Procedure for Risk Management

1. **Purpose** - This procedure establishes the process to track and identify risks and opportunities in the State Crime Laboratory (Laboratory) Quality Management System.

2. **Scope -** This procedure is applicable to all organizational units in the Laboratory.

3. **Definitions**

   - **Non-conformity** – A non-fulfillment of a specified or implied requirement of the Quality Management System.
   - **Opportunity –** an action that is proactively taken to prevent a future non-conformity from happening or otherwise improve the process
   - **Preventive action** – An endeavor to eliminate the cause of a potential non-conformity.
   - **Risk** – Any event or action that could lead to a non-conformity or failure to meet customers' expectations.

4. **Procedure**

   4.1. **Overview**

      4.1.1 Risk Management is a proactive process for improving the quality system. It is used to identify potential risks so as to reduce the likelihood and potential impact of a non-conformity and to identify opportunities for improvement. Risk Management may utilize audit results, quality records, complaints, and employee input to detect, analyze, and eliminate potential causes of non-conformities and identify opportunities for improvement.

      4.1.2 The risk management process consists of:

      - Identifying a potential risk or opportunity.
      - Assessing the risk or opportunity to determine potential impact.
      - Determining the course of action.
      - Implementing the action.
      - Ensuring the action is effective over time.

   4.2 Identification of Conditions or Situations – If a condition exists that may be improved, the Laboratory employee identifying the risk or opportunity shall notify his/her immediate supervisor and the Quality Manager (QM). If a risk or opportunity is identified through an internal audit or assessment, the Forensic Scientist Manager or designee shall initiate the process.

   4.3 The Risk Management Process

      4.3.1 When a potential risk or opportunity is identified, the employee shall document the concern by emailing the QM and copying the immediate supervisor.

      4.3.2 The QM shall document the potential risk or opportunity on the Risk Management Record (RMR). In conjunction with the appropriate Supervisor, Manager, and/or Technical Leader, the QM shall assess the risk or opportunity. Risk assessment must include the probability of occurrence and the potential impact if the risk is not prevented or the improvement is not made.

4.3.3 If preventive action is necessary, the QM shall assign an employee to develop a plan for risk mitigation. The plan shall be documented on the Failure Modes and Effects Analysis form (FMEA). The FMEA will document the following:

- Potential risk or opportunity
- Potential process failures
- Potential effects if the process failures were to occur
- Severity of the consequences if failure occurs
- Potential causes of the failure
- Rate of occurrence of each cause
- Current control mechanisms in place designed to prevent the failure
- Likelihood that current control mechanisms will detect the process failure
- Recommended action (if any)
- Expected date(s) of completion
- Person responsible for completion.

The FMEA will calculate the risk probability number (RPN). The higher the RPN, the greater the need to take preventive action.

4.3.4 The FMEA shall be completed and forwarded to the QM for review.

4.3.5 The QM shall review the FMEA. If approved, the QM shall sign and date the RMR and return to the appropriate Supervisor, Manager, and/or Technical Leader. If the recommended action(s) is not approved, the QM shall explain in writing and return the RMR to the appropriate Supervisor, Manager, and/or Technical Leader. If the implementation of the recommended action(s) involves more than one Section and/or Laboratory, the QM shall communicate with all Forensic Scientist Managers involved.

4.3.6 The Manager, Supervisor, Technical Leader, or designee shall execute the recommended actions. If the execution lasts longer than 30 days, updates shall be emailed to the QM on the implementation progress every 30 days.

4.3.7 The employee responsible for implementing the recommended actions shall notify the Manager, Supervisor, or Technical Leader upon completion. The Manager, Supervisor, or Technical Leader shall sign and date the line "Actions completed" of the FMEA.

4.4 Verification of Effectiveness - The Forensic Scientist Manager shall verify the short-term effectiveness of the preventive action. This verification may be accomplished through review of supporting documentation. Once effectiveness has been verified, the appropriate supervisor shall sign and date the line "Effectiveness verified." Additional verification must be documented during the management review.

4.5 Closing a Risk Management Record

4.5.1 The QM shall review the RMR and supporting documentation and determine if the recommended action is complete or if further action is required. Any necessary further action will be specified.

4.5.2 The Forensic Scientist Manager shall ensure that Section members are trained in any new method as applicable.

4.5.3 The appropriate Assistant Director and QM shall close the RMR by signing and dating the line "Closed". The RMR is then posted to the Laboratory intranet.

5.0 Records – The RMR and any supporting documentation shall be retained by the QM according to the record retention schedule as set forth by the North Carolina Department of Cultural Resources.

6.0 Attachments - N/A

Revision History		
Effective Date	Version Number	Reason
01/18/2019	1	Original Document

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