NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #: NQF Project:**

(for NQF staff use**) Has all requested information been provided? Yes**
Staff Notes to Submitter (*if submission returned*)**:**

Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**

Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM
Organization: Pennsylvania Patient Safety Authority
Street Address: 5200 Butler Pike
City/State/Zip: Plymouth Meeting, PA 19462
Telephone Number: 610-825-6000 x5040
Fax Number: 610-834-1275
Email Address: clacker@ecri.org

Date of Submission (*MM/DD/YY*)**: 06/16/2010**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event:
Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☒ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home

☒ Outpatient or Office-based Surgery Center ☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION
Submitter: Julie Apold **Organization:** Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations. **Street Address:** 2550 University Avenue W. Suite 350S **City/State/Zip:** Saint Paul, MN 55114 **Telephone Number:** 651-641-1121 **Fax Number:** 651-659-1477 **Email Address:** **japold@mnhospitals.org**
Date of Submission (*MM/DD/YY*)**: 6/16/10** **Is this submission about a currently endorsed SRE or a proposed new SRE?** ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event: Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility.	
Suggested Change: ☒ **Specify the Applicable Care Setting(s) marked below** ☐ **Remove Endorsement** ☐ **Modify SRE Specifications** **Describe Suggested Modification(s) in specific detail:** **Rationale for removing endorsement or modifying the SRE** *(include pertinent evidence, data)***:** **If modifications are made,** *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:** (for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)*	**Y**☐ **N**☐
Applicable Care Settings (Mark all to which event is relevant) ☒ Hospital ☒ Skilled Nursing Facility (SNF) / Nursing home ☒ Outpatient or Office-based Surgery Center	

☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.
Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Erin Graydon Baker
Organization: Partners Healthcare
Street Address: 115 4th Ave
City/State/Zip: Needham/MA/02494
Telephone Number: 781-433-3776
Fax Number: 781-433-3667
Email Address: egraydonbaker@partners.org

Date of Submission (*MM/DD/YY*)**: 06/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? x☐ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Serious disability associated with the use of contaminated drugs, devices, biologics..

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
x☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Re-define serious disability as" injury requiring extended hospitalization, prolonged loss of function (affecting the ability to perform activities of daily living) for at least 30 days".

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:** The current definition for serious disability leads to subjective interpretation.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* **x**☐ Yes ☐ No **If yes, please explain:** We err on the conservative side due to the current working definition but with exact criteria , we may see a small decrease in reporting.

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?) Yes*

Y☐
N☐

Applicable Care Settings (Mark all to which event is relevant)

x☐ Hospital x☐ Skilled Nursing Facility (SNF) / Nursing home x☐ Outpatient or Office-based Surgery Center x☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.* More accurate representation of SRE	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐

Describe why the event is important for public credibility or accountability: Y☐ N☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Y☐ N☐ A☐
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

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Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #: NQF Project:**

(for NQF staff use**) Has all requested information been provided? Yes**
Staff Notes to Submitter (*if submission returned*)**:**

Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**

Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM
Organization: Pennsylvania Patient Safety Authority
Street Address: 5200 Butler Pike
City/State/Zip: Plymouth Meeting, PA 19462
Telephone Number: 610-825-6000 x5040
Fax Number: 610-834-1275
Email Address: clacker@ecri.org

Date of Submission (*MM/DD/YY*)**: 06/16/2010**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event:
Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☒ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home

☒ Outpatient or Office-based Surgery Center ☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
OrganizationMinnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
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Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended.

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☒ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:
Modify wording to "…associated with the improper or inappropriate use of a device in patient care" and/or consider one or more separate categories of device-related events:

1. Associated with use of a device other than as intended or used for a purpose inconsistent with standard of care
2. Using a device incorrectly
3. Improper functioning of a device.

The primary purpose of this category needs to be determined and clearly stated.

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:** This category can take on many meanings. What we have debated and struggled with is whether it is intended to capture clearly using a device other than as intended (using a urinary catheter as a chest tube) or the

Y☐
N☐

improper use of a device (placing a feeding tube in the lung through improper technique). Additional clarification would be appreciated.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☒ Yes ☐ No **If yes, please explain:** Would capture more events if the category included improper use of a device.

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* *Yes*

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
☒ Ambulatory Practice / Physician Offices
☐ Other (*Please specify*):

Reviewer Comments/Rationale:

2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee:
Do you recommend the proposed change? ☐ **Y** ☐ **N** ☐ **A**
Do you recommend the proposed change with modification? ☐ Specify the modification

Comments/Rationale:

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable , and clearly defined occurrence **Y** ☐ **N** ☐
Name of Proposed New Event:

3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS

Brief Description of Event:

The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Y** ☐ **N** ☐

Briefly summarize the Evidence Base that the event is preventable and provide citations:

The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* **Y** ☐ **N** ☐
Please check the appropriate consequence and describe it
☐ Death or ☐ risk of death
☐ Loss of a body part or ☐ risk of loss **Describe:**
☐ Disability or ☐ risk of disability **Describe:**
☐ Loss of bodily function or ☐ risk of loss **Describe:**

The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Y** ☐ **N** ☐
Definitions:
Codes and descriptors (if used):
Instructions for counting events, calculating rates, and providing context for low frequency:

Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)* — Y☐ N☐

Describe how the event is indicative of a problem in a healthcare facility's safety systems: — Y☐ N☐

Describe why the event is important for public credibility or accountability: — Y☐ N☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Y☐ N☐ A☐
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS	
(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**	
National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse	
IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness	
Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy	
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Margaret Driscoll
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Date of Submission (*MM/DD/YY*)**: 06/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient Death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☒ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Include exclusions or exclusionary language addressing off-label device use for the pediatric population.

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:** The efficacy of many medical devices used in pediatric patients has not been studied or approved for use in children. Off-label use of medical devices is frequently the norm versus the exception in pediatrics, including our surgical subspecialties. For example multiple procedures performed in interventional cardiology and interventional radiology. The blanket nature of this standard does not adequately account for the practical limitations inherent in caring for children.

Y☐
N☐

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☒ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)*
Yes

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☐ Outpatient or Office-based Surgery Center
☐ Ambulatory Practice / Physician Offices
☐ Other (*Please specify*):

Reviewer Comments/Rationale:

2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered: Off-label device use in the pediatric population may preclude innovation or life saving procedures in patients where alternative treatment options are not available.

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures —N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee:
Do you recommend the proposed change? ☐
Do you recommend the proposed change with modification? ☐ Specify the modification

Comments/Rationale:

Y☐ **N**☐ **A**☐

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable , and clearly defined occurrence **Y**☐ **N**☐
Name of Proposed New Event:

3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS

Brief Description of Event:

The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Y**☐ **N**☐

Briefly summarize the Evidence Base that the event is preventable and provide citations:

The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* **Y**☐ **N**☐
Please check the appropriate consequence and describe it
☐ Death or ☐ risk of death
☐ Loss of a body part or ☐ risk of loss **Describe:**
☐ Disability or ☐ risk of disability **Describe:**
☐ Loss of bodily function or ☐ risk of loss **Describe:**

The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Y**☐ **N**☐
Definitions:
Codes and descriptors (if used):
Instructions for counting events, calculating rates, and providing context for low frequency:

Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)* — Y☐ N☐

Describe how the event is indicative of a problem in a healthcare facility's safety systems: — Y☐ N☐

Describe why the event is important for public credibility or accountability: — Y☐ N☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Y☐ N☐ A☐
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS	
(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**	
National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse	
IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness	
Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy	
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.
Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Erin Graydon Baker
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Date of Submission (*MM/DD/YY*)**: 06/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? x☐ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Device in Patient Care in Which the Device is Used Other than Intended..

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
x☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Re-define serious disability as" injury requiring extended hospitalization, prolonged loss of function (affecting the ability to perform activities of daily living) for at least 30 days". Change the definition to read "Death or serious disability caused by a device that functions other than intended". Add central monitoring to the list of included devices.

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:** The current definition for serious disability leads to subjective interpretation. There are many instances of devices that are used for purposes different than intended (life saving efforts, research) where the patient might die not due to the device but due to condition.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes x☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y☐ N☐**

Yes	
Applicable Care Settings (Mark all to which event is relevant) x☐ Hospital x☐ Skilled Nursing Facility (SNF) / Nursing home x☐ Outpatient or Office-based Surgery Center x☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.* More accurate representation of SRE	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐

Describe how the event is indicative of a problem in a healthcare facility's safety systems: Y☐ N☐

Describe why the event is important for public credibility or accountability: Y☐ N☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Y☐ N☐ A☐
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness **Consumer Care Need** ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy	
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #: NQF Project:**

(for NQF staff use**) Has all requested information been provided? Yes**
Staff Notes to Submitter (*if submission returned*)**:**

Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**

Staff Reviewer Name(s):

1. CONTACT INFORMATION

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Date of Submission (*MM/DD/YY*)**: 06/16/2010**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event:
Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y☒ N☐**

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home

☒ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION
Submitter: Julie Apold **Organization:** Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations. **Street Address:** 2550 University Avenue W Suite 350S **City/State/Zip:** Saint Paul, MN 55114 **Telephone Number:** 651-641-1121 **Fax Number:** 651-659-1477 **Email Address:** **japold@mnhospitals.org**
Date of Submission (*MM/DD/YY*)**: 6/16/10** **Is this submission about a currently endorsed SRE or a proposed new SRE?** ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event: Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	
Suggested Change: ☒ **Specify the Applicable Care Setting(s) marked below** ☐ **Remove Endorsement** ☐ **Modify SRE Specifications** **Describe Suggested Modification(s) in specific detail:** **Rationale for removing endorsement or modifying the SRE** *(include pertinent evidence, data)***:** **If modifications are made,** *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☒ No **If yes, please explain:** (for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?) Yes*	**Y**☐ **N**☐
Applicable Care Settings (Mark all to which event is relevant) ☒ Hospital ☒ Skilled Nursing Facility (SNF) / Nursing home	

☒ Outpatient or Office-based Surgery Center ☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #: NQF Project:**

(for NQF staff use**) Has all requested information been provided? Yes**
Staff Notes to Submitter (*if submission returned*)**:**

Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**

Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Margaret Driscoll
Organization: Children's Hospital Boston
Street Address: 300 Longwood Avenue
City/State/Zip: Boston, MA 02115
Telephone Number: 617-355-7359
Fax Number: 617-730-0637
Email Address: Margaret.driscoll@childrens.harvard.edu

Date of Submission (*MM/DD/YY*)**: 06/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient Death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☒ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Include exclusions or exclusionary language for pediatric patients with congenital heart disease, patients receiving ECMO and pediatric patients undergoing or cranial vault reconstruction.

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**
Related to Cardiac Patients: First, children with congenital heart disease often have sizable intracardiac shunts and thus would be at increased risk for neurological injury from air embolism that otherwise would not be harmful for patients without structural heart defects. Thus, patients with congenital heart disease should be excluded. Second, in our experience, we believe that assigning attributability of death or serious harm in patients who have had suspected intravascular air embolism may be quite difficult given that many of these patients have had open heart surgery requiring deep hypothermic circulatory arrest or have experienced periods of

Y☐
N☐

cardiopulmonary resuscitation. It is often difficult to determine the primary ideology of central nervous system injury in such patients. Thus a temporal association of air embolism does not prove causality in many patients.

Related to use of ECMO: Patients who require the use of mechanical support devices such as extracorporeal membrane oxygenation (ECMO) are at increased risk for complications related to intravascular air embolism. Nearly a third of the patients who receive ECMO within our institution have this life saving procedure initiated during cardiopulmonary resuscitation ("rapid response ECMO"). Although every effort is made to prevent air embolism during this procedure, given the urgency with which rapid response ECMO is performed, we believe that these patients should also be excluded.

Related to Neurosurgical procedures: There is a known risk of death or serious disability associated with intravascular air embolism during neurosurgical procedures. Included in the exclusion categories should be any infant or child undergoing neurosurgical procedures, craniosynostosis repair or cranial vault reconstruction.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☒ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* *Yes*

Applicable Care Settings (Mark all to which event is relevant)
- ☒ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please specify*):

Reviewer Comments/Rationale:

2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered: In conclusion, we do not regard intravascular air embolism to be always be preventable or an unexpected complication in children with congenital heart disease or in patients who require emergent and life sustaining use of ECMO.

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures N/A

Reviewer Comments:

RECOMMENDATION

Steering Committee:
Do you recommend the proposed change? ☐ **Y** ☐ **N** ☐ **A**
Do you recommend the proposed change with modification? ☐ Specify the modification

Comments/Rationale:

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable , and clearly defined occurrence **Y** ☐ **N** ☐
Name of Proposed New Event:

3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3d. SETTINGS, DATA SOURCES	
Applicable Care Settings (Mark all to which event is relevant) ☐ Hospital ☐ Skilled Nursing Facility (SNF) / Nursing home ☐ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please describe*):	
Data Source *Check the source(s) for the information on the SRE.* ☐ Electronic administrative data/ claims ☐ Electronic Clinical Data *(e.g., MDS)* ☐ Incident Reports ☐ Medical Record including Electronic ☐ Pharmacy data ☐ Public health data/vital statistics ☐ Quality / Risk Management Databases ☐ Registry data (or database) ☐ Reports to External Bodies (states, federal) ☐ Regulatory or Accreditation data (FDA, OSHA, etc.) ☐ Special or unique data, specify: **Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:** **Data dictionary/code table attached** ☐ **OR at web page URL:**	
Process(es) to Collect Data	

Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible.	
Reviewer Comments/Rationale:	
3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend for endorsement? **Comments/Rationale:**	**Y** ☐ **N** ☐ **A** ☐
Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).** **National Priority Partners Priority Area** ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse **IOM Quality Domain** ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness **Consumer Care Need** ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy	
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	