

NATIONAL QUALITY FORUM

TO: NQF Members and Public

FR: NQF Staff

RE: Pre-voting review for *Serious Reportable Events in Healthcare—2011 Update: A Consensus Report*

DA: December 1, 2010

This draft report is the second update of the NQF-endorsed[®] *Serious Reportable Events in Healthcare: A Consensus Report*, first published in 2002 and updated in 2006. The project seeks to endorse an updated list of serious reportable events (SREs) that includes 25 SREs from the 2006 list that have been updated and 4 new SREs. All the SREs have been reviewed in terms of their applicability to four specific settings of care—hospitals; ambulatory practice settings, specifically office-based practices; long-term care, specifically skilled nursing facilities; and outpatient or office-based surgery centers.

A Steering Committee of 20 individuals representing a diverse range of stakeholder perspectives reviewed and considered the 28 NQF-endorsed SREs along with 79 proposed modifications that touched each SRE and 12 proposed new events. Three Technical Advisory Panels (TAPs) assisted the Steering Committee in its review. This report recommends that 29 SREs be considered for endorsement and 3 existing SREs be retired.

The draft report, *Serious Reportable Events in Healthcare—2011 Update: A Consensus Report*, is posted on the NQF website along with the following additional information:

- SRE submission forms
- Meeting and call summaries from the Steering Committee and the TAPs

Pursuant to Section II.A of the Consensus Development Process v. 1.8, this draft document, along with the accompanying material, is being provided to you at this time for purposes of review and comment only—not voting. You may post your comments and view the comments of others on the NQF website.

NQF Member comments must be submitted no later than 6:00 pm ET, December 30, 2010. Public comments must be submitted no later than 6:00 pm ET, December 23, 2010.

NQF is now using a program that facilitates electronic submission of comments on this draft report. **All comments must be submitted using the online submission process.**

Supporting documents related to your comments may be submitted by e-mail to patientsafety@qualityforum.org with “*Comment—SRE 2011*” in the subject line and your contact information in the body of the e-mail.

Thank you for your interest in NQF’s work. We look forward to your review and comments.

**NQF DOCUMENT—DO NOT CITE, QUOTE, REPRODUCE OR DISTRIBUTE
NQF MEMBER comments due December 30, 2010, 6:00 pm ET;
PUBLIC comments due December 23, 2010, 6:00 pm ET**

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**SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE:
A CONSENSUS REPORT**

DRAFT REPORT FOR COMMENTING

**NQF REVIEW DRAFT—DO NOT CITE, QUOTE, REPRODUCE OR DISTRIBUTE
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**SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE:
A CONSENSUS REPORT**

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**SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE:
A CONSENSUS REPORT****EXECUTIVE SUMMARY**

The National Quality Forum (NQF)-endorsed[®] Serious Reportable Events in Healthcare were released initially in 2002. The purpose of the serious reportable events (SREs) is to facilitate uniform and comparable public reporting to enable systematic learning across healthcare organizations and systems and to drive systematic national improvements in patient safety based on what is learned both about the events and about how to prevent their recurrence. Originally envisioned as a set of events that might form the basis for a national state-based reporting system, the SREs continue to fill that purpose as organizations, independent of NQF, have put them into practice. Additionally, they have been used or adapted by national entities with the goal of illuminating such events in order to facilitate learning and improvement.

The purpose of the 2011 update is to 1) ensure the continued currency and appropriateness of each event in the list; 2) ensure that the events remain appropriate for public accountability in light of their standing as voluntary consensus standards; and 3) provide guidance gained by implementers to those just beginning the reporting of these events, across hospitals and for three newly specified settings of care—office-based practices, ambulatory surgery centers, and skilled nursing facilities.

This second update of NQF's serious reportable events presents the results of evaluation of the 28 NQF-endorsed SREs, with recommended modifications, and 12 new events considered under NQF's Consensus Development Process (CDP). After evaluation against the threshold criteria of unambiguous, largely preventable, and serious, 29 events are recommended for endorsement as voluntary consensus standards suitable for public reporting.

Serious Reportable Events in Healthcare—2011 Update

1. SURGICAL OR INVASIVE PROCEDURE EVENTS
 - A. Surgery or other invasive procedure performed on the wrong site
 - B. Surgery or other invasive procedure performed on the wrong patient
 - C. Wrong surgical procedure or other invasive procedure performed on a patient

- D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient
- 2. PRODUCT OR DEVICE EVENTS
 - A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
 - B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
 - C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting
- 3. PATIENT PROTECTION EVENTS
 - A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
 - B. Patient death or serious injury associated with patient elopement (disappearance)
 - C. Patient suicide, or attempted suicide, while being cared for in a healthcare setting
- 4. CARE MANAGEMENT EVENTS
 - A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
 - B. Patient death or serious injury associated with unsafe administration of blood products
 - C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
 - D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
 - E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting
 - F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting
 - G. Artificial insemination with the wrong donor sperm or wrong egg
 - H. Death or serious injury resulting from the irretrievable loss of a biological specimen
 - I. Death or serious injury resulting from failure to follow up or communicate clinical information
- 5. ENVIRONMENTAL EVENTS
 - A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
 - B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
 - C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting
 - D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting
- 6. RADIOLOGIC EVENTS
 - A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area
- 7. POTENTIAL CRIMINAL EVENTS
 - A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
 - B. Abduction of a patient/resident of any age

- C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
- D. Death or significant 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

111

112 **BACKGROUND**

113 The NQF-endorsed[®] Serious Reportable Events in Healthcare were released initially in 2002,
114 one of the first products of the ongoing effort to enable healthcare quality and safety
115 improvement through introduction of tools for assessing, measuring, and reporting organizational
116 performance. Those efforts were aimed, as they are now, at facilitating learning within the
117 healthcare industry that would lead to delivery of high-quality and safer healthcare. Then, as
118 now, the focus is on what can be done on the part of all members of the healthcare enterprise to
119 ensure that those who seek care are protected from injury while receiving “world class”
120 healthcare. This can only occur when all parts of the healthcare industry work together to find
121 and correct unsafe conditions in the spirit of providing an environment that is safe for patients
122 and for those involved in the delivery of care. Each individual event (rather than frequencies of
123 events) should be reported and investigated by healthcare institutions as they occur.

124 The purpose of the NQF-endorsed list of Serious Reportable Events in Healthcare is to
125 facilitate uniform and comparable public reporting to enable systematic learning across
126 healthcare organizations and systems and to drive systematic national improvements in patient
127 safety based on what is learned both about the events and about how to prevent their recurrence.
128 The SREs were originally envisioned as a set of events that might form the basis for a national
129 state-based reporting system, and they continue to serve that purpose. Additionally, they have
130 been used or adapted by national entities with the goal of illuminating such events in order to
131 facilitate learning and improvement.

132 Every healthcare organization is, and should want to be, accountable for the quality of care it
133 delivers and the safety of all it serves—staff, visitors, families, and most particularly, patients.
134 Accountability in this context encompasses 1) diligent effort to discover vulnerabilities that
135 could lead to adverse events; 2) focused review and analysis of events that do occur to determine
136 causal or contributing factors; and 3) public reporting to enable other organizations to apply
137 lessons learned and actions to prevent recurrence. All who report such events or sponsor reports
138 should recognize and respect the fact that using reports to fix blame is counter-productive in the
139 patient safety improvement effort. Further guidance related to publicly reporting patient safety
140 events is available in *National Voluntary Consensus Standards for Public Reporting of Patient
141 Safety Event Information: A Consensus Report*.¹

142 In keeping with the expectations set in the initial report, *Serious Reportable Events in*
143 *Healthcare—2011 Update* has undergone significant changes. The purpose of the update is to 1)
144 ensure the continued currency and appropriateness of each event in the list; 2) ensure that the
145 events remain appropriate for public accountability in light of their standing as voluntary
146 consensus standards; and 3) provide guidance gained by implementers to those just beginning the
147 reporting of these events across hospitals. Additionally, effort has been made to clarify what
148 events should be reported for three other settings of care—office-based practices, ambulatory
149 surgery centers, and skilled nursing facilities. In large part the differences across the four settings
150 are nuances that find their way into the implementation guidance rather than necessitate
151 significantly different specifications. It should be noted that a focus on these four settings of care
152 does not preclude use of the events in other settings of care.

153 In all events where “serious disability” was part of the event description, the term has been
154 replaced by “serious injury” to broaden application of the event. In some events this has been
155 further broadened to capture change in patient risk status when the risk change requires long-
156 term care or monitoring.

157 State, legal, or other jurisdictional boundaries that take precedence in the way the events are
158 interpreted should be respected in reporting the events. The Steering Committee (Committee)
159 was mindful of the jurisdictional boundaries as well as the importance of comparability within
160 settings of care over time. For these reasons, changes to existing events were made only to the
161 extent warranted by experience gained in their use and current evidence.

162 **Criteria for Inclusion of Events on the List**

163 To qualify for the list of SREs, an event must be unambiguous, largely preventable, and serious,
164 as well as adverse, indicative of a problem in a healthcare setting’s safety systems, or important
165 for public credibility or public accountability. Some SREs are universally preventable and should
166 never occur. Others are largely preventable and may be reduced to zero as knowledge and
167 improved prevention strategies evolve. SREs that are entirely preventable and those that are
168 largely preventable should be publicly reported. The criteria for inclusion (see Box A) and the
169 definitions of terms (see Appendix B, Glossary) were closely reviewed, debated, revised, and
170 subjected to public comment prior to being finalized for use in this update. The events described
171 in this report meet those criteria; however, they do not represent all adverse events that might be
172 useful to report or from which the healthcare industry can learn and make improvements.

173 Further, presence of an event on the list is not an a priori judgment either of a systems failure or
174 a lack of due care.

175 The majority of events on the list are events that, over the years since they were endorsed as
176 voluntary consensus standards, have continued to meet the criteria by which they were selected
177 and have been accepted by organizations and states as appropriate for reporting, but yet have
178 continued to occur.

179

Box A—Criteria for Inclusion

To qualify for the list of *Serious Reportable Events in Healthcare— 2011 Update* an event must be unambiguous, largely preventable, serious, and any of the following:

- adverse
- indicative of a problem in a healthcare setting’s safety systems
- important for public credibility or public accountability

Additionally, items included on the list are events that are:

- of concern to both the public and healthcare professionals and providers;
- clearly identifiable and measurable; and
- thus feasible to include in a reporting system; and
- of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility.

180

181 STRATEGIC DIRECTIONS FOR NQF

182 NQF’s mission includes three parts: 1) setting national priorities and goals for performance
183 improvement; 2) endorsing national consensus standards for measuring and publicly reporting on
184 performance; and 3) promoting the attainment of national goals through education and outreach
185 programs. As greater numbers of quality [including safety] measures are developed and brought
186 to NQF for consideration of endorsement, it is incumbent on NQF to assist stakeholders to
187 “measure what makes a difference” and address what is important to achieve the best outcomes
188 for patients and populations.

189 Several strategic issues have been identified to guide consideration of candidate
190 consensus standards:

191 • **Drive toward high performance.** Over time, the bar of performance expectations should
192 be raised to encourage achievement of higher levels of system performance.

193 • **Emphasize composites.** Composite measures provide much-needed summary
194 information pertaining to multiple dimensions of performance and are more comprehensible

195

196 • **Move toward outcome measurement.** Outcome measures provide information of keen
197 interest to consumers and purchasers, and when coupled with healthcare process measures,
198 they provide useful and actionable information to providers. Outcome measures also focus
199 attention on much-needed system-level improvements, since achieving the best patient
200 outcomes often requires carefully designed care processes, teamwork and coordinated action
201 on the part of many providers.

202 • **Consider disparities in all that we do.** Some of the greatest performance gaps relate to
203 care of minority populations. Particular attention should be focused on identifying
204 disparities-sensitive performance measures and on identifying the most relevant
205 race/ethnicity/language strata for reporting purposes.

206 These strategic directions were considered as the 2011 list of serious reportable events was under
207 development. NQF has focused on driving toward high performance through improving safety
208 across the healthcare enterprise since its inception. *Serious Reportable Events in Healthcare*,
209 published in 2002, was one of the first NQF publications. It was updated in 2006, and now has
210 been further updated and refined to attend to specific issues in four designated healthcare
211 settings. In doing so, special needs of the very young, the elderly, and those with compromised
212 decisionmaking capacity have been considered.

213

214 **NATIONAL PRIORITIES PARTNERSHIP**

215 NQF seeks to endorse measures that address the National Priorities and Goals of the NQF-
216 convened National Priorities Partnership (Partnership).² The Partnership represents those who
217 receive, pay for, provide, and evaluate healthcare. The National Priorities and Goals focus on
218 these areas:

- 219 • patient and family engagement,
- 220 • population health,
- 221 • safety,
- 222 • care coordination,
- 223 • palliative and end-of-life care,
- 224 • overuse,
- 225 • equitable access, and

226 • infrastructure supports.

227

228 **NQF'S CONSENSUS DEVELOPMENT PROCESS**

229 NQF's National Voluntary Consensus Standards for Serious Reportable Events in Healthcare—
230 2011 Update project³ seeks to endorse 29 serious adverse events for use by healthcare
231 institutions, states, and other entities for public reporting.

232 **Evaluating Potential Consensus Standards**

233 This report presents the evaluation of an initial group of 28 endorsed and 12 proposed new
234 serious reportable events. Candidate consensus standards and modifications to NQF-endorsed
235 SREs were solicited through a Call for Serious Reportable Events on May 18, 2010.

236 The events were evaluated using NQF's standard evaluation criteria for serious reportable
237 events, which were refined during this project (see Box A). Three Technical Advisory Panels
238 (TAPs) (see Appendix C) evaluated the endorsed SREs and the proposed modifications thereto
239 as well as the proposed new SREs to identify the strengths, weaknesses, and applicability to their
240 respective settings of care to assist the Committee in making recommendations. The 20 member,
241 multi-stakeholder Committee provided final evaluations of the events in terms of the three main
242 criteria: unambiguous, largely preventable, and serious as well as the recommendation for
243 endorsement.

244

245 **RELATIONSHIP TO OTHER NQF-ENDORSED CONSENSUS STANDARDS**

246 If endorsed, the 29 recommended SREs in this report will become part of a group of NQF-
247 endorsed consensus standards that specifically address healthcare safety and therefore address
248 the National Priorities Partnership focus on safety. Together with the consensus standards in *Safe*
249 *Practices for Better Healthcare—2010 Update*,⁴ *National Voluntary Consensus Standards for*
250 *Public Reporting of Patient Safety Event Information*,⁵ and the rising number of measures related
251 to patient safety that have been endorsed by NQF, the SREs comprise a group of consensus
252 standards aimed at improving patient safety. This group of safety standards provides a strong
253 array of nationally accepted tools for measuring, improving, and reporting safety-related
254 healthcare events that enable and facilitate improvements in healthcare safety.

255

256 Although the SREs have been evaluated and defined in the context of four specific healthcare
257 settings, they can be applied across multiple settings, professional disciplines, and healthcare
258 conditions.

259

260 **RECOMMENDATIONS FOR ENDORSEMENT**

261 This report presents the results of the evaluation of 28 endorsed and 12 proposed new serious
262 reportable events considered under NQF's CDP. (For more detailed specifications and
263 implementation guidance, see Appendix A.) Twenty-nine SREs are recommended for
264 endorsement as voluntary consensus standards suitable for public reporting.

265 The events are organized in seven categories—six that relate to the provision of care
266 (surgical or invasive procedure, product or device, patient protection, care management,
267 environmental, and radiologic) and one that includes four potential criminal events. These latter
268 events include both illegal acts and acts of unintentional misconduct, and they are included
269 because they could be indicative of an environment that is unsafe for patients. Although a
270 healthcare institution cannot eliminate all risk of these types of events, it can take preventive
271 measures to reduce that risk.

272 The specifications expand and offer clarification of the event to support reporting efforts,
273 while the implementation guidance provides context and otherwise facilitates understanding of
274 the events.

275 Consistent with the 2002 and 2006 lists of NQF-endorsed serious reportable events, this 2011
276 list is a relatively small and carefully constructed list of events defined to facilitate understanding
277 and wide utilization. To facilitate clear understanding, a number of terms used in this report have
278 been defined for its use (See Appendix B).

279 **Updated and New Candidate Consensus Standards Recommended for** 280 **Endorsement**

281 Each of these events is intended to be used for public reporting by healthcare institutions, states,
282 and other entities as part of healthcare enterprise-wide efforts to identify, learn from, and form
283 solutions to such events. All are largely, if not entirely, preventable, and yet all continue to
284 occur. All are potentially indicative of a problem in the healthcare institutions' safety systems

285 and are of a nature such that the risk of occurrence is significantly influenced by the policies and
286 procedures of the healthcare organization. They are of concern to the public and healthcare
287 professionals and providers, and they are important for public credibility and public
288 accountability. When used as a set for reporting, the events provide a multidimensional view of
289 the safety of a healthcare organization that cannot be achieved with single event-type reporting.
290 These characteristics make each event important for public reporting.

291 Of the 29 events proposed for endorsement, 25 are endorsed events that have been updated.
292 Based on the changes to these events, including the specified care settings, all are being
293 subjected to the CDP. The four new events are identified.

294

295 ***Surgical or Invasive Procedure Events***

296 Each of the surgical or invasive procedure events was originally specified as a surgery event and
297 each was endorsed as part of the initial set of SREs in 2002. During the past eight years, these
298 events have continued to occur without appreciable improvement. The occurrence of the first
299 four events requires additional, otherwise unnecessary, intervention and has the potential to
300 cause long-term adverse consequences for the patient. The Committee agreed that the first four
301 events should be expanded to include a broader universe of invasive procedures, many of which
302 occur outside the traditional operating room. Inclusion of invasive procedures in these four
303 events makes the determination of when surgery or a procedure ends challenging, thus the
304 definition has been updated. There was some concern that including invasive procedures with
305 surgery in these events could reduce setting-specific learning unless settings are identified in
306 reports. With respect to the first three events, it was agreed that, although the traditional “consent
307 form” might not be used for procedures outside an operating suite, documentation of informed
308 consent is essential. The definition of informed consent and a caveat in the implementation
309 guidance of each of the three clarifies the intent.

310

- 311 A. Surgery or other invasive procedure performed on the wrong site. To be more inclusive
312 of the range of occurrences that this event should capture, “body part” was changed to
313 “site..”
- 314 B. Surgery or other invasive procedure performed on the wrong patient. Because patients
315 undergoing procedures in outpatient settings typically will not be identified using

316 wristbands, the implementation guidance for this event includes a caveat about
317 identification procedures.

318 C. Wrong surgical procedure or other invasive procedure performed on a patient.

319 D. Unintended retention of a foreign object in a patient after surgery or other invasive
320 procedure. The definition of “end of surgery” has been modified to ensure that it does
321 not create a circumstance in which carrying out standard procedures for discovery of a
322 foreign object would create a reporting requirement.

323 E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1
324 patient. The Committee discussed the possibility of broadening this event or creating a
325 new event to capture any death during or within some specified period after a procedure.
326 The decision was made to be explicit about the settings to which the event as specified
327 applies and to reconsider modifying the event specifications at a future update.

328

329 ***Product or Device Events***

330 A. Patient death or serious injury associated with the use of contaminated drugs, devices, or
331 biologics provided by the healthcare setting. Initially endorsed in 2002, this event has
332 been modified to clarify the issue of detectability. Often contaminants are not visible to
333 the naked eye but can be detected through monitoring. There has been a dramatic
334 increase in the spread of pathogens such as hepatitis and HIV due to the reuse or
335 improper repurposing of medical equipment (e.g., endoscopy tubes, syringes) as well as
336 misuse of medication vials, injection devices, and containers (e.g., single-use vials used
337 for more than one patient, inappropriate access of multi-dose vials, and pooling of
338 medications). When such uses become known, it is essential that organizations
339 investigate and that appropriate patient monitoring, which follows national guidelines or
340 standards for care, occur. The serious injury that occurs in such cases could be
341 development of disease or the threat of disease that changes the patient’s risk status for
342 life, requiring monitoring not needed before the event.

343 B. Patient death or serious injury associated with the use or function of a device in patient
344 care, in which the device is used or functions other than as intended. As in the previous
345 event, failure to properly clean and maintain a device or misuse of a device that exposes a
346 patient to disease or injury imposes a “serious injury” when it changes his or her risk
347 status for life, requiring previously unneeded monitoring or treatment.

348 C. Patient death or serious injury associated with intravascular air embolism that occurs
349 while being cared for in a healthcare setting. Discussion of this endorsed event centered
350 on concern that the exclusions allow the occurrence of neurosurgical procedures
351 identified only as presenting a high risk of intravascular air embolism to remain
352 unreported. The American Academy of Neurologic Surgeons provided information that
353 in those cases where surgery is performed in a position that puts the head above the heart
354 to reduce venous pressure, development of air embolism is a known risk that is not
355 entirely preventable. Pediatric experts, while agreeing that air embolism is not entirely
356 preventable in some neurosurgical procedures, expressed differing points of view about
357 reporting. To be consistent, the exclusion is retained for both adults and children at this
358 time.

359

360 ***Patient Protection Events***

361 A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to
362 other than an authorized person. This event had been limited to infants. The Committee
363 determined that it should be expanded to apply to any individual of any age who lacks
364 decision-making capacity. The two areas of concern discussed by the Committee related
365 to the challenges associated with applying the event in an outpatient setting and the
366 meaning of the term “authorized.” The former has been addressed through the
367 implementation guidance and the latter through definition and explanatory language in
368 the implementation guidance.

369 B. Patient death or serious injury associated with patient elopement (disappearance).

370 Although the issue of accepting an individual into care who subsequently goes missing is
371 important, the struggle with this event focused on what elopement or disappearance
372 means. The determination was made that the exclusion of competent (with
373 decisionmaking capacity) adults who leave against medical advice or voluntarily leave
374 without being seen would address the concern. It was also noted that some states and
375 other jurisdictions have defined elopement and, where applicable, those definitions are to
376 be respected.

377 C. Patient suicide, or attempted suicide, while being cared for in a healthcare setting. The
378 determination was made that this remains an important event to be reported but that the
379 threshold of serious injury associated with a suicide attempt should be deleted. The

380 rationale for this decision was that once an individual is accepted into care, a
381 responsibility for ensuring his or her safety exists. The struggle lies in the determination
382 of when the individual has been accepted into care because it is not reasonable to impose
383 a duty on an institution for an individual who is on the premises of the institution but has
384 not yet presented him- or herself for care (e.g., attempts suicide in a restroom prior to
385 checking in for care). This was addressed through modification of the additional
386 specifications.

387

388 **Care Management Events**

- 389 A. Patient death or serious injury associated with a medication error (e.g., errors involving
390 the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation,
391 or wrong route of administration). The high rate of medication errors resulting in injury
392 and death makes this event important to endorse again. With this update, two significant
393 additions to the additional specifications have been made. One is the administration of a
394 medication for which there is serious contraindication. The other relates to failure to
395 observe safe injection practices (i.e., the improper use of single dose/single use and multi-
396 dose containers leading to injury or death as a result of contamination or dosages).
- 397 B. Patient death or serious injury associated with unsafe administration of blood products.
398 The Committee was of the opinion that this event should be entirely preventable in any
399 setting. Changes made to this event included broadening the event beyond hemolytic
400 reaction and changing “serious disability” to “serious injury.” There was concern about
401 operationalizing “unsafe”. Implementation guidance has been added to address this
402 concern.
- 403 C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy
404 while being cared for in a healthcare setting. The single change to this event was the
405 change from “serious disability” to “serious injury” made to all other events with this
406 language. Although there was discussion of removing the exclusions, this is not
407 recommended at this time. It will be revisited when the list is next reviewed.
- 408 D. Death or serious injury of a neonate associated with labor or delivery in a low-risk
409 pregnancy while being cared for in a healthcare setting. (NEW) This new event is a
410 companion to, and equally important as, death or serious injury of the mother in similar
411 circumstances.

- 412 E. Patient death or serious injury associated with a fall during or after being cared for and
413 prior to leaving the grounds of the healthcare setting. This event was endorsed in 2002. It
414 has been refined to improve clarity related to the boundaries within which reporting is to
415 occur, both in terms of the physical boundary and the relationship with the patient. These
416 changes were seen as especially significant in identifying the current gaps that offer
417 opportunity for improvement, such as in the case of a post-operative patient who may
418 have remaining influence of medications who is moving from the interior of a healthcare
419 setting to a vehicle. At the same time, it was important that there be no responsibility for
420 an individual prior to acceptance as a patient. The Committee decided to move this event
421 from the Environmental Events group to the Care Management Events group at this time.
422 The question of moves of other events as well as the typology used for grouping events
423 will be further considered in future updates to the SREs.
- 424 F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/
425 presentation to a healthcare setting. Updates to this event include the addition of
426 “unstageable” based on harmonization with the National Pressure Ulcer Advisory Panel’s
427 (NPUAP) position and definitions. Although possible inclusion of deep tissue injury was
428 discussed, determination was made that this would amount to reporting an unconfirmed
429 suspicion. Also, there was discussion of preventability and, while acknowledging that
430 some pressure ulcers cannot be prevented, determination was made that pressure ulcers as
431 defined by this event and the NPUAP should be reported.
- 432 G. Artificial insemination with the wrong donor sperm or wrong egg. This event, first
433 endorsed in 2006, is continued unchanged other than to specify three settings of care to
434 which it applies.
- 435 H. Death or serious injury resulting from the irretrievable loss of a biological specimen.
436 (NEW) The Committee readily agreed on the importance of this newly submitted event.
437 Discussion of this event centered on the meaning of “irretrievable,” which was addressed
438 both in the specifications and implementation guidance. As with the event related to use
439 of contaminated drugs, etc., serious injury could be the progress of an undiagnosed
440 disease or it could be the threat of disease that changes the patient’s risk status for life,
441 requiring monitoring not needed before the event.
- 442 I. Death or serious injury resulting from failure to follow up or communicate clinical
443 information. (NEW) The Committee agreed on the importance of this newly submitted

444 event and acknowledged that the issue of failure to follow up or communicate imposes
445 significant increased risk of death or serious injury (e.g., change in stage of cancer).

446

447 ***Environmental Events***

448 A. Patient or staff death or serious injury associated with an electric shock in the course of a
449 patient care process in a healthcare setting. This event, which was endorsed in 2002, has
450 been expanded to include staff death or serious injury. Explanation of the intent of the
451 addition has been added to the implementation guidance.

452 B. Any incident in which systems designated for oxygen or other gas to be delivered to a
453 patient contain no gas, the wrong gas, or is contaminated by toxic substances. This event,
454 which was endorsed in 2002, has been refined to ensure that events involving both
455 remote and bedside systems are included and that cases in which gas is not delivered
456 when it has been prescribed are captured.

457 C. Patient or staff death or serious injury associated with a burn incurred from any source in
458 the course of a patient care process in a healthcare setting. This event was endorsed in
459 2002. It has been expanded to include staff death or serious injury. Implementation
460 guidance has been added to provide examples of the array of burns that are possible.

461 D. Patient death or serious injury associated with the use of physical restraints or bedrails
462 while being cared for in a healthcare setting. The single change to this event, initially
463 endorsed in 2002, was the addition of “physical.” The Committee acknowledged concern
464 about the issue of chemical restraints but determined that difficulty in defining such
465 events makes their inclusion infeasible at present.

466

467 ***Radiologic Events***

468 A. Death or serious injury of a patient or staff associated with the introduction of a metallic
469 object into the MRI area. (NEW) This event is an adaptation of a newly proposed event.
470 The occurrence of such events continues to be recognized, suggesting that there is an
471 opportunity for discovery and learning to reduce the occurrence. After discussion and
472 consultation with experts in MRI processes and environments, the event was clarified and
473 expanded to include death or serious injury of staff as well as patients. Because
474 radiologic events of various types are occurring with increasing frequency, this event is

475 included in a new category, “Radiologic Events,” in anticipation that additional events
476 will be added to this category in future SRE updates.

477 ***Potential Criminal Events***

478 The category title has been changed by the addition of “potential,” recognizing that at the time of
479 occurrence, there may be no determination of intent. In fact, the occurrence may be determined
480 to be unintentional very early on (e.g., the patient with dementia who harms another). Although
481 the latter event results in unintentional harm, it can indicate a problem with the safety systems in
482 the healthcare setting. The overarching discussion about this group of events was related to
483 redundant reporting and the potential for compromising the event-related information.
484 Committee members experienced in medical event-related judicial proceedings noted that the
485 legal pathway has no interest in learning, improvement, or prevention; thus the events are
486 appropriately included in the SREs for those reasons. Further, these events are rare, and although
487 there is a certain amount of redundancy in data collection or reporting, the burden should be
488 relatively light. Of note, use of the term “patient” in these events is intended to convey that the
489 individual has presented for care, is under care, or has received care and has not yet left the
490 healthcare setting grounds.

- 491 A. Any instance of care ordered by or provided by someone impersonating a physician,
492 nurse, pharmacist, or other licensed healthcare provider. No changes were made to the
493 specifications of this event, which was initially endorsed in 2002. Implementation
494 guidance was added to provide some clarification regarding what it is intended to capture.
- 495 B. Abduction of a patient/resident of any age. This event, endorsed in 2002, was changed to
496 include “resident” in keeping with the nomenclature used in long-term care settings.
497 Implementation guidance was added to clarify what it is intended to be captured.
- 498 C. Sexual abuse/assault on a patient or staff member within or on the grounds of a
499 healthcare setting. This event, endorsed in 2002, was changed to add staff to the reporting
500 requirement.
- 501 D. Death or significant injury of a patient or staff member resulting from a physical assault
502 (i.e., battery) that occurs within or on the grounds of a healthcare setting. The change
503 made to this event, endorsed in 2002, is limited to changing “facility” to “setting,” where
504 applicable.
505

506 **Consensus Standards Recommended for Retirement**

507 Three Care Management events are recommended for retirement. The Committee recommends
508 that when an event represents an example of a type of event, it be reported under the rubric of the
509 event type or category rather than creating a proliferation of single events representative of the
510 type or category. Two events recommended for retirement are examples.

511 Formerly **Care Management Event 4.D. Patient death or serious disability associated with**
512 **hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare**
513 **facility**

514 Onset of hypoglycemia in a healthcare setting is an example of a medication management event,
515 and as such, the Committee recommends that events related to insulin dosing be included as an
516 explicit example of occurrences to be reported under the Care Management event related to death
517 or serious injury associated with a medication error (4.A.). Further, the “Additional
518 Specifications” of that event have been changed to include over- or under-dosing.

519

520 Formerly **Care Management Event 4.E. Death or serious disability (kernicterus) associated**
521 **with failure to identify and treat hyperbilirubinemia in neonates**

522 Development of kernicterus is an example of failure to follow up or communicate clinical
523 information, a new care management event proposed for this 2011 update. The committee,
524 therefore, recommends that the event be retired and that its intent be added to the “Additional
525 Specifications” of the new event. This recognizes the importance of continued diligence in the
526 effort to detect signs of hyperbilirubinemia and the potential for kernicterus, while providing a
527 category for capturing a wider range of events related to failure to follow up on important
528 clinical information.

529

530 Formerly **Care Management Event 4.G. Patient death or serious disability due to spinal**
531 **manipulative therapy**

532 The Committee identified this event as one that targets a specific group of healthcare providers.
533 Further, the event is related to individual provider behavior rather than facility safety systems.
534 Based on these facts, it is recommended that this event be retired.

535

536 **Candidate Consensus Standards Not Recommended for Endorsement**

537 Of the eight proposed new SREs that are not recommended for endorsement, elements of three
538 have been incorporated into the implementation guidance of other SREs for which endorsement
539 is recommended. Additionally, some of the eight events not recommended in this update can be
540 expected to be included in future updates as experience and the evidence evolves.

541

542 **Patient death or serious injury associated with prolonged fluoroscopy with cumulative dose**
543 **>1500 rads to a single field or any delivery of radiotherapy to the wrong body region or 25**
544 **percent above or below the planned radiotherapy dose**

545 The complexity of this proposed event coupled with the input from experts in fluoroscopy and
546 radiotherapy resulted in the Committee recommending against advancing this event at this time.
547 At present, fluoroscopy equipment does not provide dose maps after a procedure, and the
548 measurement systems used for dosages are changing. Further, dosages differ based on a number
549 of factors including body location. These factors would require extensive, detailed specifications
550 that would depend on the ability to clearly articulate a number of variables, some of which are
551 transitioning to new methods. The Committee recommends this event be held for consideration
552 at the next update of SREs.

553

554 **Patient death or serious injury related to a central line associated blood stream infection**
555 **(CLABSI)**

556 The development of blood stream infections associated with clinical care is an important
557 occurrence that can be related to failure of organizational policy and procedures or the
558 enforcement and surveillance of these policies and procedures. The Committee opined that
559 development of such an infection (versus death or serious injury) should be reported; however,
560 the event is not recommended for endorsement at this time because of issues related to
561 attributing causality as well as relative lack of measurement experience and reporting. The event
562 will be revisited in the next SRE update cycle.

563

564 **Death among surgical patients with serious treatable complications (failure to rescue)**

565 In the context of a SRE, ascertainment would be difficult due to the potential breadth of
566 complications to be defined and linked to failure to rescue. At this juncture, the event can best be
567 captured, albeit in the aggregate, using a performance measure. NQF has endorsed three such
568 measures, and although similar each measure applies to different populations. At some future
569 date, the feasibility of linking the SREs with performance measures should be explored;
570 however, the complexity of individual event reporting that would result requires careful
571 consideration.

572

573 **Arterial misplacement and use of a central venous catheter**

574 **Diagnostic testing error resulting in unnecessary invasive procedure, serious disability or**
575 **death**

576 **Incorrect placement of a feeding (gastrointestinal) or ventilation tube, which results in**
577 **patient harm**

578 A guiding principle applied by the Committee in its deliberations of the three foregoing proposed
579 events was that individual examples of event types should, where possible, be captured within
580 SREs that capture the broader type rather than as individual events. The three events above are
581 examples of broader categories of events in the proposed list and have been included as such in
582 the relevant event implementation guidance.

583

584 **Death or serious injury resulting from care provided by an impaired healthcare worker**

585 **Death or significant injury of a patient as a consequence of staff impaired by recreational**
586 **drugs or alcohol use**

587 The Committee acknowledged that the issue at the center of these two foregoing proposed events
588 is important. However, the issue is complex given the range of substances that could be involved,
589 including at least one that may be legalized in some states; the types of impairments that could
590 be involved; the ability to determine or verify the impairment objectively; and the point at which
591 impairment could be declared and reported. Due to these challenges, these events are not
592 recommended at this time.

593

594 **ADDITIONAL RECOMMENDATIONS**

595 Although the list of serious reportable events has been in use to varying degrees across states and
596 healthcare organizations, significant opportunity for improving the list through research remains.
597 The NQF report, *National Voluntary Consensus Standards for Public Reporting of Patient Safety*
598 *Event Information*,⁶ outlined a number of recommendations, of which four are repeated here
599 either verbatim or modified to be specific to SREs.

600

- 601 • Research and evaluation should be conducted to determine which events convey a valid,
602 reliable perspective of healthcare organization safety.
- 603 • Research should be conducted to evaluate the impact of public reporting of patient safety
604 information on patients, consumers, and healthcare institutions.
- 605 • Organizations that collect patient safety reports from healthcare providers, those that
606 design collection systems for such reports, those that design classification systems for
607 event reporting, and other stakeholders should come together and begin to harmonize
608 standardized systems for defining, measuring, reporting, analyzing, and classifying
609 patient safety information in a way that produces greater data integrity, completeness, and
610 reliability and, therefore, greater understanding of events, and reduces opportunity costs
611 associated with these activities.
- 612 • Health information technology systems and any funds that become available to improve
613 them should include provision for facilitating patient-safety related data capture in ways
614 that can be used for public reporting.

615

616 Additionally, *Serious Reportable Events in Healthcare*, 2002 and the 2006 Update included
617 recommendations that remain relevant and should be addressed. These include:

618

- 619 • exploring effective mechanisms to collect data and communicate serious reportable
620 events to the public;
- 621 • examining how data derived from using the NQF list can be disclosed in a way that meets
622 the public's needs, yet is balanced with the need for providers to learn from mistakes;
- 623 • testing the operational value and utility of the events on the list, including research on the
624 necessity to support such a list and the public's perceptions of the impact of the list;

- 625 • identifying ICD, CPT, or other codes that correlate with each serious reportable event on
626 the list; and
- 627 • identifying effective mechanisms, including standardization of reporting systems, to
628 permit institutions to report an event that occurs in their organization only once to a
629 single entity from which needed information can be extracted and to avoid double
630 reporting when a patient receives care in more than one healthcare organization;
- 631 • evaluating comparability of data reported across healthcare systems to determine the
632 degree to which comparability exists and to define next steps toward improving
633 comparability;
- 634 • evaluating outcomes of public reporting in terms of both reduction in occurrences of
635 these events and identification and use of practices to prevent such occurrences; and
- 636 • evaluating population- or geographic-based differences in rates of occurrence of these
637 events for purposes of determining reporting and/or occurrence variations and designing
638 appropriate population-specific interventions.

639

640 **NOTES**

1 National Quality Forum (NQF), *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report*, NQF: Washington, DC; publication pending.

2 NQF, *National Priorities Partnership*, Washington, DC: NQF. Available at www.nationalprioritiespartnership.org. Last accessed October 1, 2010.

3 Available at http://qualityforum.org/projects/hacs_and_sres.aspx . Last accessed October 1, 2010.

4 NQF. *Safe Practices for Better Healthcare—2010 Update: A Consensus Report*, NQF: Washington, DC; 2010.

5 NQF. *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report*, NQF: Washington, DC; publication pending.

6 Ibid.

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APPENDIX A EVENT SPECIFICATIONS AND IMPLEMENTATION GUIDANCE

The following table presents the specifications for the proposed consensus standards. The information presented represents an update of the 2006 report with revision and additions made by the Serious Reportable Events Steering Committee utilizing NQF Member and public submissions and consultation with experts in the various fields. These proposed voluntary consensus standards are the intellectual property of the National Quality Forum and as such they are open source, fully accessible, and disclosed.

Definitions of key terms are included in the Glossary (Appendix B) and, where the terms are used in the event description or additional specifications, are considered part of the specifications of the events.

Implementation Guidance is not proposed for endorsement. It amplifies statements in the Event and Additional Specifications, which are proposed for endorsement, with examples and explanations based on experience of those organizations/entities that have implemented event reporting as well as recommendations of the NQF Serious Reportable Events Steering Committee. It does not purport to be either comprehensive or even across the events and is *not* a requirement of either.

1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>A. Surgery or other invasive procedure performed on the wrong site</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Defined as any surgery or other invasive procedure performed on a body part or site that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.</p> <p>Excludes emergent situations that occur in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent.</p>	<p>It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a “surgical consent form”; however, it does require informed consent be documented in the patient record.</p> <p>Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at time the surgical mark is made on the patient. Placing a mark on the wrong body part or site does not in itself constitute wrong site surgery.</p> <p>Wrong site surgery or invasive procedure, corrected during the procedure, is still a wrong site procedure if the surgery/</p>

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
		<p>procedure had begun, based on the definition in glossary.</p> <p>This event is intended to capture instances of:</p> <ul style="list-style-type: none"> • surgery or other invasive procedure on the right body part but on the wrong location/site on the body; e.g. left/right (appendages/organs), wrong digit, level (spine), stent placed in wrong iliac artery, steroid injection into wrong knee, biopsy of wrong mole, burr hole on wrong side of skull; • delivery of fluoroscopy or radiotherapy to the wrong region of the body; • use of incorrectly placed vascular catheters; • use of incorrectly placed tubes (for example, feeding tubes placed in the lung or ventilation tubes passed into the esophagus). <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> • changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery or procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).
<p>B. Surgery or other invasive procedure performed on the wrong patient</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers 	<p>Defined as any surgery or invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.</p>	<p>It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a “surgical consent form”; however, it does require informed consent be documented in the patient record.</p> <p>This event is intended to capture:</p> <ul style="list-style-type: none"> • surgical procedures (whether or not completed) initiated on one patient intended for a different patient.

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<ul style="list-style-type: none"> • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		<p>Use of accepted patient identification procedures is key to avoiding such events.</p>
<p>C. Wrong surgical or other invasive procedure performed on a patient</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Defined as any surgical or other invasive procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.</p> <p>Excludes emergent situations that occur in the course of surgery or other invasive procedures and/or whose exigency precludes obtaining informed consent.</p>	<p>It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a “surgical consent form”; however, it does require informed consent be documented in the patient record.</p> <p>This event is intended to capture:</p> <ul style="list-style-type: none"> • insertion of the wrong medical implant into the correct surgical site. <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> • changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery/ procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).
<p>D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers 	<p>Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place.</p> <p>Excludes a) objects present prior to surgery or other invasive procedure that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery/procedure that are intentionally left</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery; • unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings.

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1. SURGICAL OR INVASIVE PROCEDURE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<ul style="list-style-type: none"> • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws).</p>	
<p>E. Intraoperative or immediately postoperative/ postprocedure death in an ASA Class I patient</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices 	<p>Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>Immediately post-operative means within 24 hours after surgery or other invasive procedure was completed or after administration of anesthesia (if surgery/procedure not completed).</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • ASA Class I patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out.

2. PRODUCT OR DEVICE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE

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2. PRODUCT OR DEVICE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Includes contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.</p> <p>Includes threat of disease that changes patient's risk status for life requiring monitoring not needed before the event</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • contaminations that can be seen with the naked eye or with use of detection mechanisms in general use. <i>Often, contaminants, including such things as hepatitis and HIV, are not visible to the naked eye. These contaminations are to be reported at such time as they become known to the provider or healthcare organization. (Detection mechanisms may include such things as cultures and tests, including sterilization monitoring devices that signal changes in pH or glucose levels.)</i> <p>This event is intended to capture:</p> <ul style="list-style-type: none"> • administration of contaminated vaccine or medication (e.g., intramuscular antibiotic); • serious infection from contaminated device used in surgery or an invasive procedure (e.g., a scalpel).

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2. PRODUCT OR DEVICE EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, and ventilators.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • occurrences whether or not the use is intended or described by the device manufacturers' literature; • occurrences related to improper cleaning or maintenance of the device.
<p>C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers, • Long-term Care/Skilled Nursing Facilities 	<p>Excludes death or serious injury associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • 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 including those related to lines placed for infusion of fluids in vascular space.

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3. PATIENT PROTECTION EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person.</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		<p>Authorized as used here includes the definition in the glossary. Other than authorized includes removing the patient/resident without specific notification and approval by staff even when the person is otherwise authorized.</p> <p>Examples of individuals who do not have decisionmaking capacity include: newborns, minors, adults with Alzheimer's.</p>
<p>B. Patient death or serious injury associated with patient elopement (disappearance).</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Includes events that occur after the individual presents him/herself for care in a healthcare setting.</p> <p>Excludes events involving competent adults with decisionmaking capacity who leave against medical advice or voluntarily leave without being seen.</p>	<p>The term "elopement" and "competent" adult should be interpreted in accordance with prevailing legal standards in applicable jurisdictions.</p> <p>This is not intended to capture:</p> <ul style="list-style-type: none"> • death or serious injury that occurs (after the patient is located) due to circumstances unrelated to the elopement.
<p>C. Patient suicide, or attempted suicide, while being cared for in a healthcare setting</p>	<p>Includes events that result from patient actions after they present themselves for care in a healthcare setting.</p>	<p>This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present</p>

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3. PATIENT PROTECTION EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Excludes deaths resulting from self-inflicted injuries that were the reason for admission/presentation to the healthcare facility.</p>	<p>in the “healthcare setting “as defined in the glossary.</p>
4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE

SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE

4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Excludes reasonable differences in clinical judgment on drug selection and dose.</p> <p>Includes, but is not limited to, death or serious injury associated with a) over- or under-dosing; b) administration of a medication to which a patient has a known allergy or serious contraindication, c) drug-drug interactions for which there is known potential for death or serious injury, d) improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of contamination or dose adjustment problems.</p>	<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • the most serious medication errors including occurrences in which a patient receives a medication for which there is a contraindication or a patient, known to have serious allergies to specific medications/ agents, receives those medications/ agents, resulting in serious injury or death. <i>These events may occur as a result of failure to collect information about contraindications or allergies, failure to review such information available in information systems, failure of the organization to assure availability of such information and prominently display such information within information systems, or other system failures that are determined through investigation to be cause of the adverse event.</i> • occurrences in which a patient dies or suffers serious injury as a result of failure to administer a prescribed medication; • occurrences in which a patient is administered an over- or under-dose of a medication including insulin, heparin, and any other high alert medication including but not limited to medications listed on the Institute for Safe Medication Practices “High Alert Medication List”; • occurrences in which a patient dies or suffers serious injury as a result of wrong administration technique. <p>This event is not intended to capture:</p> <ul style="list-style-type: none"> • patient death or serious injury associated with allergies that could not reasonably have been known or

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4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>B. Patient death or serious injury associated with unsafe administration of blood products</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facility 		<p>Unsafe administration includes, but is not limited to, hemolytic reactions and administering a) blood or blood products to the wrong patient; b) the wrong type; or c) blood or blood products that have been improperly stored or handled.</p> <p>This event is not intended to capture :</p> <ul style="list-style-type: none"> • patient death or serious injury associated with organ rejection other than those attributable to a hyperacute hemolytic reaction • patient death or injury when cause is not detectable by ABO/HLA matching.
<p>C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers 	<p>Includes events that occur within 42 days post-delivery.</p> <p>Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.</p>	<p>This event is not intended to create a new obligation. The organization's obligation is to report the event when made aware of the maternal death or serious injury either by readmittance or by the patient's family.</p>
<p>D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting</p>	<p>Includes, for the office-based surgery or birthing center setting, unplanned admission to an inpatient setting within 24 hours of delivery</p>	

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4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers 		
<p>E. Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Includes but is not limited to fractures, head injuries, and intracranial hemorrhage</p>	
<p>F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers 	<p>Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission and excludes pressure ulcers that develop in areas where deep tissue injury is documented as present on admission/presentation.</p>	<p>Although this event could occur in the ambulatory surgery environment based on patient condition and surgery time, it will be difficult to discern. Pre- and post- skin assessment will be key.</p>

SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE

4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<ul style="list-style-type: none"> • Long-term Care/ Skilled Nursing Facilities 		
<p>G. Artificial insemination with the wrong donor sperm or wrong egg</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices 		<p>The organization’s obligation is to report the event when made aware of the occurrence.</p>
<p>H. Death or serious injury resulting from the irretrievable loss of a biological specimen.</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	<p>Includes events where specimens are misidentified, where another procedure cannot be done to produce a specimen</p> <p>Includes 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</p>	<p>This event is not intended to capture:</p> <ul style="list-style-type: none"> • procedures where the specimen was properly handled, but the specimen proved to be nondiagnostic. <p>Inability to secure a replacement for a lost specimen can occur with excisional biopsy as well as in organ removal.</p>
<p>I. Death or serious injury resulting from failure to follow up or communicate clinical information.</p>	<p>Includes events where failure to report increased neonatal bilirubin levels result in kernicterus.</p>	<p>Examples of serious injury are a new diagnosis, or an advancing stage of an existing diagnosis (e.g., cancer). Examples of clinical information for which failure to follow up could occur include imaging or laboratory reports, biopsy results, or other test results.</p>

SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE

4. CARE MANAGEMENT EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
Applicable settings: <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		

5. ENVIRONMENTAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting Applicable settings: <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 	Excludes events involving patients during planned treatments such as electric countershock /elective cardioversion.	This event is intended to capture: <ul style="list-style-type: none"> • patient death or injury associated with unintended electric shock during the course of care or treatment; • staff death or injury associated with unintended electric shock while carrying out duties associated with a patient care process, including preparing for care delivery. This event is not intended to capture: <ul style="list-style-type: none"> • patient death or injury associated with emergency defibrillation in ventricular fibrillation or with electroconvulsive therapies; • injury to staff who are not involved in patient care.
B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the		This event is intended to capture: <ul style="list-style-type: none"> • events in which the line is attached to a reservoir distant from the patient care unit or in a tank near the patient such as E-cylinders, anesthesia machines.

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5. ENVIRONMENTAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>wrong gas, or is contaminated by toxic substances</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		
<p>C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		<p>This event is intended to capture burns that result from:</p> <ul style="list-style-type: none"> • operating room flash fires, including second degree burn in these cases; • hot water; • sunburn in the patient with decreased ability to sense pain; • smoking in the patient care environment.

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5. ENVIRONMENTAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		<p>The event is intended to capture:</p> <ul style="list-style-type: none"> • instances where physical restraints are implicated in the death; e.g., lead to strangulation/entrapment, etc. <p>Death/injury resulting from falls caused by lack of restraints would be captured under "falls."</p>

6. RADIOLOGIC EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE

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<p>A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices 	<p>Includes events related to material inside the patient's body or projectiles outside the patient's body.</p>	<p>This event is intended to capture injury or death as a result of projectiles including:</p> <ul style="list-style-type: none"> • retained foreign object • external projectiles • pacemakers
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7. POTENTIAL CRIMINAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • those without licensure to provide the care given; • those with licensure who represent themselves and act beyond the scope of their licensure. <p>It is not intended to capture individuals who are practicing within the scope of their license whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider.</p>

SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE

7. POTENTIAL CRIMINAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>B. Abduction of a patient/resident of any age</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		<p>This event is intended to capture:</p> <ul style="list-style-type: none"> • removal of a patient/resident, who does not have decision-making capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting. <p>Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer's.</p>
<p>C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		<p>Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction.</p>
<p>D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the</p>		<p>Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms "first degree assault" or "second degree assault" or "battery").</p>

SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE

7. POTENTIAL CRIMINAL EVENTS		
EVENT	ADDITIONAL SPECIFICATIONS	IMPLEMENTATION GUIDANCE
<p>grounds of a healthcare setting.</p> <p>Applicable settings:</p> <ul style="list-style-type: none"> • Hospitals • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/ Office-based Practices • Long-term Care/Skilled Nursing Facilities 		

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APPENDIX B

GLOSSARY

The following terms are defined as they apply to the NQF list of serious reportable events. To the extent practicable, they have been harmonized with definitions used in other NQF safety-related products, the Agency for Healthcare Research and Quality's Common Formats, and the World Health Organization's evolving International Classification for Patient Safety. The Common Formats are a product of the requirements of the Patient Safety and Quality Improvement Act of 2005 that provides a structure for reporting adverse events, while the latter provides structure for classifying such events.

- **Abduction** means the taking away of a person by persuasion, by fraud, or by open force or violence. It includes convincing someone, particularly a minor or a woman he/she is better off leaving with the persuader, telling the person he/she is needed, or that the mother or father wants him/her to come with the abductor.
- **Adverse** describes a consequence of care that results in an undesired outcome. It does not address preventability.
- **Associated with** means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation and/or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship.
- **Authorized** means the guardian or other individual(s) having the legally recognized ability to consent on behalf of a minor or incapacitated individual (surrogate), or person designated by the surrogate to release or consent for the patient.
- **Deep tissue injury** presents as a purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear.

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The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

- **Elopement** refers to a situation where a patient or resident who is cognitively, physically, mentally, emotionally, and/or chemically impaired wanders/walks/runs away, escapes, or otherwise leaves a caregiving institution or setting unsupervised, unnoticed, and/or prior to their scheduled discharge.
- **Event** means a discrete, auditable, and clearly defined occurrence.
- **Healthcare setting** means 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. Healthcare settings include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers, office-based practices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, ambulatory surgical centers, and pharmacies. The boundary of a healthcare setting (the “grounds”) is the physical area immediately adjacent to the setting’s main buildings. It does not include nonmedical businesses such as shops and restaurants located close to the setting.
- **High alert medications** are those medications that have a high risk of causing serious injury or death to a patient if they are misused. Examples of high-alert medications include anticoagulants and IV antithrombotics, insulin, cytotoxic chemotherapy, concentrated electrolytes, IV digoxin, opiate narcotics, neuromuscular blocking agents, and adrenergic agonists. A “*High Alert Medication List*” is available at the *Institute for Safe Medication Practices’ website*, <http://www.ismp.org>.
- **Infant** is a child under the age of one year. (SRE 2006; Stedman’s online dictionary)
- **Informed consent** involves a process of shared decisionmaking in which discussion between a person who would receive a treatment, including surgery or invasive

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procedure, and the caregiver/professional person who explains the treatment, provides information about possible benefits and risks, and answers questions that result in the person's authorization or agreement to undergo a specific medical intervention. Documentation of this discussion should result in an accurate and meaningful entry in the patient record, which could include a signed "consent form." Signing a consent form does not constitute informed consent; it provides a record of the discussion.

- **Injury**, as used in this report has a broad meaning. It includes physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term, which may become a disability if extended long term. Further, injury includes a substantial change in the patient's long-term risk status such that care or monitoring, based on accepted national standards, is required that was not required before the event. (*Of note, states and other entities may use alternate definitions for the term "disability."*)
- **Largely preventable** recognizes that some of the events on the SRE list are not universally avoidable, given the complexity of healthcare and current knowledge.
- **Low-risk pregnancy** refers to a woman aged 18-39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.
- **Medical device** is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or

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other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

- **Medication error** means 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, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.
- **Neonate** is a newborn less than 28 days of age.
- **Patient** means a person who is a recipient of healthcare.
- **Pressure Ulcer, Stage 3** is defined as full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, or muscle is not exposed. Some slough may be present. May include undermining and tunneling. The depth of a Stage 3 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and Stage 3 ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Stage 3 pressure ulcers. Bone/tendon is not visible or directly palpable.
- **Pressure Ulcer, Stage 4** is defined as full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present. Often includes undermining and tunneling. The depth of a Stage 4 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue, and these ulcers can be shallow. Stage 4 ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon, or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/tendon is visible or directly palpable.

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- **Pressure Ulcer, Unstageable** is defined as full thickness tissue loss in which the base of the ulcer is completely covered by slough or eschar. Unstageable pressure ulcers will, by definition, be either Stage 3 or Stage 4.
- **Preventable** describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.
- **Restraints** is defined by The Joint Commission, the Centers for Medicare & Medicaid Services, and by some states. The appropriate source(s) should be consulted for the definition required by the setting and/or jurisdiction in which a presumptive event occurs. In the event none of those definitions apply to an institution, the following definition, which is intended to capture definitions from the named organizations, is offered:
Restraints means any method of restricting a patient’s freedom of movement that is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; is not indicated to treat the patient’s medical condition or symptoms; or does not promote the patient’s independent functioning.
- **Serious** describes an event that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction (e.g., higher level of care, surgery).
- **Sexual abuse** is defined as the forcing of unwanted sexual activity by one person on another, as by the use of threats or coercion or sexual activity that is deemed improper or harmful, as between an adult and a minor or with a person of diminished mental capacity.
- **Surgery** is an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. Surgeries include a range of procedures from minimally

invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multiorgan transplantation. It does not include use of such things as otoscopes and drawing blood. *Organizations may choose to adopt a list of surgical procedures to supplement the definition above; one example of such a list in common use is that of the Institute of Clinical Systems Improvement.*

- **Surgery begins**, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs.
- **Surgery ends** after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room.
- **Unambiguous** refers to an event that is clearly defined and easily identified.
- **Unintended retention** of a foreign object refers to 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 surgeon or other practitioner did not intend to leave in the body.

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APPENDIX C STEERING COMMITTEE, TECHNICAL ADVISORY PANELS, AND NQF STAFF

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