**Section 235.150 Root Cause Analysis Findings and Corrective Action Plan**

a) *Following the occurrence of an adverse health care event, the health care facility must conduct a root cause analysis of the event. Following the analysis, the health care facility must*:

1) *Implement a corrective action plan to address the findings of the analysis; or*

2) *Report to the Department any reasons for not taking corrective action.*

b) *A copy of the findings of the root cause analysis and a copy of the corrective action plan must be filed with the Department within 90 days after the submission of the report to the Department.* (Section 10-20 of the Act)

c) The root cause analysis findings shall:

1) Focus primarily on systems and processes;

2) Progress from specific direct causes in clinical processes to contributing causes in organizational processes;

3) Contain the following key elements:

A) Details of the adverse health care event;

B) Identification of any human factors related to the adverse health care event;

C) Examination of any related processes and systems in place during the adverse health care event;

D) Analysis of staffing levels at the times before, during and after the adverse health care event;

E) Analysis of staff communication before, during and after the adverse health care event;

F) Analysis of the training and education of staff in connection with the systems and processes associated with the root cause analysis of the adverse health care event;

G) Analysis of any actions, inactions, literacy or knowledge gaps of the patient that may have contributed to the adverse health care event;

H) Assessment of the equipment involved in the adverse health care event, if any;

I) Analysis of the physical environment before, during and after the adverse health care event;

J) Identification of any external factors beyond the control of the health care facility; and

K) Identification of any other factors related to the adverse health care event;

4) Describe contributing and underlying factors to the root cause; and

5) Identify changes that could be made in systems and processes, either through redesign of existing systems or processes or development of new systems or processes, that would reduce the risk of such events occurring in the future.

d) The corrective action shall include:

1) Specific actions to correct the identified causes of the event to prevent a similar event occurring in the future, including if an apology was given to the patient and/or the patient's family;

2) Identified and measurable outcomes;

3) A designated person responsible for implementation and evaluation; and

4) A specific implementation plan with the following:

A) Completion dates;

B) Provisions for education of and communication with appropriate hospital staff; and

C) A description of how the hospital's performance will be assessed and evaluated following full implementation.

e) The Department will determine whether the root cause analysis and corrective action plan are acceptable, based on the requirements of this Section. If the root cause analysis and corrective action plan are acceptable, the Department will instruct the facility to begin follow-up activity to measure the success of the corrective action plan.

f) If the Department determines that the root cause analysis and corrective action plan are unacceptable, based on the requirements of this Section, the Department will provide consultation on the criteria that have not been met and will allow an additional time period (up to 30 calendar days) for resubmission.

g) A health care facility shall report to the Department regarding the outcome of the corrective action plans at eight and 18 months following the initiation of the plan.