Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Serious Reportable Events *(SREs)*

HSE Implementation Guidance Document

26th January 2015

1. Introduction

Serious Incidents

The HSE requires that ***all*** incidents are ***Managed, Reported and Investigated*** in line with the HSE's Safety Incident Management policy, including all incidents that result in death and serious harm.

Incidents that require reporting and subsequent Investigation can be defined as events occurring in HSE funded healthcare (including in the community) which could have or did result in unintended and/or unnecessary serious harm.

These include adverse events which result in serious harm; near misses which could have resulted in serious harm, but did not cause harm, either by chance or timely intervention; and staff or service user complaints which are associated with harm.

Incidents can be clinical or non-clinical and include serious incidents associated with;

- Unexpected or avoidable death or serious harm of one or more patients, staff or members of the public
- HSE ICT Systems and data security e.g. data protection breaches
- The environment.

Mandatory reporting of Serious Reportable Events (SREs)

One subset of all serious incidents are described by the HSE as ***Serious Reportable Events (SREs).*** These are s*erious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers*.

It is a mandatory requirement of the HSE that all SREs are reported on the National Adverse Event Management System (NAEMS) formerly the STARSWeb System and through the Safety Incident Management Communication/Escalation Form process. SREs must be reported within 24 hours to the Senior Accountable Officer. It is also mandatory that investigations commence within 48-hours of the organisation becoming aware of the incident and that these investigations are completed within four months of commencing.

This Guidance Document contains the current list of SREs (*as of 26th January 2015*) and incorporates events currently determined by designated external regulators, as being subject to mandatory event occurrence reporting.

Section 2: Sets out key accountabilities

Section 3: Contains the summary list of Serious Reportable Events

Section 4: Contains implementation guidance.

Section 5: Is a glossary of terms.

2. Serious Reportable Events

Summary List

2. SRE Summary List

1.	SURGICAL EVENTS
1A.	Surgery performed on the ***wrong body part*** by a healthcare service provider.
1B.	Surgery performed on the ***wrong patient*** by a healthcare service provider.
1C.	***Wrong surgical procedure*** performed on patient by a healthcare service provider.
1D.	***Unintended retention of a foreign object*** in an enclosed body cavity in a patient after surgery or other procedure performed by a healthcare service provider.
1E.	***Intra-operative or immediately postoperative death*** in a patient with ***no known medical problems*** (ASA Class I) occurring after surgery or other interventional procedure performed by a healthcare service provider.

2.	PRODUCT OR DEVICE EVENTS
2A.	***Patient death or serious disability*** associated with the use of ***contaminated medications, medical devices, or biologics*** provided by the healthcare service provider.
2B.	***Patient death or serious disability*** associated with the use or function of a ***medical device*** in which the medical device is used or functions other than as intended or anticipated in the care of a patient provided by the healthcare service provider.
2C.	***Patient death or serious disability*** associated with ***intravascular air embolism*** that occurs while being cared for by a healthcare service provider but excluding death or serious disability associated with certain neurosurgical procedures or cardiac procedures known to present a high risk of intravascular air embolism.

3.	PATIENT PROTECTION EVENTS
3A.	***Child or other dependent person discharged to the wrong person*** by a healthcare service provider.
3B.	***Patient death or serious disability associated with a patient absconding from a healthcare service facility*** but excluding where a patient advises the healthcare service provider that he or she is leaving against medical advice.
3C.	***All sudden unexplained deaths or injuries which result in serious disability of a person who is an inpatient/resident in a mental healthcare facility.***

4.	CARE MANAGEMENT EVENTS
4A.	**Patient death or serious disability** associated with a ***medication error*** by the healthcare service provider but excluding reasonable differences in clinical judgment involving drug selection and/*or* dose.
4B.	***Wrong formulation/route administration of chemotherapy*** by a healthcare service provider.
4C	***Intravenous administration of mis-selected concentrated potassium chloride*** by a healthcare service provider.

4D	***Patient death or serious disability*** due to the administration of ***incompatible blood or blood products*** by a healthcare service provider.
4E	***Maternal Death*** for whom the hospital has accepted medical responsibility, registered with an independent midwife for pregnancy care/ registered with a maternity hospital-during pregnancy or ***within six weeks of delivery*** (whether in the hospital or not).
4F(i)	***Perinatal death of a neonate*** occurring in a ***term infant or an infant weighing more than 2,500g.***
4F(ii)	***Death or encephalopathy of a normally formed neonate*** occurring in a ***term infant or an infant weighing more than 2,500g.***
4G	***Patient death or serious disability*** associated with ***severe hypoglycaemia*** (excluding neonates), the onset of which occurs while the patient is being cared for in a healthcare service facility.
4H	***Death or serious disability (kernicterus)*** associated with ***non detection*** by a healthcare service provider to identify and treat ***Hyperbilirubinemia in neonates within the first 28 days of life.***
4I	***Stage 3 or 4 pressure ulcers*** acquired ***after admission*** to a healthcare and social care residential facility.
4J	***Patient death or serious disability*** due to ***spinal manipulative therapy*** by a healthcare service provider.
4K	***Patient death or serious disability*** resulting from or associated with the use of ***restrictive interventions such as physical, mechanical, manual or environmental restraint (e.g. seclusion***) to a patient while being cared for in a healthcare service facility.
4L	***Diagnostic Error***: Death or serious disability associated with a wrong diagnostic result e.g. mislabelled pathology specimen.
4M	The ***non utilisation of a donor organ*** deemed suitable for transplantation.
4N	***Death of a living organ donor***.

5	**ENVIRONMENTAL EVENTS**
5A	***Patient death or serious disability*** associated with an ***electric shock*** while being cared for in a healthcare service facility but excluding events involving planned treatments such as cardioversion.
5B	An incident in which a ***line designated for oxygen or other gas*** to be delivered to a patient while being cared for by a healthcare service provider ***contains the wrong gas or is contaminated by toxic substances***.
5C	***Patient death or serious disability*** associated with a ***burn incurred*** within a healthcare service facility.
5D	**Patient death or serious disability** associated with a ***fall*** – **a.** while being cared for in a healthcare service facility and/or

	b. during a clinical intervention from a healthcare professional (includes in the community setting, pre-hospital care and the Ambulance Service).

6	CRIMINAL EVENTS
6A	Any instance of care ordered by or provided by someone ***impersonating a healthcare professional.***
6B	***Abduction of a patient*** of any age while being cared for in a healthcare service facility.
6C	**Sexual assault** on a patient or other person within or on the grounds of a healthcare service facility.
6D	***Death or serious injury/disability*** of a patient or other person resulting from a ***physical assault*** that occurs within or on the grounds of a healthcare service facility.

3. Serious Reportable Events

Implementation Guidance

3. SRE Implementation Guidance

(1) SURGICAL EVENTS

Class	Description	Additional Specification	Implementation Guidance
1A.	**Surgery performed on the wrong body part by a healthcare service provider.**	Defined as any surgery performed on a body part that is not consistent with that described in the correctly documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.	This event is intended to capture: ▪ Surgery on the right body part, but on the wrong location in the body; for example, left versus right (appendages and/or organs) or level (spine). ▪ Wrong site surgery, even if corrected intra-operatively, as long as the surgery had begun, based on the definition below. This event is not intended to capture: 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 performed on the wrong patient by a healthcare service provider.**	Defined as any surgery on a patient that is not consistent with that described in the correctly documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.	This event is intended to capture: ▪ Surgical procedures (whether or not completed) initiated on one patient that were intended for a different patient.
1C.	**Wrong surgical procedure performed on patient by a healthcare service provider.**	Defined as any surgical procedure performed on a patient that is not consistent with that described in the correctly documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.	This event is intended to capture: ▪ Insertion of the wrong medical implant into the correct surgical site
1D.	**Unintended retention of a foreign object in an enclosed body cavity in a patient after surgery or other procedure performed by a healthcare service provder.**	Excludes a) objects present prior to surgery that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as micro-needles, broken screws).	This event is intended to capture: ▪ Occurrences of unintended retention of objects such as swabs, needles or instruments other than micro-needles at any point after the surgery ends, regardless of setting or of whether the object is removed. This event is not intended to specifically capture the unintended retention of foreign objects in unenclosed body cavities, such as the vagina, nose or ear. Whilst not a Serious Reportable Event under the terms of this document, such an event remains an Adverse Event and should be managed in the appropriate manner.

Class	Description	Additional Specification	Implementation Guidance
1E.	**Intra-operative or immediately postoperative death in a patient with no known medical problems (ASA Class I) occurring after surgery or other interventional procedure performed by a healthcare service provider.**	**ASA Class I patient i.e. normal healthy patient.** Includes all ASA Class I patient deaths in situations in which anaesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately postoperative means within 24 hours after surgery or other interventional* procedure was completed, or after administration of anaesthesia (if surgery was not completed).	This event is intended to capture: ▪ ASA Class I patient death associated with the administration of anaesthesia, whether or not the planned surgical procedure was carried out. **An **interventional procedure** is defined as any **procedure** used for diagnosis or treatment that involves incision; puncture; entry into a body cavity; or the use of ionising, electromagnetic or acoustic energy.*

(2) PRODUCT OR DEVICE EVENTS

Class	Description	Additional Specification	Implementation Guidance
2A.	**Patient death or serious disability associated with the use of contaminated medications, medical devices, or biologics* provided by the healthcare service provider.**	Includes detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product. *Biologics -a medicinal preparation created by a biological process.	The term *detectable* is intended to capture contaminations that can be seen with the naked eye or with the use of detection mechanisms that are in general use; these contaminations are to be reported when they become known to the provider or healthcare facility. Detection mechanisms may include cultures and tests that signal changes in pH or glucose levels.
2B.	**Patient death or serious disability associated with the use or function of a medical device in which the medical device is used or functions other than as intended or anticipated in the care of a patient provided by a healthcare service provider.**	Includes, but is not limited to, naso-gastric tubes, endoscopes, catheters, drains and other specialised tubes, infusion pumps and ventilators.	In the Irish context the definition of a medical device refers to any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and /or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: ▪ Diagnosis, prevention, monitoring, treatment alleviation of or compensation for an injury or handicap, ▪ Investigation, replacement or modification of the anatomy or of a physiological process, ▪ Control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (HSE Medical Devices/Equipment Management Policy.
2C.	**Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by a healthcare service provider but excluding death or serious disability associated with certain neurosurgical procedures or cardiac procedures known to present a high risk of intravascular air embolism.**	Excludes death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	All High-risk procedures are reportable under this event. But excluded are those neurosurgical procedures and Left Ventricular Assist Device insertions that have a small but known and recognised risk of air embolism.

(3) PATIENT PROTECTION EVENTS

Class	Description	Additional Specification	Implementation Guidance
3A	**Child or other dependent person discharged to the wrong person by a healthcare service provider.**		Stedman's Online Medical Dictionary defines an infant as a child under the age of one year.
3B	**Patient death or serious disability associated with a patient* absconding from a healthcare service facility but excluding where a patient advises the healthcare provider that he or she is leaving against medical advice.**	In the context of a patient with mental health difficulties - Absence without leave in relation to mental health act (2001) is : 27.-(1) Where a patient in respect of whom an admission order, a renewal order or an order under section 25 is in force (a) leaves an approved centre without permission under section 26, (2001.] Mental Health Act, 2001. [No. 25.) Excludes leaving "against medical advice" in which a patient asks to leave the hospital and then does so against medical advice.	Absconding can be defined as "the unauthorised absence of an admitted patient from the boundaries of the care unit without staff knowledge." This event includes patients resident in a health care facility with an altered state of consciousness undergoing treatment for medical and / or mental health assessment / treatment who abscond. ***Patient** refers to all interpretations eg **residents and service users** also.
3C	**All sudden unexplained deaths or injuries which result in serious disability of a person who is an inpatient / resident in a mental healthcare facility.**	Defined as events that result from actions after the patient / resident has been admitted to an inpatient facility. Inpatient facility is a hospital or other facility for care and treatment of persons suffering from mental illness or mental disorder. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.	This event is not intended to capture patient suicide or attempted suicide when the patient is on approved leave from the mental health facility. ***These should however continue to be reported in accordance with the HSE's Safety Incident Management Policy***

(4) CARE MANAGEMENT EVENTS

Class	Description	Additional Specification	Implementation Guidance
4A.	**Patient death or serious disability associated with a medication error but excluding reasonable differences in clinical judgment involving drug selection and/*or* dose.**	**Medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong rout e of administration.** Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.	This event is intended to capture: ▪ The most serious medical errors, including occurrences in which a patient known to have serious allergies to specific medications / agents receives those medications / agents, resulting in serious harm or death. These events may occur as a result of failure to collect allergy information; failure to review available allergy information; failure to assure the availability of allergy information and prominently display it; or through other system failures that are determined by investigation to be the cause of the adverse event. ▪ Occurrences in which a patient dies or suffers serious disability as a result of failure to administer a prescribed medication. ▪ Occurrences in which a patient dies or suffers serious disability as a result of the wrong administration technique. ▪ This event is not intended to capture:

Class	Description	Additional Specification	Implementation Guidance
			▪ Patient death or serious disability associated with allergies that could not reasonably have been known or discerned in advance of the event. ▪ All situations in which two or more medications are administered for which there are drug-drug interactions with known potential for death or serious disability – only those that result in death or serious disability.
4B.	**Wrong formulation/ route administration of chemotherapy by a healthcare service provider.**		Intravenous or other chemotherapy (i.e. vincristine) that is correctly prescribed but administered via the wrong route (usually into intrathecal space. Cancer drugs such as vincristine continue to be given occasionally via the wrong route worldwide, sometimes resulting in paralysis or death of a patient. In 2000, *An organisation with a memory* highlighted incidents where wrong administration of a drug led to the death of a patient.
4C.	**Intravenous administration of mis-selected concentrated potassium chloride by a healthcare service provider.**		Mis-selection of a concentrated potassium chloride for intravenous administration for a flush or instead of the correct medication can have fatal effects.
4D.	**Patient death or serious disability due to the incompatible blood or blood products by a healthcare service provider.**	**Administration of ABO/HLA**	This event is not intended to capture; ▪ Patient death or disability associated with organ rejection, other than those attributable to a hyper-acute haemolytic reaction. ▪ Patient death or disability when the cause is not detectable by ABO/HLA matching.
4E.	**Maternal Death** for whom the hospital has accepted medical responsibility, registered with an independent midwife for pregnancy care/ registered with a maternity hospital-during pregnancy or within six weeks of delivery (whether in the hospital or not).		This event does not create a new obligation for organisations. **The organisation's obligation is to report the event to: Maternal Death Enquiry Office, 5th Floor, Cork University Maternity Hospital, Wilton, Cork tel: 021 4205042, email: mdeireland@hse.ie** when it learns of the maternal death either by re-admittance or by the patient's family.
4F.*(i)*	**Perinatal death of a neonate occurring in a term infant or an infant weighing more than 2,500g.**	Baby born after 37 weeks or weighing greater than 2,500g without congenital anomaly. Total number of deaths, including stillbirths and early neonatal deaths from birth up to 7 days inclusive. (Source: NPRS) Following WHO guidelines and the definition used in the NPRS, a stillbirth in this report refers to the death of a fetus weighing ≥ 500g; an early neonatal death refers to the death of a live born infant during the first seven days of life. (This measure of Perinatal death is not adjusted to exclude congenital anomalies.)	

Class	Description	Additional Specification	Implementation Guidance
4F.*(ii)*	**Death or encephalopathy of a normally formed neonate occurring in a term infant or an infant weighing more than 2,500g.**	**Neonatal Encephalopathy:** All infants ≥ 35 weeks gestation who during the first week of life have: ▪ Either seizures alone, or ▪ Signs of Neonatal Encephalopathy which is defined in clinical findings in 3 or more of the following domains: ▪ Level of consciousness ▪ Spontaneous activity when awake or aroused ▪ Posture ▪ Tone ▪ Primitive reflexes ▪ Automonic system. (Source: NMH Annual Clinical Report)	
4G.	**Patient death or serious disability associated with severe hypoglycaemia (excluding neonates), the onset of which occurs while the patient is being cared or in a healthcare services facility.**		Hypoglycaemia is defined as blood glucose levels <3.5mmol/l where the patient has been on hypoglycaemic treatment – insulin, sulfonylurea's.
4H.	**Death or serious disability (kernicterus) associated with non detection, by a healthcare service provider of Hyperbilirubinemia in neonates within the first 28 days of life.**	The level most commonly used for Hyperbilirubinemia in term infants is defined as bilirubin levels > 425mmol/l. Hyperbilirubinemia - the level is dependent on gestational age. Neonate refers to the first 28 days of life.	The healthcare provider's obligation is to report the event when it is made aware of the death or serious disability either by re-admittance or by the patient's family.
4I.	**Stage 3 or 4 pressure ulcers acquired after admission to a health and social care residential facility.**	**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 Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present.	
4J.	**Patient death or serious disability due to spinal manipulative therapy by a healthcare provider.**	▪ Excludes movement or manipulation of the spine during surgery. ▪ Includes movement of the spine during a transfer or manual handling.	Spinal manipulative therapy encompasses all types of manual techniques, including spinal mobilisation (movement of a joint within its physiologic range of motion) and manipulation (movement beyond its physiologic range of motion), regardless of their precise anatomic and physiologic focus or their discipline of origin. ▪ **Manipulation** — a passive, high velocity, low amplitude thrust applied to a joint complex within its anatomical limit (active and passive motion occurs within the range of motion of the joint complex and not beyond the joint's anatomic limit) with the intent to restore optimal motion, function, and/ or to reduce pain. (Ref www.wcpt.org/glossary).

Class	Description	Additional Specification	Implementation Guidance
			▪ This technique should only be undertaken by chartered physiotherapists who have the competencies and training to include spinal manipulative therapy within their scope of practice and by specialist doctors.
4K.	**Patient death or serious disability resulting from or associated with the use of restrictive interventions such as physical, mechanical, manual or environmental restraint (e.g. seclusion) to a patient while being cared for in a healthcare service facility.**	**Definition of Physical Restraint** For the purpose of the Section 33(3(e) Code of Practice on the Use of Physical Restraint in Approved Centres, physical restraint is defined as "the use of physical force (by one or more persons) for the purpose of preventing the free movement of a resident's body". OR Physical restraint can be defined as "any manual method or physical or mechanical device, material or equipment 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"(H.I.Q.A.) **5.1 Definition of Seclusion** The Mental Health Act 2001. Section 69(2) Rules Governing the use of Seclusion (and Mechanical Means of Bodily Restraint), seclusion is defined as "the placing or leaving of a person in any room alone, at any time, day or night, with the exit door locked or fastened or held in such a way as to prevent the person from leaving" (Section 1.1).	The event is intended to capture instances in which restraints are implicated in the death; for example, the use led to strangulation/entrapment/asphyxiation. Items or devices that are provided for support or to enable function are not classified as restraints. Death/disability resulting from falls caused by lack of restraints would be captured under falls.
4L.	**Diagnostic Error: Death or serious disability associated with a wrong diagnostic result e.g. mislabelled pathology specimen.**	Defined as a reporting error where a finding is present but is missed or one where the lesion was not present on the image due to inadequacy of the examination. If a biopsy was taken from one patient and put into a pot labelled with details of a different patient and vice versa, then the patients results would be mixed up potentially resulting in harm as one patient might get a false negative result and the other get a false positive result.	This event is intended to capture: **Radiology:** ▪ Lesions that are not perceived. ▪ Lesions those are perceived but incorrectly diagnosed or inappropriately interpreted. ▪ Lesions that may be missed due to poor quality examination due to reasons such as incorrect exposure selected, inadequate coning areas of the film, abnormalities lying outside the area of the primary examination, inappropriate views selected, incorrect type of imaging modality chosen or inappropriate imaging protocols utilised. ▪ Lesions that may be missed due to failure to consult previous examinations or reports due to reasons such as the previous images having been lost or destroyed, insufficient administrative assistance to find old images or inappropriate digital retrieval systems in place. ▪ Lesions that may be missed due to the provision of poor clinical information leading to the abnormality being outside the area of primary examination or the

Class	Description	Additional Specification	Implementation Guidance
			incorrect selection of an imaging protocol. ▪ Lesions that may be missed where the radiologist recognises one abnormality but fails to see a second lesion. Lesions that may be missed due to poor viewing conditions may lead to errors, particularly for chest x-rays.
		Defined as a reporting error where a finding is present but is missed or one where the lesion was not present on the image due to inadequacy of the examination. If a biopsy was taken from one patient and put into a pot labelled with details of a different patient and vice versa, then the patients results would be mixed up potentially resulting in harm as one patient might get a false negative result and the other get a false positive result.	***Continued:*** **Pathology:** ▪ If a biopsy was taken from one patient and put into a pot labelled with details of a different Patient and vice versa, then the patients results would be mixed up potentially resulting in harm as one patient might get a false negative result and the other get a false positive result. ▪ In some instances a diagnostic error it might be identified as a discrepant result at a multidisciplinary team meeting. For example, if Patient A had a benign breast lesion subjected to Ultrasound guided core biopsy that generated an S2R3 result and pathology result was given as B5 malignant breast, it might be identified as a discordant result, particularly if the same doctors notices that Patient B had a clinically and radiologically malignant lesion subjected to Ultrasound guided core biopsy that generated an S5R5 result and pathology result was given as B2 benign breast. Some sites such as the prostate do not have a tight concordance between PSA level, clinical and radiological findings, so if Patient C with benign disease had prostate core biopsies labelled with the details of patient D who had a cancer, there would be no way of identifying that the specimen was from the wrong patient and Patient C could have an unnecessary prostatectomy while Patient D could have disease progression either locally or systemically before the false negative result was identified as incorrect.
4M.	**The non utilisation of a donor organ deemed suitable for transplantation**	Subject to suitable recipient and following offering of an organ to international transplant services.	Such an event would be progressed via the organ procurement service through the National Organ Donation Transplant Office and the National Transplant Advisory Group will discern the accuracy of Adverse Events.
4N.	**Death of a living organ donor.**	Timeframe is 90 days post donation.	Advised by the National Renal Transplant Programme.

(5) ENVIRONMENTAL EVENTS

Class	Description	Additional Specification	Implementation Guidance
5A.	**Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility but excluding events involving planned treatments such as cardioversion.**	Excludes events involving planned treatments such as cardioversion.	This event is intended to capture: ▪ Patient death or disability associated with unintended electric shock during the course of care of treatment This event is not intended to capture: ▪ Patient death or disability associated with emergency defibrillation during ventricular fibrillation or electroconvulsive therapies.
5B.	**An incident in which a line designated for oxygen or other gas to be delivered to a patient while being cared for by a healthcare service provider contains the wrong gas or is contaminated by toxic substances.**		This event is intended to capture: Events in which the line is attached to a reservoir distant from the patient care unit or in a tank near the patient such as E-cylinders, anaesthesia machines. *(Source - page A13, the Serious Reportable Events 2011 update – National Quality Forum, USA.)*
5C.	**Patient death or serious disability associated with a burn incurred within a healthcare service facility.**		
5D.	**Patient death or serious disability associated with a fall** **a.** while being cared for in a healthcare service facility and/or **b.** during a clinical intervention from a healthcare professional (includes in the community setting, pre hospital care and Ambulance Service).	Includes but is not limited to fractures, head injuries, and intracranial haemorrhage.	b. During a clinical intervention from a healthcare professional (includes community) - the healthcare provider is obligated to report this event if the fall takes place while in the course of direct intervention and/or during a treatment session.

(6) CRIMINAL EVENTS

Class	Description	Additional Specification	Implementation Guidance
6A.	**Any instance of care ordered by or provided by someone impersonating a healthcare professional.**	Examples of healthcare professional: a physician, nurse, pharmacist or other registered healthcare provider.	
6B.	**Abduction of a patient of any age while being cared for in a healthcare service facility.**		
6C.	**Sexual assault on a patient or other person within or on the grounds of a healthcare service facility.**		

6D.	**Death or serious injury/disability of a patient or other person resulting from a physical assault that occurs within or on the grounds of a healthcare service facility.**	Defined as events that result from a physical assault whilst in the care of healthcare services. Excludes deaths or serious disability resulting from injuries that were the reason for admission to the healthcare services	This event is not intended to capture death or serious disability that occurs due to injuries associated with physical assault that were the reason for admission to the healthcare services.

3. Appendix 1 Glossary of Terms

This glossary details key terms and a description of their meaning within the context of this document.

Serious Reportable Event: 'Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.

Incident: An event or circumstance which could have, or did lead to unintended and/or unnecessary harm. Incidents include adverse events which result in harm; near-misses which could have resulted in harm, but did not cause harm, either by chance or timely intervention."

Community: All non-acute settings including the home and a healthcare facility in the community setting

Healthcare: Services received by individuals or communities to promote, maintain, monitor or restore health.

Health Care Service Facility: Anywhere health or social care is provided. Examples include but are not limited to: acute hospitals, community hospitals, district hospitals, health centres, dental clinics, GP surgeries, home care, etc.

Social Care Residential Facility: Encapsulates residential homes for children, older people and people with disabilities in Ireland.

Healthcare Service Provider: Any person organisation or part of an organisation delivering healthcare services, as described in the Health Act 2007 section 8(1)(b)(i)-(ii).

Healthcare Professional: A person who exercises skill or judgement in diagnosing, treating or caring for service users, preserving or improving the health of service users.

In the context of Mental Health Services the following apply:

Patient:

Defined to **include patient, voluntary patient and resident** defined by the Mental Health Act 2001.

Patient: as defined by the Mental Health Act 2001 is specific to a person who is involuntary detained as per Section 14 (2)

Resident: means a person receiving care and treatment in an approved centre (inpatient facility). (Section 62)

Mental health facility In-patient facility is a hospital or other facility for care and treatment of persons suffering from mental illness or mental disorder in approved centres as defined by the Mental Health Act 2001 and residential mental health services.

Mental health services means services which provide care and treatment to persons suffering from a mental illness or a mental disorder under the clinical direction of a consultant psychiatrist; (Section 2(1).

Service User
A person who uses mental health services