Definitions:

"Adverse event" means any unintended or unexpected event, accident, malfunction injury or malfunction that occurs at the hospital.

"Serious Reportable Events (SREs)" are the most serious adverse events and/or unexpected occurrences involving death or serious physical or psychological injury, or risk thereof including, but not limited to: untimely or unexpected patient death, an event that results in death or serious disability, rape, elopement that results in injury, intentional unsafe acts. SREs include the list, as amended from time to time, of serious "never" events compiled by the National Quality Forum (NQF) and available on their website at www.qualityforum.org. Serious Reportable Events are required to be reported to Patient Safety Surveillance and Improvement System (PSSIS) of the Vermont Department of Health and may be required to be reported to other authorities. Deaths associated with the use of seclusion or restraint must be reported to CMS as indicated in § IV(2)(d) below.

"**Causal analysis"** means a formal root cause analysis, similar analytic methodologies or any similarly effective but simplified processes that use a systematic approach to identify the basic or causal factors that underlie the occurrence or possible occurrence of a reportable adverse event, adverse event, or near miss.

"Corrective action plan" means a plan to implement strategies intended to eliminate or significantly reduce the risk of recurrence of an adverse event and to measure the effectiveness of such strategies.

"Intentional unsafe act" means an adverse event or near miss that results from: (A) a criminal act; (B) a purposefully unsafe act; (C) alcohol or substance abuse; or (D) patient abuse **and** that meets the criteria in this policy (see section IV. 4)).

"Near miss" means any process variation that did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.

"Serious bodily injury" means bodily injury that create a substantial risk of death or that causes substantial loss or impairment of the function of any bodily member or organ or substantial impairment of health or substantial disfigurement.

"Vermont Department of Health (VDH) Patient Safety Surveillance and Improvement System (PSSIS)" means the program at the Vermont Department of Health that monitors hospitals' patient safety programs.

CONSIDERATIONS/REQUIRED STEPS:

1) **Review of all event reports.** On a regular basis, Quality Management shall:

   a) Receive and review all reports made through the event reporting system.

   b) In collaboration with Nursing Administration and other operational leaders as indicated, ensure that the appropriate level of review and investigation has been completed.

   c) Ensure that the proper external reports are filed in a timely manner. See below for instruction on external reporting of **serious reportable events** and **intentional unsafe acts.**

2) **Continuous quality improvement**. Quality Management shall:

   a) Identify patterns and trends through compilation and analysis of event report data, and on a regular basis, provide that information to clinical and administrative leaders.

   b) In collaboration with clinical and administrative leaders:

   - review patterns and trends to identify opportunities for performance improvement.
   - Develop and implement corrective actions plans that address both human and systemic factors that contributed to adverse events.

   c) Ensure that outcome(s) of performance improvement initiative(s) are reported to appropriate leadership and quality committees.

3) **Reportable Adverse Events**

   a) Conduct causal analyses on each serious reportable event. Quality Management shall be responsible for conducting a casual analysis on each reportable adverse event. A causal analysis shall include, at a minimum:
      i) Interdisciplinary participation including individuals closely involved in the processes and systems under review.
      ii) A detailed description of the reportable adverse event including date, day of week, time and location and services involved and chronology of events.
      iii) A primary focus on systems and processes rather than individual performance.
      iv) A systematic and comprehensive assessment of factors contributing to the reportable adverse event, as applicable to the specific event.
      v) Consideration of literature relevant to the specific reportable adverse event.

   b) Develop and implement a corrective action plan for each serious reportable event.
      i) Quality Management shall be responsible for developing and ensuring the implementation of a corrective action plan on each reportable adverse event. A corrective action plan shall include, at a minimum:
         (1) Specific actions to correct the identified causes of the event to prevent a similar event occurring in the future.
         (2) Identified and measurable outcome(s).

(3) A specific implementation plan, including completion dates and provisions for education of and communication with appropriate hospital staff and a description of how the corrective action plan will be assessed and evaluated following full implementation.
(4) A designated person(s) responsible for implementation and evaluation.

c) Serious reportable events to VDH Patient Safety Surveillance and Improvement System.

i) **Initial Report.** Quality Management shall be responsible for submitting an initial report to the VDH PSSIS as soon as reasonably possible and no later than seven (7) calendar days after the discovery or recognition of a reportable adverse event.
ii) **Casual analysis and corrective action plan.** Quality Management shall re responsible for ensuring that each causal analysis and corrective action plan related to a reportable adverse event is submitted to VDH PSSIS no later than sixty (60) calendar days from the submission of the initial report.
iii) Reports to PSSIS shall be on approved forms and shall not include the names of individuals involved in any adverse event.

d) Reporting deaths associated with the use of seclusion or restraint to CMS.

i) **Deaths requiring a report.** VPCH must report the following information to CMS:
(1) Each death that occurs while a patient is in seclusion or restraint.
(2) Each death that occurs within 24 hours after the patient has been released from seclusion or restraint.
(3) Each death known to the hospital that occurs within 1 week after seclusion or restraint where it is reasonable to assume that the use of seclusion or restraint contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time. Or death related to chest compression, restriction of breathing or asphyxiation.
ii) Each death requiring a report must be reported to CMS by telephone no later that the close of business the next business day following knowledge of the patient's death.
iii) The date and time the death was reported to CMS must be documented in the patient's medical record.

4) Intentional Unsafe Acts

a) An intentional unsafe act is an act or omission by hospital staff resulting in an adverse event or near miss **only if all of the following criteria are met**:

i) The act or omission was directly associated with patient care or services,
ii) The act or omission affected or could have affected a patient or patients, regardless of whether an actual patient injury occurred, and
iii) The information available to the hospital supports a reasonable, good faith belief that the adverse event or near miss resulted from one or more of the following:
(1) The act or omission was a criminal act, including circumstances where there may have been an intent to harm; or
(2) The act or omission was **purposefully unsafe** as defined below

(3) The act or omission took place while the individual involved was under the influence of alcohol or other substances; or

(4) The act or omission was of a type or nature that Vermont law makes reportable to a designated department or agency as abuse, neglect or exploitation.

b) An act or omission by hospital staff resulting in an adverse event or near miss shall be considered to be purposefully unsafe it **only if meets all of the following criteria:**

i) There was a conscious act or omission or reckless behavior,

ii) The adverse event or near miss did not happen as a result of understandable accident or inadvertence,

iii) No reasonable person with similar qualifications, training and experience would have acted the same way under similar circumstances; and

iv) There were no extenuating circumstances that could justify the act or omission.

c) Reporting Intentional Unsafe Acts

i) VPCH shall report an intentional unsafe act to the VDH PSSIS as soon as reasonably possible, but no later than seven (7) calendar days after the information available to the hospital supports a reasonable, good faith belief that an intentional unsafe act has occurred.

ii) The report shall be submitted on a form approved by the Department of Health or, if the intentional unsafe act has been reported in writing to another department or agency, the hospital may provide a copy of that written report. The Patient Safety Surveillance and Improvement System will review the report and may require additional information from the hospital.

iii) Complete names of individuals involved in the intentional unsafe act shall be provided in the report to the Patient Safety Surveillance and Improvement System.

iv) Intentional Unsafe Acts must be reported to all other appropriate agencies.

5) Disclosures to patients of Serious Reportable Events. In the unfortunate event of a reportable adverse event, VPCH shall disclose to patients, or, in the case of a patient death, an adult member of the immediate family, any adverse events that cause death or serious bodily injury, including those resulting from intentional unsafe acts. Adverse events shall be reported on an event form; employees shall not document the submission of an event form in the patient's medical record. Disclosures shall always be made by the appropriate professional staff and shall be done in such a way as to minimize trauma and protect the confidentiality and emotional health of all of the participants to the extent possible. At a minimum any disclosure shall comply with the following requirements:

a) Disclosures shall be timely and done as soon as possible after the hospital becomes aware of the reportable adverse event and its consequence.

b) Disclosures will be made to the patient or, in the case of a patient death, an adult member of the immediate family. Disclosures may also be made to a patient's health care agent or guardian if applicable and appropriate and/or to any other person as requested by the patient.

c) Disclosures will most often be done by the treating physician with a member of the leadership team. The staff members of the affected patient's treatment team shall meet with members of the leadership team to determine which individual(s) will be responsible

for participating in the disclosures and what resources will be available to assist individual(s) responsible for disclosures.

d) Disclosures shall be documented in the patient medical record, including a description of the disclosure, who was present and any response or requests made by the patient or the patient's family.

e) Quality Management shall facilitate root cause analysis as indicated:

i) Performs preliminary analysis of the event

ii) Initiates root cause analysis for events according to the following criteria:

(1) Meets PSSIS definition of Serious Reportable Event.

(2) Meets the Joint Commission definition of a sentinel event or reviewable event.

(3) Is otherwise a reportable event under state or federal law.

(4) At the discretion of Quality Management for systems issues deemed to be a potential risk to patient safety.

(5) Identifies root cause team members.

(6) Notifies the appropriate managers, physicians and other staff involved in the event and establishes purpose, time frame and expectations for the analysis.

f) Conducts comprehensive analysis.

i) Reviews the root cause analysis process steps with participants.

ii) Reviews the details of the event using appropriate performance improvement methodology.

iii) If variation in system performance is identified by the root cause analysis, the team:

(1) Determines if all practices met acceptable standards.

(2) Determines which systems issues contributed to the variation in performance.

(3) Reviews staffing in affected areas of service

(4) Determines appropriate attendees for a meeting, which will focus on performance improvement.

g) Facilitates performance improvement meeting if variation in performance or opportunity to improve safety of systems has been identified. During this meeting the team:

i) Reviews system issues identified during the comprehensive analysis meeting.

ii) Identifies potential systems improvement(s).

iii) Identifies measures of success for monitoring the systems improvements.

iv) Designates accountable individuals for implementation of components of the performance improvement plan.

v) Establishes time frame and method for reporting results of plan at designated intervals.

h) Sends draft of root cause analysis report to identified team members for review/edit.

i) Revises root cause analysis report as necessary. Final report is sent to the appropriate leadership and/or managers as indicated.

j) Identifies opportunities to replicate improvement plan in all areas which may contain similar risk and facilitates rapid cycle improvement as indicated.

k) Sends follow-up notification to accountable individuals at determined time intervals.

l) Ensures outcome(s) of root cause analysis and performance improvement initiative(s) are reported to appropriate leadership and quality committees.

6) **Retention of records. VPCH** shall retain all documents and data (in any format) relating to the investigation of any adverse event, near miss or intentional unsafe act for a period of at least seven (7) years. Discarding or destroying such documentation or data during that period is prohibited.

Approved by	**Signature**	**Date**
Frank Reed, Commissioner of DMH	Frank Reed	11/29/16