Policy:	**Serious Reportable Events Reporting Policy**		
Originating Branch:	**Quality & Patient Safety**		
Original Approval Date:	12/13/2012	***Effective Date:***	12/22/2013 Revised 02/01/2021
Approved By:	**Deputy Minister Health and Wellness**		

Version:2

1. POLICY STATEMENT

1.1 This policy aims to inform the Department of Health and Wellness (DHW) of current risks to patient safety and quality issues facing the health system by requiring the Nova Scotia Health Authority (NSHA) and the Izaak Walton Killam Health Centre (IWK) to report Serious Reportable Events (SREs) (as defined in this policy) in a timely and standardized manner.

1.2 The duties and powers for the development of this policy are derived from the *Health Authorities Act* and the *Quality-improvement Information Protection Act* (QIIPA).

- As per section 6 of the *Health Authorities Act,* the Minister has the authority to set the strategic direction of the health system; establish policies, standards and guidelines for the provision and administration of health services and establish informational requirements and standards for health-information systems. As per section 8, the Minister has the authority to ensure accountability for monitoring, measuring, and evaluating the quality, efficiency, accessibility, and comprehensiveness of health services delivered by the NSHA/IWK.
- As per the *Quality-improvement Information Protection Act*, section 4, the Minister may direct a quality-improvement committee (of the NSHA and/or IWK) to provide to the Minister such quality-improvement information that does not include personal health information or personal information and recommendations that do not include personal health information or personal information, as the Minister directs, in any form the Minister directs, for the purposes of planning and managing the health system or conducting province-wide quality-improvement activities.

2. DEFINITIONS

2.1 **Disability:** A physical or mental impairment that substantially limits one or more of the major life activities of an individual.
2.2 **Patient:** An individual who receives services or support from health care providers who are employed by or privileged to NSHA/IWK. For the purpose of this policy, the term also includes those referred to as clients and/or residents.
2.3 **Patient Safety Incident:** An event or circumstance that could have resulted or did result in unnecessary harm to a patient.
2.4 **Quality Improvement Activity:** As defined in the *Quality-improvement Information Protection Act*, it means an activity of a quality improvement committee or any other activity that is part of a program or plan
    (i) approved by a health authority, the Minister or an entity referred to in clause 3(1)(c), and
    (ii) implemented for the purpose of assessing, investigating, evaluating or making recommendations respecting the provision of health services by a health authority, the Minister or an entity referred to in clause 3(1)(c), with a view to maintaining or improving the quality of health services
2.5 **Quality Improvement Committee:** A committee established to carry out quality improvement activities.
2.6 **Quality Improvement Information:** Information in any form that is communicated for the purpose of or created in the course of carrying out a quality improvement activity.
2.7 **Quality Review Recommendations:** For the purpose of this policy, Quality Review recommendations refer to recommendations arising out of the review of a Serious Reportable Event by a Quality Improvement Committee of the NSHA / IWK. The recommendations do not include personal health information as defined in the Personal Health Information Act or personal information related to an individual's role within the health authority as defined in the Freedom of Information and Protection of Privacy Act.
2.8 **Quarterly Reporting:** For the purpose of this policy, quarterly reporting refers to reporting on fiscal year quarters (Q1: April – June, Q2: July – September, Q3: October – December and Q4: January – March).
2.9 **Serious Reportable Events:** A subset of Patient Safety Incidents reportable to the Department of Health and Wellness, as outlined in Appendix A. These events are adopted from Saskatchewan's Critical Incident Reporting Guidelines (2004).

3. POLICY OBJECTIVES

3.1 Provide a standardized reporting process for SREs from NSHA / IWK to the DHW.
3.2 Enhance communication between NSHA / IWK and the DHW regarding SREs including the response to these events in a timely and consistent manner.
3.3 Allow the NSHA / IWK and the DHW to collaboratively monitor, measure and evaluate SRE data.
3.4 Enhance collaboration between NSHA / IWK and the DHW for the purpose of identifying opportunities for coordinated province-wide, preventative and proactive improvements to the health care system through the analysis of SRE data.
3.5 Improve NSHA / IWK / DHW accountability and transparency of SRE reporting in the Nova Scotia health care system.
3.6 Ensure DHW oversight of SREs and maintain public trust in the health care system.

4. APPLICATION

4.1 This policy applies to DHW, NSHA and IWK.

4.2 This policy does not apply to continuing care service providers including licensed nursing homes, resident care facilities, or funded and approved Home Care Agencies or Home Oxygen Vendors. These facilities will continue their current reporting practices to the Continuing Care branch at DHW. Any events that fall under the jurisdiction of the *Protection for Persons in Care Act* will continue to be reported as per established processes.

4.3 This policy does not remove the obligation of the NSHA / IWK to follow existing processes to notify the Chief Medical Officer of Health pursuant to the requirements of the *Health Protection Act,* to report disaster management events through the Emergency Response System, to report incidents pursuant to the requirements under the *Protection for Persons in Care Act*, or replace any other DHW policy which may require specific reporting to the DHW Duty Officer / Administration.

5. POLICY DIRECTIVES

5.1 This policy will require two streams of reporting of SREs to the DHW.

5.1.1. Telephone notification of a specific subset of SREs (as outlined in sections 5.2 to 5.5 below) and

5.1.2. Aggregate quarterly reporting of SREs (as outlined in sections 5.6 to 5.11 below).

Telephone Notification of Specific Subset of SREs (see Appendix B)

5.2 The NSHA / IWK shall notify the DHW Duty Officer by telephone to 1-877-408-4394, option 1, as soon as reasonably practical, of all SREs which meet any one of the following criteria:

- Involve multi-person disclosure that may have significant system-wide or cross jurisdictional implications; or
- Are perceived as a threat to the safety of the public; or
- Have the potential to undermine public confidence in the health system.

5.3 The NSHA / IWK shall communicate only factual details of the SRE, without disclosing personal identifying information of patients or providers. The following information shall be provided and will be documented by the DHW Duty Officer:

5.3.1 Name of caller
5.3.2 Health Authority (NSHA or IWK) and Zone (if applicable)
5.3.3 Location of the event (geographic)
5.3.4 Applicable Service / Care Area (such as Emergency Room, Surgical Unit etc)
5.3.5 Date of the event
5.3.6 Time of the event
5.3.7 Nature of the event limited to the provision of the category of the incident from the DHW / NSHA / IWK list of SREs (see Appendix A)
5.3.8 Type of persons involved in the incident (staff, patient, others)
5.3.9 Who has been notified within the Health Authority
5.3.10 Whether the requirements of the NSHA / IWK's policy(s) in relation to disclosure of the event have been met (has the information been shared with the patient/family)
5.3.11 Contact Information for follow-up if needed.

5.4 The Duty Officer will document all incoming calls (See Appendix B) and use the information received to inform the:

- Deputy Minister
- Executive Member on Call
- Senior Executive Director Quality & Patient Safety
- Senior Executive Director/Executive Director for impacted Branch
- DHW Communications Officer on Call

The DHW Duty Officer will use their judgement regarding method of above communication (telephone, email, text message)

5.5 The DHW shall provide support (as necessary) to the NSHA/IWK throughout the health authority's investigation of the event. The DHW and the NSHA / IWK shall work collaboratively to coordinate their respective communications in relation to responding to the SRE, as necessary.

Aggregate Quarterly Reporting of SREs

5.6 The NSHA / IWK shall report quarterly, to the DHW, the aggregate number of events for each event type as defined in the DHW / NSHA / IWK List of SREs (See Appendix A)

5.7 The validated quarterly reports of SREs shall be submitted via Secure File Transfer to the DHW no later than 20 business days after the end of each fiscal quarter.

5.8 An SRE is to be part of the quarterly report provided for the quarter in which it is discovered. SREs newly discovered from past reporting quarters will be reported in the quarter they are discovered but will be identified or noted separately as having occurred in an earlier quarter.

5.9 DHW shall publicly report on SREs on the DHW website no later than 35 business days after the end of a fiscal quarter.

5.10 Quarterly reports to the DHW and publicly posted information will not be retroactively changed.

Submission of Quality Review Recommendations

5.11 Pursuant to Section 4 of the *Quality-improvement Information Protection Act*, the NSHA/IWK shall submit to DHW all Quality Review recommendations, that do not include personal health information or personal information, arising out of the review of an SRE by a Quality Improvement Committee of the NSHA /IWK.

5.12 The Quality Review recommendations will be submitted to the Senior Executive Director, Quality and Patient Safety, within 20 business days after a review is completed.

Analysis and Sharing Lessons Learned

5.13 The NSHA/IWK/DHW will collate, analyse, and provide information regarding trends in the SRE data and quality review recommendations to:

- Identify any areas of high risk to patient safety which may extend beyond the health authority which has experienced the event(s).
- Explore opportunities for greater implementation of preventative practices and quality review recommendations on a province-wide basis; and
- Share, subject to the any applicable legislation or policies, lessons learned and aggregate data with other health systems stakeholders.

6. POLICY GUIDELINES

6.1 The NSHA / IWK will continue to manage SREs according to their own policies and procedures.

6.2 The NSHA/IWK/DHW shall ensure that their staff are trained and knowledgeable about this policy.

7. ACCOUNTABILITY

7.1 For the purpose of the administration of this policy, accountability is delegated to the Deputy Minister of Health and Wellness.

7.2 The Senior Executive Director of Quality and Patient Safety has responsibility for ongoing monitoring and enforcement of this policy.

8. MONITORING / OUTCOME MEASUREMENT

8.1 The Senior Executive Director of Quality and Patient Safety will monitor the implementation, performance and effectiveness of this policy.

9. REPORTS

9.1 NSHA / IWK will submit aggregate quarterly reports and quality review recommendations as directed in Section 5 of this policy.

10. REFERENCES

10.1 Disclosure of Adverse Events Policy, 2005
10.2 *Health Protection Act* 2004 (amended 2010)
10.3 *Protection for Persons in Care Act* (2007)
10.4 Saskatchewan Health Critical Incident Reporting Guidelines, 2004
10.5 Critical Incident Report Policy
10.6 *Health Authorities Act,* 2014
10.7 *Quality Improvement Information Protection Act*, 2015
10.8 Canadian Patient Safety Institute (2012) Critical Incident Analysis Framework
10.9 Canadian Patient Safety Institute (2015) Never Events for Hospital Care in Canada
10.10 National Quality Forum (2011). Serious Reportable Events in Healthcare – 2011

11. APPENDICES

11.1 *Appendix* A: DHW / NSHA / IWK List of Serious Reportable Events
11.2 *Appendix* B: Telephone Notification Algorithm

12. VERSION CONTROL

Version _____:	Department of Health and Wellness Serious Reportable Event Interim Reporting Policy Version 1.0, Dec. 13, 2013 REVISED FEBRUARY 1, 2021

13. INQUIRIES

13.1 Inquiries regarding this policy should be directed to:

Ruby Knowles
Senior Executive Director
Quality and Patient Safety Branch
Nova Scotia Department of Health & Wellness
Tel: 902-424-3221
Email: Ruby.Knowles@novascotia.ca

APPENDIX A

DHW / NSHA / IWK List of Serious Reportable Events

The following is a list of Serious Reportable Events that must be reported to the Nova Scotia Department of Health & Wellness pursuant to the Serious Reportable Events Reporting Policy.

The final item in each category allows for the possibility of SREs that were not anticipated when the list was created.

1. SURGICAL EVENTS

Surgery includes endoscopies and other major invasive procedures

a. Surgery performed on a wrong body part
Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.

b. Surgery performed on the wrong patient.
Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

c. The wrong surgical procedure performed on a patient
Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.

d. Retention of a foreign object in a patient after surgery or other procedure
Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.

e. Death during or immediately after surgery of an ASA Class I or II patient[1]
Includes procedures where anesthesia was administered; the planned surgical procedures may or may not have been carried out. Immediately after surgery means within 24 hours of surgery or other invasive procedure, or if surgery was not completed, within 24 hours of induction of anesthesia.

f. A patient safety incident leading to death or serious disability associated with any other surgical event while a patient is receiving a health care service provided by the NSHA/IWK.

2. PRODUCT OR DEVICE EVENTS

[1] ASA Classification I- Normal healthy patient, II-A patient with mild systemic disease. Canadian Anesthesiologists' Society. Appendix II: American society of Anesthesiologists Classification of Physical Status.

a. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the NSHA/IWK.
Includes generally detectable contaminants such as infectious matter or foreign substances in drugs, devices, or biologics regardless of the source of contamination and/or product

b. 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
Includes, but is not limited to catheters, drains, and other specialized tubes, infusion pumps, ventilators, and mechanical devices used to lift, bathe or shower patients

c. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by NSHA/IWK.
Excludes deaths associated with neurosurgical procedures known to present a high risk of intravenous air embolism.

d. A Patient Safety Incident leading to death or serious disability associated with any other product or device while a patient is receiving a health care service provided by the NSHA/IWK.

3. PATIENT PROTECTION EVENTS

a. An infant discharged to the wrong person.

b. Patient death or serious disability associated with patient disappearance
Excludes events involving competent adults

c. Patient suicide or attempted suicide resulting in serious disability while being cared for by NSHA/IWK.
Defined as events that result from patient actions after admission to a facility or program of the NSHA/IWK. Excludes deaths resulting from self- inflicted injuries that were the reason for admission to a hospital.

d. A Patient Safety Incident leading to death or serious disability associated with any other patient protection event while a patient is receiving a health care service provided by NSHA/IWK.

4. CARE MANAGEMENT EVENTS

a. Patient death or serious disability associated with a medication or fluid error including but not limited to errors involving the wrong drug, wrong dose, wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration
Excludes reasonable differences in clinical judgment on drug selection and dose.

b. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

c. Maternal death or serious disability while being cared for by NSHA/IWK.
Includes events that occur within 42 days post-delivery.

d. Full-term fetal or neonatal death or serious disability associated with labour or delivery while being cared for by NSHA/IWK.
Full-term fetus is >37 completed weeks gestation. Neonate refers to the first 28 days of life. Includes failure to screen for and prevent neonatal post-discharge dehydration of illness related to phenylketonuria.

e. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for by NSHA/IWK.

f. Neonatal death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia.
Hyperbilirubinemia is defined as bilirubin levels>500 mol/L. Neonate refers to the first 28 days of life.

g. Stage 3 or 4 pressure ulcers acquired after admission to a facility of the NSHA/IWK.
Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

h. Patient Safety Incident, related to diagnosis, where the treatment provided or not provided leads to patient death or serious disability.

i. A patient Safety Incident leading to death or serious disability associated with any other care management event while a patient is receiving a health care service provided by NSHA/IWK.

5. ENVIRONMENTAL EVENTS

a. Patient death or serious disability associated with electric shock while being cared for by the NSHA/IWK.
Excludes events involving planned treatments such as electric countershock.

b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.

c. Patient death or serious disability associated with a burn incurred from any source while being cared for by the NSHA/IWK.

d. Patient death associated with a fall while being cared for by the NSHA/IWK.

e. Patient death or serious disability associated with the use or lack of restraints or bedrails while being cared for in a facility.

f. A patient safety Incident leading to death or serious disability associated with any other environmental event while a patient is receiving health care service provided by the NSHA/IWK.

6. CRIMINAL EVENTS

a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other health care provider.

b. Abduction of a patient of any age.

c. Sexual abuse/assault of a patient that occurs on grounds owned or controlled by the NSHA/IWK.

d. Patient death or serious disability from a physical assault that occurs on grounds owned or controlled by the NSHA/IWK.

e. Any sexual or physical assault of a patient perpetrated by an employee, member of the medical staff, volunteer, student, or an individual under contract with the NSHA/IWK. Includes, but is not limited to, assaults perpetrated at a patient's home while receiving home care or mental health services.

f. A Patient Safety Incident leading to death or serious disability associated with any other criminal event while a patient is receiving a health care service provided by NSHA/IWK.

APPENDIX B:

Telephone Notification Algorithm

Process for NSHA / IWK

NSHA/IWK will adhere to the following process:

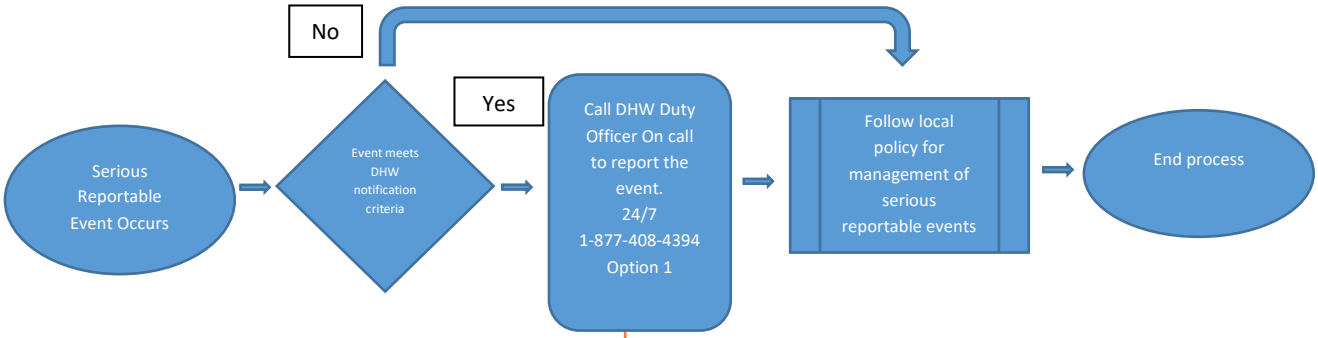

Table 1

Be prepared to provide the following:

1.1.1. Name of caller
1.1.2. Health Authority (NSHA or IWK) and Zone (if applicable)
1.1.3. Location of the Event(geographical)
1.1.4. Applicable service/Care Area (such as Emergency Room, Surgical Unit etc)
1.1.5. Date of the event
1.1.6. Time of the event
1.1.7. Nature of the event, limited to the provision of the category of the incident from the DHW/NSHA/IWK List of Serious Reportable Events in Appendix A
1.1.8. Type of persons involved in the incident (staff, patient, others)
1.1.9. Who has been notified within the Health Authority?
1.1.10. Whether the requirements of the NSHA or IWK's policy(s)in relation to disclosure of the event have been met (i.e., if the information been shared with the patient/family)
1.1.11. Contact Information for follow-up if needed.

Process for DHW

The Duty Officer will document all incoming calls and use the information received to inform the:

- Deputy Minister
- Executive Member on Call
- Senior Executive Director Quality & Patient Safety
- Senior Executive Director/Executive Director for impacted Branch
- DHW Communications Officer on Call

The DHW Duty Officer will use their judgement regarding method of above communication (telephone, email, text message)