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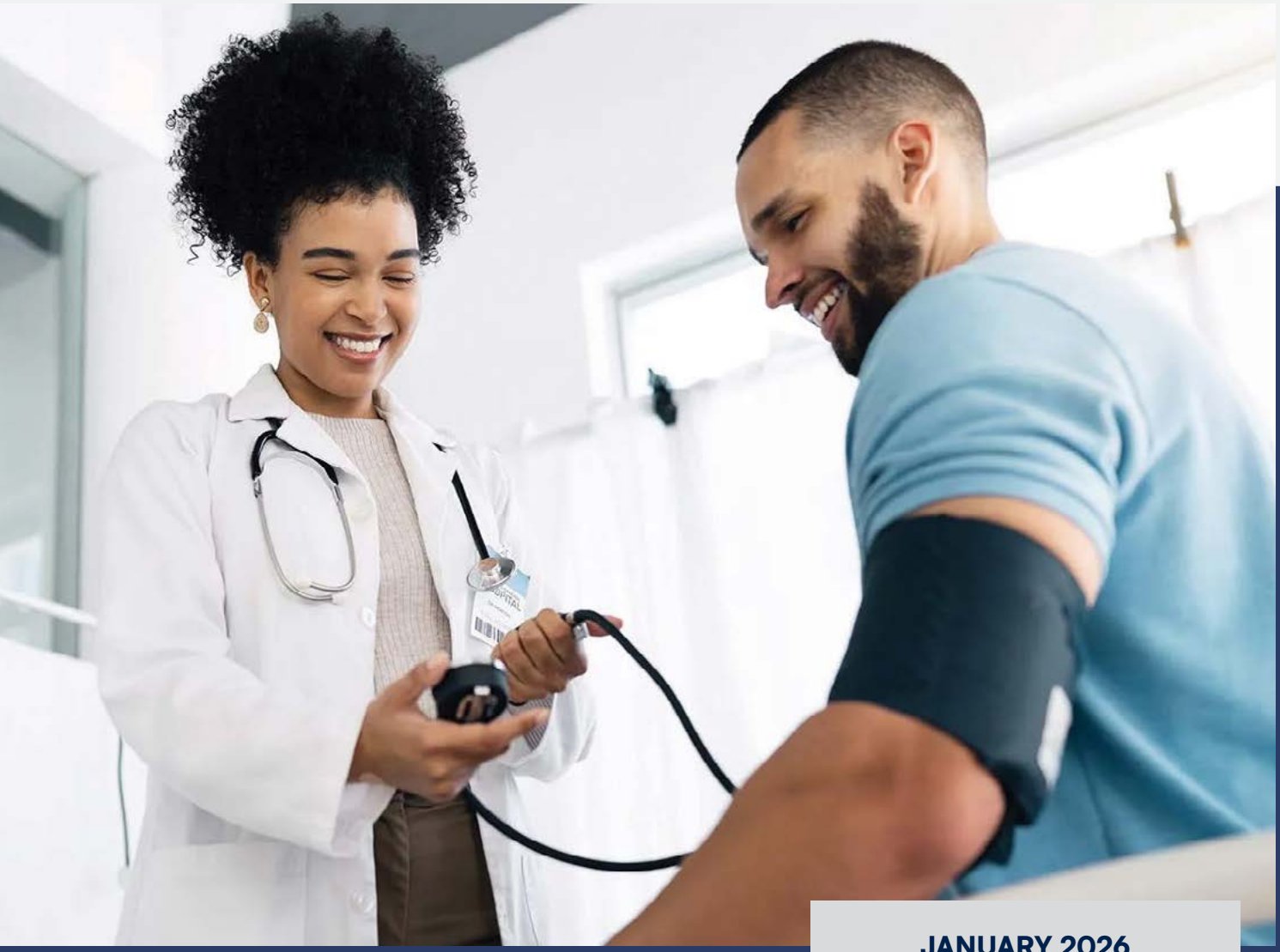

JANUARY 2026

Aligning Patient Safety Event Reporting:

2025 Updates to Sentinel Events and Serious Reportable Events

About the National Quality Forum

The National Quality Forum (NQF) is a not-for-profit, nonpartisan, membership-based organization that works to improve healthcare outcomes, safety, and affordability for all people. Our unique role is to bring all voices to our table to forge multistakeholder consensus on quality measurement and improvement standards and practices that achieve measurable health improvements for all. NQF is a proud affiliate of Joint Commission. Learn more at www.qualityforum.org.

About Joint Commission

Joint Commission enables and affirms the highest standards of healthcare quality and patient safety for all. Founded in 1951, it is the nation's oldest and largest standards-setting and accrediting body in healthcare, evaluating more than 23,000 healthcare organizations and programs across the United States. As an independent, nonprofit organization, Joint Commission inspires healthcare organizations across all settings to excel in providing safe and effective care of the highest quality and value. Learn more at www.jointcommission.org.

Ackowledgements

NQF launched its initial work to update the Serious Reportable Events List in 2023 with support from Elevance Health and the Centers for Medicare & Medicaid Services (CMS). Recognizing the importance of the project and its relevance to accredited organizations, Joint Commission supported its completion.

NQF thanks the many individuals listed in Appendix A who contributed their technical expertise to inform this report. The conclusions, findings, and opinions expressed by individuals who contributed to this publication are based on specialized expertise and are not intended to reflect the official position of any contributor's affiliated organization.

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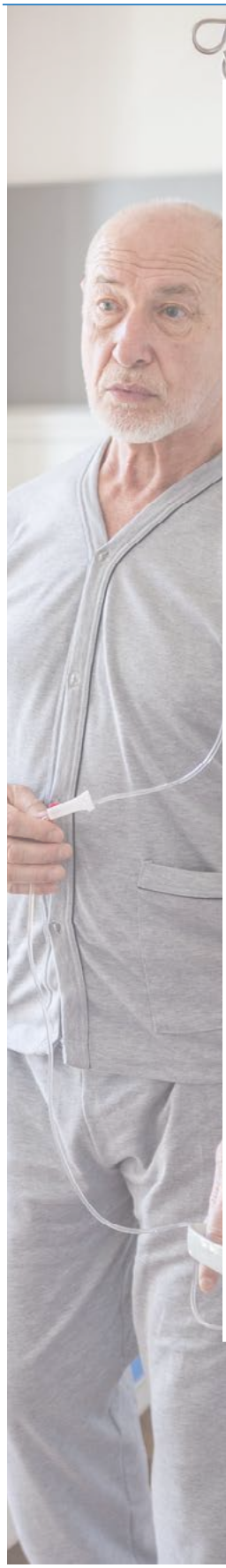


Executive Summary

Although notable progress has been made in patient safety over the past 25 years, preventable harm continues to occur at an alarming rate. A 2022 U.S. Department of Health and Human Services (HHS) report suggests that approximately one in four patients may be harmed during hospital stays, and many of these events are preventable.[1] Joint Commission and the National Quality Forum (NQF) have consistently led efforts to address these challenges, particularly through the tools of measurement, including Joint Commission's Sentinel Events List and NQF's Serious Reportable Events (SRE) List. The Sentinel Events List was developed by Joint Commission in 1996 and is used by more than 23,000 healthcare organizations in their accreditation programs. These organizations are expected to use the list to evaluate events in their organizations and encouraged to voluntarily report adverse events to Joint Commission to improve safety and learn from those sentinel events. The most recent Sentinel Events List update occurred in 2023. The NQF SRE List, first introduced in 2002, comprises a subset of patient safety events that are *serious* and *largely preventable* and may be indicative of an issue with a healthcare setting's underlying safety systems.

Today, more than 30 states and the District of Columbia have statutes, regulations, or policies addressing SRE reporting requirements and countless other jurisdictions and healthcare organizations across the country use the NQF SRE List to guide reporting and event analysis.[2] However, changes over the past decade—including new patient safety initiatives and terminologies, nontraditional care delivery settings, and emerging safety risks—mean healthcare looks very different than it did in 2011 when the NQF SRE List was last updated.[3–6]

In 2023 NQF embarked on a comprehensive update to address the changes that have occurred throughout the healthcare landscape, mitigate state-level differences in event reporting, and drive systemic national improvements in patient safety based on what is learned both about events and about how to prevent their reoccurrence. As part of a consensus-based process, NQF aimed to modernize the SRE List to be patient-focused, reflect the current healthcare landscape, and provide event-specific guidance that fosters consistent reporting. This update was supported by Elevance Health and the Centers for Medicare & Medicaid Services (CMS), and the final phase of the work was supported by Joint Commission.

Adoption of SREs by Joint Commission

In addition to an updated NQF SRE List, a key outcome of this work is that Joint Commission is aligning its patient safety event reporting framework with the updated SRE List. Joint Commission leaders and representatives from Joint Commission–accredited organizations actively participated in the NQF update and reviewed the updated and improved NQF SRE List. Joint Commission will adopt the 2025 NQF SRE List, with reporting to Joint Commission continuing to be voluntary. Joint Commission will maintain its expectation that all accredited healthcare organizations identify sentinel events, examine the root causes and contributing factors, and make improvements to mitigate the risk of reoccurrence.

Streamlining the measurement ecosystem to reduce burden and advance progress in improvement was an expressed goal of the Joint Commission and NQF alliance announced in 2023. Alignment of these previously parallel measurement systems aims to reduce healthcare organization reporting burden and allows organizations to focus more on improvement.

Joint Commission will update the Sentinel Events List by adopting the updated NQF SRE List while also including three legacy sentinel events that address workforce safety—Homicide, Sexual Abuse/Assault, and Physical Assault of a staff member. This transition will go into effect in January 2027 to allow time to support and prepare accredited healthcare organizations.

Key SRE Updates

As a result of a consensus-based process, NQF made the following changes:

Simplified Inclusion Criteria – NQF streamlined the criteria used for identifying an SRE and updated each criterion's definitions to create alignment with patient safety advancements. To qualify for the 2025 NQF SRE List, an event that is clearly tied to a *patient encounter* with a healthcare delivery system must be *serious* and *largely preventable*. To support event review, NQF also developed supporting definitions for each criterion (see pages 24-29).

Expanded Applicable Healthcare Settings – NQF expanded the applicable healthcare settings to **all** patient care environments, which include ambulatory/outpatient care, hospital/acute care, post-hospital/sub-acute care, home care, and virtual care settings. Recognizing that not all SREs may be relevant to all care settings, NQF developed a crosswalk showing which SREs are most likely relevant to each healthcare setting type (see pages 140-150).

Focused on Patient Harm – Expert review and discussion throughout this update acknowledged workforce safety as a critical and complex issue that should be addressed separately. NQF, in agreement, updated the 2025 NQF SRE List to focus primarily on patient harm, only including harm to healthcare workers in three SREs. Given Joint Commission's focus on workforce safety, the revised Sentinel Events List will include three legacy sentinel event workforce safety events.

Updated Events – The 2025 NQF SRE List consists of four categories and 28 events: 23 events are updated or modified from the 2011 list, and 5 events are new. NQF standardized SRE names to clarify event reporting. Nineteen SRE names include "patient harm," which signifies that the event in review must be clearly tied to a *patient encounter* with a healthcare delivery system and meet both the *serious* and *largely preventable* criteria to qualify as an SRE. Nine SRE names include "regardless of the outcome," which signifies that all instances in review that are clearly tied to a *patient encounter* with a healthcare delivery system qualify as an SRE.

Developed SRE-Specific Guidance – NQF developed robust SRE–specific guidance to reduce ambiguity in whether an event qualifies as an SRE and to enhance consistent SRE interpretation and reporting (see Part II of the report). Varied SRE implementation across the states and health systems that have adopted but modified definitions create significant barriers to tracking and trending these events consistently at a national level and over time. The goal is to improve consistency in reporting to allow aggregation and trending more effectively than in the past, enabling meaningful measurement across geographies and time frames.

2025 Serious Reportable Events

The 2025 NQF SRE List includes 28 SREs, 23 of which were previously on the 2011 NQF SRE List and have been updated or modified, and 5 of which are new. Part II of the report provides detailed Clinical Application Guidance for the identification and reporting of SREs.

Procedural Events

SRE 1. Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure, regardless of the type of procedure or the outcome

SRE 2. Unintended retention of a medical or surgical item in a patient after surgery or other invasive procedure, regardless of the type of procedure or the outcome

SRE 3. Patient harm associated with perioperative or periprocedural sedation of an ASA Class I or ASA Class II patient

SRE 4. Medically assisted reproduction with the wrong donor sperm or egg, regardless of the outcome

SRE 5. Introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area, regardless of the outcome

NEW **SRE 6.** Patient harm associated with an MRI–related thermal injury

NEW **SRE 7.** Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose, regardless of the outcome

Product or Device Events

SRE 8. Patient harm associated with the use of contaminated drugs, devices, or biologics

SRE 9. Patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended

SRE 10. Patient harm occurring when systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances

NEW **SRE 11.** Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting, regardless of the outcome

Patient Protection Events

SRE 12. Discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity, regardless of the outcome

SRE 13. Patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity

SRE 14. Patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release, regardless of the outcome

SRE 15. Patient harm associated with the use of chemical restraints, physical restraints, or seclusion

SRE 16. Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome

Care Provision Events

SRE 17. Patient harm associated with a fall

SRE 18. Patient harm associated with an unintended burn from any source

SRE 19. Patient harm associated with a medication error

SRE 20. Patient harm associated with unsafe processing or administration of blood products

SRE 21. Patient harm associated with a Stage 3 pressure injury, Stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission

SRE 22. Patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable by an invasive procedure

SRE 23. Patient harm resulting from failure to act on clinically significant laboratory, pathology, or radiology test results

SRE 24. Patient harm associated with an intravascular air embolism

SRE 25. Maternal patient harm associated with labor or delivery in a low-risk pregnancy

SRE 26. Neonatal patient harm associated with labor or delivery in a low-risk pregnancy

NEW **SRE 27.** Patient harm associated with the care of a neonate

NEW **SRE 28.** Patient harm associated with unrecognized clinical deterioration

Part I: Alignment Overview

Terms to Know

The *Aligning Patient Safety Event Reporting: 2025 Updates to Sentinel Events and Serious Reportable Events* report references key terms defined below:

Clinical Care Team: Healthcare teams that provide direct patient care or key support services

Healthcare Organization: Healthcare entities responsible for providing services or assessing the health status of patients. Healthcare organizations have an associated location or modality by which patients interact with clinical care teams, including synchronous and asynchronous communication

Patient: Individual interacting with a healthcare setting for the purpose of seeking healthcare services or assessment of their health status

Reviewer: Healthcare professional who reviews patient safety events for qualification as SREs

2025 NQF Serious Reportable Events List Update

Since its inception in 2002, the purpose of the NQF SRE List has included facilitating consistent reporting, driving national improvement via shared learning, and preventing the reoccurrence of SREs.[7] The NQF SRE List aimed to highlight patient safety events that are serious, harmful, preventable, and therefore indicative of vulnerabilities in a healthcare setting's safety systems that jeopardize the safety of patients. To date, numerous national healthcare organizations have recognized the NQF SRE List; more than 30 states and the District of Columbia have incorporated the full list or elements of it into required or voluntary reporting programs; and many private and public organizations have leveraged the list to inform their own policies and practice.[2] Although the NQF SRE List fosters the review of serious and largely preventable patient safety events, it has not kept pace with the changing healthcare ecosystem. In addition, healthcare organizations receive disparate guidance on event reporting from multiple stakeholders, such as local, state, and federal reporting systems or accreditation requirements, which leads to fragmented information and missed opportunities for systemic patient safety improvements.[8]

Through its convening role, NQF engaged a wide range of healthcare stakeholders (henceforth collectively referred to as "experts") and the public to develop a consensus-based list that reflects the current healthcare landscape, centers on patient safety, and fosters consistent reporting (see Appendix A for a full list of key contributors).

Revisions Overview

NQF solicited expert and public insights through a consensus-based process to conduct the following revisions to the NQF SRE List:

- Simplified Inclusion Criteria;
- Expanded Applicable Healthcare Settings;
- Updated Events; and
- Improved Clinical Application Guidance.

Simplified Inclusion Criteria

As a result of the 2025 update, to qualify for the NQF SRE List, an event that is clearly tied to a *patient encounter* with a healthcare delivery system must be *serious* and *largely preventable*.

Through an inclusive stakeholder process, NQF synthesized feedback and established streamlined SRE Inclusion Criteria which state that to qualify for the 2025 NQF SRE List, an event that is clearly tied to a *patient encounter* with a healthcare delivery system must be *serious* and *largely preventable*. NQF developed definitions for each criterion of the SRE Inclusion Criteria, as noted in **Figure 1**. In addition, while assessing physical harm, emotional harm, and the preventability of an event have been a requirement for SRE identification since the 2011 SRE update, NQF has provided existing classification systems and definitions to aid with the interpretation of key terms within each criterion (see pages 24-29). In 2011 NQF recognized that patient injury may include "physical or mental damage that substantially limits one or more of the major life activities of an individual."[7] In this update, NQF further clarified these components specifically to reduce ambiguity and promote consistent interpretation.

Figure 1. 2025 SRE Inclusion Criteria and Supporting Definitions

To qualify for the NQF SRE List, an event that is clearly tied to a ***patient encounter*** with a healthcare delivery system must be ***serious*** and ***largely preventable***.

Patient Encounter:
An interaction between an individual and a healthcare setting for the purposes of providing healthcare services or assessing the health status of the individual. Encounters can be billable events but are not limited to billable interactions. The patient encounter has an associated location or modality (e.g., office, home, electronic health record [EHR], phone, e-mail, other telemedicine methods)within which the interaction occurred, including synchronous and asynchronous communication.[9,10]

Serious:
An event resulting in death or contributing to patient harm that includes physical, emotional, or psychological harm(s) that requires major intervention (e.g., surgery, higher level of care, or treatment postdischarge) or impairs a patient's ability to perform activities of daily living (ADLs).

Largely Preventable:
An event that is likely avoidable by any means currently available within the generally accepted performance standards (GAPS) of care and triggers further investigation into causative factors.

Expanded Applicable Healthcare Settings

As a result of the 2025 update, the SRE applicable healthcare settings have been expanded to all patient care environments.

The applicable healthcare settings depict which sectors of healthcare should consider reporting SREs. Recognizing that patient safety events can occur in different care environments, and to promote accountability and inclusivity across both traditional and new modalities, NQF has expanded the 2025 SRE applicable healthcare settings list to all patient care environments, including but not limited to those listed in **Figure 2**. This update reflects the prioritization of reporting serious and largely preventable events, regardless of location. Recognizing that not all SREs are relevant to all environments, NQF developed a crosswalk that depicts which SRES may be applicable to each setting type (pages 140-150).

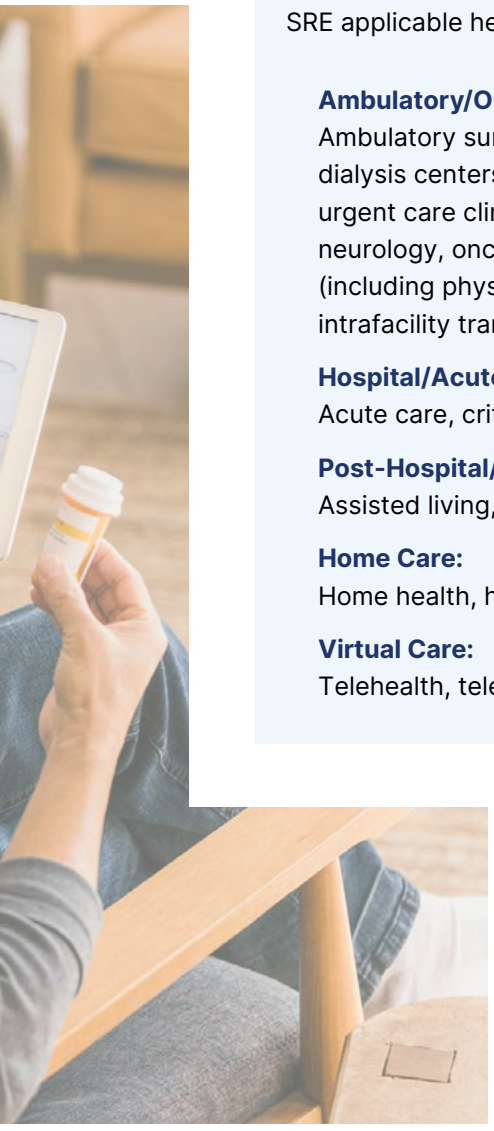


Figure 2. 2025 SRE Applicable Healthcare Setting Types and Examples

SRE applicable healthcare setting types include but are not limited to the following examples:

Ambulatory/Outpatient Care:
Ambulatory surgery centers, behavioral health services, community-based care, dental health, dialysis centers, federally qualified health centers, freestanding and hospital-based emergency/urgent care clinics, mobile clinics/radiology, office-based specialty care (e.g., cardiology, neurology, oncology), outpatient laboratories, outpatient radiology, outpatient rehabilitation (including physical, occupational, and speech-language therapy), pharmacies, pre-hospital and intrafacility transport services, primary care, and wound care clinics

Hospital/Acute Care:
Acute care, critical access, inpatient hospice, psychiatric, and specialty care

Post-Hospital/Sub-Acute Care:
Assisted living, hospice care, rehabilitation, swing bed, and skilled nursing facilities

Home Care:
Home health, home hospice, and hospital at home

Virtual Care:
Telehealth, telemedicine, and telemonitoring

Updated Events: Key Changes

As a result of the 2025 update, the NQF SRE List consists of 28 events: 23 events are updated or modified from the 2011 list, and 5 events are new.

The NQF SRE List is a subset of all patient safety events and focuses on the most serious events that indicate vulnerabilities in a healthcare setting's safety systems. NQF engaged in a consensus-based process that included expert discussion and public input to review the 2011 SREs as well as other patient safety events that have emerged since the last update. In total, NQF facilitated expert review of more than 70 candidate events during the update. Specifically, the SRE revisions include the following:

Standardization of Event Names

The revised NQF SRE List adopts a standardized naming convention that lends insights into reporting qualifications with the use of two naming conventions, "patient harm" and "regardless of the outcome," and focuses the list on patient safety.

Overview of the Consensus-Based Process

NQF facilitated a consensus-based process that included garnering input from three expert panels (see Appendix A) and the public. NQF solicited expert feedback offline and during virtual convenings and invited public feedback during three comment periods. NQF established a consensus threshold and voting process that was used during the evaluation of candidate events. For an event to be included or excluded from the NQF SRE List, the vote for a candidate event had to meet the consensus threshold. If a 2011 SRE did not meet the consensus threshold for inclusion or exclusion, NQF retained the event.

- **"Patient harm" indicates that the Reviewer must identify the level of harm experienced by the patient to determine if the event should be reported.** SREs with "patient harm" in the name require that the event in review is clearly tied to a *patient encounter* with a healthcare delivery system and meet both the *serious* and *largely preventable* criteria to qualify as an SRE.
- **"Regardless of the outcome" indicates that the Reviewer does not need to identify the level of harm experienced by the patient to report the event.** The nine SREs that include "regardless of the outcome" signal a vulnerability in a healthcare setting's safety system that could lead to serious patient harm and can be prevented by following generally accepted performance standards of care. Although all SREs are serious and should never occur, those denoted "regardless of the outcome" signal that there are no circumstances under which the occurrence of this event should go unreported and its occurrence, including a near miss event, qualifies as an SRE.
- **"Staff harm" has been removed from event names and is now highlighted as a population in SRE–specific Clinical Application Guidance.** Expert and public comment feedback supported focusing the NQF SRE List on patient safety and highlighted the need for a healthcare worker harm–related list. This need is further supported by the fact that, in 2020, healthcare worker harm made up 36% of all nonfatal occupational injuries and illnesses in the United States, the largest of any industry.[11] Healthcare workforce safety is linked to workforce well-being, retention, and overall care quality.[12] Experts identified the need to focus primarily on patient harm and leverage existing occupational safety programs, workplace violence prevention initiatives, and regulatory frameworks to track staff harm until a dedicated healthcare workforce safety list is established. Three of the 28 events, SRE 5, SRE 11, and SRE 16, include reporting healthcare worker harm and are highlighted in the SRE–specific application guidance.

Maintenance of Previously Recognized Events

The experts discussed needed modifications to the existing 2011 SREs to align with the updated SRE Inclusion Criteria and to update the events based on how and where care is delivered today. Through a consensus-based process, the experts recommended maintaining 24 previously recognized SREs for continued inclusion and updated the scope of each event to drive consistent understanding and alignment with subject matter experts. One event, SRE 16: Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome, did not meet the consensus threshold for removal or inclusion. Therefore, due to its long history on the SRE List, NQF maintained SRE 16 with the previously recognized intent.

Consolidation or Removal of Events

The experts recommended against including four 2011 events on the updated NQF SRE List. When applicable, the experts recommended incorporating an event with another SRE.

- Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting: Instead of an individual event, experts recommended consolidating this event into SRE 9 and SRE 11.
- Abduction of a patient/resident of any age: Instead of an individual event, experts recommended consolidating this event into SRE 13.
- Surgery or other invasive procedure performed on the wrong site, Surgery or other invasive procedure performed on the wrong patient, and Wrong surgical or other invasive procedure performed on a patient: Instead of individual events, experts recommended consolidating these three events into SRE 1.
- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider and 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: Experts recommended against including these events due to challenges in meeting the *largely preventable* criterion. In addition, because these events are reported to and investigated by other law enforcement and regulatory bodies, experts requested removing these to reduce duplicative reporting requirements.

Addition of New Events

The experts recommended five new events for the 2025 NQF SRE List. These five events, which are reflective of today's healthcare environment, met the SRE Inclusion Criteria, and each depicts a patient safety event that can be clearly tied to a patient encounter, is serious in nature, and is largely preventable based on generally accepted performance standards of care.

- Patient harm associated with the care of a neonate
- Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or 25% above the planned radiotherapy dose, regardless of the outcome
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting, regardless of the outcome
- Patient harm associated with unrecognized clinical deterioration
- Patient harm associated with an MRI–related thermal injury

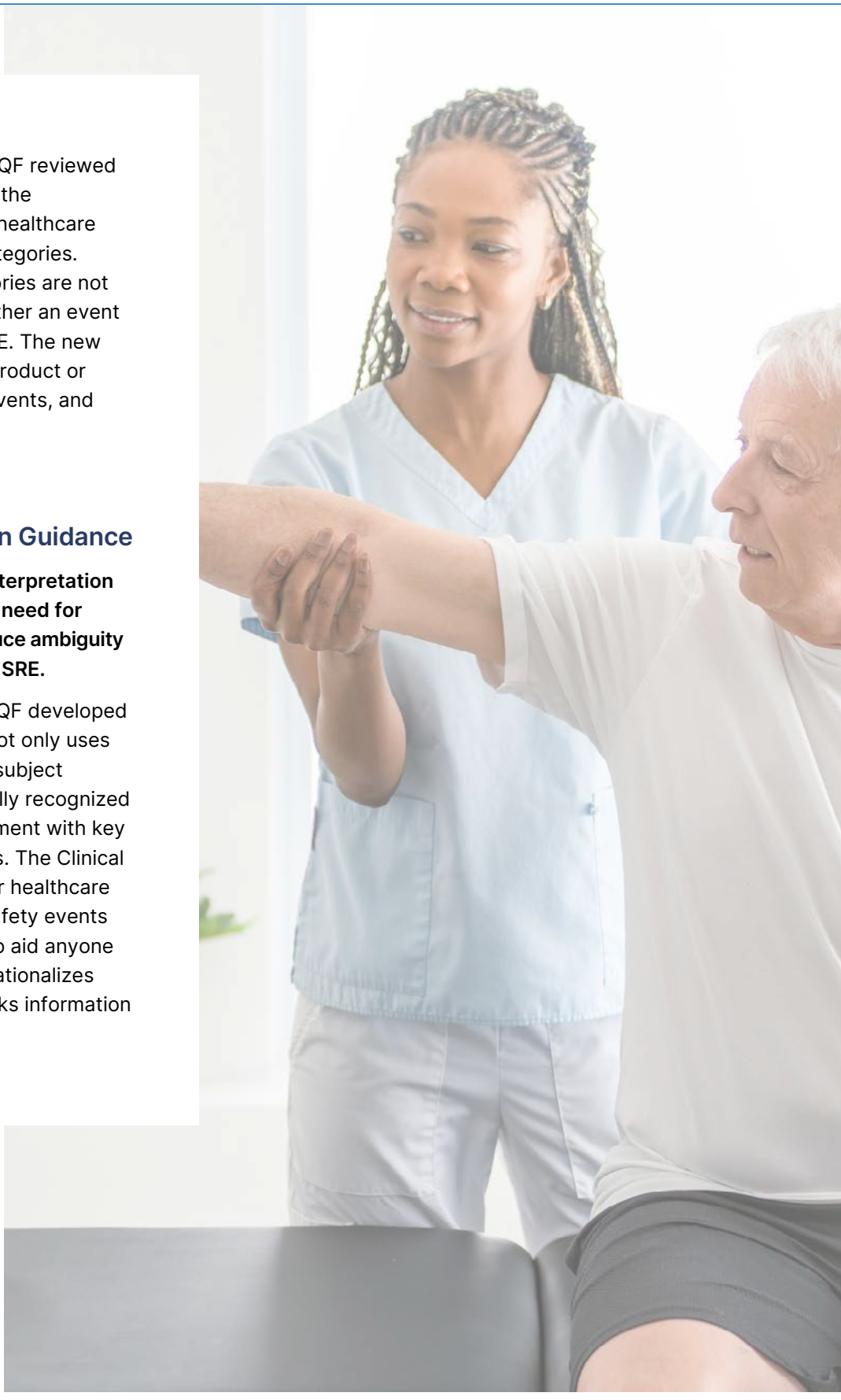
Recategorization of Events

Based on feedback from experts, NQF reviewed the full list of SREs and streamlined the categories to better reflect today's healthcare ecosystem, resulting in four SRE categories. Like prior SRE reports, these categories are not strict divisions for determining whether an event should be reported as a specific SRE. The new categories are Procedural Events, Product or Device Events, Patient Protection Events, and Care Provision Events.

Improved Clinical Application Guidance

To enhance both consistent SRE interpretation and reporting, NQF recognized the need for clear, SRE–specific guidance to reduce ambiguity in whether an event qualifies as an SRE.

With expert and public feedback, NQF developed Clinical Application Guidance that not only uses terms and definitions derived from subject matter experts and used by nationally recognized organizations but also fosters alignment with key patient safety policies and practices. The Clinical Application Guidance is intended for healthcare professionals who review patient safety events for qualification as SREs and aims to aid anyone who oversees, implements, or operationalizes SRE reporting programs or who seeks information on SREs.



Alignment of Sentinel Events and Serious Reportable Events

Through its Sentinel Event Policy, Joint Commission expects all accredited healthcare organizations to identify sentinel events, examine root causes and contributing factors, and make improvements to mitigate the risk of reoccurrence. Through voluntary reporting, Joint Commission works with its accredited organizations to provide information critical to the prevention of sentinel events, publishing an annual report that is publicly available. For accredited organizations in states with mandated SRE reporting, differences in reporting requirements between the SRE and Sentinel Events Lists have led to increased burden.

To streamline the reporting of patient safety events, Joint Commission will update the Sentinel Events List by aligning with and adopting the updated NQF SRE List and including three legacy sentinel events that address workforce safety. This alignment will enhance the effectiveness of safety event reporting and drive learning opportunities that will ultimately reduce the occurrence of preventable harm and contribute to safer care environments.

Adopting the NQF SRE List is a step toward alignment on tracking, reporting, and monitoring patient safety events and will decrease reporting burdens for many healthcare organizations. In recognition of the time and planning required to update reporting structures, Joint Commission will make this transition globally **no later than January 1, 2027**. Key points of the transition include the following:

Voluntary Reporting – The reporting of events to Joint Commission will remain voluntary. U.S.–based healthcare organizations should refer to their state's legislation to determine any reporting requirements or mandates at the state level. Accredited organizations wishing to voluntarily report events to Joint Commission should plan to transition to the new list no later than January 1, 2027.

28 SREs – The Sentinel Events List will adopt the 28 SREs, the updated SRE Inclusion Criteria, and the Clinical Application Guidance detailed in this report. Of the 28 SREs, 13 align with current sentinel events, and 15 are new for Joint Commission. The crosswalk tables 1–4 below provide an overview of these events as compared to prior sentinel events to support healthcare organizations in their understanding of the transition. The newly added Clinical Application Guidance provided for each SRE will support healthcare organizations in understanding the parameters and considerations of each event to determine if an SRE occurred and should be reported.

Workforce Safety Events – Joint Commission continues to champion workforce safety as a vital priority throughout its accredited healthcare organizations. In accordance with this priority, the updated Sentinel Events List will include three legacy workforce sentinel events:

- Homicide of a staff member
- Sexual abuse/assault of a staff member
- Physical assault of a staff member

In addition, the updated Sentinel Event Policy will address CMS reporting requirements for accredited organizations via the following four events:

- For the Hospital program, SRE 15: Patient harm associated with the use of chemical restraints, physical restraints, or seclusion
- For the Ambulatory Surgery Center program, SRE 16: Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome
- For the Rural Health Care program, SRE 19: Patient harm associated with a medication error
- For the Laboratory program, SRE 20: Patient harm associated with unsafe processing or administration of blood products

Sentinel Events and Serious Reportable Events Crosswalk

The following section provides a crosswalk of Joint Commission's sentinel events with NQF's 2025 SREs (Tables 1–4). This crosswalk highlights the changes Joint Commission–accredited healthcare organizations can expect with the upcoming transition, which will be effective no later than January 1, 2027. Specifically, the last column highlights whether the event will be new for Joint Commission or if existing events will have updated reporting considerations.

Of the 28 SREs, 13 are already established sentinel events. The remaining 15 SREs are not listed as individual sentinel events, but meet the broader sentinel event definition, which states, "A sentinel event is a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm)."[13] Under the Sentinel Event Policy, healthcare organizations must have a policy detailing how the organization addresses sentinel events and are encouraged to voluntarily report any event that meets this definition, regardless of whether it was specifically on the Sentinel Events List.

Table 1. Procedural Events Crosswalk Summary

NATIONAL QUALITY FORUM SERIOUS REPORTABLE EVENTS (2025)	JOINT COMMISSION SENTINEL EVENTS LIST (2025)	UPDATED SENTINEL EVENTS LIST (2027)
SRE 1: Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure, regardless of the type of procedure or the outcome	Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome	Event will be updated to align with SRE 1
SRE 2: Unintended retention of a medical or surgical item in a patient after surgery or other invasive procedure, regardless of the type of procedure or the outcome	Unintended retention of a foreign object in a patient after an invasive procedure, including surgery	Event will be updated to align with SRE 2
SRE 3: Patient harm associated with perioperative or periprocedural sedation of an ASA Class I or ASA Class II patient	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 4: Medically assisted reproduction with the wrong donor sperm or egg, regardless of the outcome	Not listed as an individual event, but may be considered under the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 5: Introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area, regardless of the outcome	Not listed as an individual event, but may be considered under the broader sentinel event definition	Event will be added to the Sentinel Events List
NEW **SRE 6:** Patient harm associated with an MRI–related thermal injury	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
NEW **SRE 7:** Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose, regardless of the outcome	Any delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose	Event will be updated to align with SRE 7

Table 2. Product or Device Events Crosswalk Summary

NATIONAL QUALITY FORUM SERIOUS REPORTABLE EVENTS (2025)	JOINT COMMISSION SENTINEL EVENTS LIST (2025)	UPDATED SENTINEL EVENTS LIST (2027)
SRE 8: Patient harm associated with the use of contaminated drugs, devices, or biologics	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 9: Patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 10: Patient harm occurring when systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
NEW **SRE 11:** Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting, regardless of the outcome	Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the organization. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present.	Event will be updated to align with SRE 11

Table 3. Patient Protection Events Crosswalk Summary

NATIONAL QUALITY FORUM SERIOUS REPORTABLE EVENTS (2025)	JOINT COMMISSION SENTINEL EVENTS LIST (2025)	UPDATED SENTINEL EVENTS LIST (2027)
SRE 12: Discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity, regardless of the outcome	Discharge of an infant to the wrong family	Event will be updated to align with SRE 12
SRE 13: Patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity	Any elopement (that is, unauthorized departure) of a patient from a staffed-around-the-clock care setting (including the ED), leading to death, permanent harm, or severe harm to the patient	Event will be updated to align with SRE 13
SRE 14: Patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release, regardless of the outcome	Death caused by self-inflicted injurious behavior if any of the following apply: • While in a health care setting • Within 7 days of discharge from inpatient services • Within 7 days of discharge from emergency department (ED) • While receiving or within 7 days of discharge from the following behavioral health care services: Day Treatment/ Partial Hospitalization Program (PHP)/Intensive Outpatient Program (IOP), Residential, Group Home, and Transitional Supportive Living	Event will be updated to align with SRE 14
SRE 15: Patient harm associated with the use of chemical restraints, physical restraints, or seclusion	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 16: Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome	Sexual abuse/assault of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization	Event will be updated to align with SRE 16

Table 4. Care Provision Events Crosswalk Summary

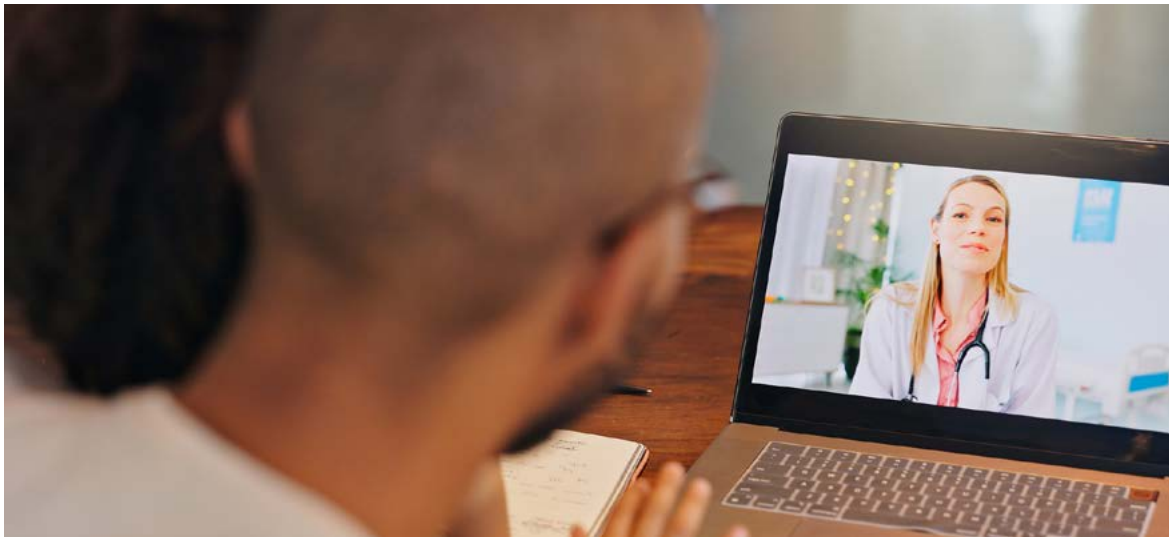
NATIONAL QUALITY FORUM SERIOUS REPORTABLE EVENTS (2025)	JOINT COMMISSION SENTINEL EVENTS LIST (2025)	UPDATED SENTINEL EVENTS LIST (2027)
SRE 17: Patient harm associated with a fall	Fall in a staffed-around-the-clock care setting or fall in a care setting not staffed around the clock during a time when staff are present resulting in any of the following: • Any fracture • Surgery, casting, or traction • Required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury • A patient with coagulopathy who receives blood products because of the fall • Death or permanent harm because of injuries sustained from the fall (not from physiologic events causing the fall)	Event will be updated to align with SRE 17
SRE 18: Patient harm associated with an unintended burn from any source	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 19: Patient harm associated with a medication error	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 20: Patient harm associated with unsafe processing or administration of blood products	Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusions resulting in death, permanent harm, or severe harm	Event will be updated to align with SRE 20
SRE 21: Patient harm associated with a Stage 3 pressure injury, Stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List

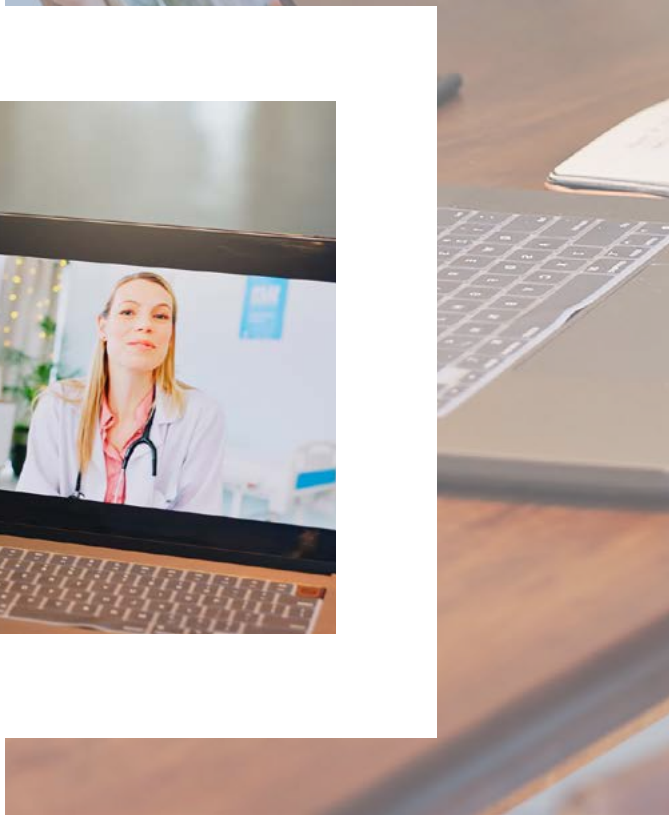
Table 4. Care Provision Events Crosswalk Summary *(continued)*

NATIONAL QUALITY FORUM SERIOUS REPORTABLE EVENTS (2025)	JOINT COMMISSION SENTINEL EVENTS LIST (2025)	UPDATED SENTINEL EVENTS LIST (2027)
SRE 22: Patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable through an invasive procedure	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 23: Patient harm resulting from failure to act on clinically significant laboratory, pathology, or radiology test results	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 24: Patient harm associated with an intravascular air embolism	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List
SRE 25: Maternal patient harm associated with labor or delivery in a low-risk pregnancy	• Any intrapartum maternal death • Severe maternal morbidity (leading to permanent harm or severe harm)	Event will be updated to align with SRE 25
SRE 26: Neonatal patient harm associated with labor or delivery in a low-risk pregnancy	Unanticipated death of a full-term infant	Event will be updated to align with SRE 26
NEW **SRE 27:** Patient harm associated with the care of a neonate	Severe neonatal hyperbilirubinemia (bilirubin greater than 30 milligrams/deciliter)	Event will be updated to align with SRE 27
NEW **SRE 28:** Patient harm associated with unrecognized clinical deterioration	Not listed as an individual event, but meets the broader sentinel event definition	Event will be added to the Sentinel Events List

Conclusion

When Joint Commission and NQF came together in 2023, an expressed goal of the alliance was to streamline the measurement ecosystem to reduce burden and advance progress in improvement was an expressed goal. The alignment of these previously parallel measurement systems aims to reduce healthcare organization reporting burden and allows organizations to focus more on improvement. Given the pressing need to accelerate harm reduction, we believe this alignment of taxonomies can better help everyone focus on the important work of improving safety.





Part II: SRE Technical Guidance

Introduction to Clinical Application Guidance

The 2025 NQF SRE List consists of four categories and 28 SREs. NQF developed SRE–specific Clinical Application Guidance to help Reviewers determine if an event qualifies and should be reported as an SRE. This guidance serves as a catalyst for clear understanding and consistent reporting by identifying key considerations for each SRE, including what is and is not intended to be captured, as recommended by experts. The Clinical Application Guidance is reflective of how and where care is provided today; however, care modalities, improvement science, and care practices will continue to evolve.

NQF acknowledges that the SRE List showcases events that are critical for reporting, as they may be indicative of vulnerabilities in a healthcare setting's safety systems. However, reporting is only one component of a healthcare organization's responsibility. Healthcare organizations should also identify contributing factors, mitigate the risk of recurrence, and commit to applying lessons learned to drive continuous quality improvement.

Unless cited, the application guidance in this report is informed by the diverse perspectives of key contributors, including patients, frontline clinicians, healthcare administrators, and representatives from federal agencies, payers, professional societies, and patient safety organizations. The guidance in this report does not replace existing guidance from professional societies, associations, and/or other agencies.

REPORTING REMINDERS

State, legal, or other jurisdictional boundaries that take precedence in the way events are interpreted should be respected when reporting SREs.

When evaluating events for SRE reporting, NQF recognizes that some events may qualify for multiple SREs. Reviewers are encouraged to select the SRE that is most directly associated with the event outcome. However, to drive systemic learning and reduce preventable harm, Reviewers may need to report one event as multiple SREs, particularly when more than one contributing factor exists.

How to Use SRE Clinical Application Guidance

The purpose of this section is to provide healthcare professionals who review patient safety events for qualification as SREs (henceforth referred to as "Reviewers") with additional guidance for evaluating whether an event aligns with the updated SRE Inclusion Criteria and qualifies for reporting as an SRE. This section also aims to aid anyone who oversees, implements, or operationalizes SRE reporting programs or who seeks information on SREs.

The SRE Clinical Application Guidance provides Reviewers with detailed information for each SRE, organized into four categories. These categories are not strict divisions for deciding whether an event should be reported as a specific SRE, as some SREs may be applicable to more than one category. Event-specific Clinical Application Guidance comprises four key components: the event name, intent, key definitions, and reporting considerations.

Event Name

The event name lends Reviewers insights into reporting qualifications with the use of two naming conventions: "patient harm" and "regardless of the outcome."

- **"Patient Harm"** indicates that the level of harm experienced by the patient must be identified for reporting. There are 19 SREs that require Reviewers to assess the level of harm.
- **"Regardless of the outcome"** indicates that identifying the level of harm experienced by the patient is not needed for reporting. Nine SREs require Reviewers to report all instances, including near misses.

Intent

The intent summarizes the event and highlights applicable healthcare settings and populations. This section includes whether the event is new or was previously in the NQF Serious Reportable Events In Healthcare—2011 Update: A Consensus Report, noting any modifications or changes. To help with interpretation, the intent also provides examples of clinical circumstances that are excluded from reporting.

Reviewers should use the SRE Inclusion Criteria and reference the Clinical Application Guidance components to determine whether an event qualifies as an SRE.

To qualify for the NQF SRE List, an event that is clearly tied to a ***patient encounter*** with a healthcare delivery system must be ***serious*** and ***largely preventable***.

Patient Encounter:
An interaction between an individual and a healthcare setting for the purposes of providing healthcare services or assessing the health status of the individual. Encounters can be billable events but are not limited to billable interactions. The patient encounter has an associated location or modality (e.g., office, home, electronic health record [EHR], phone, e-mail, other telemedicine methods)within which the interaction occurred, including synchronous and asynchronous communication.[9,10]

Serious:
An event resulting in death or contributing to patient harm that includes physical, emotional, or psychological harm(s) that requires major intervention (e.g., surgery, higher level of care, or treatment postdischarge) or impairs a patient's ability to perform activities of daily living (ADLs).

Largely Preventable:
An event that is likely avoidable by any means currently available within the generally accepted performance standards (GAPS) of care and triggers further investigation into causative factors.

Key Definitions

For each event, NQF provides definitions for critical terms used in the event name, intent, or reporting considerations that will aid Reviewers in understanding and interpreting the SRE Clinical Application Guidance. The definitions are sourced from nationally recognized organizations and subject matter experts.

Reporting Considerations

The reporting considerations translate the high-level intent into specific clinical circumstances that further clarify whether an event qualifies as an SRE. These circumstances do not capture every possible clinical scenario, nor do they provide exhaustive examples of event classifications. Instead, this section provides Reviewers with three actionable prompts for use when evaluating whether an event should be reported as an SRE. These prompts align with the SRE Inclusion Criteria and associated definitions for *patient encounter, serious,* and *largely preventable*.

IS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

This Clinical Application Guidance section prompts Reviewers to gauge whether the event aligns with the *Patient Encounter* definition: An interaction between an individual and a healthcare setting, for the purposes of providing healthcare services or assessing the health status of the individual. Encounters can be billable events but are not limited to billable interactions. The patient encounter has an associated location or modality (e.g., office, EHR, phone, e-mail, other telemedicine methods) within which the interaction occurred, including synchronous and asynchronous communication.[14,15]

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

This Clinical Application Guidance section prompts Reviewers to evaluate the degree of patient harm associated with the event and decide whether it aligns with the *Serious* definition: An event resulting in death or contributing to patient harm that includes physical, emotional, or psychological harm(s) that require major intervention (e.g., surgery, higher level of care, or treatment postdischarge), or impairs a patient's ability to perform activities of daily living (ADLs).

For an event in review, the Reviewer should consider each of the four components in the Serious criterion definition:

1. Physical harm;
2. Emotional or psychological harm;
3. Major intervention; and
4. Impairs a patient's ability to perform ADLs.

IMPORTANT: If the patient experienced one or more of these components, the event resulted in serious patient harm and aligns with the *Serious* criterion. For "patient harm" events, Reviewers are encouraged to track physical and emotional or psychological harm separately for continuous learning and process improvement. In addition, for "regardless of the outcome" events, Reviewers should report any instance of occurrence and reference the SRE-specific guidance for consistent review and reporting practices.

1 PHYSICAL HARM

NQF recognizes that organizations may use their own harm classification terminology or leverage one of the commonly used safety event classification systems. To support consistent interpretation of physical harm, NQF provides Table 5, a crosswalk of commonly used patient safety event classification systems, to illustrate which harm levels align with the Serious criterion. **IMPORTANT: Table 5 does not depict the full scale of harm for each classification system, only those relevant to the SRE *Serious* criterion.**

Table 5. Physical Harm Categories in Commonly Used Harm Classification Systems That Align with the *Serious* Criterion

JOINT COMMISSION SENTINEL EVENT POLICY[13]	PRESS GANEY HPI SEC®[16]*	NCC MERP INDEX[17]*	AHRQ HARM SCALE[18]	WHO INTERNATIONAL CLASSIFICATION FOR PATIENT SAFETY[19]
Death	SSE 1: Death	I: An error occurred that may have contributed to or resulted in the patient's death	Death	Death
Severe Harm	SSE 2: Severe Permanent Harm	H: An error occurred that required intervention necessary to sustain life	Severe Harm	Severe
Permanent Harm	SSE 3: Moderate Permanent Harm	G: An error occurred that may have contributed to or resulted in permanent patient harm	Moderate Harm	Moderate
†	SSE 4: Severe Temporary Harm	F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	†	†
†	SSE 5: Moderate Temporary Harm	E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	†	†

* Depicts only those categories that align with the *Serious* criterion.

† Cell left intentionally blank; the table does not depict the full scale of harm for each classification system, only those relevant to the *Serious* criterion.

2 EMOTIONAL OR PSYCHOLOGICAL HARM

Emotional and psychological harm are inherently subjective and are characterized by a lack of compassion, empathy, or respect by clinical care teams toward the patient or family member as a human being, undermining their sense of dignity.[20] The occurrence of an SRE can negatively affect a patient's mental, emotional, or behavioral functioning and result in a traumatic experience or chronic stress, or damage the patient–clinical care team–healthcare organization relationship.[20,21] NQF recognizes that healthcare organizations may interpret emotional or psychological harm in different ways. To foster shared understanding and interpretation, NQF provides the following emotional or psychological harm definition and harm classification scale:

Press Ganey's Emotional Harm Classification & Severity Scale provides a structured framework for identifying emotional or psychological harm from the patient's perspective. The scale includes five levels listed below. Emotional Harm (EH) One is the only threshold that aligns with the *Serious* criterion; however, healthcare organizations may want to track EH2 and EH3 for internal learning and improvement.[20]

- **Emotional Harm One (EH1): Severe; long-term or permanent impact (consider indicators like life-changing events of physical harm, claims/lawsuits, complaints to a regulatory body, media notification) [NOTE:** This level aligns with the *Serious* criterion.**]**
- Emotional Harm Two (EH2): Moderate; temporary impact (consider indicators like service recovery interventions, requests to speak with a manager, patient/family states they feel a loss of dignity/respect/trust)
- Emotional Harm Three (EH3): Minor; short-term, incidental impact (consider indicators like an expression of a concern or issue resolved through apology/explanation)
- Emotional Harm Four (EH4): Emotional harm not perceived by the patient
- Not Assessed/Unable to Determine: Emotional impact on the patient was not assessed or unable to be assessed

3 MAJOR INTERVENTION

NQF recognizes that major interventions may be characterized by both the clinical significance of the intervention and the impact on the patient's overall care trajectory. Major interventions typically involve actions taken to prevent death, significant disability, or further clinical deterioration. To foster shared understanding and interpretation, NQF presents the following definition:

Major Intervention:
Medical, surgical, or diagnostic procedure(s) that involves significant risk, general anesthetic, or substantial invasion of bodily integrity. These interventions often require hospitalization, prolonged care, or result in significant pain, discomfort, debilitation, or a lengthy recovery period.[22,23]

4 IMPAIRS A PATIENT'S ABILITY TO PERFORM ACTIVITIES OF DAILY LIVING (ADLS)

The evaluation of an event's impact on a patient's ability to perform ADLs should consider the degree of aid required by an individual for mobility and self-care daily tasks, taking into consideration pre-event status. To foster shared understanding and interpretation, NQF presents the following definition:

Activities of Daily Living:
Routine tasks essential to an individual's personal care and independent living. ADL tasks include but are not limited to basic self-care activities such as eating, dressing, getting into and out of bed or chairs, bathing, grooming, and using the toilet. The inability to accomplish ADLs may lead to unsafe conditions and a diminished quality of life.[24,25]

To support consistent interpretation of events that impair a person's ability to perform ADLs, NQF provides the following validated tools:

- The Barthel Index
- Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI)
- Functional Independence Measure (FIM)

WAS THE EVENT *LARGELY PREVENTABLE*?

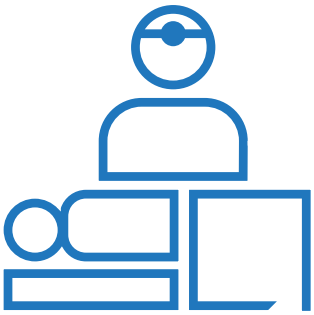
This Clinical Application Guidance section prompts Reviewers to determine whether an event was preventable. For an event in review to meet the *Largely Preventable* criterion, it should be likely avoidable by any means currently available within the generally accepted performance standards (GAPS) of care and should trigger further investigation into causative factors. The components of (1) avoidable by any means currently available and (2) generally accepted performance standards (GAPS) of care are defined below:

Avoidable By Any Means Currently Available:
The potential for preventing an event using existing technologies, clinical methods, or interventions that are accessible within the healthcare system at the time of the patient encounter.[26]

Generally Accepted Performance Standards (GAPS) of Care:
The widely recognized and established standards of care that healthcare professionals are expected to follow. These standards are based on evidence-based practices, regulatory requirements, clinical guidelines, and subject matter expert consensus.[27]

IMPORTANT: If at least one of these components is associated with an event, the event aligns with the *Largely Preventable* criterion.

Procedural Events



This category includes events associated with a surgical procedure, an invasive procedure, or other procedure for diagnosis or treatment. Events in this category are periprocedural (i.e., before, during, and after care) and may occur in specialized care environments (e.g., operating room, imaging suite) or involve specially trained staff (e.g., radiotherapy technician, anesthesiologist).

This Category Consists of 7 SREs:

SRE 1. Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure, regardless of the type of procedure or the outcome

SRE 2: Unintended retention of a medical or surgical item in a patient after surgery or other invasive procedure, regardless of the type of procedure or the outcome

SRE 3: Patient harm associated with perioperative or periprocedural sedation of an ASA Class I or ASA Class II patient

SRE 4: Medically assisted reproduction with the wrong donor sperm or egg, regardless of the outcome

SRE 5: Introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area, regardless of the outcome

NEW **SRE 6:** Patient harm associated with an MRI–related thermal injury

NEW **SRE 7:** Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose, regardless of the outcome

SRE 1: Surgery or Other Invasive Procedure Performed at the Wrong Site, on the Wrong Patient, or That Is the Wrong Procedure, Regardless of the Type of Procedure or the Outcome

Event Intent

This event captures **any** surgery or other invasive procedure performed on a body part, site, or patient, which was not consistent with the correctly documented informed consent for that patient, even if corrected during the procedure. When procedures are not performed in an operating room, and do not involve a specific surgical consent form, clinicians must execute the informed consent process and document this in the medical record. Documentation may be recorded in a form, in progress notes, or elsewhere in the record.

Although the level of harm experienced by the patient can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of a surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure to better understand system vulnerabilities, regardless of whether the event was caught before reaching the patient (i.e., near miss), reached the patient and resulted in no harm, or reached the patient and resulted in any level of harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that perform surgery or other invasive procedures.
POPULATION	This event applies to all patients, regardless of the outcome.
UPDATES SINCE 2011	The experts recommended consolidating three events from the 2011 NQF SRE List into one event and expanding the intent to include all instances, regardless of the outcome.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 1.
NOTE: *This list is not meant to be exhaustive.*

- An incorrectly placed surgical mark that occurs prior to the procedure/surgery start time. Placing a mark on the wrong body part or site does not in itself constitute wrong-site surgery but may be indicative of a precursor event.
- Changes in plan upon entry into the patient with discovery of unusual physical configuration (e.g., adhesions, spine level/extra vertebrae) or pathology near the intended place where risk of a second surgery or procedure outweighs benefit of patient consultation
- Noninvasive procedures (e.g., wrong imaging, contrast dye administered to the wrong patient)
- Known complications of surgery or other invasive procedures (e.g., lung injury during central line placement, injury to and repair of an adjacent organ during abdominal surgery)
- Emergent situations requiring urgent intervention to sustain life that preclude obtaining informed consent
- Interventions that fall under general patient care and do not involve instrumentation or procedural consent such as venipuncture, urinary catheter placement, arterial blood gas, peripheral intravascular line, or phlebotomy

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

informed consent: A process that outlines a clinician's responsibility for ensuring that patients, or individuals legally authorized to make medical decisions on their behalf, "are fully informed about any [proposed] medical procedures or treatments before they agree to them."[28]

invasive procedure: A procedure "where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. It begins when entry to the body is gained and ends when the instrument is removed, and/or the skin is closed. Invasive procedures are performed by trained healthcare professionals using instruments, which include, but are not limited to, endoscopes, catheters, scalpels, scissors, devices and tubes."[29]

known surgical or invasive procedure complication: A known and understood possible result of certain high-risk procedures, treatments, or tests. For an event to be considered a known complication, it must meet all the following criteria[27]:

1. The complication is recognized as a known risk of the procedure, treatment, or test, and appropriate measures according to the standard of care were taken to mitigate this risk.
2. The complication was identified promptly.
3. The complication was managed and treated in a timely manner in alignment with the standard of care.

surgical procedure: An operative procedure "in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice."[30] Surgery begins at the point of surgical incision, tissue puncture, or insertion of an instrument into tissues, cavities, or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, devices such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded.[31]

wrong patient: A surgical or other invasive procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient.[32]

wrong procedure: A surgical or other invasive procedure performed that is not consistent with the correctly documented informed consent for that patient.[32]

wrong site: A surgical or other invasive procedure performed on a body part that is "not consistent with the correctly documented informed consent for that patient."[30] Wrong site may include the correct body part but performed on the wrong location/site on the body (e.g., left/right, wrong digit, wrong level spine surgery or procedure, stent placed in the wrong artery, injection into the wrong knee, removal of the wrong tooth, biopsy of the wrong site, burr hole on the wrong side of the skull, chest tube insertion on the wrong side).[31]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 1: Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure, regardless of the type of procedure or the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- To establish an occurrence of SRE 1, Reviewers are encouraged to identify the following:
  - » Surgery or other invasive procedure start and end time
  - » Any surgery or other invasive procedure that differs in postoperative notes than from the procedure planned in the preoperative notes or documented in the consent; if it is not clearly indicated that the procedure was planned, consider that it was unplanned and conduct a review.

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure, should be reported, regardless of whether the event was caught before reaching the patient, reached the patient and resulted in no harm, or reached the patient and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Removal of the wrong body part (e.g., unintended bladder removal, wrong dental extraction)
  - » Wrong-sided prosthetic (e.g., left knee prosthetic component implanted in the right knee)
  - » Surgery or other invasive procedure on the right body part but on the wrong location or site on the body (e.g., left or right, wrong lesion removed, wrong digit, wrong dental extraction, wrong level spine surgery or procedure, wrong section of organ or vessel, wrong nerve block, stent placed in the wrong artery, injection into the wrong joint, biopsy of the wrong site, burr hole on the wrong side of the skull, chest tube insertion on the wrong side)
  - » Use of an incorrectly placed tube or catheter (e.g., feeding tubes placed in the lung, ventilation tubes placed in the esophagus)
  - » Insertion of the wrong medical implant into the correct surgical site (e.g., wrong intraocular lens style or strength, wrong size joint replacement)
  - » Surgery or other invasive procedure performed on the wrong patient (e.g., radioisotope injected into the wrong patient, knee aspiration performed on the wrong patient, vascular access catheter or tube placed in the wrong patient, nerve block for pain management performed on the wrong patient)

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- A surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure is considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Presurgical or preprocedural checklists
  - » Universal Protocol practices (i.e., preprocedure verification process, marking the procedure site, and performing a time-out)
  - » Patient identification
  - » Informed consent processes that involve shared decision-making with patients, families, and caregivers
- Procedure planning, ordering, and management may be supported by different healthcare settings and pertinent to understanding deviations in generally accepted performance standards of care.

SRE 2: Unintended Retention of a Medical or Surgical Item in a Patient After Surgery or Other Invasive Procedure, Regardless of the Type of Procedure or the Outcome

Event Intent

This event captures **any** occurrence of unintended retention of a medical or surgical item in a patient after the surgery or invasive procedure ends, after completion of skin closure, regardless of whether the patient is still in the procedure room under anesthesia, the size of the object, type of procedure, or the outcome. This event also includes instances when the clinical care team decides to leave the object in place or removal is delayed. Retained surgical items may include two groups of medical or surgical items used during a surgery or other invasive procedure: (1) surgical items that require a surgical count by the clinical care team (i.e., surgical sponges, surgical towels, sharps, small miscellaneous items, and instruments), and (2) other surgical items used during the delivery of care that do not usually require a surgical count by the clinical care team (i.e., dressings, drape towels, devices, device fragments, implant systems, trial devices, inserts, and sizer component parts).[33] This event includes any retained medical or surgical item that was not consistent with the correctly documented informed consent for that patient. When procedures are not performed in an operating room, and do not involve a surgical consent form, clinicians must execute the informed consent process and document this in the medical record. Documentation may be recorded in a form, in progress notes, or elsewhere in the record. Because the unintended retention of a medical or surgical item may not be known at the time of the patient encounter, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

Although the level of harm experienced by the patient can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of unintended retention of a medical or surgical item in a patient after surgery or other invasive procedure to better understand system vulnerabilities, regardless of whether the event was caught before reaching the patient (i.e., near miss), reached the patient and resulted in no harm, or reached the patient and resulted in any level of harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that perform surgery or other invasive procedures.
POPULATION	This event applies to all patients, regardless of the outcome.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended expanding the intent to include all instances, regardless of the outcome, and updating the event terminology from “foreign object” to “medical or surgical item.”

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 2.
NOTE: *This list is not meant to be exhaustive.*

- Items present prior to surgery or other invasive procedure, which may include previously identified retained medical or surgical items, and their presence is clearly documented in the medical record
- Items present prior to surgery or other invasive procedure that a patient may ingest, insert, or aspirate, or that may result from a shooting or stabbing incident (e.g., ingested batteries, dentures, safety pins, screws and other sharp objects, inserted sex toys, bullets, shrapnel, polymer projectiles)
- Items intentionally implanted with documented consent as part of a planned intervention
- Items intentionally placed that are intended to release on their own (e.g., hemostasis devices)
- Items intentionally placed for treatment or therapy that are intended to temporarily remain in a patient after the procedure (e.g., therapeutic packing)
- Items not related to the current procedure, discovered and removed prior to the end of the surgery or other invasive procedure

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

device fragments: "Broken parts or pieces of tools or devices."[33]

informed consent: A process that outlines a clinician's responsibility for ensuring that patients, or individuals legally authorized to make medical decisions on their behalf, "are fully informed about any [proposed] medical procedures or treatments before they agree to them."[28]

invasive procedure: A procedure "where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. It begins when entry to the body is gained and ends when the instrument is removed, and/or the skin is closed. Invasive procedures are performed by trained healthcare professionals using instruments, which include, but are not limited to, endoscopes, catheters, scalpels, scissors, devices and tubes."[29]

retained surgical item: "A foreign object introduced into the body during a surgical or other invasive procedure, without removal prior to the end of the surgery or procedure, which the [clinical care team] did not intend to leave in the body."[7]

surgical procedure: An operative procedure "in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice."30 Surgery begins at the point of surgical incision, tissue puncture, or insertion of an instrument into tissues, cavities, or organs. Surgery ends after all incisions or procedural access routes have been closed in their entirety, devices such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded.[31]

unretrieved device fragments: Device fragments that "are unretrieved because a clinical determination has been made. . .that the risk of removing the object exceeds the risk of leaving it where it is."[33]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 2: Unintended retention of a medical or surgical item in a patient after surgery or other invasive procedure, regardless of the type of procedure or the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- To establish an occurrence of SRE 2, Reviewers should identify the following:
  - » Surgery or invasive procedure start and end time
  - » Preprocedure documentation of whether the medical or surgical item was intended to be retained as an expected part of the procedure by reviewing the correctly documented informed consent
  - » Timing of object discovery, which may occur by another clinician, team, or facility after the procedure or the patient encounter, and may differ based on the item type (e.g., a device fragment may be discovered during the use of the device)

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any unintended retention of a medical or surgical item in a patient after surgery or invasive procedure ends should be reported, regardless of whether the event reached the patient and resulted in no harm, or reached the patient and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Retained device fragments (e.g., tip of a guidewire, piece of a catheter or drain, stent fragment, piece of a drill bit)
  - » Retained surgical sponge (e.g., laparotomy pads, round sponges, tonsil sponges, peanut sponges, radiopaque sponges)
  - » Retained surgical instrument
  - » Retained sharps (e.g., suture needles, scalpel blades, hypodermic needles)
  - » Unplanned retained device fragment or sponge in an orifice postoperatively when the orifice was used to gain access to a body cavity or tissue (e.g., ears, nose, and throat procedures, obstetrics and gynecology procedures)
  - » Retained miscellaneous surgical items (e.g., vessel loops, vascular inserts, electrosurgical scratch pads, umbilical tape)
  - » Items intentionally placed for treatment or therapy that are intended to temporarily remain in a patient after the procedure (e.g., therapeutic packing) but are later not removed

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any unintended retention of a medical or surgical item in a patient after a surgery or invasive procedure ends is considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Radiopaque surgical item use and appropriate imaging to identify such items
  - » Evidence-based surgical count processes
  - » Resolution of an incorrect instrument or sponge count
  - » Methodical wound exploration before closure of a surgical site

SRE 3: Patient Harm Associated with Perioperative or Periprocedural Anesthesia or Sedation of an ASA Class I or ASA Class II Patient

Event Intent

This event captures patient harm associated with perioperative or periprocedural anesthesia or sedation (i.e., minimal, moderate, and deep sedation) of a normal healthy patient (i.e., American Society of Anesthesiologists [ASA] Class I) or a patient with mild systemic disease (i.e., ASA Class II).[34] The ASA Physical Status Classification System is used by clinicians to "assess and communicate a patient's pre-anesthesia medical co-morbidities" and ranges from ASA Class I to VI.[34] This event focuses on ASA Class I and II patients and includes events whether or not the planned procedure was carried out or the administration of anesthesia or sedation was completed.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with perioperative or periprocedural anesthesia or sedation of an ASA Class I or ASA Class II patient that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that administer perioperative or periprocedural anesthesia or sedation.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended expanding the intent to include both ASA Class I and ASA Class II patients and events related to the administration of anesthesia or sedation. In addition, the experts recommended removing the time restriction from this event, as the level of patient harm may not be determined within 24 hours after procedure completion.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 3. **NOTE:** *This list is not meant to be exhaustive.*

- Patients with ASA Physical Status Classification other than ASA I or II[34]:
  - » ASA III: a patient with severe systemic disease
  - » ASA IV: a patient with severe systemic disease that is a constant threat to life
  - » ASA V: a moribund patient who is not expected to survive without the operation
  - » ASA VI: a declared brain-dead patient whose organs are being removed for donor purposes
  - » Emergent surgery or procedural cases (e.g., ASA "E" classifications, trauma surgery, emergent intubation)

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

anesthesia awareness: A rare occurrence in which "patients who have general anesthesia become aware or conscious during the procedure when the intention was for the patient to be unconscious."[35]

ASA Class I: "A normal healthy patient."[34]

ASA Class II: "A patient with mild systemic disease."[34]

general anesthesia: "A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired."[36]

perioperative: "The preoperative, intraoperative/intraprocedural, and postoperative phases of a medical and/or surgical procedure, extending from the time a patient is prepared for a procedure until he or she is discharged home after the procedure or transferred out of the perioperative setting, usually to an inpatient bed."[37]

sedation: The levels of sedation/analgesia defined by the American Society of Anesthesiologists include the following[36]:

minimal sedation (anxiolysis): "A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected. This is typically accomplished by a single oral dose of a sedative or an analgesic administered before the procedure."

moderate sedation/analgesia (conscious sedation): "A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. This is typically accomplished by titration of IV sedatives and/or analgesics during the procedure."

deep sedation/analgesia: "A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. This is typically accomplished by titration of IV sedatives and/or analgesics and/or anesthetics during the procedure."

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 3: Patient harm associated with perioperative or periprocedural anesthesia or sedation of an ASA Class I or ASA Class II patient.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 3, the provision of anesthesia or sedation is clearly tied to a *patient encounter.*
- Encounters may include instances of unplanned transfer or admission to another healthcare setting, treatment team, or level of care for anesthesia or sedation-related adverse events (e.g., sedation administered in an outpatient setting and the patient is admitted for monitoring or treatment).

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if perioperative or periprocedural anesthesia or sedation of an ASA Class I or ASA Class II patient resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Noninvasive or minimally invasive procedures (e.g., endoscopy, interventional radiology, orthopedic closed reduction)
  - » Anesthesia awareness that results in physical, emotional, or psychological harm
  - » Administration of medications that have sedative, analgesic, and amnestic properties, given alone or in combination, to achieve the desired effect of general anesthesia or sedation
  - » Severe pharmacogenetic reactions that occur on administration of anesthesia drugs (i.e., malignant hyperthermia)

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with perioperative or periprocedural anesthesia or sedation was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Evidence-based risk stratification to identify those at increased risk of adverse perioperative events who may benefit from targeted interventions (i.e., risk score for population-based mortality: ASA Physical Status Classification)
  - » Staff training and competency to ensure that the clinical care team has the skill set, training, and credentialing to rescue patients whose level of sedation becomes deeper than initially intended
  - » Preprocedure screening and assessment of contraindications for procedural sedation (e.g., high risk for aspiration, availability of monitoring and resuscitation equipment, availability of personnel)

SRE 4: Medically Assisted Reproduction with the Wrong Donor Sperm or Egg, Regardless of the Outcome

Event Intent

This event captures **any** medically assisted reproduction (e.g., artificial insemination, in vitro fertilization) that occurs with the wrong donor sperm or egg. These also include wrong gamete intrafallopian transfer, zygote intrafallopian transfer, egg and embryo cryopreservation, or the use of the wrong egg and embryo donation. Events should be reported when there is evidence of system failures such as mismatched consent forms, labeling discrepancies, misidentified specimens, or documentation errors indicating the use of the wrong donor material. Instances of this event may often result in psychological and emotional harm for parties involved and may be discovered during treatment or years later. Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

Although the level of harm experienced by the patient can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of medically assisted reproduction with the wrong donor sperm or egg to better understand system vulnerabilities, regardless of whether the event was caught before reaching the patient (i.e., near miss), reached the patient and resulted in no harm, or reached the patient and resulted in any level of harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that perform medically assisted reproduction.
POPULATION	This event applies to all patients, regardless of the outcome.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended expanding the intent to include all instances, regardless of the outcome, and updating the event terminology from “artificial insemination” to “medically assisted reproduction.”

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 4. **NOTE:** *This list is not meant to be exhaustive.*

- Voluntary gamete switching (e.g., known donor change) that is clearly documented with updated consent
- Situations where a patient consents to anonymous donation and later expresses regret about the donor selection, and there is no indication of an error

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

artificial insemination: "A medical procedure in which sperm is introduced into a woman's reproductive system using methods other than sexual intercourse, with the aim of achieving pregnancy."[38]

assisted reproductive technology: "All treatments or procedures that include the handling of human eggs or embryos to help achieve a pregnancy. The most common type of [assisted reproductive technology] is in vitro fertilization."[39]

intrauterine insemination: "A medical procedure that involves placing sperm into a woman's uterus to facilitate fertilization."[39]

in vitro fertilization: A procedure "that involves removing eggs from a woman's ovaries and fertilizing them outside her body. The resulting embryos are then transferred into a woman's uterus through the cervix."[39]

medically assisted reproduction: "Reproduction brought about through various interventions, procedures, surgeries and technologies to treat different forms of fertility impairment and infertility."[40]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 4: Medically assisted reproduction with the wrong donor sperm or egg, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 4, a medically assisted reproduction is clearly tied to a *patient encounter* and may be identified after discharge.

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any medically assisted reproduction that occurs with the wrong donor sperm or wrong egg should be reported, regardless of whether the event was caught before reaching the patient, reached the patient and resulted in no harm, or reached the patient and resulted in harm.
- Events should not require genetic testing to qualify for reporting, particularly when there is credible evidence of process breakdowns indicating the use of the wrong donor material.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Wrong sperm or egg in the wrong patient
  - » Wrong sperm or egg in the correct patient
  - » Fertilization of an egg with the wrong sperm
  - » Embryo implantation in the wrong patient
  - » Wrong embryo implantation in the correct patient
  - » Donor mix-ups involving incorrect gamete identity despite correct labeling
  - » Cryopreserved material labeling errors
  - » Batch process errors during embryo thawing or insemination
  - » Correct gamete received but from unintended donor due to internal system confusion (e.g., similar donor ID numbers)

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any medically assisted reproduction with the wrong donor sperm or egg is considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Gamete collection, labeling, and storage
  - » Patient identification
- Gamete collection, storage, and transfer may be supported by different healthcare settings (e.g., donor facilities, fertility clinics, obstetrics and gynecology outpatient offices) and pertinent to understanding deviations in generally accepted performance standards of care.

SRE 5: Introduction of an Unapproved, Unscreened, or Inappropriately Approved Device, Implant, or Object Into an MR Zone IV Area, Regardless of the Outcome

Event Intent

This event captures any instance when an unapproved, unscreened, or inappropriately approved device, implant, or object (e.g., medical device, medical implant, retained foreign object, ferromagnetic object), whether in, on, or external to any person, crosses the door threshold from magnetic resonance (MR) Zone III into the MR Zone IV area (i.e., the MR scanner room), regardless of the outcome. The MR scanner is located within a controlled access area, and prior to entering scanner room, clinical care team members must conduct MR safety screening protocols and decision processes properly to ensure the safety and protection of people and equipment.

This event is intended to capture unmitigated risks of patient harm that result from interactions with the energies used in the MR environment, which include (1) motion of an implant (e.g., intracranial aneurysm clip) or foreign object (e.g., shrapnel fragment) in the patient; (2) an alteration of function or malfunction of an implant or device (e.g., insulin pump, pacemaker) external to, on, or in the patient; (3) introduction of an item into MR Zone IV that could present a projectile risk (e.g., tools, jewelry, equipment); and are associated with either improper screening and/or decision processes. Due to the static magnetic field of an MR scanner, which remains active even when not imaging, this event applies to all individuals, including patients, healthcare workers, visitors, and vendors.

Although the level of harm experienced by the individual can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of an unapproved, unscreened, or inappropriately approved device, implant, or object that is introduced into an MR Zone IV area to better understand system vulnerabilities, regardless of whether the event was caught before reaching the individual (i.e., near miss), reached the individual and resulted in no harm, or reached the individual and resulted in any level harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that perform MRI.
POPULATION	This event applies to all individuals, including patients, healthcare workers, visitors, and vendors, regardless of the outcome.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended expanding the intent beyond the introduction of metallic objects and including all instances, not just those that result in patient harm. The event terminology was also updated from “MRI area” to “MR Zone IV area.”

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 5. **NOTE:** *This list is not meant to be exhaustive.*

- Instances where a device, implant, or object was screened and approved following appropriate prospective risk-benefit assessment and decision-making process regardless of whether such exposure did or did not result in harm

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

magnetic resonance imaging (MRI): "A non-invasive imaging technology that produces three dimensional detailed anatomical images. It is often used for disease detection, diagnosis, and treatment monitoring. It is based on sophisticated technology that excites and detects the change in the direction of the rotational axis of protons found in the water that makes up living tissues."[41] Magnetic resonance (MR) is the modality by which images are created and commonly referred to as MRI.

MR screening: An evaluation of individuals and objects that occurs before admittance to the controlled access areas of the MR suite (i.e., MR Zones III and IV) to identify and mitigate risks relative to interactions between objects, devices, or materials, and the electromagnetic fields of the MR scanner. For persons, this involves clinical screening (identifying and assessing pertinent prior medical history) and physical screening (identifying and removing unnecessary metallic and/or electrically conductive objects from those about to enter MR Zone IV regions).[42,43]

MR Zones: Safety zones, as defined by the American College of Radiology, that range from Zone I to Zone IV and correspond to the increasing exposure to the magnetic field and potential safety risks. The MR Zones are as follows[44]:

MR Zone I: This includes any area that is freely accessible to the general public and through which individuals, including clinical care teams, access the MRI environment.

MR Zone II: This area connects Zone III and Zone I. This area typically contains a patient waiting room and areas where patients are prepped, including screening, robing, and ferromagnetic detection. Access to Zone II should be controlled so that only patients and clinical care team members may access Zone II.

MR Zone III: This controlled access area provides direct access to the MR scanner room(s). One Zone III area can service multiple Zone IVs. Entrance to Zone III should be restricted to designated personnel using methods that limit the possibility of unauthorized access (e.g., key locks, access badges). Entrance doors should remain locked and identified with appropriate signage indicating restricted access. MR personnel should closely monitor entry of any person into this zone. Because magnetic fields are three dimensional, certain areas outside of the directly connected Zone III room may be included in the Zone III designation.

MR Zone IV: This is the MR scanner room where the actual scanner is located. This room is generally surrounded by controlled access areas. Zone IV should have clear labeling and warning signs for potential hazards due to presence of strong magnetic fields. The door to Zone IV should remain closed except when it must be opened for patient care or room maintenance. Entry into Zone IV should be actively monitored to prevent ferromagnetic objects entering the room. Zone IV rooms should have a readily accessible system for communicating emergencies.

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 5: Introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 5, an MRI procedure, including MR scanner room preparation and reset, is clearly tied to a *patient encounter*.
  - » Due to the inherent risk of this event, Reviewers should report instances where a patient, healthcare worker, or other individual (e.g., visitor, vendor, caregiver) experienced this event even if not directly tied to a patient encounter, regardless of the outcome.

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any unapproved, unscreened, or inappropriately approved device, implant, or object that is introduced into an MR Zone IV area should be reported, regardless of whether the event was caught before reaching the individual, reached the individual and resulted in no harm, or reached the individual and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Projectile risks from objects, devices, implants, or equipment
  - » MR–triggered alterations to the function or positioning of a medical device that was unapproved, unscreened, or inappropriately approved following appropriate prospective risk-benefit assessment (e.g., medication pump, pacemaker, deep brain stimulator), including external devices (e.g., infusion pump, ventilator, patient monitoring device)
  - » Access to MR Zones III or IV by non-MR personnel who have not been properly cleared to enter the controlled access region by appropriately trained Level 2 MR personnel, or who are not under the supervision of Level 2 MR personnel while in Zones III and/or IV

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area is considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » MR screening protocols that include clearance processes for the patient, support staff, equipment, and personnel prior to entering MR Zones III and/or IV
  - » MR area access control and prevention efforts (e.g., appropriate key codes, locks, access keys)
  - » Patient, family, and caregiver education on MR safety
  - » Clinical care team MR safety–specific training and competency requirements
  - » Monitoring of non-MR personnel by qualified MR personnel throughout their duration within Zones III and/or IV
  - » Emergency response and management protocols
- MRI planning, ordering, and procedure management may be supported by different healthcare settings and pertinent to understanding deviations in generally accepted performance standards of care.

NEW

SRE 6: Patient Harm Associated with an MRI–Related Thermal Injury

Event Intent

This new event captures patient harm associated with a magnetic resonance imaging (MRI)–related thermal injury or burn. During an MRI scan, a patient may develop an external and/or internal thermal injury or burn from exposure to the transmitted radiofrequency oscillating magnetic field energies used in the MRI process.[45] MRI–related thermal injuries are often distinct from other burns in that they may originate below the skin, in tissues without temperature or pain-sensing nerves. Therefore, a patient may experience a serious thermal injury or burn several minutes prior to the patient sensing that any injury has occurred, and perhaps hours before it might become externally and objectively detected or observed by others.[46] The skin may appear normal or minimally inflamed initially but may develop into more serious or even full-thickness burns hours or days later. Such MRI–related burns can result from various mechanisms, but often result from the interaction with conductive materials that are in contact with the patient's skin, or from improper positioning during the MRI scan.[45] Because the extent of the thermal injury may not be known at the time of the patient encounter, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with MRI–related thermal injury that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that perform MRI.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This is a new event, introduced in 2025.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 6. **NOTE:** *This list is not meant to be exhaustive.*

- Burn events not associated with an MRI should be reviewed for reporting SRE 18: Patient harm associated with an unintended burn from any source.
- Thermal injury and burns associated with the function of MRI equipment should be reviewed for reporting under SRE 9: Patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended.

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

burn: "An injury to the skin or other organic tissue primarily caused by heat or due to radiation, radioactivity, electricity, friction or contact with chemicals."[47]

full-thickness burn: A third-degree burn affecting the epidermis and dermis skin layers. "[Full-thickness burns] extend into the subcutaneous tissue. These burns result in a leathery, stiff, and dry appearance. At this depth, the affected area does not blanch under pressure due to compromised blood supply. The nerves at this depth are also damaged, resulting in the patient experiencing no sensation or pain. These burns take more than 8 weeks to heal and require surgical treatment."[48]

magnetic resonance imaging (MRI): "A non-invasive imaging technology that produces three dimensional detailed anatomical images. It is often used for disease detection, diagnosis, and treatment monitoring. It is based on sophisticated technology that excites and detects the change in the direction of the rotational axis of protons found in the water that makes up living tissues."[41] Magnetic resonance (MR) is the modality by which images are created and commonly referred to as MRI.

MRI–related thermal injury: A burn or injury caused by exposure to radiofrequency energy that may occur during an MRI scan. These injuries often result from interaction with conductive materials that are in contact with the skin, or from improper positioning during the scan. Although most thermal injuries occur on the skin of the upper extremities or torso, they can occur anywhere in or on the body. Injuries may initially appear minor (minimal redness and discomfort), but more serious symptoms such as blisters or even ulcers can develop within 24 hours after completion of the MRI examination.[49–51]

partial-thickness burn: A second-degree burn, also known as a superficial partial-thickness burn, affecting the superficial layer of the dermis. "Blisters are common and may still be intact when first evaluated. Once the blister is unroofed, the underlying wound bed is homogeneously red or pink and will blanch with pressure. These burns are painful. Healing typically occurs within 2 to 3 weeks with minimal scarring."[52]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 6: Patient harm associated with an MRI–related thermal injury.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 6, an MRI procedure, including MR scanner room preparation and reset, is clearly tied to a *patient encounter* and may be identified after discharge.
- Encounters may include instances of unplanned transfer or admission to another healthcare setting, treatment team, or level of care related to burn treatment.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if MRI–related thermal injury resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Electrically conductive material–related burns (e.g., conductive clothing)
  - » Transmitting radiofrequency coil–related proximity burns
  - » Conducted tissue loop–related burns
  - » Electrically conductive wires/leads
  - » Resonant wavelength–related heating of conductors
  - » Skin staples, dermal implants, or piercings near each other
  - » Drug-delivery patches and pads

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with MRI–related thermal injury was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Identification and removal of all removable electrically conductive materials
  - » Appropriate insulation, distance, and positioning of patient body and conductive material (e.g., leads, wires)
  - » Instructions for patients to communicate, if able, warmth or burning sensations
- MRI planning, ordering, and procedure management may be supported by different healthcare settings and pertinent to understanding deviations in generally accepted performance standards of care.

NEW

SRE 7: Delivery of Radiotherapy to the Wrong Patient, Wrong Body Region, Unintended Procedure, or Greater Than 25% Above the Planned Radiotherapy Dose, Regardless of the Outcome

Event Intent

This new event captures **any** occurrence of radiotherapy delivery to the wrong patient, wrong body region, the wrong dose (e.g., greater than 25% above the planned radiotherapy dose, cumulative dosing considerations), or that is an unintended procedure, regardless of the outcome. Radiotherapy is a common treatment for various types of cancer but is also used for in the management of non-cancer-related disorders. This event includes treatment planning, ordering, or administration errors, with an understanding that radiotherapy may extend beyond intended anatomic areas based on variation in anatomy and physiology. Therefore, deviations within the same anatomical location, that cannot be predicted, are not intended to be captured.

Although the level of harm experienced by the patient can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of radiotherapy delivery to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose to better understand system vulnerabilities, regardless of whether the event was caught before reaching the patient (i.e., near miss), reached the patient and resulted in no harm, or reached the patient and resulted in any level of harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that provide radiotherapy services.
POPULATION	This event applies to all patients, regardless of the outcome.
UPDATES SINCE 2011	This is a new event, introduced in 2025.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 7. **NOTE:** *This list is not meant to be exhaustive.*

- Radiation for diagnostic use (e.g., nuclear medicine, x-rays)
- Deviations within the same anatomical location, particularly in endovascular treatments where anatomical variation (e.g., segmental liver anatomy, regional blood flow) cannot be predicted

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

radiotherapy: "The use of high-energy radiation from x-rays, gamma rays, neutrons, protons, and other sources to kill cancer cells and shrink tumors. Radiation may come from a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy or brachytherapy). Systemic radiotherapy uses a radioactive substance, such as a radiolabeled monoclonal antibody, which travels in the blood to tissues throughout the body. Also called irradiation and radiation therapy."[53]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 7: Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

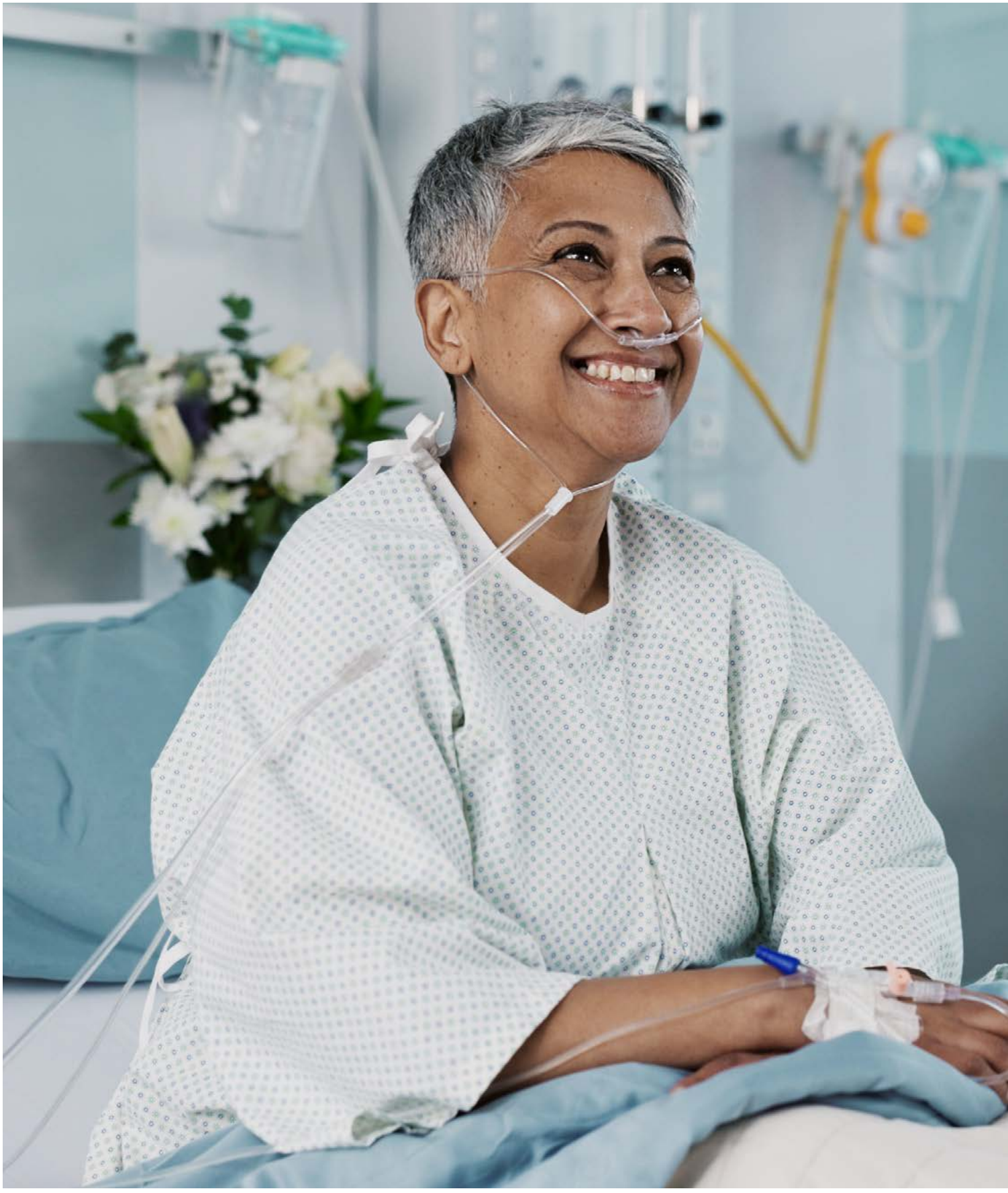
- For SRE 7, delivery of radiotherapy is clearly tied to a *patient encounter*.

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

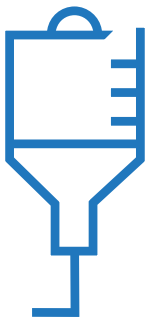
- Any delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose should be reported, regardless of whether the event was caught before reaching the patient, reached the patient and resulted in no harm, or reached the patient and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Radiation treatments for various conditions (e.g., kill cancer cells, reduce pain, treat medical conditions)
  - » Radiotherapy dosing errors (e.g., unplanned underdosing, cumulative dosing considerations, greater than 25% above the planned dose)
  - » Screening errors associated with radiotherapy delivery to the wrong patient, wrong body region, wrong dose, or an unintended procedure
  - » Correct order, but the wrong dose was administered to the patient
  - » Wrong order, recognized and corrected prior to administration
  - » Wrong patient called from the waiting room and set up for another patient's radiotherapy
  - » Deviation from the intended anatomic location (e.g., radiotherapy to the right breast when treatment was indicated for the left breast)
  - » Wrong type of energy, wrong radiopharmaceutical, wrong type of radiation (i.e., x-ray, protons, electrons), or wrong treatment modality

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any delivery of radiotherapy to the wrong patient, wrong dose, wrong region, or an unintended procedure is considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Radiation screening and assessment
  - » Radiotherapy dosing
  - » Patient identification
- Radiotherapy planning, ordering, and administration may be supported by different healthcare settings (e.g., outpatient clinic, cancer center, inpatient setting, surgical unit) and pertinent to understanding deviations in generally accepted performance standards of care.



Product or Device Events



This category includes events that occur during diagnostic or treatment services involving the use of a product, medical device, or digital tools and technologies. These events may occur in any healthcare setting and include products or devices that come in direct contact with the patient or that provide support for patient care.

This Category Consists of 4 SREs:

SRE 8: Patient harm associated with the use of contaminated drugs, devices, or biologics

SRE 9: Patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended

SRE 10: Patient harm occurring when systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances

NEW **SRE 11:** Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting, regardless of the outcome

SRE 8: Patient Harm Associated with the Use of Contaminated Drugs, Devices, or Biologics

Event Intent

This event captures patient harm associated with the use of contaminated products (i.e., drugs, devices, and biologics) provided by the healthcare setting, regardless of the contamination source (e.g., people, supplier, manufacturer, healthcare facility) and/or product. Contaminants may be biological, chemical, or physical and may not be visible with the naked eye (e.g., hepatitis, biofilm) or readily detected using generally available or more specialized testing mechanisms (e.g., cultures, nucleic acid testing, mass spectrometry, tests that signal changes in pH or glucose levels). This event also includes contamination that is inferred and changes risk status for life (e.g., consider a syringe or needle contaminated after 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). Determination of the contamination source may be delayed; therefore, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with the use of contaminated drugs, devices, or biologics that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that use drugs, devices, and biologics in the provision of patient care except virtual care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 8. **NOTE:** *This list is not meant to be exhaustive.*

- Events where a patient has primary control of the product (e.g., home use medical devices intended for users in an environment outside of a healthcare facility)
- Drugs, devices, and biologics found to be contaminated prior to patient use regardless of the product or source (e.g., pre-hospital, manufacturer, healthcare facility)
- Healthcare-associated infections that are not associated with contaminated drugs, devices, or biologics

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

biofilm: "Accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed."[54]

biological products (biologics): "Include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies."[55]

Class I recall: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."[56]

contaminated: The state in which a product has actual or likely contact with substances that can cause harm with use or administration. Contaminants that can cause illness or injury include biological contaminants (e.g., blood, bodily fluids), chemical contaminants (e.g., antimicrobial residues), and physical contaminants (e.g., glass, metal, plastic).[57–59]

drug (or medication): Any substance (other than food) recognized by an official pharmacopoeia or formulary, intended to affect the structure or any function of the body, and administered to persons to diagnose, treat, or prevent disease or other abnormal conditions. This includes any product designated as a drug by the U.S. Food and Drug Administration.[55]

medical device: "Any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes (includes both medical equipment [e.g., walker, hearing aid] and medical/surgical supply, including disposable product [e.g., incontinence supply])."[60]

medical device safety alerts: Alerts "issued in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls."[56]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 5: Introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- To establish an occurrence of SRE 8, Reviewers are encouraged to identify the following:
  - When the product was received by the healthcare delivery system and condition on arrival
  - When the product was used in the provision of care and condition at time of patient care

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the use of contaminated drugs, devices, or biologics resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living
- Events may be associated with but are not limited to the following clinical circumstances:
  - Administration of a contaminated vaccine or medication
  - Use of medication vials, injection devices, and containers (e.g., single-use vials used for more than one patient, inappropriate access of multidose vials, pooling of medications)
  - Infection from a contaminated drug or device used in surgery or an invasive procedure (e.g., surgical instrument, implant, syringes)
  - Threat of disease that changes a patient's risk status for life requiring medical monitoring or treatment not needed before the event occurred
  - Use of a drug, device, or biologic that has been recalled (e.g., U.S. Food and Drug Administration Class I recall or medical device alert)
  - Use of improperly cleaned or maintained devices or equipment (e.g., not following manufacturers' cleaning instructions, associated with cleaning, disinfecting, and sterilizing instrumentation or high-level disinfection)
  - Healthcare-associated infections related to contaminated drugs, devices, or biologics
  - Use of single-use or reusable medical instruments (e.g., surgical forceps, endoscopes, bronchoscopes, transesophageal echographs, laryngoscopes)
  - Use of expired medications or expired biological implants
  - Improper storage of medications or biologics (e.g., prolonged power outage affecting refrigeration)

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with the use of contaminated drugs, devices, or biologics was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Drug, device, and biologic integrity checks prior to use
  - » Preventing transmission of contaminants in healthcare settings (e.g., infection control, proper handling, diversion prevention, tampering detection)
  - » Receipt and storage of drugs, devices, or biologics
  - » Preparation and inspection of drugs, devices, or biologics prior to patient use (e.g., use of single-dose versus multidose vials; cleaning, disinfecting, and sterilizing instrumentation)
  - » Manufacturer's guidance for recall management (e.g., quarantine, visual inspection, return of product)

SRE 9: Patient Harm Associated with the Use or Function of a Medical Device in Patient Care, in Which the Device Is Used or Functions Other Than as Intended

Event Intent

This event captures patient harm associated with the use or function of a medical device in patient care. This event includes use errors (e.g., misuse, misapplication), or the use of a medical device in patient care that malfunctions or is defective. This event is not limited to device use as outlined by the manufacturers' literature but also incorporates guidelines or instructions for use that apply specifically to the device involved.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended, that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that use medical devices in the provision of patient care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 9. **NOTE:** *This list is not meant to be exhaustive.*

- Events related to device damage when the patient or family has primary control of the device (e.g., patient tampering)
- Events associated with a research study involving use of a device that does not align with manufacturer's guidelines
- Events occurring when a device functions as designed but with the wrong effect due to other circumstances

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

direct patient care: "Hands-on, face-to-face contact with patients for the purpose of diagnosis, treatment, and monitoring."[61]

intended use: The purpose for which a product is meant to be used, as determined by the manufacturer or distributor. This intent can be shown through labeling, advertising, design, or how the product is distributed. It includes any claims made about the product and how it is marketed. For further guidance, reference U.S. Food and Drug Administration (FDA) guidelines on the *"Classification of Products as Drugs or Devices and Additional Product Classification Issues."*[62,63]

medical device: "Any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes (includes both medical equipment [e.g., walker, hearing aid] and medical/surgical supply, including disposable product [e.g., incontinence supply])."[60]

use error: "A situation in which the outcome of device use was different than intended, but not due to malfunction of the device."[64]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 9: Patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 9, the use of a medical device in patient care is clearly tied to a *patient encounter*.
- Reviewers are encouraged to identify guidelines or instructions for use that apply specifically to the device involved in the event (e.g., FDA regulations, manufacturer's guidelines, device manuals).

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the use or function of a medical device in patient care, in which the device is used or functions other than as intended, resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, or treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Device used by a clinical team member for a purpose for which it is not intended, labeled, or advertised
  - » Lack of proper maintenance of a device
  - » Device provided to a patient for personal use that did not operate as intended
  - » Device used by persons with lack of training or competency
  - » Failure to assess, inspect, and evaluate devices for proper functioning prior to use

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended, was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Medical device storage and maintenance
  - » Routine device safety checks throughout the product life cycle
  - » Review of the medical device's intended use or indications for use statement

SRE 10: Patient Harm Occurring When Systems Designated for Oxygen or Other Gas to Be Delivered to a Patient Contain No Gas, the Wrong Gas, or are Contaminated by Toxic Substances

Event Intent

This event captures instances where systems designated for oxygen or other gas delivery contain no gas, contain the wrong gas, or are contaminated by toxic substances that reach the patient and cause patient harm. This event includes oxygen or other gas lines attached to a reservoir distant from the patient care unit or in a tank near the patient (e.g., e-cylinders, anesthesia machines). This event may occur during an exchange of care where the patient is moving or being moved from one setting or department to another (e.g., movement to another department or unit, interfacility transfer, discharge home on oxygen therapy).

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm occurring when systems designated for oxygen or other gas to be delivered to a patient contain no gas, contain the wrong gas, or are contaminated by toxic substances that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that have systems designated for oxygen, or other gas, to be delivered to a patient, except virtual care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended narrowing the intent from any instance to only instances associated with serious patient harm.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 10. **NOTE:** *This list is not meant to be exhaustive.*

- Instances in which there is no reasonable risk to a patient (e.g., a supplemental oxygen tank is replaced or replenished when low or empty and there is no reasonable clinical risk to the patient during the time it takes to replace the tank)
- Events associated with external factors that are beyond the healthcare setting's control (e.g., gas supply is interrupted during tank exchanges by a contracted supplier)
- Correction of an oxygen delivery event that does not result in patient harm and returns the patient to the originally intended level of oxygenation

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

interfacility transfer: "Any transfer, after initial assessment and stabilization, from and to a healthcare facility." Examples include hospital to hospital, outpatient to acute care, and hospital to post-hospital care.[65]

medical gas: "A drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state and is administered as a gas." Medical gases include oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, carbon monoxide, medical air, and any other medical gas deemed appropriate by the Secretary of Health and Human Services (and by delegation, FDA).[66]

toxic substances: "Substances that cause or are suspected of causing cancer, birth defects, or other serious harms. They can be gases, such as hydrogen chloride, benzene and toluene or compounds and metals such as asbestos, cadmium, mercury and chromium."[67]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 10: Patient harm occurring when systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 10, the delivery of oxygen or other gas is clearly tied to a *patient encounter*.
- Encounters may include instances of unplanned transfer or admission to another healthcare setting, treatment team, or level of care.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if a system designated for oxygen or other gas to be delivered to a patient contains no gas, contains the wrong gas, or is contaminated by toxic substances that resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Gas is not delivered when it has been prescribed because of the oxygen or other gas delivery system, including bedside gas delivery systems or reservoirs distant from the patient care unit.
  - » Human factors such as improper tubing connections
  - » Oxygen or other medical gas interruption during tank exchanges that result in patient harm

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm from a system designated for oxygen or other gas to be delivered to a patient contains no gas, contains the wrong gas, or is contaminated by toxic substances was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Medical gas storage and handling
  - » Use of color-coded gas connectors
  - » Care variations for specific settings (e.g., patient management of home oxygen therapy)
  - » Management of gas delivery during an exchange of care (e.g., interfacility transfer, discharge home on oxygen therapy)

NEW

SRE 11: Fire, Flame, or Unanticipated Smoke, Heat, or Flashes Occurring During Direct Patient Care Caused by Equipment Operated and Used by the Healthcare Setting, Regardless of the Outcome

Event Intent

This new event captures **any** occurrence of fire, flame, or unanticipated smoke, heat, or flashes caused by equipment operated and used during direct patient care. This event includes instances that occur during the set up and preparation for direct care processes or in the room where patient care occurs, with emphasis on oxygen-rich, high-risk settings such as surgical and procedural areas. Due to the inherent risk of exposure to fire, flame, unanticipated smoke, heat, or flashes, this event applies to all individuals, including patients, healthcare workers, visitors, and vendors.

Although the level of harm experienced by the individual can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of a fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting to better understand system vulnerabilities, regardless of whether the event was caught before reaching the individual (i.e., near miss), reached the individual and resulted in no harm, or reached the individual and resulted in any level of harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that operate equipment during direct patient care, except virtual care.
POPULATION	This event applies to all individuals, including patients, healthcare workers, visitors, and vendors, who experienced this event, regardless of the outcome.
UPDATES SINCE 2011	This is a new event, introduced in 2025.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 11.
NOTE: *This list is not meant to be exhaustive.*

- Events related to electronic devices (e.g., tablet, phone, game system) brought to the setting by a patient for their personal use
- Events related to care outside of a patient encounter or healthcare setting (e.g., home care where family has primary responsibility)
- Events related to the use and operation of equipment intended to produce smoke or heat, in which there is an unanticipated increase in the amount of smoke or heat generated

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

direct patient care: "Hands-on, face-to-face contact with patients for the purpose of diagnosis, treatment, and monitoring."[61]

fire: "A rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities."[68]

flash (flash fire): "A type of short-duration fire that spreads by means of a flame front rapidly through a diffuse fuel, such as dust, gas, or the vapors of an ignitable liquid, without the production of damaging pressure."[68]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 11: Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 11, a fire, flame, or anticipated smoke, heat, or flashes caused by equipment operated and used during the preparation for or delivery of direct patient care is clearly tied to a *patient encounter*.
- Due to the inherent risk of this event, Reviewers should report instances where a patient, healthcare worker, or other individual (e.g., visitor, vendor, caregiver) experienced this event.

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting should be reported, regardless of whether the event was caught before reaching the individual, reached the individual and resulted in no harm, or reached the individual and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Improperly holstered electrosurgical and electrocautery equipment resulting in fire, flame, or smoke (e.g., flames involving surgical drapes resulting in a burn to the patient's arm)
  - » Smoke associated with overheating of equipment or equipment power source (e.g., battery)
  - » Equipment use outside of the healthcare setting, but with direction and guidance provided by the healthcare setting (e.g., home infusion equipment)
  - » Equipment used by persons with insufficient or inadequate training or competency
  - » Failure to assess, inspect, and evaluate equipment for proper functioning prior to use
  - » Failure to properly monitor equipment during care
  - » Failure to inspect personal medical equipment (e.g., home continuous positive airway pressure [CPAP] machine) brought into a healthcare setting by a patient for their own use

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care are considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Staff training and competency in equipment use and maintenance
  - » Patient, family, and caregiver education on fire safety and hazards
  - » Equipment storage and maintenance
  - » Routine equipment safety checks
  - » Fire risk assessment prior to the start of procedures involving ignition sources (e.g., electrosurgery, lasers)

Patient Protection Events

This category includes events that affect the intrapersonal or interpersonal safety in a healthcare setting during diagnosis or treatment services. These events may involve but are not limited to vulnerable populations such as patients who do not have decision-making capacity or patients who are a danger to themselves or others.

This Category Consists of 5 SREs:

SRE 12: Discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity, regardless of the outcome

SRE 13: Patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity

SRE 14: Patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release, regardless of the outcome

SRE 15: Patient harm associated with the use of chemical restraints, physical restraints, or seclusion

SRE 16: Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome

SRE 12: Discharge or Release of a Patient Who Does Not Have Decision-Making Capacity to Other Than an Authorized Person or Entity, Regardless of the Outcome

Event Intent

This event captures any discharge, release, or transport of a patient of any age who does not have decision-making capacity to other than an authorized person or entity. Patients may lack decision-making capacity for many reasons, including acute or chronic illness, cognitive impairment, psychiatric conditions, or legal restrictions (e.g., emergency custody order, temporary detention order). State, legal, or other jurisdictional boundaries for assessing decision-making capacity and an authorized person take precedence in the way these events are interpreted and should be respected when reporting the events. This event does not apply to adults with decision-making capacity who leave against medical advice or voluntarily leave prior to a clinical evaluation. Determination of this event may not be known until after the patient encounter; therefore, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

Although the level of harm experienced by the patient can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of a discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity to better understand system vulnerabilities, regardless of whether the event was caught before reaching the patient (i.e., near miss), reached the patient and resulted in no harm, or reached the patient and resulted in any level of harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that provide care or services to patients who do not have decision-making capacity.
POPULATION	This event applies to all patients, regardless of the outcome.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended including all instances regardless of the outcome, not just those that result in patient harm, and modifying the event to include discharge or release to an authorized entity in addition to an authorized person. In addition, the experts recommended updating the terminology from patients who are “unable to make decisions” to patients who “do not have decision-making capacity.”

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 12.
NOTE: *This list is not meant to be exhaustive.*

- Patients with decision-making capacity who leave against medical advice or leave prior to a clinical evaluation
- Elopement, disappearance, or unauthorized departure of a patient who does not have decision-making capacity. These events should be considered for reporting SRE 13: Patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity.
- Events associated with the discharge or release to individuals reasonably determined to be acting in the patient's best interest such as default surrogates permitted under state law or those identified through clinical judgment in the absence of a healthcare power of attorney
- Discharges to individuals accompanying the discharging patient who present themselves as authorized surrogates as verification of legal authority is not always feasible

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

against medical advice: "When a patient decides to leave the hospital or other healthcare setting (i.e., emergency department, outpatient clinics) before the medical team recommends discharge or disposition."[69]

authorized person: "A person authorized (under State or other applicable law, e.g., tribal or military law) to act on behalf of the patient in making health care related decisions."[70]

> **For an adult or emancipated minor:** "A person with legal authority to make health care decisions on behalf of the individual."[70]
>
> **For an unemancipated minor:** "A parent, guardian, or other person acting in loco parentis with legal authority to make health care decisions on behalf of the minor child."[70]

healthcare decision-making capacity: "The ability (as defined by State law) to make decisions regarding health care and related treatment choices."[71]

medical or healthcare power of attorney: "A type of advance directive in which [a patient] name[s] a person to make healthcare decisions [on their behalf when they] are unable to do so. In some states this directive may also be called a durable power of attorney for healthcare or a healthcare proxy."[72]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 12: Discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 12, the discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity is clearly tied to a *patient encounter*.
- Discharge or release from a patient encounter may vary across healthcare settings (e.g., release after an outpatient test, discharge from a skilled nursing facility facility).

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity should be reported, regardless of whether the event was caught before reaching the patient, reached the patient and resulted in no harm, or reached the patient and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Discharge of a patient with Alzheimer's disease or dementia, behavioral health diagnosis, or altered mental status to other than an authorized person
  - » Transfer or discharge of a patient who does not have decision-making capacity to an incorrect entity (e.g., skilled nursing facility, memory care facility)
  - » Patient of any age who does not have decision-making capacity
  - » Infant or child discharged or released to someone other than their legally designated family member or guardian
  - » Patients deemed to not have capacity due to an acute or chronic illness, whether determined by medical or legal pathways
  - » Patient whose right to decision-making is legally restricted (e.g., temporary detention order, emergency custody order, involuntary psychiatric hospitalization, incarcerated person)
  - » Patient who is cognitively impaired is released from outpatient testing without an authorized person present

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity is considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Decision-making capacity screening, assessment, and documentation
  - » Authorized person identification and management
  - » Parental or guardian identification procedures
  - » Patient identification procedures

SRE 13: Patient Harm Associated with the Disappearance or Unauthorized Departure of a Patient Who Does Not Have Decision-Making Capacity

Event Intent

This event includes the disappearance of a patient who does not have decision-making capacity from the healthcare setting, while under control of the healthcare setting (e.g., during transport), or the removal of a patient who does not have decision-making capacity prior to discharge or release without specific notification and approval by staff, which includes an abduction of a minor. Patients may lack decision-making capacity for many reasons, including acute or chronic illness, cognitive impairment, psychiatric conditions, or legal restrictions (e.g., emergency custody order, temporary detention order). State, legal, or other jurisdictional boundaries for assessing decision-making capacity take precedence in the way these events are interpreted and should be respected when reporting the events. This event does not apply to adults with decision-making capacity who leave against medical advice or voluntarily leave prior to a clinical evaluation. The extent of patient harm may not be known at the time of the patient encounter and may not be related to the reason for seeking care with the healthcare setting. Therefore, Reviewers may need to delay reporting until the extent of patient harm is known, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that provide care or services to patients who do not have decision-making capacity.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 13. **NOTE:** *This list is not meant to be exhaustive.*

- Patients with decision-making capacity who leave against medical advice or leave prior to a clinical evaluation (i.e., without being seen)
- Events occurring prior to presentation for care (e.g., community, healthcare setting grounds)
- Patients with limited or questionable decision-making capacity who leave the healthcare setting and cannot be legally detained under existing state laws (e.g., in some states, patients cannot be held unless they have a behavioral health disorder and pose imminent danger to themselves or others)
- Events in which the healthcare setting could not have known of a legal protection or detention order

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

against medical advice: "When a patient decides to leave the hospital or other healthcare setting (i.e., emergency department, outpatient clinics) before the medical team recommends discharge or disposition."[69]

elopement: A situation where a patient or resident wanders away, walks away, runs away, escapes, or otherwise leaves a healthcare setting unsupervised, unnoticed, and/or prior to their scheduled discharge.[31]

healthcare decision-making capacity: "The ability (as defined by State law) to make decisions regarding health care and related treatment choices."[71]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 13: Patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 13, the disappearance or unauthorized departure of a patient who does not have decision-making capacity after the patient encounter has been initiated (e.g., has arrived and checked in with the healthcare setting) is clearly tied to a *patient encounter*.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the disappearance or unauthorized departure of a patient who does not have decision-making capacity resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Removal of a patient of any age who does not have decision-making capacity prior to discharge or release
  - » Removal of a patient of any age 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
  - » Patient whose right to decision-making is legally restricted (e.g., temporary detention order, emergency custody order, involuntary psychiatric hospitalization, incarcerated person)
  - » Abduction of a minor from a healthcare setting

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Decision-making capacity screening, assessment, and documentation
  - » Elopement risk assessment, identification, monitoring, and management (e.g., patient safety interventions for those identified as not having decision-making capacity and are at risk for elopement)
  - » Safety and security protocols (e.g., minor abduction, controlled access areas, missing patient)

SRE 14: Patient Suicide or Suicide Attempt That Occurs After Presentation for Care or Within Seven Days of Discharge or Release, Regardless of the Outcome

Event Intent

This event captures any suicide or suicide attempt, regardless of the outcome and applies to events that occur after a patient presents for care in a healthcare setting or within seven days of discharge or release. Patient suicide or suicide attempt can be a result of a major depressive episode, substance use disorder, or other physical or mental disorder.[73] An act to end one's life can also be a result of stressful circumstances, including but not limited to prolonged bereavement, bullying, financial difficulties, or declining health.[73] Because this event may occur after the patient encounter, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event and regardless of the outcome.

Although the level of harm experienced by the patient can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of patient suicide or suicide attempt that occur after presentation for care or within seven days of discharge or release to better understand system vulnerabilities, regardless of whether the event was caught before reaching the patient (i.e., near miss), reached the patient and resulted in no harm, or reached the patient and resulted in any level of harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that screen for suicide/suicide ideation. Although most commonly occurring in hospital and acute care settings, this event also applies to outpatient settings that provide primary care or mental health services.
POPULATION	This event applies to all patients, regardless of the outcome.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended expanding the intent from those resulting in serious injury or death, to all instances of patient suicide or suicide attempt, regardless of the outcome. The experts also expanded the intent to capture all instances that occur within seven days of discharge or release to enhance identification of vulnerabilities in healthcare settings' safety systems that may involve safe discharge planning and transitions of care to other settings. In addition, the experts recommended removing the term *self-harm* as it covers a wide range of events for which causality may be difficult to determine and may not occur with the intent to end one's life (e.g., cutting, pica).

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 14. **NOTE:** *This list is not meant to be exhaustive.*

- Self-inflicted injury that occurred prior to and was the cause of admission to the healthcare setting
- Suicide or suicide attempt that occurred prior to presentation for care at the healthcare setting and did not occur within seven days of discharge or release from another patient encounter
- Suicide or suicide attempt that occurred after seven days of discharge or release
- A person who entered a healthcare setting and left prior to initiating a patient encounter
- Patients with decision-making capacity who left the healthcare setting against medical advice
- Hospice patients engaged in physician-assisted dying or death with dignity practices
- Self-harm that occurred without the intent to end one's life (e.g., cutting, pica)

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

against medical advice: "When a patient decides to leave the hospital or other healthcare setting (i.e., emergency department, outpatient clinics) before the medical team recommends discharge or disposition."[69]

presentation for care: When a person becomes a patient and engages with the healthcare setting for the purposes of seeking healthcare services or is recognized as seeking healthcare services, regardless of whether a formal clinical encounter has begun. This includes pre-encounter interactions that signal the patient's intent to receive care, such as being greeted by a triage nurse, registering for clinical care, or being escorted by a phlebotomist for a lab draw.[31]

suicide: "The act of intentionally taking one's own life."[73]

suicide attempt: "When people harm themselves with the goal of ending their life, but they do not die."[74]

suicide screening: "A procedure in which a standardized instrument or protocol is used to identify individuals who may be at risk for suicide."[75] Examples of suicide screening tools include but are not limited to Patient Health Questionnaire (PHQ-9) and Columbia–Suicide Severity Rating Scale (C-SSRS).

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 14: Patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- To establish occurrence of SRE 14, Reviewers are encouraged to identify the following:
  - The patient engaged with a healthcare setting for the purposes of seeking healthcare services or was recognized as seeking healthcare services, regardless of whether a formal clinical encounter began.
  - The event occurred within seven days of treatment, discharge, or release.

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release should be reported, regardless of whether the event was caught before reaching the patient, reached the patient and resulted in no harm, or reached the patient and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - Patient suicide attempt that occurs within seven days of discharge from an inpatient (e.g., acute psychiatric unit) or outpatient setting that screens for suicide/suicide ideation (e.g., emergency department visit, telehealth appointment, medical office visit)
  - Harm event related to pulling out sutures/reinjury to a site that requires additional treatment, if determined to be a result of suicide ideation
  - Suicide or suicide attempt attributed to medication side effects (e.g., antipsychotics)
  - Suicide attempt that occurs while in the direct presence of and is immediately controlled by the clinical care team during the course of treatment

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release is considered avoidable by any means currently available within the generally accepted performance standards of care and should trigger further analysis into causative factors for identifying trends and patterns. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to the following policies, procedures, and guidelines for the following:
  - » Suicide risk screening, use of screening tools, and documentation requirements
  - » Safety measures for patients with positive screen for suicide/suicide ideation (e.g., sitter use, removal of ligature risks, safe meal trays)
  - » Discharge Safety Plan practices that include patient-centered follow-up instructions (e.g., tailored instructions from behavioral health clinicians, planned outpatient therapy) that include caregivers and family members
  - » Staff training and competency requirements

SRE 15: Patient Harm Associated with the Use of Chemical Restraints, Physical Restraints, or Seclusion

Event Intent

This event captures patient harm associated with the use of any restraint or seclusion while being cared for in a healthcare setting. "Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time."[76] A restraint can be physical or chemical and is used to restrict a patient's ability to move or their freedom of movement.[76] Seclusion confines a patient to one area or room, restricting their ability to leave.[76] This event applies to patients in restraints or seclusion as well as any patient who is no longer in restraint or seclusion and whose death or injury can be attributed to the use of restraints or seclusion. This event includes but is not limited to strangulation, entrapment, respiratory depression, or trauma. State, legal, or other jurisdictional boundaries for restraint and seclusion use take precedence in the way these events are interpreted and should be respected when reporting the events.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with the use of chemical restraints, physical restraints, or seclusion that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event is applicable to all healthcare settings that use restraints or seclusion except home or virtual care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended expanding the intent to include chemical restraints and seclusion.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 15. **NOTE:** *This list is not meant to be exhaustive.*

- Events not related to restraint or seclusion (e.g., attributable to a separate clinical condition or event)
- Events related to devices, such as "orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm"[76]
- Law enforcement officer use of their own restraint devices (e.g., handcuffs, shackles) that result in patient harm

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

law enforcement restraint devices: "Handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety reasons."[77]

restraint: "Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition."[76]

seclusion: "The involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior."[76]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 15: Patient harm associated with the use of chemical restraints, physical restraints, or seclusion.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 15, the use of restraints or seclusion while being cared for in a healthcare setting is clearly tied to a *patient encounter.*
- Encounters may include instances of unplanned transfer or admission to another healthcare setting, treatment team, or level of care to treat harm from use of restraints or seclusion.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the use of chemical restraints, physical restraints, or seclusion resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Injury when the restraint or seclusion hindered the patient's ability to self-rescue
  - » Neurovascular trauma or injury (e.g., ischemia, necrosis, neurological deficit)
  - » Medication effects, side effects, or drug interactions associated with chemical restraints
  - » Use of chemical restraints on a patient within a jurisdiction where its use is illegal under state law

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with the use of chemical restraints, physical restraints, or seclusion was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Restraint and seclusion documentation requirements
  - » Initiation and renewal of restraint or seclusion orders
  - » Patient safety monitoring requirements
  - » State and other jurisdictional requirements
  - » Staff training and competency requirements for the management of restraints or seclusion

SRE 16: Sexual Abuse or Sexual Assault Within or on the Grounds of a Healthcare Setting, Regardless of the Outcome

Event Intent

This event captures any instance of sexual abuse or sexual assault on a patient who has presented for care, is under care, or has received care and has not yet left the healthcare setting grounds. This event also applies to staff members, licensed practitioners, visitors, or vendors sexually abused or sexually assaulted while providing care or supervision to patients. State, legal, or other jurisdictional boundaries for sexual abuse and sexual assault take precedence in the way these events are interpreted and reported. Reviewers must coordinate with law enforcement in necessary jurisdictions, recognizing that legal requirements and investigative processes may vary significantly across different types of healthcare settings and geographic locations.

Although the level of harm experienced by the patient can vary from no visible or detectable harm to serious harm and death, these events are indicative of potential safety system issues. Therefore, Reviewers should report and analyze **all instances** of sexual abuse or sexual assault within or on the grounds of a healthcare setting to better understand system vulnerabilities, regardless of whether the event was caught before reaching the individual (i.e., near miss), reached the individual and resulted in no harm, or reached the individual and resulted in any level harm.

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings, with emphasis on newer care modalities where traditional physical boundaries may not apply but patient vulnerability exists.
POPULATION	This event applies to all individuals, including patients, healthcare workers, visitors, and vendors, regardless of the outcome.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent of this event.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 16.
NOTE: *This list is not meant to be exhaustive.*

- Sexual abuse or sexual assault that occurs prior to presentation for care at a healthcare setting (e.g., at home, on the grounds of the healthcare setting)
- Events that were clearly outside of the healthcare setting's control or awareness may be excluded after review (e.g., unsecured areas not affiliated with the healthcare setting)

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

consent for sexual activity: "An agreement that is willfully given without any external pressure or factors. In order for someone to consent to sexual activity participants must continuously communicate—before, during, and after sexual activity."[78]

healthcare setting: "Any facility or office, including a discrete unit of care within such 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."7

- "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."[7]

medical chaperone: "A chaperone is a trained person who acts as a support and witness for a patient and a [clinician] during a sensitive exam or procedure. If properly trained to do so, they may also assist the [clinical care team] with equipment and specimen handling…A chaperone is utilized to help protect and enhance the patient's comfort, safety, security, and dignity during a sensitive exam or procedure." The medical chaperone can be a healthcare professional or a trained unlicensed staff member.[79]

presentation for care: When a person becomes a patient and engages with the healthcare setting for the purposes of seeking healthcare services or is recognized as seeking healthcare services, regardless of whether a formal clinical encounter has begun. This includes pre-encounter interactions that signal the patient's intent to receive care, such as being greeted by a triage nurse, registering for clinical care, or being escorted by a phlebotomist for a lab draw.[31]

sexual assault: Any sexual activity, contact, or experience that happens without consent,80 including "completed or attempted sex acts that are against [the individual's] will. Sometimes it can involve a victim who is unable to consent. It also includes abusive sexual contact. It can happen to men, women or children."[81]

sexual abuse: "When a person knowingly causes another person to engage in a sex act by threatening or placing the other person in fear, or if someone engages in a sexual act with a person who is incapable of appraising the nature of the act or unable to give consent."[82]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 16: Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- This event includes any instance of sexual abuse or sexual assault in which an individual has presented for care, is under care, or has received care and has not yet left the healthcare setting grounds.
- For SRE 16, Reviewers should report instances of sexual abuse or sexual assault within or on the grounds of a healthcare setting on a patient, healthcare worker, or other individual (e.g., visitor, vendor, caregiver).

REGARDLESS OF THE OUTCOME, DID THE EVENT TAKE PLACE?

- Any sexual abuse or sexual assault that occurs within or on the grounds of a healthcare setting should be reported, regardless of whether the event was caught before reaching the individual, reached the individual and resulted in no harm, or reached the individual and resulted in harm.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Any kind of sexual activity, contact, or experience that happens without consent
  - » All types of sexual abuse or sexual assault, such as rape, attempted rape, sodomy, and coerced nudity (partial or complete)
  - » Forced to perform sexual acts on another individual
  - » Forced observation of masturbation or sexually explicit images, including pornography, text messages, or social media
  - » Taking sexually explicit photographs and/or audio/video recordings of an individual and maintaining and/or distributing them, including but not limited to photos, audio, or video of nudity, fondling, or intercourse
  - » Any kind of sexual contact where an individual is sedated, temporarily unconscious, or is in a coma

WHAT WERE THE DEVIATIONS FROM GENERALLY ACCEPTED PERFORMANCE STANDARDS (GAPS) OF CARE?

- Any sexual abuse or sexual assault within or on the grounds of a healthcare setting should be assessed to identify if the event was likely avoidable based on generally accepted performance standards of care and should trigger further analysis into causative factors. All instances should be reported, regardless of the outcome.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Use of and adherence to medical chaperones
  - » Structural and procedural practices (e.g., employee screening, employee identification, security cameras in nonprivate areas)
  - » Protocols and protections specific to pediatric and adolescent patients
  - » Enhanced protections for patients with developmental disabilities or cognitive impairments
  - » Culturally sensitive approaches to care for diverse patient populations

Care Provision Events

This category includes events associated with processes of care during diagnostic or treatment services. These events may involve direct care processes as well as processes that support direct care.

This Category Consists of 12 SREs:

SRE 17. Patient harm associated with a fall

SRE 18: Patient harm associated with an unintended burn from any source

SRE 19: Patient harm associated with a medication error

SRE 20: Patient harm associated with unsafe processing or administration of blood products

SRE 21: Patient harm associated with a Stage 3 pressure injury, Stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission

SRE 22: Patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable through an invasive procedure

SRE 23: Patient harm resulting from failure to act on clinically significant laboratory, pathology, or radiology test results

SRE 24: Patient harm associated with an intravascular air embolism

SRE 25: Maternal patient harm associated with labor or delivery in a low-risk pregnancy

SRE 26: Neonatal patient harm associated with labor or delivery in a low-risk pregnancy

NEW **SRE 27:** Patient harm associated with the care of a neonate

NEW **SRE 28:** Patient harm associated with unrecognized clinical deterioration

SRE 17: Patient Harm Associated with a Fall

Event Intent

This event captures patient harm associated with a fall while being cared for in a healthcare setting. A fall may be witnessed, attended or unattended, assisted or unassisted, reported by a patient or an observer, or identified when the patient is found on the floor or ground. This event includes falls that occur after the initiation of a patient encounter with a healthcare setting or after discharge and while the patient is still on the grounds of the healthcare setting (e.g., a patient who is moving from the interior of a healthcare setting to a vehicle with or without staff assistance). This event includes injuries sustained from a fall rather than from physiological events causing the fall and includes but is not limited to fractures, head injuries, and intracranial hemorrhage.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with a fall that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings except virtual care. Although most commonly occurring in inpatient and long-term care settings, this event should be reported by all healthcare settings, particularly those providing direct care for patients at higher risk of falling.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 17. **NOTE:** *This list is not meant to be exhaustive.*

- Falls occurring prior to presentation for care (e.g., home, community, parking lot, lobby, waiting area before check-in)
- Injuries from a fall that require minor intervention (e.g., bruising, cold/heat application, minor skin care)
- Falls that occur after discharge while the patient is still on healthcare premises, if the patient has decision-making capacity and refuses assistance
- Falls occurring after a patient with decision-making capacity leaves against medical advice
- Events associated with a suspected intentional fall
- Falls that occur during normal play in designated play areas, or are developmental in nature (e.g., those experienced by infants, toddlers, or preschoolers learning to stand, walk, or run)

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

against medical advice: "When a patient decides to leave the hospital or other health care setting (i.e., emergency department, outpatient clinics) before the medical team recommends discharge or disposition."[69]

developmental fall: "A fall by an infant, toddler, or preschooler who is learning to stand, walk, run, or pivot."[83]

fall: A sudden, unintentional, or unplanned descent that results in the patient coming to rest on the floor, on or against some other surface (e.g., a counter), on another person, or on an object (e.g., a trash can).[84]

healthcare decision-making capacity: "The ability (as defined by State law) to make decisions regarding health care and related treatment choices."[71]

healthcare setting: "Any facility or office, including a discrete unit of care within such 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."[7]

- "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."[7]

presentation for care: When a person becomes a patient and engages with the healthcare setting for the purposes of seeking healthcare services or is recognized as seeking healthcare services, regardless of whether a formal clinical encounter has begun. This includes pre-encounter interactions that signal the patient's intent to receive care, such as being greeted by a triage nurse, registering for clinical care, or being escorted by a phlebotomist for a lab draw.[31]

suspected intentional fall: "A fall event by a patient that is unwitnessed or witnessed, whereby the patient appears to fall for the purpose of secondary gain, such as attention seeking."[85]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 17: Patient harm associated with a fall.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- To establish an occurrence of SRE 17, Reviewers are encouraged to identify the following:
  - » Patient's fall risk status at the start of the patient encounter and any additional fall risk screening and/or assessment documentation
  - » The time frame to complete fall risk screening and assessment may differ across healthcare settings, but may be useful in both event review and analysis.
- Falls in the home setting should be reported only if they occur during the provision of care and are directly attributable to the care team's action or inaction.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if a fall resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Injuries from a fall that require a major intervention (e.g., surgery, casting, traction, decreased mobility requiring longer length of stay or postdischarge care, sutures)
  - » Consultation for management of comfort care for a neurological injury (e.g., skull fracture, subdural or intracranial hemorrhage, head injury)
  - » Administration of blood or blood-derived products because of injuries from a fall (e.g., patients with coagulopathy)

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with a fall was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Fall risk screening and assessment
  - » Fall risk documentation and prevention measures (e.g., falls band, door signs, sitter)
  - » Assessment and documentation of risk factors for falls (e.g., age, cognitive status, decreased bone mass, use of multiple lines/equipment, medical and medication history)
  - » Engagement of patients, families, and caregivers in fall prevention planning

SRE 18: Patient Harm Associated with an Unintended Burn from Any Source

Event Intent

This event captures patient harm associated with an unintended burn from any source during patient care and may include thermal (hot or cold), chemical, or electrical burns, or burns from radiation or fire. This event focuses on injuries that lead to partial- or full-thickness burns that may result in permanent scarring, skin damage, or require major intervention. The extent of a burn injury may not be known at the time of the patient encounter; therefore, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with an unintended burn, from any source, that are ***serious* and *largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings except virtual care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 18. **NOTE:** *This list is not meant to be exhaustive.*

- Events where burns are a known outcome or complication of a treatment or procedure (e.g., cardioversion, electrocautery)
- Events related to care outside of a patient encounter or healthcare setting (e.g., at home where family has primary responsibility)
- Injuries from a superficial burn that requires first aid treatment or minor intervention (e.g., burn cream, simple dressing, cold pack)
- Magnetic resonance imaging-related burns should be reviewed for reporting as SRE 6: Patient harm associated with an MRI–related thermal injury

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

burn: "An injury to the skin or other organic tissue primarily caused by heat or due to radiation, radioactivity, electricity, friction or contact with chemicals."[47] Common burn mechanisms include the following[86]:

- **chemical burn:** "A wide range of caustic reactions, including alteration of pH, disruption of cellular membranes, and direct toxic effects on metabolic processes, cause injury. In addition to the duration of exposure, the nature of the agent will determine injury severity. Contact with acid causes coagulation necrosis of the tissue, while alkaline burns generate liquefaction necrosis. Systemic absorption of some chemicals is life-threatening, and local damage can include the full thickness of skin and underlying tissues."
- **friction burn:** "Injury from friction can occur due to a combination of mechanical disruption of tissues and heat generated by friction."
- **radiation burn:** "Radiofrequency energy or ionizing radiation can cause damage to skin and tissues. The most common type of radiation burn is sunburn. Radiation burns are most commonly seen today following therapeutic radiation therapy and are also seen in patients who receive excessive radiation from diagnostic procedures."
- **thermal (heat) burn:** "The depth of the thermal injury is related to contact temperature, duration of contact with the external heat source, and the thickness of the skin. Because the thermal conductivity of skin is low, most thermal burns involve the epidermis and part of the dermis. The most common thermal burns are associated with flames, hot liquids, hot solid objects, and steam."

deep partial-thickness burn: A burn that "involves the deeper reticular dermis. Similar to superficial partial-thickness burns, these burns can also present with blisters intact. Once the blisters are debrided, the underlying wound bed is mottled and will sluggishly blanch with pressure. The patient with a partial-thickness burn experiences minimal pain, which may only be present with deep pressure. These burns can heal without surgery, but it takes longer, and scarring is unavoidable."[48]

full-thickness burn: A third-degree burn affecting the epidermis and dermis skin layers. "[Full-thickness burns] extend into the subcutaneous tissue. These burns result in a leathery, stiff, and dry appearance. At this depth, the affected area does not blanch under pressure due to compromised blood supply. The nerves at this depth are also damaged, resulting in the patient experiencing no sensation or pain. These burns take more than 8 weeks to heal and require surgical treatment."[48]

partial-thickness burn: A second-degree burn affecting the superficial layer of the dermis. "Blisters are common and may still be intact when first evaluated. Once the blister is unroofed, the underlying wound bed is homogeneously red or pink and will blanch with pressure. These burns are painful. Healing typically occurs within 2 to 3 weeks with minimal scarring."[48]

superficial burn: A burn that "involves the epidermis only. These burns can be pink-to-red, without blistering, are dry, and can be moderately painful. Superficial burns heal without scarring within 5 to 10 days."[48]

Reporting Considerations

This section provides key questions and considerations for evaluating if an event should be reported as SRE 18: Patient harm associated with an unintended burn from any source.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 18, an unintended burn experienced by the patient during the provision of care is clearly tied to a *patient encounter* and may be identified after discharge.
- Encounters may include instances of unplanned transfer or admission to another healthcare setting, treatment team, or level of care for burn treatment.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if an unintended burn, from any source, resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Injuries from a burn that require major intervention (e.g., burn or skin debridement, surgical or procedural intervention, skin grafting, evaluation by a specialist)
  - » Unintended burn associated with the proper or improper use of a device
  - » Harm associated with a sunburn obtained during the provision of care (e.g., sun exposure while receiving care at a residential treatment setting, long-term care facility, skilled nursing facility)
  - » Burn occurring from solutions or fluids (e.g., acetic acid, alcohol)
  - » Burn associated with fire from someone smoking in a patient care area
  - » Injury caused by hot liquids that were provided during the patient encounter
  - » Burn associated with radiation for diagnostic use or procedure

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with an unintended burn from any source was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Patient, family, and caregiver education on fire safety and hazards
  - » Staff training and competency

SRE 19: Patient Harm Associated with a Medication Error

Event Intent

This event captures patient harm resulting from a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, wrong route of administration). This event is associated with medication errors that include but are not limited to over- or underdosing, administration of a medication to which the patient has a known allergy or serious contraindication, drug-drug interactions for which there is known potential for serious patient harm, and improper use of single-dose/single-use and multidose vials and containers. The extent of patient harm associated with a medication error may not be known at the time of the patient encounter; therefore, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm resulting from a medication error that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that prescribe, prepare, dispense, and administer medications.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 19. **NOTE:** ***This list is not meant to be exhaustive.***

- Events related to care outside of a patient encounter or healthcare setting (e.g., home care where family has primary responsibility, manufacturer-related errors)
- Evidence-based differences in clinical judgment on drug selection and dose
- Error associated with medical information or allergies that could not reasonably have been known or discerned in advance of the event
- Errors in medication use or management related to external factors that are beyond the healthcare setting's control (e.g., unauthorized patient self-administration of a medication, improper storage of a home medication)

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

drug (or medication): Any substance (other than food) recognized by an official pharmacopoeia or formulary, intended to affect the structure or any function of the body, and administered to persons to diagnose, treat, or prevent disease or other abnormal conditions. This includes any product designated as a drug by the U.S. Food and Drug Administration.[55]

high-alert medications: "Medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are more devastating to patients. Examples of high-alert medications include heparin, warfarin, insulin, chemotherapy, potassium chloride for injection concentrate, opioids, neuromuscular blocking agents, antithrombotic agents, and adrenergic agonists."[87]

medical gas: "A drug that is manufactured or stored in a liquefied, nonliquefied, or cryogenic state and is administered as a gas." Medical gases include oxygen, nitrogen, nitrous oxide, carbon dioxide, helium, carbon monoxide, medical air, and any other medical gas deemed appropriate by the Secretary of Health and Human Services (and by delegation, FDA).[66]

medication error: "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."[88]

safe administration: The process of delivering medications or treatments in a manner that ensures patient safety and minimizes the risk of errors. The "five rights" of safe medication administration, traditionally taught to healthcare workers, include right patient, right product, right dose, right route, and right time.[89,90]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 19: Patient harm associated with medication error.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 19, a medication error is clearly tied to a *patient encounter*.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if a medication error resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Administration of medication that should not be given, which is attributed to a failure to collect information about contraindications or allergies, failure to review information available in the health record, or other system failures
  - » Failure to administer a prescribed medication (e.g., omission of a home medication during a hospital stay, order not submitted and/or not reconciled in the electronic health record, medication reconciliation errors, oxygen ordered but not applied)
  - » Over- or underdosing of a medication, including but not limited to medications listed on the Institute for Safe Medication Practices "List of High-Alert Medications," medical gases, or other medications or drugs
  - » Administration of a medication via the wrong route or technique (e.g., oral medication administered intravenously)
  - » Discontinuation of or a failure to prescribe or renew a medication (e.g., failure to renew prescriptions for management of conditions such as hypoglycemia)
  - » Opiate overdose/oversedation events while being cared for in a healthcare setting
  - » Errors related to monitoring medication effects and duration (e.g., anticoagulants, antihypertensives, oxygen)
  - » Events attributed to cognitive error in selecting the wrong medication
  - » Medication order is filled incorrectly and dispensed to a patient.
  - » Medication order is filled correctly and dispensed to the wrong patient.
  - » Improper use of single-dose/single-use and multidose medication vials and containers, including failure to adhere to appropriate sterile procedure

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with a medication error was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Medication reconciliation requirements
  - » Documentation of patient medical conditions (e.g., chronic kidney disease, lung disease, obesity, sleep apnea) and other risk factors (e.g., opioid naïve, polypharmacy, age)
  - » Home medication management while in the care of the healthcare setting (e.g., self-administered medications)
  - » Safe medication administration protocols (e.g., titration protocols, bar code scanning)
  - » Documentation of patient demographics (e.g., current weight)
  - » Standard practices for vulnerable populations (e.g., the American Geriatrics Society Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults)
- Prescribing, preparation, and administration of medication may be supported by different healthcare settings (e.g., compounding pharmacy, cancer center, inpatient setting) and pertinent to understanding deviations in generally accepted performance standards of care.

SRE 20: Patient Harm Associated with Unsafe Processing or Administration of Blood Products

Event Intent

This event captures patient harm associated with the unsafe processing or administration of blood or blood-derived products. The administration of blood or blood-derived products involves multiple clinical care decisions to ensure proper identification of the blood product and the patient, the best treatment modality, product preparation and administration, and recipient monitoring and evaluation.[91] This event includes but is not limited to hemolytic transfusion reactions and administering (a) blood or blood-derived products to the wrong patient, (b) the wrong blood or blood-derived product type, or (c) blood or blood-derived products that have been improperly stored or handled. This event does not include events that are not detectable by ABO blood grouping/human leukocyte antigen (HLA) matching.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with unsafe processing or administration of blood products that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings where blood or blood-derived products are processed and/or administered.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended modifying this event to include both blood products and blood-derived products, as well as processing and administration errors.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 20. **NOTE:** *This list is not meant to be exhaustive.*

- Organ rejection that is not attributable to a hyperacute transfusion reaction
- Event that is not detectable by ABO blood grouping/human leukocyte antigen (HLA) matching
- Events related to unsafe management or processing of blood products that are outside the control of the healthcare setting (e.g., local/regional blood bank, blood product transport)

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

ABO incompatibility: The immune system reaction that occurs when people who have one blood type receive blood from someone with a different blood type.[92]

blood products: "Any therapeutic substance derived from human blood, including whole blood and other blood components for transfusion, and plasma-derived medicinal products."[93]

hemolytic transfusion reaction: "A serious complication that can occur after a blood transfusion. The reaction occurs when the red blood cells that were given during the transfusion are destroyed by the person's immune system. When red blood cells are destroyed, the process is called hemolysis."[94]

plasma-derived medicinal products: Products that are prepared industrially from human plasma and include products such as albumin, coagulation factors, and immunoglobulins.[95]

safe administration: The process of delivering medications or treatments in a manner that ensures patient safety and minimizes the risk of errors. The "five rights" of safe administration, traditionally taught to healthcare workers, include right patient, right product, right dose, right route, and right time.[89,90]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 20: Patient harm associated with unsafe processing or administration of blood products.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 20, the processing and administration of a blood product is clearly tied to a *patient encounter* and may be identified after discharge.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the unsafe processing or administration of blood products resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
  - » Events may be associated with but are not limited to the following clinical circumstances:
  - » Blood product administered to the wrong patient
  - » Blood product administered to the correct patient but is the wrong blood type or wrong blood product for that patient
  - » Inadequate monitoring during a transfusion (e.g., monitoring vital signs, identifying signs of a transfusion reaction)
  - » Blood transfusion led to a severe and potentially life-threatening acute or delayed hemolytic transfusion reaction.
  - » Procedural failures in cross-matching, verification, or compatibility testing

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with the unsafe processing or administration of blood products was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Blood product administration (e.g., laboratory, nursing)
  - » Transfusion monitoring and documentation practices
  - » Patient identification and preparation (e.g., matching the blood product to the order, matching the patient to the blood product, two-person verification process)
  - » Lab specimen collection, labeling, handling, and processing procedures
- The processing and administration of blood products may be supported by different healthcare settings (e.g., presurgical lab work, outpatient infusion, inpatient care) and pertinent to understanding deviations in generally accepted performance standards of care.

SRE 21: Patient Harm Associated with a Stage 3 Pressure Injury, Stage 4 Pressure Injury, Unstageable Pressure Injury, or Deep Tissue Pressure Injury Acquired After Admission

Event Intent

This event captures patient harm associated with the development of a new Stage 3 pressure injury, Stage 4 pressure injury, or unstageable pressure injury that develops after the initiation of a patient encounter and is not documented as present on admission (found on exam greater than 24 hours after arrival).[96] This event also captures patient harm associated with the development of a new deep tissue pressure injury that develops after the initiation of a patient encounter and is not documented as present on admission (found on exam greater than 72 hours after arrival).[96] Deep tissue pressure injuries may not be visible on the skin surface at the time of admission; therefore, if a deep tissue pressure injury is identified after admission and documentation supports an event of significant pressure at that site, it may still be determined to be present on admission.

This event requires accurate classification of a pressure injury and confirmation that appropriate and consistent pressure injury prevention strategies were provided while being cared for in a healthcare setting. Because many preadmission (e.g., immobility after a fall) and clinical circumstances (e.g., unstable spine injury, severe sepsis) may contribute to the development of pressure injuries or deep tissue pressure injuries, this event focuses on occurrences of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with a Stage 3, Stage 4, unstageable, or deep tissue pressure injury that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that provide round-the-clock observation, monitoring, and care. This event does not apply to ambulatory/ outpatient, home, or virtual care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. Experts recommended limiting the scope of this event from any occurrence to only those events that are likely avoidable, noting that many clinical circumstances exist that can limit or restrict the implementation and effectiveness of prevention strategies. In addition, experts recommended reporting only newly developed pressure injuries (i.e., Stage 3, Stage 4, unstageable, or deep tissue pressure injuries) that require major intervention to capture events that meet the *serious* criterion and to help drive the review of and learning about avoidable healthcare-acquired pressure injuries.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 21.
NOTE: *This list is not meant to be exhaustive.*

- Progression of a present on admission pressure injury or deep tissue pressure injury (e.g., from Stage 2 to Stage 3, if Stage 2 was recognized and documented as present on admission)
- Unstageable pressure injury documented as present on admission that is later debrided and determined to be a Stage 3 or 4 deep tissue pressure injury that requires minor or no intervention(s) (e.g., specialized mattresses, occlusive and nonocclusive dressings)
- Refusal of preventative measures in instances such as end-of-life care
- Skin changes identified during end-of-life care (i.e., Kennedy terminal ulcer, Trembly-Bromley ulcer)
- Circumstances occurring prior to admission that are known causative factors for pressure injuries or deep tissue pressure injuries (e.g., immobility after a fall, prolonged interfacility transport) and are documented in the medical record
- Pressure injuries associated with clinical circumstances where preventive measures are limited or restricted, which may include patients with the following:
  - » Hemodynamic instability with turning despite implementation of small increasing incremental turns (e.g., patients requiring high doses of vasopressors, patients on extracorporeal membrane oxygenation treatment for whom cannula dislodgement is a high risk)
  - » An unstable or unrepaired fracture (e.g., spinal, pelvic)
  - » An open chest

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

avoidable pressure injury: "Can develop when the [clinical care team] did not do one or more of the following: evaluate the individual's clinical condition and pressure ulcer risk factors; define and implement interventions consistent with individual needs, individual goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate."[97]

deep tissue pressure injury: "Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3, or Stage 4)."[98]

Stage 3 pressure injury: "Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury."[98]

Stage 4 pressure injury: "Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury."[98]

unavoidable pressure injury: "Can develop even though the [clinical care team] evaluated the individual's clinical condition and pressure ulcer risk factors; defined and implemented interventions consistent with individual needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate."[97]

unstageable pressure injury: "Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e., dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed."[98]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 21: Patient harm associated with a Stage 3 pressure injury, Stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- To establish the occurrence of SRE 21, Reviewers are encouraged to leverage skin assessment documentation to establish the baseline condition of the skin at the start of the patient encounter.
  - » Due to evolving care modalities, the start of a patient encounter is not limited to the time of admission to a unit or based on admission status (e.g., inpatient, observation). This also applies to extended emergency department boarding, emergency department to emergency department transfers, and observation stays.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if a Stage 3 pressure injury, Stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission resulted in death or contributes to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, or treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Pressure injury that requires surgical intervention or other major intervention(s) (e.g., wound debridement, flap reconstruction, negative pressure wound therapy)
  - » Prolonged outpatient treatment which may include intravenous antibiotics for osteomyelitis or other complications
  - » Pressure injuries that result from the use of devices designed and applied for diagnostic or therapeutic purposes (e.g., oxygen delivery devices, feeding tubes, orthopedic devices)
  - » Failure to address modifiable risk factors, including but not limited to immobility, nutrition, moisture, or incontinence through the use of appropriate prevention interventions (e.g., heel offloading devices, foam dressings, turning and repositioning, dietary recommendations, moisture management)

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with a Stage 3 pressure injury, Stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Skin assessment and documentation practices
  - » Implementation and documentation of organizationally defined prevention strategies (e.g., risk assessment, regular turning and repositioning, skin care, support surfaces)
  - » Assessment and documentation of risk factors for pressure injury and deep tissue pressure injury
  - » Implementation of individualized care plans for complex medical conditions (e.g., stroke, spinal injury, prolonged prone positioning, multisystem organ failure)

SRE 22: Patient Harm Associated with the Irretrievable Loss of a Biological Specimen That Is Irreplaceable or Is Only Replaceable by an Invasive Procedure

Event Intent

This event captures patient harm associated with the irretrievable loss of an irreplaceable biological specimen (e.g., tissue, organ, blood, body fluid), where another procedure cannot be done to produce a specimen or is only replaceable by an invasive procedure. Specimen loss includes those that are disposed of, mislabeled, stored incorrectly, or misidentified within the healthcare setting or during transport. This intent includes the progression of an undiagnosed disease or threat of disease that changes the patient's risk status for life, requiring monitoring not needed before the event. Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable by an invasive procedure that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings where the collection and management of a biological specimen occur except virtual care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended expanding the intent of the event to include the irretrievable loss of an irreplaceable biological specimen and replaceable specimens that require an invasive procedure.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 22. **NOTE:** *This list is not meant to be exhaustive.*

- Specimens that are properly managed, but proved to be nondiagnostic
- Events related to care outside of a patient encounter or healthcare setting (e.g., where patient and/or family has primary responsibility for specimen collection and transport)
- Specimen loss associated with a catastrophic event such as a wildfire or hurricane

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

Biological specimen: A specimen for which a quantity of tissue, blood, urine, or other biologically derived material is collected for diagnostic or therapeutic use.[99]

invasive procedure: A procedure "where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. It begins when entry to the body is gained and ends when the instrument is removed, and/or the skin is closed. Invasive procedures are performed by trained healthcare professionals using instruments, which include but are not limited to endoscopes, catheters, scalpels, scissors, devices, and tubes."[29]

irretrievable specimen: A specimen "for which recollection is difficult or impossible. This could be due to the nature or availability of the specimen or the exceptionally distressful means of their collection" (e.g., time-specific specimens, tissue biopsies, body cavity fluids, products of conception, cerebrospinal fluid, kidney stones).[100]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 22: Patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable by an invasive procedure.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 22, any collection of a biological specimen by a healthcare setting is clearly tied to a *patient encounter* and may be identified after discharge.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable by an invasive procedure resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Loss of a biological specimen may also lead to delayed diagnosis or treatment and have particularly strong psychological and emotional effects on patients, including the erosion of trust in a healthcare organization as well as the impact of repeated specimen collection and/or procedures.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » The unintentional destruction of biological specimens (e.g., embryo, placenta, polyp, product of biopsy, transplant organ)
  - » Events where specimen loss is the result of misidentified or mislabeled specimen
  - » Progression of an undiagnosed disease or threat of disease that changes the patient's risk status for life, requiring monitoring not needed before the event (e.g., loss of blood sample: unable to determine if a blood exposure subjects a person to a communicable disease; loss of tissue sample: unable to determine risk of or presence of cancer)
  - » Biological specimen can be reproduced but is only replaceable by an invasive procedure (e.g., stereotactic brain biopsy, paraspinous mass biopsy, intraocular tissue)

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable by an invasive procedure was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Standard practices for safe handling and transport of biological specimens
  - » Adherence to specimen collection, labeling, handling, processing, preserving, and storage protocols
- Biological specimen management may be supported by different healthcare settings and pertinent to understanding deviations in generally accepted performance standards of care.

SRE 23: Patient Harm Resulting from Failure to Act on Clinically Significant Laboratory, Pathology, or Radiology Test Results

Event Intent

This event captures a failure to act on clinically significant laboratory, pathology, or medical imaging test results, including clinically significant test results that require timely attention and appropriate action by the clinical care team as well as incidental findings that may or may not be part of the ordered test. This event may include but is not limited to a failure in a clinical care team's action for reviewing, recognizing, initiating, and completing a diagnostic or therapeutic response to clinically significant test results by communicating within or across different healthcare settings (e.g., failure of one department or setting to communicate an essential action to another department or setting) and also communicating to the patient, an authorized person, or entity. For purposes of this event, *communication* refers to synchronous and asynchronous communication. A failure to act on clinically significant laboratory, pathology, or radiology test results may not be known at the time of the patient encounter; therefore, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm resulting from failure to act on clinically significant laboratory, pathology, or radiology test results that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings where laboratory, pathology, or radiology test results are ordered, processed, resulted, and communicated to the ordering clinician or clinical care team and where results are interpreted, assessed, acted upon, and communicated to the patient, authorized person, or entity.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts recommended modifying the event to emphasize the importance of acting on clinically significant test results rather than the failure to communicate, acknowledging that communication and follow-up remain key components of this event.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 23.
NOTE: *This list is not meant to be exhaustive.*

- Events related to care outside of a patient encounter or healthcare setting (e.g., action needed is communicated to the patient and/or family but is not followed)
- Events where a clinically significant test result is not acted on, but the harm is attributed to another physiological condition
- Patients with clinically significant test results noted during the final stages of life and actions during palliative care are not applicable.

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

Asynchronous communication: "A type of communication that occurs when parties involved in communication are not present at the same time, such as through electronic notifications in the [electronic health record], secure messaging, automated messaging, fax or letter."[101]

clinically significant test result: "Any result that requires further clinical action to avoid morbidity or mortality, regardless of the urgency of that action."[102]

critical value: A test result that falls "significantly outside the normal range and may indicate a life-threatening situation."[4]

patient notification: "The process of communicating test results to patients and, if appropriate, a surrogate, including additional context and follow-up action as needed. Patient notification occurs through synchronous or asynchronous methods."[101]

synchronous communication: "Communication that occurs when parties involved are all present at the same time, such as in person, telephone or Clinical Video Telehealth conversations."[101]

test results: "The outcomes of patient testing and include the results of laboratory and pathology testing, diagnostic imaging and other diagnostic procedures."[101]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 23: Patient harm resulting from failure to act on clinically significant laboratory, pathology, or radiology test results.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- To establish an occurrence of SRE 23, Reviewers are encouraged to identify set time frames and protocols, as the clinical context, parameters for reviewing, and communicating test results and requirements for action may be setting-specific.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the failure to act on a clinically significant laboratory, pathology, or radiology test resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Results indicating a new diagnosis or an advancing stage of an existing diagnosis requiring timely intervention (e.g., cancer)
  - » Incidental but clinically significant findings that may or may not be part of the requested test (e.g., imaging studies for evaluation of a fracture show a suspect growth)
  - » Clinically significant laboratory tests may include but are not limited to coagulation studies and electrolytes (e.g., potassium, sodium, glucose).
  - » Failure to communicate test results such as send-out labs that return after a patient has been discharged from the healthcare setting

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with failure to act on clinically significant laboratory, pathology, or radiology test results was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Identification and management of clinically significant test results and/or critical values
  - » Test result management and follow-up

SRE 24: Patient Harm Associated with an Intravascular Air Embolism

Event Intent

This event captures patient harm associated with an intravascular air embolism, including low-risk procedures (e.g., lines placed for infusion of fluids or medications into a vascular space, hemodialysis) or high-risk procedures (e.g., vaginal delivery, caesarean section, spinal instrumentation procedures, interventional cardiac procedures such as cardiac catheterization).

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with an intravascular air embolism that are ***serious* and *largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings except virtual care.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent of this event.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 24. **NOTE:** ***This list is not meant to be exhaustive.***

- Events associated with neurosurgical procedures known to present a high risk of intravascular air embolism for both adults and children (e.g., where surgery is performed in a position that puts the head above the heart to reduce venous pressure, and development of air embolism is a known risk that is not entirely preventable)
- Clinical circumstances related to external factors that are beyond the healthcare setting's control (e.g., patient tampering of a vascular access device)
- An air embolism that is not associated with a procedure (e.g., trauma)

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

Air embolism: A blockage of blood flow caused by one or more air bubbles entering or forming in a vein or artery; also called a gas embolism.[103]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 24: Patient harm associated with an intravascular air embolism.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 24, an intravascular air embolism is clearly tied to a *patient encounter*.

  Encounters may include instances of unplanned transfer or admission to another healthcare setting, treatment team, or level of care (e.g., direct intravascular injection in an outpatient setting triggering transfer to an emergency department).

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if an intravascular air embolism resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » High-risk procedures, other than neurosurgical procedures, 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 that include but are not limited to lines placed for infusion of fluids or medications into a vascular space, angiography, tissue biopsy, and hemodialysis
  - » Air embolism related to tubing misconnections (e.g., cuff inflation device connected to an intravascular line) or disconnections without proper clamping
  - » Direct intravascular injections (e.g., intravenous contrast injections, including those using an automatic injector) or improper catheter flushing

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with an intravascular air embolism was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Standardized risk reduction practices of catheter removal, including but not limited to positioning the patient in the Trendelenburg position, using the Valsalva maneuver, applying direct pressure to the puncture site, using air-occlusive dressings, and monitoring the patient for a reasonable period after catheter removal
  - » Central venous access placement and discontinuation
  - » Vascular access device management, including steps to prevent and manage air embolism
  - » Staffing training and competency: Clinical staff involved in vascular access and removal procedures should have the necessary training, competencies, and credentialing to recognize, mitigate, and respond to air embolism events, including emergency response protocols if complications arise.

SRE 25: Maternal Patient Harm Associated with Labor or Delivery in a Low-Risk Pregnancy

Event Intent

This event captures maternal patient harm associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting and up to 42 days after labor or delivery. Because maternal status may evolve during labor, *low-risk* refers to the maternal condition at the time of admission or onset of labor, not at the time of delivery. The extent of maternal patient harm may not be known during the patient encounter or within the 42 days after delivery (e.g., long-term effects of nerve damage); therefore, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event. Reviewers should use postdischarge follow-up and treatment to inform reporting decisions and identify causative factors.

This event focuses on instances of serious maternal patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of maternal patient harm associated with labor or delivery in a low-risk pregnancy that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings where labor or delivery occurs.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent of this event.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 25. **NOTE:** ***This list is not meant to be exhaustive.***

- Pregnancy with no active complications, but the fetus is determined to have a high-risk condition
- Pregnancy with known maternal factors that place the pregnancy at increased risk for complication (e.g., placenta previa, preeclampsia/eclampsia)
- Events that occur more than 42 days after delivery

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

high-risk pregnancy: A pregnancy that involves increased health risks for the pregnant person, fetus, or both. These pregnancies require close monitoring to reduce the chance of complications. Factors leading to a pregnancy being considered high risk include but are not limited to preexisting health conditions, pregnancy-related health conditions, age factors (i.e., being over 35 or under 17 when pregnant), and lifestyle factors (e.g., substance use disorder, alcohol use disorder, exposure to toxins).[104]

low-risk pregnancy: A healthy term patient with a singleton fetus in cephalic (vertex) presentation who is expected to have an uncomplicated birth.[105] "Low-risk generally includes [patients] who have no meconium staining, intrapartum bleeding, or abnormal or undetermined fetal test results before giving birth or at initial admission; no increased risk of developing fetal acidemia during labor (e.g., congenital anomalies, intrauterine growth restriction); no maternal condition that may affect fetal well-being (e.g., prior cesarean scar, diabetes, hypertensive disease); and no requirement for oxytocin induction or augmentation of labor."[106]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 25: Maternal patient harm associated with labor or delivery in a low-risk pregnancy.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 25, care of a maternal patient during labor or delivery is clearly tied to a *patient encounter* and may be identified after discharge and up to 42 days after labor or delivery.
  - » Although most commonly occurring in healthcare settings that specialize in labor or delivery (e.g., hospitals, birthing centers), this event includes all healthcare settings with or without the presence of formal obstetrical care.
- Encounters may include instances of unplanned transfer or admission of a maternal patient to another healthcare setting, treatment team, or level of care after labor or delivery (e.g., delivery services provided in a nonhospital setting and the maternal patient is admitted for monitoring or treatment).

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if labor or delivery in a low-risk pregnancy resulted in maternal death or contributed to *serious* maternal patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Severe sepsis, including septic shock, with no specified source in a maternal patient with obstetrician-assisted birth
  - » Pulmonary embolism and venous thromboembolism, including deep vein thrombosis and portal vein thrombosis
  - » Stroke related to hypertension, postpartum hemorrhage, amniotic fluid embolism, or peripartum cardiomyopathy
  - » Events related to chorioamnionitis
  - » Hemorrhage requiring blood transfusion that occurs during the intra- or postpartum periods

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if maternal patient harm associated with labor or delivery in a low-risk pregnancy was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Assessment and documentation of maternal and fetal risk factors
  - » Clinically specific conditions in pregnant and postpartum people

SRE 26: Neonatal Patient Harm Associated with Labor or Delivery in a Low-Risk Pregnancy

Event Intent

This event captures neonatal patient harm associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting, including but not limited to a birth injury that is not related to any congenital condition. Because maternal status may evolve during labor, *low-risk* refers to the maternal condition at the time of admission or onset of labor, not at the time of delivery. The extent of neonatal patient harm may not be known during the patient encounter, and events may be identified after discharge, when the event is clearly linked to the labor or delivery process (e.g., evolving neurologic injury recognized within the first week of life). Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event. Reviewers should use postdischarge follow-up and treatment to inform reporting decisions and identify causative factors.

This event focuses on instances of serious neonatal patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of neonatal patient harm associated with labor or delivery in a low-risk pregnancy that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings where labor or delivery occurs.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This event was on the 2011 NQF SRE List. The experts did not recommend any major revisions to the intent of this event.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 26. **NOTE:** *This list is not meant to be exhaustive.*

- Events associated with external factors beyond the control of the birthing setting (e.g., neonates with conditions that are incompatible with life)
- Events associated with "entered care too late," where the opportunity to provide appropriate monitoring or intervention was not possible due to circumstances such as the following:
  - » Maternal arrival in the second stage of labor, with delivery imminent upon arrival
  - » Births occurring in triage, a hallway, or an ambulance before the appropriate team or setting was available
- Out-of-hospital births with delayed presentation due to transport issues or refusal of care
- Pregnancy deemed low risk, but the fetus has a high-risk condition
- Events related to maternal factors that place the pregnancy at increased risk for complication (e.g., placenta previa, preeclampsia)
- Infants who are more than 28 days old
- Neonatal harm events not associated with labor or delivery. These events should be reviewed for reporting SRE 27: Patient harm associated with the care of a neonate.

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

Birth injury: An injury "that can happen to a [neonate] during the birthing process, usually in the process of passing through the birth canal" (e.g., swelling, bruising, cuts, broken bones, nerve damage) that is not related to any congenital condition.[107]

high-risk pregnancy: A pregnancy that involves increased health risks for the pregnant person, fetus, or both. These pregnancies require close monitoring to reduce the chance of complications. Factors leading to a pregnancy being considered high risk include but are not limited to preexisting health conditions, pregnancy-related health conditions, age factors (i.e., being over 35 or under 17 when pregnant), and lifestyle factors (e.g., substance use disorder, alcohol use disorder, exposure to toxins).[104]

low-risk pregnancy: A healthy term patient with a singleton fetus in cephalic (vertex) presentation who is expected to have an uncomplicated birth.[105] Low-risk generally includes patients who have "no meconium staining, intrapartum bleeding, or abnormal or undetermined fetal test results before giving birth or at initial admission; no increased risk of developing fetal acidemia during labor (e.g., congenital anomalies, intrauterine growth restriction); no maternal condition that may affect fetal well-being (e.g., prior cesarean scar, diabetes, hypertensive disease); and no requirement for oxytocin induction or augmentation of labor."[106]

neonate: "Newborn from birth through the first 28 days of life."[108]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 26: Neonatal patient harm associated with labor or delivery in a low-risk pregnancy.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 26, care of a neonatal patient during labor or delivery is clearly tied to a *patient encounter* and may be identified after discharge.
- Encounters may include instances of unplanned transfer or admission of a neonatal patient to another healthcare setting, treatment team, or level of care after labor or delivery (e.g., delivery services provided in a nonhospital setting and the neonate is admitted for monitoring or treatment).

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if labor or delivery in a low-risk pregnancy resulted in neonatal death or contributed to *serious* neonatal patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Event associated with proper use and function of a device (e.g., forceps, vacuum-assisted delivery)
  - » Untimely recognition of fetal heart abnormalities and decompensation
  - » Shoulder dystocia
  - » Anoxic brain injury, encephalopathy, or intracranial hemorrhage
  - » Nerve damage
  - » Event contributing to a transfer to a higher level of care
  - » Apgar score of 0–3 at 5 minutes followed by neonatal intensive care unit admission
  - » Birth injuries requiring therapeutic hypothermia
  - » Neonatal seizures with hypoxic-ischemic encephalopathy
  - » Brachial plexus injuries with functional impact

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if neonatal patient harm associated with labor or delivery in a low-risk pregnancy was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Fetal monitoring
  - » Assessment and documentation of maternal and fetal risk factors

NEW

SRE 27: Patient Harm Associated with the Care of a Neonate

Event Intent

This new event captures patient harm associated with the care of a term or late preterm infant following birth and during the neonatal period (i.e., less than or equal to 28 days after delivery). This event includes neonatal care that is not associated with labor or delivery and may extend across multiple healthcare settings. The extent of patient harm associated with the care of a neonate may not be known during the patient encounter or within 28 days after delivery; therefore, Reviewers should report this event when made aware of the occurrence, regardless of the time passed after the event. Reviewers should use postdischarge follow-up and treatment to inform reporting decisions and further causative factors.

This event focuses on instances of serious neonatal patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of neonatal patient harm associated with the care of a neonate that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings that provide neonatal care from birth to less than or equal to 28 days after delivery.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This is a new event, introduced in 2025.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 27. **NOTE:** *This list is not meant to be exhaustive.*

- Events related to care outside of a patient encounter or healthcare setting (e.g., home care where family has primary responsibility)
- Events associated with care beyond the neonatal period
- Neonates born at a gestational age less than 34 weeks and 0 days
- Birth injury events associated with labor or delivery (e.g., shoulder dystocia). These events should be considered for reporting SRE 26: Neonatal patient harm associated with labor or delivery in a low-risk pregnancy.

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

gestational age: The "number of weeks from the first day of the last menstrual period until birth."[108]
The following are common terms used to describe the gestational age of a neonate[108]:

late preterm: "Neonate born at 34 0/7 to 36 6/7 weeks gestational age"

early term: "Neonate born at 37 0/7 to 38 6/7 weeks gestational age"

full term: "Neonate born at 39 0/7 to 40 6/7 weeks gestational age"

late term: "Neonate born at 41 0/7 to 41 6/7 weeks gestational age"

post term: "Neonate born at ≥ 42 weeks gestational age"

infant: "A child from 0 days through the first 12 months of life."[108]

kernicterus: A type of brain damage that can result from high levels of bilirubin in the blood, hyperbilirubinemia, during infancy.[109]

neonate: "Newborn from birth through the first 28 days of life."[108]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 27: Patient harm associated with the care of a neonate.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 27, care of a neonate from birth to less than or equal to 28 days after delivery is clearly tied to a *patient encounter*.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if the care of a term or late preterm neonate resulted in neonatal death or contributed to *serious* neonatal patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Failure to diagnose and treat neonatal jaundice, also known as hyperbilirubinemia, that results in kernicterus
  - » Key omissions and commissions of care (e.g., recognizing maternal anti-Kell antibodies)
  - » Untimely recognition of fetal heart rate abnormalities or congenital heart disease
  - » Misdiagnosis of neonatal infection or sepsis
  - » Misidentification events
  - » Patient treatment that was based on an inaccurate weight

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with the care of a neonate was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further investigation into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, and guidelines for the following:
  - » Patient identification
  - » Parental or guardian identification
  - » Maternal risk factors and antenatal care protocols
  - » Patient assessment and management following birth (e.g., thermal control, breastfeeding, neonatal jaundice, weight)

NEW

SRE 28: Patient Harm Associated with Unrecognized Clinical Deterioration

Event Intent

This new event captures patient harm associated with missed, delayed, or ineffective recognition and response to clinically significant signs and symptoms of deterioration. This event highlights instances when clinically significant information is available, or—according to generally accepted performance standards of care—should be available, to the clinical care team but is not recognized or relayed to the appropriate party/parties and acted upon in a timely manner. Unrecognized clinical deterioration can lead to "failure to rescue" situations and can occur at any time regardless of the patient's age, diagnosis, or disease process. Healthcare settings should implement reliable processes to monitor and assess patient conditions and escalate clinical concerns in a timely manner (e.g., electronic monitoring, rapid response teams, warning systems). Symptoms of clinical deterioration may be reversible or irreversible and may include but are not limited to changes in vital signs, organ functionality, intake or output volumes, test results, or mental status, and are associated with a worsening clinical state, complications, or functional deterioration that was not anticipated or inevitable.[110] This event does not include harm that may be considered nonpreventable, such as rapid, unforeseeable changes in condition despite timely monitoring and response, or expected progression of an illness, disease, or traumatic event. Details such as whether patient harm occurred, whether it was clearly tied to the encounter, or if there was lack of recognition may not be known at the time of the patient encounter. Therefore, Reviewers should report this event when this knowledge is available, regardless of the time passed after the event.

This event focuses on instances of serious patient harm that are likely avoidable when generally accepted performance standards of care are implemented. Reviewers should only report instances of patient harm associated with unrecognized clinical deterioration that are ***serious*** **and** ***largely preventable***, as established by the SRE Inclusion Criteria (pages 25-29).

APPLICABLE HEALTHCARE SETTINGS	This event applies to all healthcare settings.
POPULATION	This event applies to patients who have experienced *serious* harm.
UPDATES SINCE 2011	This is a new event, introduced in 2025.

Exclusions

To aid with event interpretation, this list provides examples of clinical circumstances that are **excluded from** SRE 28.
NOTE: *This list is not meant to be exhaustive.*

- Clinical deterioration primarily related to the natural course of a patient's illness or underlying condition, where intervention was not appropriate (e.g., hospice) or not possible (e.g., pulmonary embolism with no early warning signs in a patient on appropriate prophylaxis)
- Events associated with patient refusal for treatment, when the patient was deemed to have decision-making capacity, and patient refusal is documented and communicated to the clinical care team

Key Definitions

To foster alignment, definitions referenced below are directly quoted or adapted from the respective cited sources.

clinical deterioration: Moving from "one clinical state to a worse clinical state which increases [the patient's] individual risk of morbidity, including organ dysfunction, protracted hospital stay, disability, or death."[111]

clinically significant test result: Any test result that requires further clinical action to avoid morbidity or mortality, regardless of the urgency of that action.[102]

failure to rescue: "When a clinical team is unable to adequately anticipate, identify, and thereby mitigate the consequences of an event or condition involving patient harm."[112]

Reporting Considerations

This section provides actionable questions and specific clinical considerations to further clarify if an event qualifies as SRE 28: Patient harm associated with unrecognized clinical deterioration.

WAS THE EVENT CLEARLY TIED TO A *PATIENT ENCOUNTER* WITH A HEALTHCARE DELIVERY SYSTEM?

- For SRE 28, the management of clinically significant information is tied to a *patient encounter* and may be identified after discharge.
  - » This event may affect patients who are high-risk and commonly treated in an intensive care or critical care unit and those patients where care does not typically require close monitoring.
- Encounters may include instances of unplanned patient transfer or admission to another healthcare setting, treatment team, or level of care after labor or delivery.

DID THE EVENT RESULT IN *SERIOUS* PATIENT HARM?

- Consider reporting if unrecognized clinical deterioration resulted in death or contributed to *serious* patient harm, including physical, emotional, or psychological harm(s), that required major intervention (e.g., surgery, higher level of care, treatment postdischarge) or impaired a patient's ability to perform activities of daily living.
- Events may involve a failure to recognize complications, failure to relay information in a timely fashion regarding the patient condition to the appropriate party/parties, or failure to react in a timely manner.[112]
- Events may be associated with but are not limited to the following clinical circumstances:
  - » Monitoring (e.g., vital signs, neurological checks, invasive monitoring, telemetry) indicated clinical deterioration but was not recognized or no action was taken.
  - » Patient suffered a stroke while being cared for in a healthcare setting and upon review the team discovered that the patient developed new-onset atrial fibrillation that was captured by heart monitoring, but the arrythmia was not recognized by the clinical care team.
  - » Patient reported increased pain but no diagnostic steps were taken to reassess diagnoses or the treatment plan.
  - » Fetal monitoring showed clinical deterioration during labor, but labor continued without appropriate interventions, and the baby was born with severe complications.
  - » Abnormal clinical findings indicated the need for additional active management, but insufficient or inappropriate action was taken by the clinical care team (e.g., delayed action during an outpatient or inpatient encounter).
  - » Family or caregivers reported changes in the patient's condition, which were not recognized or acted upon in a timely manner by the clinical care team.
  - » Clinical documentation reflected early signs of deterioration, but the clinical care team did not perform a reassessment or escalate concerns in a timely manner.

WAS THE EVENT *LARGELY PREVENTABLE*?

- Consider reporting if patient harm associated with unrecognized clinical deterioration was likely avoidable by any means currently available within the generally accepted performance standards of care or if the event triggers further analysis into causative factors.
- In addition to reviewing generally accepted performance standards of care, setting-specific standards should be reviewed because deviations from either could signal that the event was preventable. Setting-specific standards of care may include but are not limited to policies, procedures, or guidelines for the following:
  - » Patient assessment and monitoring
  - » Activation of early recognition and escalation practices (e.g., rapid response team)
  - » Staff compliance with the use of tools that generate warnings and deterioration scores as well as completion of physical assessments in conjunction with tools
  - » Escalation of concerns that trigger rapid response systems that ensure the right people are present at the right time with the right equipment
  - » Safety culture practices where clinicians and staff do not fear negative responses to communication or escalation of concerns
  - » Staff training and competency requirements for standard processes to monitor and assess patient condition and escalate clinical concerns in a timely manner

SRE Applicable Healthcare Settings Crosswalk

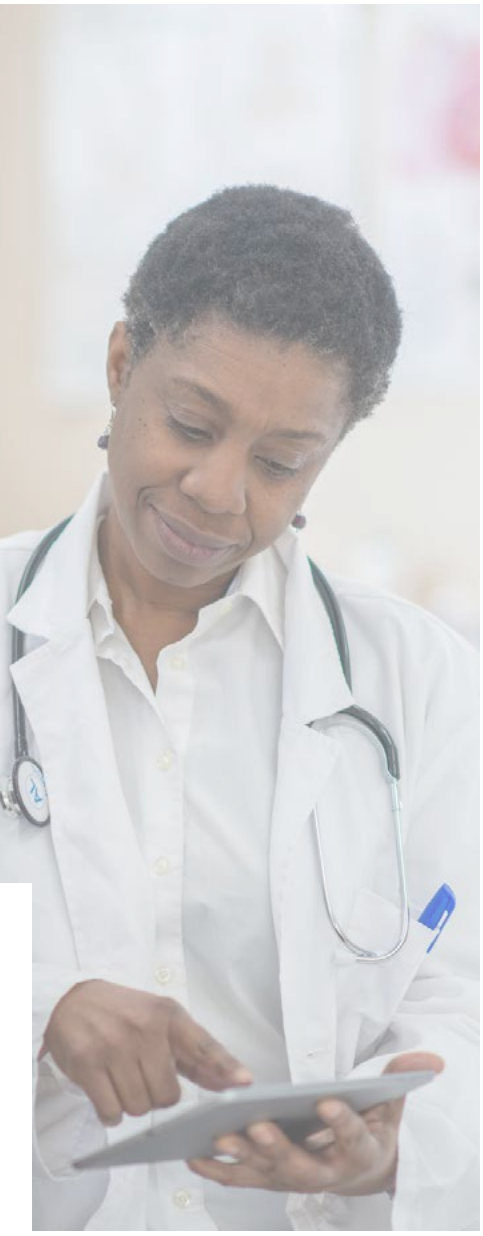
Overview

The applicable healthcare settings depict which sectors of healthcare should consider reporting SREs. Recognizing that patient safety events can occur in different patient care environments, and to promote accountability and inclusivity across both traditional and new modalities, NQF has expanded the 2025 SRE applicable healthcare settings to all patient care environments. This update reflects the prioritization of reporting serious and largely preventable events, regardless of location.

This crosswalk is an overview of which SREs may be applicable to each setting type, ambulatory/outpatient care, hospital/acute care, post-hospital/sub-acute care, home care, and virtual care, and is not intended to guide reporting practices. Joint Commission and NQF acknowledge that the provision of care is constantly evolving and recognizes that even if a setting type is marked as not applicable (N/A), Reviewers should reference SRE–specific Clinical Application Guidance in Part II: SRE Technical Guidance Contents to guide event interpretation and reporting efforts.

REPORTING REMINDERS

If in a rare instance an SRE occurs in a setting marked “N/A” on the tables below, the Reviewer should consider reporting. The 2025 NQF SRE List applies to all healthcare settings, and this crosswalk is not intended to deter reporting by any one setting or setting type.



Applicable Healthcare Setting Types and Examples

SRE applicable healthcare setting types include but are not limited to the following examples:

Ambulatory/Outpatient Care:
Ambulatory surgery centers, behavioral health services, community-based care, dental health, dialysis centers, federally qualified health centers, freestanding and hospital-based emergency/urgent care clinics, mobile clinics/radiology, office-based specialty care (e.g., cardiology, neurology, oncology), outpatient laboratories, outpatient radiology, outpatient rehabilitation (including physical, occupational, and speech-language therapy), pharmacies, pre-hospital and intrafacility transport services, primary care, and wound care clinics

Hospital/Acute Care:
Acute care, critical access, inpatient hospice, psychiatric, and specialty care

Post-Hospital/Sub-Acute Care:
Assisted living, hospice care, rehabilitation, swing bed, and skilled nursing facilities

Home Care:
Home health, home hospice, and hospital at home

Virtual Care:
Telehealth, telemedicine, and telemonitoring

Table 6. Procedural Events by Applicable Healthcare Settings

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 1: Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong procedure, regardless of the type of procedure or the outcome This event applies to all healthcare settings that perform surgery or other invasive procedures.	Applicable	Applicable	N/A	N/A	N/A
SRE 2: Unintended retention of a foreign object in a patient after surgery or other invasive procedure, regardless of the type of procedure or the outcome This event applies to all healthcare settings that perform surgery or other invasive procedures.	Applicable	Applicable	N/A	N/A	N/A
SRE 3: Patient harm associated with perioperative or periprocedural anesthesia or sedation of an ASA Class I or ASA Class II patient This event applies to all healthcare settings that administer perioperative or periprocedural anesthesia or sedation.	Applicable	Applicable	N/A	N/A	N/A
SRE 4: Medically assisted reproduction with the wrong donor sperm or egg, regardless of the outcome This event applies to all healthcare settings that perform medically assisted reproduction.	Applicable	Applicable	N/A	N/A	N/A

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 5: Introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area, regardless of the outcome This event applies to all healthcare settings that perform MRI.	Applicable	Applicable	N/A	N/A	N/A
SRE 6: Patient harm associated with an MRI–related thermal injury This event applies to all healthcare settings that perform MRI.	Applicable	Applicable	N/A	N/A	N/A
SRE 7: Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose, regardless of the outcome This event applies to all healthcare settings that provide radiotherapy services.	Applicable	Applicable	N/A	N/A	N/A

Table 7. Product or Device Events by Applicable Healthcare Settings

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 8: Patient harm associated with the use of contaminated drugs, devices, or biologics This event applies to all healthcare settings that use drugs, devices, and biologics in the provision of patient care except virtual care.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 9: Patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended This event applies to all healthcare settings that use medical devices in the provision of patient care.	Applicable	Applicable	Applicable	Applicable	Applicable
SRE 10: Patient harm occurring when systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances This event applies to all healthcare settings that have systems designated for oxygen, or other gas, to be delivered to a patient, except virtual care.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 11: Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting, regardless of the outcome This event applies to all healthcare settings that operate equipment during direct patient care, except virtual care.	Applicable	Applicable	Applicable	Applicable	N/A

Table 8. Patient Protection Events by Applicable Healthcare Settings

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 12: Discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity, regardless of the outcome This event applies to all healthcare settings that provide care or services to patients who do not have decision-making capacity.	Applicable	Applicable	Applicable	N/A	Applicable
SRE 13: Patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity This event applies to all healthcare settings that provide care or services to patients who do not have decision-making capacity.	Applicable	Applicable	Applicable	Applicable	Applicable
SRE 14: Patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release, regardless of the outcome This event applies to all healthcare settings that screen for suicide/suicide ideation. Although most commonly occurring in hospital and acute care settings, this event also applies to outpatient settings that provide primary care or mental health services.	Applicable	Applicable	Applicable	Applicable	Applicable

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 15: Patient harm associated with the use of chemical restraints, physical restraints, or seclusion This event is applicable to all healthcare settings that use restraints or seclusion except home or virtual care.	Applicable	Applicable	Applicable	N/A	N/A
SRE 16: Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome This event applies to all healthcare settings, with emphasis on newer care modalities where traditional physical boundaries may not apply but patient vulnerability exists.	Applicable	Applicable	Applicable	Applicable	Applicable

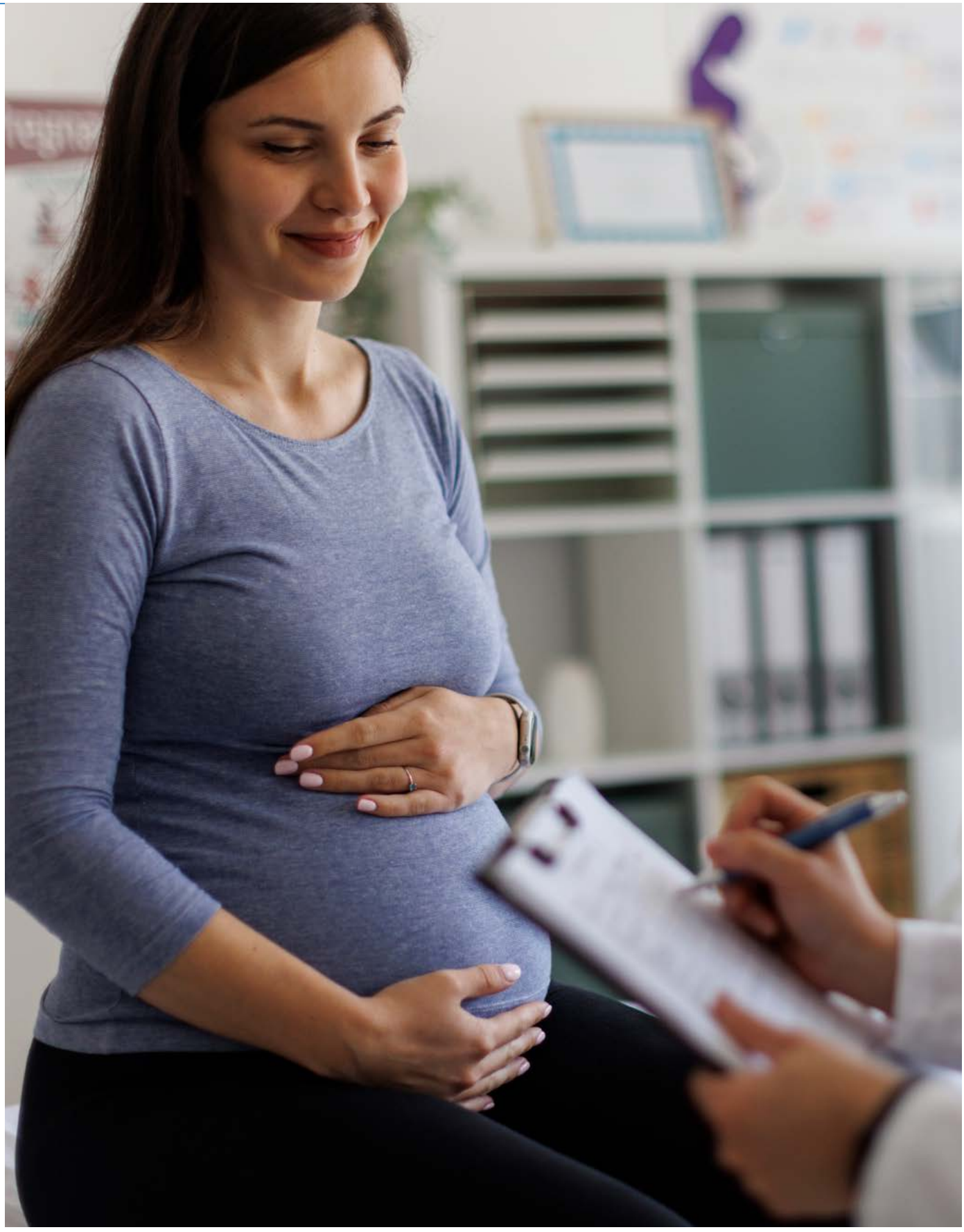
Table 9. Care Provision Events by Applicable Healthcare Settings

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 17: Patient harm associated with a fall This event applies to all healthcare settings except virtual care. Although most commonly occurring in inpatient and long-term care settings, this event should be reported by all healthcare settings, particularly those providing direct care for patients at higher risk of falling.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 18: Patient harm associated with an unintended burn from any source This event applies to all healthcare settings except virtual care.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 19: Patient harm associated with a medication error This event applies to all healthcare settings that prescribe, prepare, dispense, and administer medications.	Applicable	Applicable	Applicable	Applicable	Applicable
SRE 20: Patient harm associated with unsafe processing or administration of blood products This event applies to all healthcare settings where blood or blood-derived products are processed and/or administered.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 21: Patient harm associated with a Stage 3 pressure injury, Stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission This event applies to all healthcare settings that provide round-the-clock observation, monitoring, and care. This event does not apply to ambulatory/outpatient, home, or virtual care.	N/A	Applicable	Applicable	N/A	N/A

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 22: Patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable through an invasive procedure This event applies to all healthcare settings where the collection and management of a biological specimen occur except virtual care.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 23: Patient harm resulting from failure to act on clinically significant laboratory, pathology, or radiology test results This event applies to all healthcare settings where laboratory, pathology, or radiology test results are ordered, processed, resulted, and communicated to the ordering clinician or clinical care team and where results are interpreted, assessed, acted upon, and communicated to the patient, authorized person, or entity.	Applicable	Applicable	Applicable	Applicable	Applicable
SRE 24: Patient harm associated with an intravascular air embolism This event applies to all healthcare settings except virtual care.	Applicable	Applicable	Applicable	Applicable	N/A

Table 9. Care Provision Events by Applicable Healthcare Settings

SERIOUS REPORTABLE EVENT	AMBULATORY/ OUTPATIENT CARE	HOSPITAL/ACUTE CARE	POST-HOSPITAL/ SUB-ACUTE CARE	HOME CARE	VIRTUAL CARE
SRE 25: Maternal patient harm associated with labor or delivery in a low-risk pregnancy This event applies to all healthcare settings where labor or delivery occurs.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 26: Neonatal patient harm associated with labor or delivery in a low-risk pregnancy This event applies to all healthcare settings where labor or delivery occurs.	Applicable	Applicable	Applicable	Applicable	N/A
SRE 27: Patient harm associated with the care of a neonate This event applies to all healthcare settings that provide neonatal care from birth to less than or equal to 28 days after delivery.	Applicable	Applicable	Applicable	Applicable	Applicable
SRE 28: Patient harm associated with unrecognized clinical deterioration This event applies to all healthcare settings.	Applicable	Applicable	Applicable	Applicable	Applicable



Appendices

Appendix A: Key Contributors

National Quality Forum (NQF) thanks and acknowledges the experts who shared their time and experience to update the Serious Reportable Events (SRE) List. Experts served various roles, including technical expert panelists, expert advisors, content reviewers, and key informants between 2024 and 2025. The conclusions, findings, and opinions expressed by individuals who contributed to this publication do not necessarily reflect the official position of the expert's affiliated organization.

Serious Reportable Events Review Technical Expert Panel

The Serious Reportable Events Review Technical Expert Panel contributed to the review of candidate SREs and voted on events for inclusion on the updated NQF SRE List.

Eva Besserman, DO, MBA, FCCM
Clinical Director of the Patient Safety Reporting System, New Jersey Department of Health

Heather Bradley, RN, BSN
Chief of Credentialing and Privileging and Healthcare Risk Management, Evans Army Community Hospital

Gerard Castro, PhD, MPH
Managing Director of Research, Policy, and Quality Improvement, ATW Health Solutions

Elissa Charbonneau, DO, MS
Chief Medical Officer, Encompass Health Corporation

Doreen Donohue, RN, DNP, NEA-BC, CPHQ
Director, Office of Quality & Patient Safety, Joint Commission

Madina R. Gerasimov, MD, MS
Medical Director, Presurgical Testing, North Shore University Hospital; Director of Quality Assurance and Assistant Professor, Anesthesia Department, Zucker School of Medicine, Hofstra/Northwell

Carmen González, MD, MSHQS, FACP, FACMQ
Chief Patient Safety Officer, University of Texas MD Anderson Cancer Center

Richard T. Griffey, MD, MPH
Professor of Emergency Medicine; Vice Chair for Quality and Patient Safety, Department of Emergency Medicine; GME Director of Patient Safety and Quality, Washington University in St. Louis School of Medicine

Helen Haskell, MA
President, Mothers Against Medical Error

Rebecca Jones, MBA, BSN, RN, CPHRM, CPPS, CPHFH
Director of Data Science and Research, Patient Safety Authority

Emanuel Kanal, MD, FACR, FISMRM, MRMD, MRSE, AANG
Chief, Division of Emergency Radiology; Director, Magnetic Resonance Services; Professor of Radiology and Neuroradiology, University of Pittsburgh Medical Center

Michael Korvink, MA, PStat®
Principal, Research & Innovation, Premier Inc.

Erin Lawler-Hart, MS, CPPS
Associate Director, Office of Quality and Patient Safety, Joint Commission

Stefanie Ledbetter, BSN, MSHI
Director of Research and Quality, East Alabama Health

Rebecca McAllister, MSHQS, BSN, RN, CPHQ, CPPS
Director of Quality, Community Health Network

Dean McKay, PhD, ABPP
Professor of Psychology, Fordham University; Co-Director, Wellness Associates LLC.; Chief Clinical Science Officer, Better Living Center for Behavioral Health

Kevin O'Leary, MD, MS
Vice President, Quality, Northwestern Memorial HealthCare; Chief, Division of Hospital Medicine, Northwestern University Feinberg School of Medicine

Joyce Pittman, PhD, RN, ANP-BC, FNP-BC, CWOCN, WOCNF, FAAN
Associate Professor, College of Nursing, University of South Alabama

Edward Pollak, MD, FASA, CPPS
Chief Quality Officer, Henry Ford Health

Patrick Romano, MD, MPH
Professor of Internal Medicine and Pediatrics, University of California Davis Division of General Medicine; Clinical Lead, AHRQ Quality Indicators Program Agency for Healthcare Research and Quality

Diane Rydrych, MA
Director of Health Policy, Minnesota Department of Health

Melinda D. Sawyer, DrPH, MSN, RN, CNS-BC, FAAN
Vice President and Chief Quality and Patient Safety Officer, UnitedHealth Group

Leah Scalf, DNP, RN, LNC, NE-BC
Risk Manager, Franciscan Health Central Indiana

Lisa Schilling, RN, MPH, CPHQ
Chief Quality and Integration Officer, Contra Costa

Hardeep Singh, MD, MPH
Co-Chief, Health Policy, Quality, and Informatics Program and Professor of Medicine, Center for Innovations in Quality, Effectiveness and Safety Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine, Houston

David Stockwell, MD, MBA
Chief Medical Officer, Johns Hopkins Children's Center

Tametha L. Stroh, RN, MSN, CPPS, CPHRM, CPHFH, LSS GB
Senior Director, National Risk Management and Patient Safety, National Health Plan and Hospital Quality, Kaiser Permanente

Janice Tufte
Patient/Public Collaborator, Hassanah

Ann West, MA, BSN, RN
Quality Services Management Manager, Mayo Clinic Health System

Kezia Windham, RN, BSN, CNOR, CPHRM
Senior Risk Specialist, Risk Management and Analytics, Coverys

Serious Reportable Events Guidance Technical Expert Panel

The Serious Reportable Events Guidance Technical Expert Panel reviewed the final SREs and contributed to the Clinical Application Guidance for each SRE (e.g., intent description, clinical examples, relevant settings, accompanying definitions).

Kelly Aldrich, DNP, RN, NI-BC, FHIMSS, FAAN
Professor of Nursing, Informatics and Director of Innovation, Vanderbilt University School of Nursing

Komal Bajaj, MD, MS-HPEd
Chief Quality Officer NYC Health + Hospitals/Jacobi, North Central Bronx; Medical Director of Sustainability NYC Health + Hospitals; Professor, Obstetrics & Gynecology and Women's Health Albert Einstein College of Medicine

Emily Barr, OTD, MBA, OTR/L, BCG
Executive Director, Nebraska Coalition for Patient Safety

Samuel T. Bauer, MD, MBA, FACHE
Professor, Obstetrics and Gynecology, Oakland University William Beaumont School of Medicine; Vice President Medical Affairs – Farmington Hills, Corewell Health

Andrew J. Bierhals, MD, MPH, FACR
Professor of Radiology, Medicine, and Pediatrics; Senior Vice Chair, Quality & Safety and Community Practice, and Director, Cardiothoracic Imaging Barnes Jewish West County Hospital; Medical Director (CT), Center for Clinical Imaging Research, Cardiothoracic Imaging Section, Mallinckrodt Institute of Radiology Washington University in St. Louis

Katherine Du Fresne, RN, MSN, CPHRM
Executive Director, Clinical Risk Management, Indiana University Health

Kristin Duncan, RN, BSN, MBA, CPPS
Senior Director of Patient Safety-Risk Management, Texas Health Resources

Dawn M. Evans, DNP, MSN, MBA, RN, PHN, CPPS, CPHQ
Director of Patient Safety, Quality, and Infection Prevention, Barton Health

Danielle Galán, PA-C, MSHF
Director, Accreditation and Patient Safety, Hospital for Special Surgery

Amrit Gill, MD, FAAP
Associate Chief Safety Officer, Cleveland Clinic

Tobias Gilk, MRSO, MRSE
Founder, Gilk Radiology Consultants; Senior Vice President, RAD-Planning

Amanda J. Hays, PharmD, MHA, DPLA, BCPS, CPHQ, FASHP
Director, Medical Affairs, Becton, Dickinson & Co

Carole Hemmelgarn, MS, MS
Founding Member, Patients for Patient Safety US; Program Director, Executive Master's Clinical Quality, Safety and Leadership, Georgetown University; Senior Director Education, MedStar Institute for Quality and Safety

Angela Hokanson, RN, MHA, CPHQ, CPPS
Patient Safety Program Manager, Methodist Hospital of Sacramento

Libby Hoy
Founder and CEO, PFCCpartners

Ralph Johnson, MS, CPHQ, FHIMSS
Vice President of Informatics and Technology, The Leapfrog Group

Eileen Kasda, DrPH, MHS
President and CEO, Patient Safety, SafeTower

George Louli Tewfik, MD, MBA, FASA, CPE, MSBA
Associate Professor, Department of Anesthesiology; Director of Quality Assurance and Director of Clinical Informatics Rutgers New Jersey Medical School

Dahlia Mak, MHA
Senior Consultant, Strategy and Lean, Ellit Groups

Julia Morrissey, JD, BSN, RN, CPPS
System Director – Patient Safety, Mercy

Madeline Orange, MSN, RN
Social Services Manager, Sentinel Events Division of Licensing and Certification, State of Maine Sentinel Event Program

Arun R. Patel, MD, JD, MBE
Chief Patient Safety and Clinical Risk Management Officer, Los Angeles County Department of Health Services

Keshia Sandidge, LCSW
Consumer Rights Officer Supervisor, Partners Health Management

Susanne E. Schultz, RN, BSN, MBA, CPHQ
Vice President, Clinical Excellence, Quality & Patient Safety, Northwell Health

Bruce Spurlock, MD
President & CEO, Convergence Health

Divvy K. Upadhyay, MD, MPH, CPHRM, CPPS
Program Leader, Diagnostic Safety, Geisinger Health System; Assistant Professor, Health System Sciences Geisinger Commonwealth School of Medicine

Katie Witherspoon, MSN, RN-BC, CPHQ
Quality Manger of Risk and Patient Safety, Henry Ford Health

Federal Liaisons

Federal Liaisons participated as nonvoting members and contributed to Technical Expert Panel meetings and activities to provide federal agency perspectives and insights.

Philippe Champagne, MD, MPH
Physician Senior Advisor, Office of Quality, Indian Health Services

Chien Chen, DNP, MS, RN-BC, PMH-BC, NPD-BC, NEA-BC, FNAP, FAAN
Chief Officer and Nurse Executive, National Center for Healthcare Advancement and Partnerships, Veterans Health Administration

Judy George, PhD
Program Lead, AHRQ Quality Indicators, Agency for Healthcare Quality and Research

Susan Kirsh, MD, MPH, CMQ
Deputy Assistant Under Secretary for Health (DAUSH), Office of Discovery, Education and Affiliate Networks (DEAN), Department of Veterans Affairs

CDR Michelle Livingston, MSN, RN, CNL, CIC, CCM, CPPS
Nurse Consultant, Patient Safety, Division of Quality Assurance and Patient Safety, Office of Quality, Indian Health Services

Yelena Maslov, PharmD
Team Leader, Division of Mitigation Assessment and Medication Error Surveillance (DMAMES), Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), Food and Drug Administration

Michelle Schreiber, MD
Deputy Director, Center for Clinical Standards and Quality and Director, Quality Measures and Value-Based Incentives Group, Centers for Medicare & Medicaid Services

Heather Sherman, PhD, MS, MPH
Health Science Administrator and Deputy Director, Division of Patient Safety, Organization, Center for Quality Improvement and Patient Safety (CQuIPS), Agency for Healthcare Research and Quality

Arjun Srinivasan, MD
Deputy Director for Program Improvement, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

Abigail Viall, ScD, MA
Data Policy and Standards Division/Office of Public Health Data, Surveillance, and Technology, Centers for Disease Control and Prevention

Expert Advisors

Expert Advisors contributed to the development of the updated SRE Inclusion Criteria and contributed to Technical Expert Panel meetings and activities.

David Classen, MD, MS
Professor of Medicine, University of Utah

Melissa Danforth
Senior Vice President Health Care Ratings,
The Leapfrog Group

Tejal Gandhi, MD, MPH, CPPS
Chief Safety and Transformation Officer, Press Ganey

Kenneth Kizer, MD, MPH, CPE, DCM, FAAAS, FACEP, FACPM, FACOEM, FACMT, FAACT, DFAAPL, FRSM, FRSPH, MFAWM, FAAMA(Hon), NAM, FNAPA, FNEC
Distinguished Professor Emeritus, University of California Davis, School of Medicine; Senior Scholar, Clinical Excellence Research Center, Stanford University, School of Medicine

Elizabeth Mort, MD, MPH
Vice President and Chief Medical Officer,
Joint Commission

Sue Sheridan
President and CEO, Patients for Patient Safety US

Carole Stockmeier, MHA
Senior Vice President, Safety and Reliability,
Press Ganey

Terrie Van Buren, RN, MBA, CPPS
Vice President, Community Health Systems

Edward Yackle, DNP, FNP-C, FAANP
Executive Director, National Center for Patient Safety,
Veterans Health Administration

Appendix B: Contributing Staff

Elizabeth Mort, MD, MPH
Vice President and Chief Medical Officer,
Joint Commission

Kimberly Streett, RN, MSN, CPHQ
Director, Performance Improvement,
National Quality Forum

Chuck Amos, MBA
Director, Performance Improvement,
National Quality Forum

Doreen Donohue RN, DNP, NEA-BC, CPHQ
Director, Office of Quality and Patient Safety,
Joint Commission

Kathryn Berryman, MPAP, PMP
Project Director, Operations,
National Quality Forum

Carolee Lantigua, MPA
Senior Program Manager, Performance Improvement,
National Quality Forum

Rebecca Payne, MPH
Senior Program Manager, Performance Improvement,
National Quality Forum

Farjad Khan, PharmD, MHA
Senior Healthcare Analyst, Performance Improvement,
National Quality Forum

Rashmi Singh, MBA, MS
Senior Healthcare Analyst, Performance Improvement,
National Quality Forum

Debbie Olawuyi, MPH
Analyst, Performance Improvement,
National Quality Forum

Emily Bell, MPH
Analyst, Quality Measurement,
National Quality Forum

Tristen Griffith-Smith, MPH
Analyst, Performance Improvement,
National Quality Forum

Sherine Bonsu
Program Operations Coordinator,
National Quality Forum

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NATIONAL QUALITY FORUM
1099 14th Street, NW
Washington, DC 20005

qualityforum.org

JOINT COMMISSION
One Renaissance Blvd
Oakbrook Terrace, IL 60181

jointcommission.org