2012 SRE Reporting Guidance[1,2]

1. Surgical or Invasive Procedure Events[3]

Event	Additional Specifications	Implementation[4]
A. Surgery ***or other invasive procedure*** performed on the wrong ***site***	Defined as any surgery or other invasive procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. [5] For a list of invasive procedures, please see Appendix 2. Please note that this list is **not** all-inclusive, and should only be used as a guideline. If you are not sure if a procedure must be reported, please contact DPH. This event is intended to capture instances of: • surgery or other invasive procedure on the right body part but on the wrong location/site on the body; e.g., left/right (appendages/organs), wrong digit, level (spine), stent placed in wrong iliac artery, steroid injection into wrong knee, biopsy of wrong mole, burr hole on wrong side of skull; • delivery of fluoroscopy or radiotherapy to the wrong region of the body; • use of incorrectly placed vascular catheters; • use of incorrectly placed tubes (for	Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. It does not include use of such things as otoscopes and drawing blood. Surgery begins, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded, regardless of setting. Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at time surgical mark is made on the patient. Placing a mark on the wrong body part does not in itself constitute wrong site surgery. It should be noted that a 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, it does require informed consent be documented in the patient record.

[1] For this document, the proposed events are based on the December 2011 NQF issued Serious Reportable Events 2011 Update. All new event language is marked in bold/italics.

[2] For the definition of Serious Injury, please see Appendix 1

[3] For reporting purposes, an example of the types of procedures that can be referred to as an invasive procedure can be found in Appendix 2.

[4] Implementation Guidance is based on the information provided in the 2011 update. It is not intended to be either comprehensive or to outline the expected clinical/operational practice of any specific health care facility, but it is intended for guidance for purposes of state DPH reporting purposes.

[5] Except in the case of an emergency, a physician must obtain a patient's agreement (informed consent) to any course of treatment. Physicians are required to tell the patient anything that would substantially affect the patient's decision. Such information typically includes the nature and purpose of the treatment, including its risks and benefits and alternative courses of treatment, including risks/benefits. The American Medical Association definition of informed consent is "a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention" http://www.ama-assn.org/ama/pub/category/4608.html

	example, feeding tubes placed in the lung or ventilation tubes passed into the esophagus); • wrong site surgery or invasive procedure, corrected during the procedure, is still a wrong site procedure if the surgery/procedure had begun, based on the definition above. This event is not intended to capture: • changes in plan upon surgical entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae); • emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent; • lines inserted into an artery instead of a vein, provided the error was corrected before the line was utilized.	
B. Surgery ***or other invasive procedure*** performed on the wrong patient	Defined as any surgery or other invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient. This event is intended to capture: • surgical and/or invasive procedures (whether or not completed) initiated on one patient intended for a different patient.	Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. It does not include use of such things as otoscopes and drawing blood. Surgery begins, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded, regardless of setting. It should be noted that a 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, it does

		require informed consent be documented in the patient record.
C. Wrong surgical ***or other invasive procedure*** performed on a patient	Defined as any surgical and/or invasive procedure or other invasive procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. This event is intended to capture: • insertion of the wrong medical implant into the correct surgical site This event is not intended to capture: • changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery/ procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae). • emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.	Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. It does not include use of such things as otoscopes and drawing blood. Surgery begins, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded, regardless of setting.
D. Unintended retention of a foreign object in a patient after surgery or other ***invasive*** procedure	This event is intended to capture: • occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) **and regardless of whether the object is to be removed after discovery**; • unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) Excludes: • objects present prior to surgery or other	Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. It does not include use of such things as otoscopes and drawing blood. Surgery begins, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded, regardless of setting.

	invasive procedure that are intentionally left in place; • objects intentionally implanted as part of a planned intervention; • objects not present prior to surgery/procedure that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws); • a retained foreign body that results from a device failure, if the retained object from this device failure causes serious injury, as this should be reported under section 2B; • objects retained during the first part of a two-part procedure that are removed during the second part of the procedure.	
E. Intraoperative or immediately post-operative***/post-procedure*** death in an ASA Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after surgery or other invasive procedure (if surgery or procedure completed) or after administration of anesthesia (if surgery or procedure not completed). This event is intended to capture: • ASA Class I patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out.	Note: If the provider determines, post-procedure, that the patient was improperly classified as ASA Class I, and should have been classified as being at higher anesthesia risk, the event is still an SRE, and must be reported to DPH. Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. It does not include use of such things as otoscopes and drawing blood. Surgery begins, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded, regardless of setting.

2. Product or Device Events

Event	Additional Specifications	Implementation Guidance
A. Patient death or	Includes contaminants in drugs, devices, or	The term contamination refers to those that can be seen with the naked eye or with use of detection

serious ***injury*** associated with the use of contaminated drugs, devices, or biologics provided by the healthcare ***setting***	biologics regardless of the source of contamination and/or product. Includes threat of disease that changes patient's risk status for life requiring medical monitoring not needed before the event. This event is intended to capture: • administration of contaminated vaccine or medication (e.g. intramuscular antibiotic) • serious infection from contaminated drug or device used in surgery or other invasive procedure (e.g. scalpel) • occurrences related to use of improperly cleaned or maintained device	mechanisms in general use. These contaminations are to be reported at such time as they become known to the provider or healthcare organization. Contaminants may be physical, chemical, or biological in nature. Not all contaminations can be seen with the naked eye (e.g., hepatitis and HIV) or readily detected using generally available or more specialized testing mechanisms (e.g., cultures, nucleic acid testing, mass spectrometry, and tests that signal changes in pH or glucose levels). Contamination that is inferred and changes risk status for life must be reported.
B. Patient death or serious ***injury*** associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment. Excludes: • operator error or mistakes made by individual care providers. If the provider attempted to use the device correctly, any resulting injury or death would not qualify as a Device Use or Function SRE. However, proper intention encompasses provider obligation to observe all protocols put in place around the use of a device. If a provider fails to follow an institutional protocol for using a device, and the patient experiences death or serious injury as a result, the event must be reported to DPH.	The U.S. Food and Drug Administration (FDA) defines medical device as: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: • recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; • intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or • intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."
C**.** Patient death or serious ***injury*** associated with intravascular air embolism that occurs	Excludes death or serious injury associated with neurosurgical procedures that are known to present a high risk of intravascular air embolism.	Those specific neurosurgical procedures that are known to present a high risk of air embolism are excluded from this event.

while being cared for in a healthcare ***setting***	This event is intended to capture: • high-risk procedures, other than specific neurosurgical procedures known to present a high-risk for air embolism, that include, but are not limited to, procedures involving the head and neck, vaginal delivery and caesarean section, spinal instrumentation procedures, and liver transplantation; • low-risk procedures, including those related to lines placed for infusion of fluids in vascular space.	

3. Patient Protection Events

Event	Additional Specifications	Implementation Guidance
A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person ***(NEW)***	Examples of individuals who do not have decision making capacity include infants, minors or adults with Alzheimer's disease.	Decision making capacity is defined as the ability to understand information relevant to a decision and the ability to appreciate the reasonably foreseeable consequences of a decision (or lack of a decision). Release to "other than authorized person" includes removing the patient/resident without specific notification and approval by staff, even when the person is otherwise authorized. Authorized means the guardian or other individual(s) having the legally recognized ability to consent on behalf of a minor or incapacitated individual (surrogate), or person designated by the surrogate to release or consent for the patient. Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decision making capacity.
B. Patient death or serious ***injury*** associated with patient elopement (disappearance).	This event is not intended to capture death or serious injury that occurs due to circumstances unrelated to the elopement after the patient is located.	Elopement refers to a situation where a patient or resident who is cognitively, physically, mentally, emotionally, and/or chemically impaired wanders/walks/runs away, escapes, or otherwise leaves a care giving institution or setting unsupervised, unnoticed, and/or prior to their scheduled discharge. By definition, elopement does not have to involve harm to the patient. However, an elopement only qualifies as an SRE IF the patient experiences serious injury or death associated with the elopement. Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decision making capacity. Excludes events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen.

C. Patient suicide, attempted suicide***, or self- harm*** that results in serious ***injury***, while being cared for in a healthcare ***setting***	Defined as events that result from patient actions after admission/presentation to a healthcare setting. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility. Further excludes patient suicide or attempted suicide when the patient is not physically present in the "healthcare setting"	Please note that if the person who committed or attempted to commit suicide is physically present in the healthcare setting, but is **not** a patient of the facility, the suicide/attempted suicide would not qualify as an SRE, but should still be reported to DPH. Does not include an event that occurs in non-medical businesses such as shops and restaurants located close to the healthcare facility.

4. Care Management Events

Event	Additional Specifications	Implementation Guidance
A. Patient death or serious ***injury*** associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration.	This event includes death or serious injury associated with: • over- or under-dosing; • administration of a medication to which a patient has a known allergy or serious contraindication, • drug-drug interactions for which there is known potential for death or serious injury, • improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of dose adjustment problems. This event is not intended to capture: • reasonable differences in clinical judgment on drug selection and dose; • patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event.	This event is intended to capture: • the most serious medication errors including occurrences in which a patient receives a medication for which there is a contraindication, or a patient known to have serious allergies to specific medications/agents, receives those medications/agents, resulting in 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 organization to ensure availability of such information and prominently display such information within information systems, or other system failures that are determined through investigation to be cause of the adverse event; • occurrences in which a patient dies or suffers serious injury as a result of failure to administer a prescribed medication; • occurrences in which a patient is administered an over- or under-dose of a medication including insulin, heparin, and any other high alert medication including but not limited to medications listed on the Institute for Safe Medication Practices "High Alert Medication List"; • occurrences in which a patient dies or suffers serious injury as a result of wrong administration technique.
B. Patient death or	This event is not intended to capture:	Unsafe administration includes, but is not limited to, hemolytic reactions and administering: a) blood

serious ***injury*** associated with a unsafe administration of blood products ***Revised***	• patient death or serious injury associated with organ rejection other than those attributable to a hyperacute hemolytic reaction • patient death or injury when cause is not detectable by ABO/HLA matching.	or blood products to the wrong patient; b) the wrong type; c) blood or blood products that have been improperly stored or handled.
C. Maternal death or serious ***injury*** associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Includes events that occur within 42 days post-delivery. Excludes: • death from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.	This event is not intended to create a new obligation. The organization's obligation is to report the event when made aware of the maternal death or serious injury either by readmittance or by the patient's family. Low risk pregnancy refers to a woman aged 18-39 with no diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, pre-eclampsia, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth restriction, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.
D. Death or serious injury of a neonate associated with labor and delivery in a low-risk pregnancy ***(NEW)***	Includes unplanned admission to an inpatient setting within 24 hours of delivery for the office-based surgery, birthing center, or "home" setting. However, the SRE is attributable to the facility where the neonate was born, not the admitting facility. Therefore, death or serious injury that occurs during a birth that takes place in a home setting is not an SRE, because only hospitals and ASCs are required to report SREs.	Unplanned admission to other than the birth setting should be verified with the identified birth setting. Low risk pregnancy is defined as a pregnancy occurring in a woman aged 18-39 who has no diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, pre-eclampsia, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth restriction, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.
E. Patient death or serious ***injury*** associated with a fall while being cared for in a healthcare setting (previously *in Environmental events)*	Includes falls resulting in bone fractures and head injuries with intracranial bleeding that requires intervention. Also includes any fracture of the wrist or ribs. Excludes falls that result in: • minor lacerations and minor fractures (finger, thumb, toes, nose, hairline fractures (unless those fractures substantially limit one or more major life activities or require major intervention)); • fall post-discharge or post-end of outpatient visit.	An assessment that identifies patients at risk of fall, findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis. Patient means a person who is a recipient of healthcare. A person becomes a patient at the point that they are being "cared for" in the facility. Being "cared for" begins when they are first engaged by a member of the care team, e.g., assessment by the triage nurse in the E.D., walking with the phlebotomist to the lab for a lab draw. A patient is not longer considered a patient at the point that he is no longer under the care of a member of the care team, e.g. the nursing assistant has safely assisted the patient to the car from an inpatient stay; the ambulating patient that does not need assistance leaves the radiology department following an outpatient test. Would exclude patients with multiple pre-scheduled appointments at a facility during one day, if they finish one appointment and are going to another appointment within the facility. However, if a person requires supervision or assistance ambulating, he remains a patient until he has been delivered into the care of a family member or aide.

	For reporting purposes a fall is defined as: an unplanned descent to the floor (or extension of the floor, e.g., bed, chair or other equipment) with or without injury to the patient. All types of falls are to be included whether they result from physiological reasons (fainting) or environmental reasons (slippery floor). Include assisted and controlled falls (when a staff member attempts to minimize the impact of the fall).	Therefore, if the person experienced a fall with serious injury before being delivered to the adult responsible for his care, the event would qualify as an SRE, as the person would still be considered a patient.
F. Any Stage 3**,** Stage 4, ***and unstageable*** pressure ulcers acquired after admission/presentation to a healthcare ***setting***	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission. Excludes pressure ulcers that develop in areas where deep tissue injury was documented as present on admission/presentation. If a patient who is seriously critically ill (e.g., patients with multi organ failure, patients for whom routine turning and repositioning poses a significant risk to their respiratory or cardiovascular status, or patients for whom turning is physically prohibitive (i.e., the morbidly obese patient and in the setting of organ failure)) develops a reportable pressure ulcer, the facility should alert DPH, which will make a case-by-case determination as to whether or not the pressure ulcer should be considered an SRE.	Although this event could occur in the ambulatory surgery environment based on a patient condition and surgery time, it will be difficult to discern. Pre- and post- skin assessments will be key. For reporting purposes pressure ulcer stages to be defined using the current National Pressure Ulcer Advisory Panel definitions. http://www.npuap.org/pr2.htm Please see Appendix 3 for an explanation of which pressure ulcers must be reported to DPH.
G. Artificial insemination with the wrong donor sperm or wrong egg		The organization's obligation is to report the event when made aware of the occurrence.
H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen. ***(NEW)***	Includes events where specimens are misidentified, where another procedure cannot be done to produce another specimen. Includes progression of an undiagnosed disease or threat of disease that changes the patient's risk status for life, requiring monitoring not needed	This event is not intended to capture procedures where the specimen was properly handled, but the specimen proved to be non-diagnostic. Inability to secure a replacement for a lost specimen can occur with excisional biopsy as well as organ removal.

	before the event.	
I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results ***(NEW)***	Includes events where failure to report increased neonatal bilirubin levels results in kernicterus. Includes communication between healthcare professionals, or between healthcare professional and the patient/patient's family. Excludes events that the hospital first learned about through legal action against the organization and/or provider.	Examples of a serious injury are a new diagnosis, or an advanced stage of an existing diagnosis such as cancer.

5. Environmental Events

Event	Additional Specifications	Implementation Guidance
A. Patient ***or staff death*** or serious ***injury*** associated with an electronic shock ***in the course of a patient care process*** in a healthcare ***setting***	This event is intended to capture: • patient death or injury associated with unintended electric shock during the course of care or treatment; • staff death or injury associated with unintended electric shock while carrying out duties directly associated with a patient care process, including preparing for care delivery. This event is not intended to capture: • patient death or injury associated with emergency defibrillation in ventricular fibrillation or with electroconvulsive therapies; • injury to staff who are not involved in patient care; • events involving planned treatments such as electric countershock /elective cardioversion.	
B. Any incident in which ***systems*** designated for oxygen or other gas to be delivered to a patient	This event includes events in which the line is attached to a reservoir distant from the patient care unit or in a tank near a patient such as E-cylinders, anesthesia machines.	

contains ***no gas,*** the wrong gas, or ***are*** contaminated by toxic substances		
C. Patient ***or staff death*** or serious ***injury*** associated with a burn incurred from any source ***in the course of a patient care process*** in a healthcare ***setting***	This event is intended to capture burns that result from: • operating room flash fire, including second degree burn cases • hot water • sunburn in the patient with decreased ability to sense pain • smoking in any patient care environment Excludes any event that results in only first degree burns.	
D. Patient death or serious ***injury*** associated with the use of ***physical*** restraints or bedrails while being cared for in a healthcare ***setting***		The event is intended to capture instances where restraints are implicated in the death; e.g., lead to strangulation/entrapment, etc. Death/injury resulting from falls caused by lack of restraints would be captured under "falls" in 4E. Restraints are currently defined by The Joint Commission, the Centers for Medicare and Medicaid Services and by some states. In the event none of those definitions apply to an institution, the following definition, which is intended to capture definitions from the named organizations, is offered: Restraints means any method of restricting a patient's freedom of movement that is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; is not indicated to treat the patient's medical condition or symptoms; or does not promote the patient's independent functioning.

6. Radiologic Events (NEW)

Event	Additional Specifications	Implementation Guidance
A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area	This event is intended to capture injury or death as a result of projectiles including: • retained foreign object • external projectiles • pacemakers	Includes events related to material inside the patient's body or projectiles outside the patient's body.

7. *Potential* Criminal Events

Event	Additional Specifications	Implementation Guidance
A. Any instance of care	This event is intended to capture:	

ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	• those without licensure to provide the care given • those with licensure who represent themselves and practice beyond the scope of their license. This event is not intended to capture individuals who are practicing within the scope of their license on whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider.	
B. Abduction of a patient***/resident*** of any age	This event is intended to capture removal of a patient/resident, who does not have decision making capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting. Examples of individuals who do not have decision making capacity include infants, minors and patients with Alzheimer's.	Decision making capacity is defined as the ability to understand information relevant to a decision and the ability to appreciate the reasonably foreseeable consequences of a decision (or lack of a decision).
C. Sexual ***abuse/***assault on a patient ***or staff member*** within or on the grounds of the healthcare ***setting***		Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction.
D. Death or ***serious*** injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare ***setting.***		Language and definitions may vary based on state statute

Appendix 1

The definition of serious injury shall include:

Physical or mental damage that substantially limits or results in loss of one or more of the major life activities (e.g., breathing; dressing/undressing; drinking; eating; eliminating waste products; getting into or out of bed, chair, etc.; hearing; seeing; sitting; sleeping; walking; and working) of an individual in the short term, which may become a disability if extended long term. A serious injury can result in death, loss of a body part, long or short term disability, loss of bodily function, or require a major intervention for correction (e.g., higher level of care, surgery, and dialysis). Serious injury includes a substantial change in the patient's risk status such that care or monitoring, based on national accepted standards, whether provided or not, is required that was not required before the event.

Examples include but are not limited to:

- The patient's discharge status or discharge plan was changed as a result of the serious injury
- As a result of the incident, there was a change in the treatment plan that required a change in the level of care provided to the patient
- Any incident requiring major intervention, such as resuscitation, surgical intervention in the OR, new dialysis treatment, a higher level of care, e.g., transfer to critical care unit, for correction
- The patient's length of stay was extended, either at the hospital or at their post-acute placement to address the serious injury
- Bone fractures including wrist and rib fractures. Excludes hairline fractures and fractures of the fingers, toes, thumbs and nose
- Loss of a body part
- Permanent or temporary loss or substantial limitation of bodily function
- Any potential exposure to blood borne pathogens (e.g., Hepatitis or HIV) through reuse or improper repurposing of medical equipment, e.g., endoscopy tubes, syringes, regardless of whether or not the patient is actually infected
- Laceration that requires repair by suture or staple
- Second-degree or more severe burn

Appendix 2

Please note that the following list, which is taken directly from the Institute for Clinical Systems Improvement (ICSI), **only includes procedures that are deemed to be invasive.** The Department of Public Health **has not adopted** the list of procedures that ICSI does not consider invasive. Questions about whether or not a procedure not included below is invasive should be directed to DPH. Updated guidance will be disseminated as DPH makes case-by-case determinations.

Examples of invasive procedures:

- Any procedures involving skin incision
- Any procedures involving general or regional anesthesia, monitored anesthesia care, or conscious sedation
- Injections of any substance into a joint space or body cavity
- Percutaneous aspiration of bodily fluids or air through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization, chest tube)
- Biopsy (e.g., bone marrow, breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin)
- Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent-implantation, intra-aortic balloon catheter insertion, elective cardioversion)
- Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, percutaneous endoscopic gastronomy, J-tube placements, nephrostomy tube placements)
- Invasive radiologic procedures (e.g., angiography, angioplasty, percutaneous biopsy)
- Dermatology procedures (biopsy, excision and deep cryotherapy for malignant lesions- excluding cryotherapy for benign lesions)
- Invasive ophthalmic procedures including miscellaneous procedures involving implants
- Oral procedures including tooth extraction or gingival biopsy
- Podiatric invasive procedures (e.g., removal of ingrown toenail)
- Skin or wound debridement
- Electroconvulsive therapy
- Radiation oncology procedures
- Central line placements or PICC
- Kidney stone lithotripsy
- Colposcopy and/or endometrial biopsy

Appendix 3

Patient is admitted to hospital with:	During the hospital stay Pressure Ulcer becomes:	SRE or Not?
No Pressure Ulcer	Stage 3, 4 or unstageable	SRE
Stage 1	Stage 3 or 4 or unstageable	SRE
Stage 2	Stage 4 or unstageable	SRE
Stage 2	Stage 3	Not SRE
Stage 3	Stage 4 or unstageable	Reportable*
Stage 4	---	Not SRE
Unstageable	Stage 3 or 4	Reportable*
Deep Tissue Injury	Pressure Ulcer (any stage)	Not SRE

*In these cases, the pressure ulcer should be reported to DPH, which will decide on a case-by-case basis whether or not the pressure ulcer should be considered a Serious Reportable Event. A determination will be made within 7 days of reporting.