STATE OF CONNECTICUT DEPARTMENT OF PUBLIC HEALTH
Adverse Event Reporting Form

"Adverse" describes a consequence of care that results in an undesired outcome. It does not address preventability.

"*Event"* means a discrete, auditable, and clearly defined occurrence.

"Associated with" means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation and/or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship.

"Injury," means physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term, which may become a disability if extended long term. Further, injury includes a substantial change in the patient's long-term risk status such that care or monitoring, based on accepted national standards, is required that was not required before the event.

"Serious" describes an event that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction (e.g., higher level of care, surgery).

(as defined by the National Quality Forum, Glossary for Serious Reportable Events, 2011)

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EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
SURGICAL OR INVASIVE PROCEDURE EVENTS		
NQF 1A. Surgery or other invasive procedure performed on the wrong site.	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery of other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.	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. 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. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsies, excision and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It does not include use of such things as otoscopes and drawing blood. Organizations may choose to adopt a list of surgical procedures to supplement the definition above; one example of such a list in common use is that of the Institute of Clinical Systems Improvement. 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 and the patient has been taken from the operating/procedure room. 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 example, feeding tubes placed in the lung or ventilation tubes passed into the esophagus). The 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 or procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
NQF 1B. Surgery or other invasive procedure performed on the wrong patient.	Defined as any surgery or invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery of other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.	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. This event is intended to capture: • Surgical procedures (whether or not completed) initiated on one patient intended for a different patient. Use of accepted patient identification procedures is key to avoiding such events.
NQF 1C. Wrong surgical or other invasive procedure performed on a patient.	Defined as any surgery or invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery of other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints. Excludes emergent situations in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent.	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. 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).

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NQF 1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure.	Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place. Excludes a) objects present prior to surgery or other invasive procedure that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) 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).	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) in all applicable settings.
NQF 1E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient.	Includes all ASA Class 1 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 was completed or after administration of anesthesia (if surgery/procedure not completed).	This event is intended to capture: • ASA Class 1 patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out.

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
PRODUCT OR DEVICE EVENTS		
NQF 2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting.	Includes contaminants in drugs, devices, or 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: • Contaminations that can be seen with the naked eye or with use of detection 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. culture, 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 (e.g., consider a syringe or needle contaminated once it has been used to administer medication to a patient by injection or via connection to a patient's intravenous infusion bag or administration set). • Administration of contaminated vaccine or medication (e.g., intramuscular antibiotic); • Serious infection from contaminated drug or device used in surgery or an invasive procedure (e.g., a scalpel); • Occurrences related to use of improperly cleaned or maintained device.
NQF 2B. 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.	This event is intended to capture: • Occurrences whether or not the use is intended or described by the device manufacturers' literature.
NQF 2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.	Excludes death or serious injury associated with neurosurgical procedures known to present a high risk of intravascular air embolism.	This event is intended to capture: • High-risk procedure, other than neurosurgical procedures, that include, but are not limited to, procedures involving the head and neck, vaginal delivery an caesarean section, spinal instrumentation procedures, and liver transplantation; • Low-risk procedures, including those related to lines placed for infusion of fluids in vascular space.

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
PATIENT PROTECTION EVENTS		
NQF 3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person.		"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. "Decision-making capacity" is 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 an authorized person" includes removing the patient/resident without specific notification and approval by staff, even when the person is otherwise authorized. Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer's. Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decision-making capacity.
NQF 3B. Patient death or serious injury associated with patient elopement (disappearance).	Includes events that occur after the individual presents him/herself for care in a healthcare setting. Excludes events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen.	The term "elopement" and "competent" adult should be interpreted with prevailing legal standards in applicable jurisdictions. An assessment that identifies patients at "risk" of elopement or a chief complaint and findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis. This is not intended to capture: • Death or serious injury that occurs (after the patient is located) due to circumstances unrelated to the elopement.
NQF 3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting.	Includes events that result from patient actions after they present themselves for care in a healthcare setting. Excludes deaths from self-inflicted injuries that were the reason for admission/presentation to the healthcare facility.	This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the "healthcare setting," which means any facility or office, including a discrete unit of care within such a facility, that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence or other care of human illness or injury, physical or mental, including care during and after pregnancy. Healthcare settings include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers, office-based practices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, ambulatory surgical centers, and pharmacies. The boundary of a healthcare setting (the "grounds") is the physical area immediately adjacent to the setting's main buildings. It does not include nonmedical businesses such as shops and restaurants located close to the setting.

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
CARE MANAGEMENT EVENTS		
NQF 4A. 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).	Excludes reasonable differences in clinical judgment on drug selection and dose. Includes, but is not limited to, death or serious injury associated with: a) over- or under-dosing; b) administration of a medication to which a patient has a known allergy or serious contraindication; c) drug-drug interactions for which there is a known potential for death or serious injury, and d) 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 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 an 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, or 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. This event is not intended to capture: Patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event.
NQF 4B. Patient death or serious injury associated with unsafe administration of blood products.		Unsafe administration includes, but is not limited to, hemolytic reactions and administering: a) blood or blood products to the wrong patient; b) the wrong type; or c) blood or blood products that have been improperly stored or handled. This event is not intended to capture: • 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.
NQF 4C. 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 deaths 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, under this event, is to report only maternal death or serious injury associated with labor or delivery in a low risk pregnancy when made aware of the maternal death or serious injury either by readmittance or by the patient's family.

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NQF 4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy.	Includes, for the office-based surgery, birthing center or "home" setting, unplanned admission to an inpatient setting within 24 hours of delivery.	Unplanned admission to other than the birth setting should be verified with the identified birth setting.
NQF 4E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting.	Includes but is not limited to fractures, head injuries, and intracranial hemorrhage.	An assessment that identifies patients at "risk" to fall, findings or risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis.
NQF 4F. 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 and excludes pressure ulcers that develop in areas where deep tissue injury is documented as present on admission/presentation.	Although this event could occur in the ambulatory surgery environment based on patient condition and surgery time, it will be difficult to discern. Pre- and post-skin assessment will be key.
NQF 4G. 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.
NQF 4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen.	Includes events where specimens are misidentified, where another procedure cannot be done to produce a specimen. Includes progression of an undiagnosed disease or threat of disease that changes the patient's status for life, requiring monitoring not needed before the event.	This event is not intended to capture: • Procedures where the specimen was properly handled, but the specimen proved to be nondiagnostic. Inability to secure a replacement for a lost specimen can occur with excisional biopsy as well as in organ removal.
NQF 4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.	Includes but is not limited to, events where failure to report increased neonatal bilirubin levels result in kernicterus.	Examples of serious injury are a new diagnosis, or an advancing stage of an existing diagnosis (e.g., cancer). Failure to follow up or communicate can be limited to healthcare staff or can involve communication to the patient.

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
ENVIRONMENTAL EVENTS		
NQF 5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting.	Excludes events involving patients during planned treatments such as electric countershock/elective cardioversion.	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.
NQF 5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substance.		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, anesthesia machines.
NQF 5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting.		This event is intended to capture burns that result from: • Operating room flash fires, including second-degree burn in these cases; • Hot water; • Sunburn in the patient with decreased ability to sense pain; • Smoking in the patient care environment
NQF 5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting.		This event is intended to capture: Instances where physical restraints are implicated in the death, e.g., lead to strangulation/entrapment, etc.

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RADIOLOGIC EVENTS		
NQF 6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.	Includes events related to material inside the patient's body or projectiles outside the patient's body.	This event is intended to capture injury or death as a result of projectiles including: • Retained foreign object • External projectiles • Pacemakers
POTENTIAL CRIMINAL EVENTS		
NQF 7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.		This event is intended to capture: • Those without licensure to provide the care given; • Those with licensure who represent themselves and act beyond the scope of their license. It is not intended to capture individuals who are practicing within the scope of their license on whom patients or others mistakenly bestow the titles beyond that scope when such is not encouraged by the provider.
NQF 7B. 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: newborns, minors, adults with Alzheimer's.
NQF 7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting.		Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction.
NQF 7D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting.		Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms "first degree assault" or "second degree assault" or "battery"). The Connecticut Penal Code defines the threat of violence upon a person as "Threatening." See Conn. Gen. Stat. § 53a-61aa and § 53a-62. It defines physical violence upon a person as "assault." See Conn. Gen. Stat. § 53a-59 to § 53a-61a.

EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
CONNECTICUT-SPECIFIC EVENTS		
CT 1. Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious injury.		Includes perforations which require resection.
CT 2. Patient death or serious injury as a result of surgery.	Excludes events reported at NQF 1E and CT 1.	Includes: • Hemorrhage greater than 30% of circulating blood volume; and/or • Unanticipated death or serious disability in an ASA Class 2 patient intraoperatively, or post-operatively within twenty-four hours of the surgery. Class III Hemorrhage according to the American College of Surgeons' Advanced Trauma life Support (ATLS) is defined as loss of 30-40% of circulating blood volume. This is intended to capture: • ASA Class 2 patient death associated with administration of anesthesia whether or not the planned surgical procedure was carried out. Please refer to the Cleveland Clinic, ASA Physical Status Classification for guidance. http://my.clevelandclinic.org/services/anesthesia/hic_asa_physical_classification_system.aspx