified to PSQI pursuant to paragraph 5.1(b) above.

6. COMPOSITION OF THE SERIOUS REPORTABLE EVENT QAC

6.1. Where only one Licensee or person is directly and/or indirectly involved in a serious reportable event, the Licensee (if any) shall convene a Serious Reportable Event QAC that comprises the following individuals:

a) a Serious Reportable Event QAC supervisor pursuant to paragraphs 4.1f and 4.1g above;
b) a fully registered medical practitioner doctor who has experience in the relevant discipline;

c) a medical, nursing or allied health professional;
d) a non-clinical staff (including but not limited to an administrator, Quality Coordinator, Quality Manager or equivalent);
e) such other individual(s) as the Director-General of Health may appoint; and
f) such other individual(s) as required by the HCSA, any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder[3].

6.2. The individual referred to in paragraph 6.1e above may be appointed at the sole discretion of the Director-General of Health:

a) at any stage of the review by the Serious Reportable Event QAC, to observe the said review as MOH's representative;
b) within **thirty (30) calendar days** of the date of the Serious Reportable Event QAC's submission of its report pursuant to paragraph 8.1, to evaluate the findings and recommendations in that report and provide his/their views as independent expert in the relevant discipline(s) to the relevant Serious Reportable Event QAC that is reconvened by the Licensee pursuant to paragraph 8.3.

6.3. Where more than one Licensee and/or person are directly and/or indirectly involved in a serious reportable event ("**Several Persons**"), the Licensee(s) shall convene a Serious Reportable Event QAC comprising of the following individuals, who may be appointed and/or assigned by any one of the Several Persons:

a) the individuals set out in paragraphs 6.1a to 6.1d and 6.1f;
b) at least one representative from each of the Several Persons; and
c) at least one independent expert in the relevant disciplines. The independent expert(s) shall not be employed by the Several Persons.

6.4. Depending on the size of the approved permanent premises and the volume of cases to be reviewed:

[3] For example, Licensees that are licensed to provide ambulatory surgical centre services are still required to adhere to the requirements on the composition of QACs set out in Regulation 9 of the Healthcare Services (Ambulatory Surgical Centre Service) Regulations 2023.

a) the same members may sit on multiple Serious Reportable Event QACs, Mortality and Morbidity Quality Assurance Committee(s) and/or Peer Review Learning Quality Assurance Committee(s); and
b) the reviews by the QACs referred to in paragraph 6.4a may be held concurrently,

provided that each review is carried out in accordance with the relevant licence conditions.

7. REVIEW OF SERIOUS REPORTABLE EVENTS

7.1. For each identified serious reportable event, the Licensee shall ensure that the Serious Reportable Event QAC conducts an RCA to identify system errors or failures, and contributing factors, and make recommendations to the Licensee to improve the quality of the licensable healthcare service and to prevent the occurrence or recurrence of similar serious reportable events. The Licensee shall also ensure that the Serious Reportable Event QAC reviews the feasibility of any measures that were put in place by the Licensee following a recommendation given under this paragraph 7.1 and any interim measures that were put in place by the Licensee pursuant to paragraph 5.1a.

7.2. Aggregate RCAs may be performed on a quarterly basis for the following serious reportable events when the circumstances surrounding the events are similar:

a) serious reportable event No. 12 of Table 1 of paragraph 3.1, where it relates to attempted suicide or self-harm by a patient that did not result in that patient's death; and
b) serious reportable event No. 16 of Table 1 of paragraph 3.1, where it relates to medication errors falling within Categories E and I of Appendix 2.

An aggregate RCA refers to one or more Serious Reportable Event QAC meetings convened to conduct RCA on a category of cases specified in paragraph 7.2 that have been identified over the preceding quarter of the relevant calendar year. For example, if 12 serious reportable events falling under S/No. 12 of Table 1 of paragraph 3.1, involving attempted suicide by a patient that did not result in that patient's death were identified from 1 January to 31 March 2022, then only one Serious Reportable Event QAC meeting may be convened to conduct an RCA on those 12 cases collectively.

7.3. The review of a serious reportable event by the Serious Reportable Event QAC

shall be carried out regardless of whether the serious reportable event is reportable under any other statutory requirements such as the Coroners Act 2010 or any prevailing policy.

8. SUBMISSION OF REPORTS AND REVIEW BY MOH

8.1. The Licensee shall ensure that the Serious Reportable Event QAC completes its review and submits a report containing its findings and recommendations to PSQI within **60 calendar days** of the date the PSQI was notified of the serious reportable event pursuant to paragraph 5.1b. The report shall be submitted:

a) on NQAS[4] in the provided form titled '*SRE Review Report Form*'; or
b) in the event of network connection or technical issues, via electronic mail to moh_nqas@moh.gov.sg or such other address as may be prescribed, in the form of the '*SRE Review Report Form*' as set out in Annex B to Appendix 4.

8.2. Notwithstanding paragraph 8.1, if the Serious Reportable Event QAC opts to conduct an aggregate RCA pursuant to paragraph 7.2, the Licensee shall ensure that the Serious Reportable Event QAC completes its review and submits a report containing its findings and recommendations to PSQI within **sixty** (**60) calendar days** of the last day of the relevant quarter of the calendar year in which PSQI was notified of the serious reportable event pursuant to paragraph 5.1(b) in accordance with paragraph 8.1(a) and (b). For example, if the Licensee notifies PSQI of three (3) serious reportable events occurring between 1 January 2022 and 20 March 2022 for which an aggregate RCA can be performed in accordance with paragraph 7.2 above, a Serious Reportable Event QAC that opts to carry out an aggregate RCA for these three (3) serious reportable events shall submit its report for the aggregate RCA to PSQI within sixty (60) calendar days from 31 March 2022.

8.3. If the Director-General of Health is of the view that any of the reports submitted by the Serious Reportable Event QACs pursuant to paragraph 8.1 and 8.2 are inadequate or in need of further clarification he may, at his sole discretion, require the Licensee to and the Licensee shall, reconvene the relevant Serious Reportable Event QAC to review its report and incorporate the views on any independent expert(s) that may be appointed by the Director-General of Health pursuant to paragraph 6.2(b). The reconvened Serious Reportable Event QAC

[4] Available at https://elis.moh.gov.sg/NQAS/login/login.action.

shall then submit its revised report to PSQI within **thirty (30) calendar days** of the date of notification by the Director-General of Health to revise its report. The report shall be submitted:

a) on NQAS[5] in the provided form titled '*SRE Review Report Form*'; or
b) in the event of network connection or technical issues, via electronic mail to moh_nqas@moh.gov.sg or such other address as may be prescribed, in the form of the '*SRE Review Report Form*' as set out in Annex B to Appendix 4.

8.4. If any of the reports submitted pursuant to paragraphs 8.1 to 8.3 have recommendations that have yet to be implemented by the Licensee, the Licensee shall ensure that the relevant Serious Reportable Event QAC that submitted the report, submits progress reports regarding the status of the implementation to PSQI at half-yearly intervals until all the recommendations have been implemented. The progress reports shall be submitted:

a) on NQAS[6] in the provided form titled '*SRE Follow-up Report Form*'; or
b) in the event of network connection or technical issues, via electronic mail to moh_nqas@moh.gov.sg or such other address as may be prescribed, in the form of the '*SRE Follow-up Report Form*' as set out in Annex C to Appendix 4.

8.5. Where more than one Licensee or person are directly and/or indirectly involved in a serious reportable event, the Licensee(s) shall ensure that at least one review report and one follow-up report is submitted pursuant to paragraphs 8.1 to 8.4.

8.6. The Licensee shall furnish the Director-General of Health, as and when required by him, with:

a) the details of the implementation status of specific recommendations made by the Serious Reportable Event QAC(s); and
b) such records relating to any other quality assurance activity undertaken by the Licensee.

[5] Available at https://elis.moh.gov.sg/NQAS/login/login.action.
[6] This also applies to HCSA licensees that are not Licensees if the implementation of the recommendations involves them in any way.

9. MATTERS TO BE REFERRED FOR DISCIPLINARY INQUIRY

9.1. The Licensee shall convene a separate disciplinary inquiry[7] if the serious reportable event resulted from:

a) a criminal act or deliberate patient harm;
b) the use of alcohol or illicit drugs;
c) a deliberate or grossly negligent unsafe act; and/or
d) professionally unethical practice

on the part of the registered healthcare professional(s) who had attended to the patient in the serious reportable event case, regardless of whether these actions were identified prior to the commencement or during the course of a Serious Reportable Event QAC review.

9.2. The Licensee shall ensure that policies are in place for the relevant healthcare professional(s)' suspension, limitation, reduction of privileges or termination at the point when cases are being referred for disciplinary inquiry to prevent any harm or danger to any individual and that such policies are compiled with.

10. ACTION BY MOH

10.1. The Director-General of Health may, at his sole discretion direct the Licensee to conduct a Serious Reportable Event QAC review for any patient safety incident. MOH may also, at its sole discretion, conduct on-site reviews on selected patient safety incidents at the approved permanent premises of the Licensee.

10.2. To ensure that the requirements of these LCs are complied with, MOH may, at its discretion, conduct periodic checks to ensure that:

a) the recommendations of the Serious Reportable Event QACs have been implemented;
b) patient safety measures have been instituted in the approved permanent premises of a Licensee; and
c) the patient safety measures that were recommended by the Serious Reportable Event QACs and/or implemented by the Licensees are effective in preventing the recurrence of similar events.

[7] For the registered healthcare professional(s) who had attended to the patient in the serious reportable event case

APPENDIX 1

SPECIFICATIONS OF SERIOUS REPORTABLE EVENTS

I. SURGICAL OR INVASIVE PROCEDURE

1. Surgery or other invasive procedure performed on the wrong body site

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Surgery or other invasive procedure*" includes but is not limited to image-guided interventional procedures, endoscopies, lesion removal, and injection into joints. • "*Performed on the wrong body site*" means that the procedure is carried out on a body site that is not consistent with the correctly documented informed consent for that patient. .	The correctly documented informed consent for patients whose procedures are carried out beyond the confines of an operating room (e.g. radiology suite, ward, ICU, etc.) may not involve a "surgical consent form"; however, the informed consent of that patient is still required to be documented in the patient record. An incorrectly placed surgical mark (i.e., site marking) does not, in itself, constitute a surgery or other invasive procedure being performed on the wrong body site. It is necessary for the surgery or other invasive procedure to have begun in order to give rise to this serious reportable event. A surgery or other invasive procedure that was performed at the wrong body site and corrected during the procedure still falls within the ambit of this serious reportable event. Events that fall within this serious reportable event include: • Surgery or other invasive procedure performed on the correct body *part* but on the wrong body site (e.g. left/right, appendages/organs, wrong digit, wrong level of the spine, stent place in the wrong iliac artery, steroid injection into the wrong knee, biopsy of the wrong mole, burr hole on the wrong side of the skull)

	regardless of the setting in which it occurs (e.g. post-anaesthesia recovery unit, surgical suite, endoscopy unit, ward or clinic, etc.). • Surgery or other invasive procedure that inserted the correct implant, prosthesis or invasive device, but on the wrong body site. Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Changes in procedural plan upon entry into the patient 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). • Emergent situations that occur in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent.

2. Surgery or other invasive procedure performed on the wrong patient

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Surgery or other invasive procedure*" includes but is not limited to image-guided interventional procedures, endoscopies, lens implants, lesion removal,	The correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, the informed consent of that patient is still required to be documented in the patient record. Events that fall within this serious reportable event include:

injection into joints. • "*Performed on the wrong patient*" means that the procedure is carried out on a patient who is not the patient who gave the correctly documented informed consent to undergo the procedure.	• Surgery or other invasive procedure (whether or not completed) that has begun on one patient but was intended for a different patient.

3. Wrong surgery or other invasive procedure performed on a patient

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Surgery or other invasive procedure*" includes but is not limited to image-guided interventional procedures, endoscopies, lens implants, lesion removal, injection into joints. • "*Wrong surgery or other invasive procedure performed*" means that the procedure performed on a patient is not consistent with the correctly documented informed consent for that patient.	The correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, the informed consent of that patient is still required to be documented in the patient record. Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Changes in procedural plan upon entry into the patient 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). • Emergent situations that occur in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent.

	• Surgery or other invasive procedure that inserted the wrong implant, prosthesis or invasive device. Those events will fall within serious reportable event No. 4.

4. Wrong implant/prosthesis/invasive device inserted

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Wrong implant/prosthesis/ invasive device inserted*" means the placement of an implant/prosthesis/invasive device into a patient that is other than the implant/prosthesis/invasive device specified in the procedural plan either before or during the procedure. • "*Implant/prosthesis/invasive device"* include but is not limited to intraocular lens, coronary stents and orthopaedic screws, plates, rods, joint replacements, artificial spinal discs, central venous lines and dialysis catheters.	For the avoidance of doubt, a wrong implant/prosthesis/invasive device that is inserted into a patient but detected at any time after it is inserted (even before the end of the surgery or other invasive procedure) still falls within the ambit of this serious reportable event. Events that fall within this serious reportable event include: • The insertion of the wrong implant/prosthesis/invasive device into the correct body site stated in the procedural plan. Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • 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. • The correct implant/prosthesis/invasive device was placed as per the procedural plan but later found to be suboptimal.

5. Unintended retention of a foreign object in a patient after surgery or other invasive procedure

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Unintended retention of a foreign object in a patient after surgery or other invasive procedure*" refers to 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.	For the avoidance of doubt, a foreign object that was unintentionally retained in a patient after surgery or other invasive procedure has concluded and is later removed still falls within the ambit of this serious reportable event. Events that fall within this serious reportable event include: • The unintended retention of foreign objects after surgery or other invasive procedure regardless of setting (e.g., post anaesthesia recovery unit, surgical suite, emergency department, patient bedside, etc.). Events that <u>do</u> not fall within this serious reportable event or are excluded from this serious reportable event include: • 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. • Foreign objects that were introduced into the patient's body but removed within the same sitting, and not requiring patient to undergo unnecessary procedures. • Foreign objects that were unintentionally retained in the patient's body but cannot be detected through X-ray (e.g., micro needles) and the risk of its removal

	had been assessed to exceed the risk of continued retention.

6. Intraoperative or immediate post-operative/post-procedure death in an ASA[8] Class I patient

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Immediately post-operative/post-procedure death*" means a death that occurred within 24 hours after: (1) surgery or other invasive procedure was completed; or (2) if the surgery or other invasive procedure was not completed, the administration of anaesthesia.	Events that fall within this serious reportable event include: • Intraoperative or immediately post-operative/post-procedure death of ASA Class I patients, whether or not the planned procedure was carried out.

II. PRODUCT OR MEDICAL DEVICE

7. Patient death or serious injury associated with the use of contaminated drugs, medical devices, or biologics provided by the Licensee

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event:	For the avoidance of doubt, all patient deaths or serious injuries associated with the use of contaminated drugs, medical devices, or biologics provided in the approved

[8] American Society of Anesthesiologists Physical Status Classification System

• "*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 specialised testing mechanisms (e.g., cultures, nucleic acid testing, mass spectrometry and tests that signal changes in pH or glucose levels). It 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 haemodialysis can be inferred as being contaminated) • "*Drugs*" include vaccines or medication (e.g., intramuscular antibiotics) • "*Medical devices*" include the tools used in	permanent premises of a Licensee will fall within this serious reportable event regardless of the source of the contamination and/or the drug, medical device or biologics in question. The Licensee shall report contaminations that can be seen with the naked eye or with the use of detection mechanisms in general use at such time as they become known to the Licensee. Events that fall within this serious reportable event include: • Patient death or serious injury associated with the use of contaminated medical devices or drugs. These could be a result of improper cleaning or maintenance.

surgery or other invasive procedure (e.g., scalpels)	

8. Patient death or serious injury associated with the use or function of a medical device in patient care

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Medical devices*" include but are not limited to catheters, drains and other specialised tubes, infusion pumps, ventilators and procedural and monitoring equipment.	For the avoidance of doubt, all patient deaths or serious injuries associated with the use or function of a medical device in patient care will fall within this serious reportable event regardless of whether or not the use or function is intended or described by the medical device manufacturers' literature. Events that fall within this serious reportable event include: • Patient death or serious injury associated with parts related to the medical device (e.g., drill bits and broken screws) that were unintentionally retained in the patient's body.

9. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in the approved permanent premises.

Additional specifications	*Implementation guidance*
NIL	Events that fall within this serious reportable event include: • Patient death or serious injury associated with intravascular air embolism that occurs while undergoing procedures that have a high risk of harm including but not limited to procedures involving the head and neck, vaginal delivery and caesarean section, spinal instrumentation

	procedures, and liver transplantation, but does not include neurosurgical procedures; • Patient death or serious injury associated with intravascular air embolism that occurs while undergoing procedures that have a low risk of harm including those related to lines placed for infusion of fluids in vascular space. Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Patient death or serious injury associated with intravascular air embolism that occurs while undergoing neurosurgical procedures, including those that are known to present a high risk of intravascular air embolism occurring.

III. PATIENT PROTECTION

10. Unauthorised discharge or release of an infant, a child or any person who lacks capacity, as referred to in section 4(1) of the Mental Capacity Act 2008

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Unauthorised discharge or release*" refers to the removal of an infant, child or any person who lacks capacity, as referred to in section 4(1) of the Mental Capacity Act 2008 by an unauthorised person or	NIL

by an authorised person without specific notification to and approval by the staff of the approved permanent premises of the Licensee to do so.	

11. Patient death or serious injury associated with patient abscondment

Additional specifications	*Implementation guidance*
NIL	For the avoidance of doubt, only patient deaths or serious injuries that are associated with abscondments occurring after the patient presents him or herself for care in the approved permanent premises of a Licensee will fall within the ambit of this serious reportable event. Events that do not fall within this serious reportable event or are excluded from this serious reportable event include: • Death or serious injury associated with abscondment befalling patients who are competent adults with mental capacity that decide to leave the approved permanent premises of a Licensee, from which care was received, against medical advice. • Death or serious injury associated with abscondment befalling patients who have attempted or committed suicide more than 24 hours after abscondment. • Death or serious injury to patients that have absconded but whose death or serious injury is not associated with the abscondment.

12. Patient suicide, attempted suicide or self-harm that results in patient death or serious injury while being cared for in the approved permanent premises

Additional specifications	*Implementation guidance*
NIL	For the avoidance of doubt, all patient suicide, attempted suicide or self-harm that results in patient death or serious injury occurring after the patient presents him or herself for care in the approved permanent premises of a Licensee will fall within the ambit of this serious reportable event, regardless of whether the patient had been admitted or not. Events that fall within this serious reportable event include: • Patient suicide, attempted suicide or self-harm that results in patient death or serious injury while that patient is on home leave (i.e. where the patient is still officially an inpatient of the Licensee but is authorised to go home). Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Patient suicide, attempted suicide or self-harm that results in patient death or serious injury while that patient is not physically present in the approved permanent premises of a Licensee were provided (other than those patients who are on home leave). • Deaths resulting from patient suicide, attempted suicide or self-harm that were the reason for admission to or presentation of the patient at the approved permanent premises of a Licensee. • Death or serious injury to the patient after the patient had absconded from the approved

	permanent premises of a Licensee.

IV. ENVIRONMENTAL

13. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas or are contaminated by toxic substances

Additional specifications	*Implementation guidance*
NIL	Events that fall within this serious reportable event include: • Incidents where the oxygen or gas line is attached to a reservoir that is situated distant from the patient care unit or in a tank near the patient such as E-cylinders, anaesthesia machines.

14. Patient death or serious injury associated with a burn incurred while being cared for in the approved permanent premises

Additional specifications	*Implementation guidance*
NIL	Events that fall within this serious reportable event include: • Burns resulting from operating room flash fires, hot water, smoking, heated equipment, and any device brought in by the patient. For the avoidance of doubt, the abovementioned events resulting in burns are not exhaustive.

15. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in the approved permanent premises

Additional specifications	*Implementation guidance*
NIL	Events that fall within this serious reportable event

	include: • Death or serious injury to the Patient where physical restraints or bedrails are implicated in the death (e.g. led to strangulation or entrapment, etc.)

V. CARE MANAGEMENT

16. Patient harm, death or serious injury associated with a medication error falling within Categories E to I of Appendix 2

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*medication error*" includes but is not limited to the following events: - o Where there is erroneous, absent, or inappropriate prescription of the drug; o where the wrong drug was administered; o where the wrong dosage was administered. o where the drug was administered to the wrong patient; o where the drug was administered at the wrong time; o where the drug was administered at the wrong rate; o when the administered drug was wrongly prepared; o where the drug was administered through the wrong route or with the wrong/poor technique; o where the indicated drug was omitted from being administered; o where an expired drug was	Events that fall within this serious reportable event include: • 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); • For the avoidance of doubt, medication errors including occurrences in which a patient receives a contraindicated medication or for which the patient is known to have serious allergies to, resulting in harm, serious injury or death. These events may occur as a result of failure to collect information about contraindications or allergies, failure to review such information available in information systems, failure of the organisation to ensure availability of such information in the care delivery process or other system failures that are determined through investigation to be the cause of the adverse event.

administered; o the administration of a drug to a Patient where the Patient has a known allergy or serious contraindication to the said drug; o 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; o 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.	Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Harm, death or serious injury to the Patient associated with allergies or adverse drug reactions that could not reasonably have been known or discerned in advance of the event. • Harm, death or serious injury to the Patient associated with reasonable differences in clinical judgment on the drug selection and dose.

17. Patient death or serious injury or risk thereof associated with the unsafe administration of blood or blood products

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Patient death or serious injury*" includes but is not limited to haemolytic reactions, and organ rejections that are attributable to hyper-acute haemolytic reactions. • "*unsafe administration of blood and blood products*" includes but is not limited to, administering blood or	This event is intended to capture patient death or injury that could be prevented by blood typing/screening. Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Organ rejection that is not attributable to a hyper-acute haemolytic reaction

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; and where the Rhesus Status, Antibody, Cross-Matching and ABO-Matching screenings were not done adequately.	

18. Transmission of communicable diseases following blood transfusion or organ/tissue transplant

Additional specifications	*Implementation guidance*
NIL	For the avoidance of doubt, this event is not intended to capture cases of non-seroconversion – *i.e.,* cases where the Patient is positive for a certain communicable disease prior to the transfusion or transplant (e.g., a HBV patient receiving a transplant). Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Where the transmission of the communicable disease occurred more than 1-year after the transfusion or transplant.

19. Maternal death or serious injury associated with pregnancy or delivery

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Pregnancy or delivery*" includes all pregnancies or deliveries regardless of the risk.	Includes maternal death or serious injury that occur within 42 days post-delivery. Root Cause Analysis (Annex B) is not required for maternal death resulting from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy, where the Licensee has reviewed the incident and concluded that there is no potential learning value.

20. Infant death or serious injury associated with labour or delivery in a low-risk pregnancy

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Infant death or serious injury*" includes but is not limited to fractures, head injuries and intracranial haemorrhage.	NIL

21. Patient death or serious injury resulting from the irretrievable loss of a biological specimen

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event:	For the avoidance of doubt, this event can occur with incisional and excisional biopsy, and in organ removal.

• "*Death or serious injury*" includes the changing of the patient's risk status for life (as a result of an undiagnosed disease or threat of disease), requiring monitoring that was not needed before the event. • "*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.	Events that fall within this serious reportable event include: • Death or serious injury to the Patient where biological specimens are misidentified, analysed 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.

22. Patient death or serious injury resulting from failure to follow up or communicate clinical test results

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Death or serious injury*" includes the new diagnosis of an advancing stage of an existing diagnosis (e.g., cancer).	Events that fall within this serious reportable event include: • Patient suffering from kernicterus as a result of the failure to report an increased neonatal bilirubin levels between the healthcare staff.

• "*Failure to follow up or communicate*" includes both communication between healthcare staff and communication with the Patient or the Patient's authorised person. • "*Clinical tests*" include but are not limited to laboratory, pathology and radiology tests.	

23. Unexpected death[9] or serious injury as a result of lack of treatment or delay in treatment which was preventable

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Death or serious injury*" includes: o all cases falling under Category 3 Mortality as identified via Mortality & Morbidity Review (see Appendix 3); and o all preventable mortalities arising from the lack of treatment/diagnosis not classified above.	NIL

[9] Category 3 mortality, see Appendix 3

24. Unexpected death[10] or serious injury as a result of medical intervention which was preventable

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Death or serious injury*" includes: o all cases falling under Category 3 Mortality as identified via Mortality & Morbidity Review (see Appendix 3); and o all preventable mortalities arising from a medical treatment/procedure/diagnosis not classified above and the deleterious effects associated with it. .	NIL

25. Any assisted human reproductive procedure which has, or may have, resulted in insemination of wrong gamete or transfer of wrong embryo

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event:	NIL

[10] Category 3 mortality, see Appendix 3

• "*Assisted human reproductive procedure"* is defined as any procedure associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application, and any event in relation to a donor of gametes or a person who receives treatment or services on assisted reproduction.	

VI. Radiological

26. Ionising radiological procedure performed on (i) wrong patient; (ii) wrong site; or (iii) wrong ionising radiological procedure performed on patient

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "Ionising *radiological procedure"* includes, but is not limited to, X-Ray, CT Scans, but excludes image-guided interventional procedures which are reportable under serious reportable event No. 1 and 2. • "*Performed on … wrong*	For the avoidance of doubt, this event applies to diagnostic radiology. Events that fall within this serious reportable event include: • Ionising radiological procedures initiated on one patient when it is intended for a different patient; • Ionising radiological procedures initiated on the wrong location/site on the body; • Wrong ionising radiological procedure initiated on the intended patient.

patient" means that the procedure is carried out on a patient who is not the patient who gave the correctly documented informed consent to undergo the procedure. • "*Performed on … wrong site*" means that the procedure is carried out on a body site that is not consistent with the correctly documented informed consent for that patient • "*Wrong radiological procedure performed*" means that the procedure performed on a patient is not consistent with the correctly documented informed consent for that patient.	Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • Bone mineral densitometry and general x-rays performed outside the abdominal pelvic region; and • Mammography and dental x-rays

27. Ionising radiological procedure performed on pregnant patient

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*Ionising radiological procedure"* includes, but is not limited to, x-ray, CT Scans, but excludes	For the avoidance of doubt, this event applies to diagnostic radiology. This event is intended to capture any ionising radiological procedure that may result in unintended delivery of radiation to the foetus in a pregnant patient, as may occur due to failure to confirm the pregnancy

image-guided interventional procedures which are reportable under serious reportable event No. 1 and 2.	status of the patient before carrying out the procedure; or the failure to adequately and appropriately shield the patient for the procedure. Events that do not fall within this serious reportable event or are excluded from this serious reportable event include: • Emergent situations where the benefit of performing the procedure outweighs the risk of radiation to the foetus due to the procedure; • Bone mineral densitometry and general x-rays performed outside the abdominal pelvic region; and • Mammography and dental x-rays

28. Radiopharmaceutical and contrast media administered (i) to the wrong patient; (ii) through the wrong route; (iii) with a wrong type; or (iv) with wrong dose

Additional specifications	Implementation guidance
For the purposes of this serious reportable event: • "Administered … to the wrong patient" means that the radiopharmaceutical and contrast media is administered to a patient who is not the patient who gave the correctly documented informed consent to undergo the procedure.	For the avoidance of doubt, this event applies to diagnostic and therapeutic procedures. Events that fall within this serious reportable event include: • A nuclear medicine study performed on the wrong patient; • Administration of radiopharmaceutical or contrast media to the wrong patient; • Wrong type or dose of radiopharmaceutical or contrast media administered – whether for

• "Administered … to the 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.	diagnostic[11] or therapeutic[12] purposes.

29. Radiation therapy delivered (i) to the wrong body site; (ii) to the wrong patient; or (iii) with a wrong dose

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*delivered … to the wrong body site*" means that the 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	For the avoidance of doubt, this event applies to radiation oncology procedures.

[11] "any diagnostic exposure greater than 50% of the intended dose or resulting in doses repeatedly or substantially exceeding the established normal doses for diagnostic radiological examinations" *Radiation Protection (Ionising Radiation) Regulations 2023, 71(2)(b)*

[12] "any therapeutic treatment delivered with a dose or dose fractionation which differs by more than 10% from the value prescribed by the medical practitioner or which may lead to acute effects" *Radiation Protection (Ionising Radiation) Regulations 2023, 71(2)(a)(iii)*

informed consent to undergo the procedure. • "*delivered… to the wrong dose*" means that the radiation therapy is carried out with a radiation dose different from the dose intended for the patient.	

30. Death or serious injury of a patient associated with the introduction of a metallic object into the MRI area

Additional specifications	*Implementation guidance*
For the purposes of this serious reportable event: • "*metallic object*" includes those that are inside the patient's body (e.g., retained foreign objects, pacemakers and other metal implants or pumps such as implantable pumps and penile implants) and those that are outside the patient's body but act as projectiles.	NIL

VII. PATIENT SAFETY

31. Unintended harm or risk thereof to a patient while being cared for in the approved permanent premises

Additional specifications	*Implementation guidance*
NIL	This is intended to capture any patient safety incident that: a) is not an adverse event falling within serious reportable events No. 1 to 30; and b) has significant learning value. Events that <u>do not</u> fall within this serious reportable event or are excluded from this serious reportable event include: • fall during the process of care, and the root cause of the event is solely attributable to patient factor(s); • pressure ulcer acquired after admission/presentation to the approved permanent premises providing licensable healthcare services, and the root cause of the event is solely attributable to patient factor(s); • NCC MERP Medication Error Categories A to D (refer to Appendix 2); • expected complications that arose from appropriate care; • patient harm or risk due to change(s) in care plan or procedure where the deemed benefit of the change outweighs the risk from the initial plan or procedure. In the event of a patient safety incident that (a) is not an adverse event falling within serious reportable events No. 1 to 30 and (b) <u>does not</u> have significant learning value, a Licensee who wishes to alert and prevent the recurrence of such patient safety incidents in the approved permanent premises may also rely on

	this serious reportable event No. 31 to report and investigate the patient safety incident under the existing Serious Reportable Event QAC process.

APPENDIX 2

CATEGORIES OF MEDICATION ERRORS[13]

1. **Category A** Circumstances or events that have the capacity to cause error
2. **Category B** An error occurred but the error did not reach the patient
3. **Category C** An error occurred that reached the patient but did not cause harm to the patient
4. **Category D** An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
5. **Category E** An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
6. **Category F** An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalisation
7. **Category G** An error occurred that may have contributed to or resulted in permanent harm to the patient
8. **Category H** An error occurred that required intervention necessary to sustain life
9. **Category I** An error occurred that may have contributed to or resulted in the patient's death

[13] As defined by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)

APPENDIX 3

CATEGORIES OF MORTALITY[14]

Category 1: Expected death.

Includes death:

a) due to terminal illness (anticipated by clinicians and family);
b) following cardiac or respiratory arrest before arriving at the hospital; or
c) which occurred despite medical interventions.

Category 2: Unexpected death which was not reasonably preventable.

Category 3: Unexpected death which was possibly preventable and was:

a) due to lack of treatment or delay in treatment; or
b) caused by medical intervention.

[14] Adapted from Western Australia Review of Mortality

APPENDIX 4

Annex A - serious reportable event Notification Form

Downloadable version:	SRE Notification Form - Annex A.xlsx

Annex A. SRE Notification Form

To:

SRE Notification Officer
Clinical Quality, Performance and Value Division
Ministry of Health
College of Medicine Building
16 College Road
Singapore 169854

Email: moh_nqas@moh.gov.sg

From:

Name: _____
Designation: _____
Tel: _____
E-mail: _____
Date: _____

(For MOH's use) MOH's Remarks:

(For MOH's use) Status:

Potential Media Sensitive?: No

Institution*: _____

Incident Ref Number: 2020[1] / ___[2]

Institution (others): _____

Date of event occurrence*: ___ / ___ / ___ (dd) (mm) (yy)

Date identified as SRE[3]*: ___ / ___ / ___ (dd) (mm) (yy)

Time of Event Occurrence: ___ : ___ (24-hr format)

Case reported to the Coroner*: _____

Location*: _____

Discipline*: _____

Other Location: _____

Other Discipline: _____

Age of patient*: _____

Gender*: _____

Race*: _____

Admission/Consultation Date*: ___ / ___ / ___ (dd) (mm) (yy)

Discharge Date: ___ / ___ / ___ (dd) (mm) (yy)

Ward Class (Inpatient): _____

Paying Status (Outpatient): _____

Subject Outcome[4]*: _____

Other Subject Outcome: _____

Incident Type*: _____

Specify 'Others': _____

[1] *Refers to the calendar year in which the serious reportable event has occurred*

[2] *This number is to be assigned by the institution to serialize all serious reportable events that occur during the calendar year.*

[3] *The QAC that reviews the SRE shall notify the Clinical Quality, Performance and Value Division, Ministry of Health, of a SRE within 2 working days of the date of the event being identified*

[4] *Indicate outcome of the event as of the report date.*

Incident Summary:

Additional Information:

Patient/Family Notified*:

Notification Source:

Other Notification Source:

SMS Notification:

Annex B - serious reportable event Review Report Form

Downloadable version:	SRE Review Report Form - Annex B.xlsx

Annex B. SRE Review Report

(For MOH's use) Status:

(For MOH's use) MOH's Remarks:

To:

SRE Notification Officer
Clinical Quality, Performance and Value Division
Ministry of Health
College of Medicine Building
16 College Road
Singapore 169854

Email: moh_nqas@moh.gov.sg

From:

Name:
Designation:
Tel:
E-mail:
Date:
Institution:
Incident Ref No.: 2022 [1] / 00 [2]

[1] *Should correspond to the serial number assigned in the Serious Reportable Event Notification Form*

The QAC that reviews the serious reportable event shall complete the review and submit this Serious Reportable Event Review Report within 60 calendar days from the date of the Serious Reportable Event Notification Form.

LEVEL OF ANALYSIS	
1. EVENT	**(a) Detailed chronological description of the event**
(1) Describe in detail what happened in chronological order. For serious reportable events which resulted in death, please state the cause of death signed up in the Certificate of Death; **<u>OR</u>** If the event is reported as a Coroner's case, please state that it is a Coroner's case and indicate the cause of death, ascertained by the Coroner (if available).	

LEVEL OF ANALYSIS			
2. FAILED PROCESS(ES) INVOLVED IN THE SERIOUS REPORTABLE EVENT		**(a) Breakdown of process(es) into key steps**	**Tick failed process(es) identified**
(2) Refers to the process(es) that culminated in the serious reportable event (a) Process(es) can be broken down into a series of concise, pertinent key steps i.e. Step 1 → step 2 → step 3, etc., eventually resulting in the serious reportable event. This information can be distilled from column 1(a). (b) Only tick failed process(es) identified.	1		☐
	2		☐
	3		☐
	4		☐
	5		☐
	6		☐
	7		☐
	8		☐
	9		☐
	10		☐
	11		☐
	12		☐
	13		☐
	14		☐
	15		☐

LEVEL OF ANALYSIS			
3. SYSTEM AND HUMAN FACTORS CONTRIBUTING TO FAILED PROCESS(ES)	**(a) Failed process(es) identified**	**(b) System and human factors identified (i.e. root causes)**	**(c) Risk reduction strategies and proposed implementation – what, when and who**
(3) Refers to specific factors that contributed to the failed process(es) in 2(a) which can either be system, human factors or a combination of both (usually the case) (a) Indicate failed process(es). (b) Identify system and human factors and state root cause(s) within brackets E.g. Lack of formalised protocol for determining the side of operation in OT (lack of protocol). (c) Detail the risk reduction strategies to correct the root cause(s) that contributed to the failed process(es). Please indicate what these strategies are, when these strategies will be implemented and who these strategies target. E.g. To implement a preoperation protocol by dd/mm/yy, to be circulated to all OT staff and doctors for compliance.			

Annex C - serious reportable event Follow-up Report Form

Downloadable version:	SRE Follow-up Report Form - Annex

Annex C. SRE Follow-up Report

To:

SRE Notification Officer
Clinical Quality, Performance and Value Division
Ministry of Health
College of Medicine Building
16 College Road
Singapore 169854

Email: moh_nqas@moh.gov.sg

From:

Name:	
Designation:	
Tel:	
E-mail:	
Date:	
Institution:	
Incident Ref No.:	2022[1] / 00[2]

Root causes identified:

1) _____
2) _____
3) _____
4) _____
5) _____

S/N	Recommendations	Proposed date of Implementation	Date of Implementation	Remarks
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				