FBI Laboratory
Practices for Addressing a Nonconformity

1 Purpose

These practices specify steps and requirements to ensure that a nonconformity is addressed, that the effect(s) on prior work or records, if appropriate, is remediated, and that the possibility of recurrence is minimized, in order to bring about continuous improvement. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the American Society of Crime Laboratory Directors/Laboratory Accreditation Board-*International*® (ASCLD/LAB-*International*) accreditation program.

2 Scope

These practices apply to FBI Laboratory personnel who are involved in addressing nonconformities.

3 Responsibilities

3.1 An individual identifying a nonconformity will:

- Notify appropriate Unit Technical Management at the time the nonconformity is identified.

3.2 The Unit Chief will:

- Ensure unit concession and/or correction records are reviewed on at least an annual basis to determine any trends that may need to be addressed through a corrective action.
- Ensure that corrective action is implemented as appropriate.
- Sign a *Corrective Action Request* (7-254) or a *Follow-Up Action Request* (7-255) appropriately.

3.3 Executive Management, Unit Technical Management, and when appropriate, Program Managers will:

- Evaluate the significance of the reported nonconformity.
- Notify the Quality Manager when situations or conditions are determined to be adverse to quality, including analytical/interpretative nonconformities in casework, DNA databasing, and/or proficiency tests or unsatisfactory rating(s) for testimony monitoring.
- Ensure that the appropriate actions are implemented, when necessary, to address analytical/interpretative nonconformities in casework, DNA

databasing, and/or proficiency tests, or unsatisfactory rating(s) for testimony monitoring.

3.4 The Quality Manager will:

- Determine if the situation or condition is a significant condition adverse to quality.
- Ensure a *Corrective Action Request* or *Follow-Up Action Request* is initiated, as necessary.
- Ensure that an individual is assigned the responsibility of managing the corrective action.
- Ensure a *Corrective Action Request* or *Follow-Up Action Request* is reviewed for adequacy, acceptability of the action steps, and the stated time frame.
- Ensure that the progress of a corrective action is tracked.
- Ensure that the action steps have been completed.
- Ensure that the effectiveness of corrective actions is verified, as necessary.
- Sign a *Corrective Action Request* or *Follow-Up Action Request* appropriately.

3.5 An individual responsible for managing a corrective action will:

- Investigate and determine the root cause of the nonconformity and record how the root cause was determined.
- Liaise with a QA Specialist(s), if necessary, regarding root cause analysis, action step(s), and verification of effectiveness of action step(s).
- Plan and implement action step(s) to remediate the nonconformity and prevent recurrence.
- Ensure the timeliness of completion of such entries and/or ascertain if the expected completion date needs to be extended. If the expected completion date needs to be extended, the individual will notify the assigned QA Specialist.
- Provide objective evidence of completion of the action step(s) to the assigned QA Specialist.

3.6 A Quality Assurance Specialist will:

- Review and evaluate unit concession and/or correction records at a minimum, on an annual basis.
- Review a *Corrective Action Request or Follow-Up Action Request* for adequacy, acceptability of the action steps, and the stated time frame.
- Liaise with unit personnel regarding root cause analysis, action steps, and verification of effectiveness of action steps.
- Ensure the timeliness of completion of a *Corrective Action Request* or *Follow-Up Action Request* as assigned and/or ascertain if expected completion date needs to be extended.

3.7 An appropriate Technical Leader in the unit responsible for managing a corrective action will:

- Sign a *Corrective Action Request* or *Follow-Up Action Request* appropriately.

3.8 The Assistant Director (AD) will:

- Sign a *Corrective Action Request* appropriately.

4 Practices

4.1 Nonconformity

4.1.1 A nonconformity is the non-fulfillment of a requirement. Any FBI Laboratory employee, internal or external customer, and/or external auditor/assessor may identify a situation or condition where a concession, correction, or corrective action is required. Unit technical management will evaluate the situation or condition when it is reported. The significance of a nonconformity will be evaluated and categorized as requiring a concession, a correction, or a corrective action.

4.1.2 Responses to Nonconformity

The responses to a nonconformity are defined as:

- A **concession** is an acknowledgement that a nonconformity has occurred, but the work is deemed acceptable and the nonconformity will not be corrected.
- A **correction**[1] is an action to eliminate a detected nonconformity.
- A **corrective action** is an action to eliminate the ***cause*** of a detected nonconformity.
    - Corrective action will be categorized as Level 1 or Level 2.
        - A Level 1 corrective action is an action to eliminate a situation or condition that directly affects and has a fundamental impact on the quality of the work or testimony, the integrity of the evidence, or the reliability of the testimony.
        - A Level 2 corrective action is an action to eliminate a situation or condition that may affect the quality of the work or testimony but does not, to any significant degree, affect the fundamental reliability of the work or testimony, or the integrity of the evidence.

In general, the following diagrams may be referenced to aid in the determination of how a nonconformity can be addressed.

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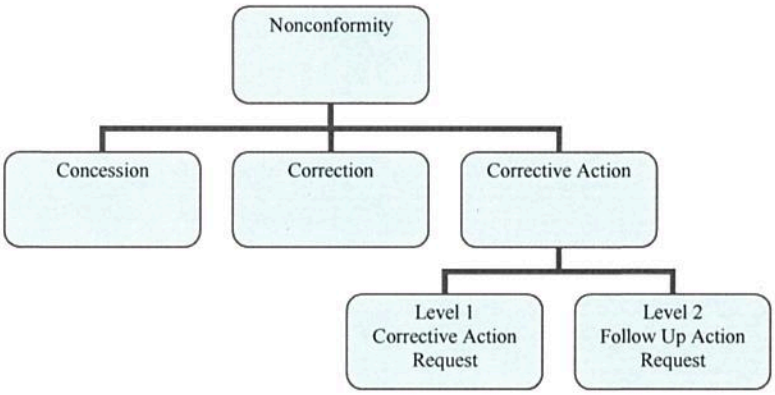
1 Correction as defined in these Practices does not refer to a correction that occurs in case records involving an initialed single strikeout where the correction is entered alongside, or those similar corrections tracked in electronic case records.



Potential Impact				
	HIGH	Level 1	Level 1	Level 1
	MEDIUM	Level 2	Level 2	Level 1
	LOW	Correction	Level 2	Level 1
		Concession		
		LOW	MEDIUM	HIGH
		Frequency of Occurrence		

4.1.3 If the evaluation indicates that the potential impact of the nonconformity is:

- Low, and the work is deemed acceptable and will only be acknowledged, then a concession is appropriate.
- Low, and the work is deemed not acceptable and will be corrected, then a correction is appropriate.

A concession or correction does not require a root cause analysis of the situation or condition. Units will have procedures for recording concessions and corrections. Records will include specific information to allow for a unit to determine any trends that may need to be addressed through a corrective action.

4.1.4 If the evaluation indicates that the situation or condition is adverse to quality (i.e., recurrence is possible or the potential impact is increased), then corrective action will be taken. Corrective actions will begin with a root cause analysis of the situation or condition. Next, a determination will be made as to the level of the corrective action (1 or 2). Depending on the level, a *Corrective Action Request* (Appendix A) for a Level 1 or a *Follow-Up Action Request* (Appendix

A) for a Level 2, will be initiated. Corrective actions will be initiated in a timely manner to minimize the impact of the nonconformity, including meeting the requirements in QAM - 3.3.2.

4.2 Notification, Completion, and Review of Concessions and Corrections

An individual identifying a nonconformity that can be resolved as a concession or with a correction will notify appropriate Unit Technical Management at the time the nonconformity is identified. Units will record concessions and/or corrections according to unit quality documents. Appropriate unit personnel will review the records, at a minimum on an annual basis, to determine what, if any, trends are occurring. If a trend(s) is identified, units will implement corrective action(s) as appropriate.

4.3 Notification of Situations or Conditions Adverse to Quality

A member of Executive Management, Unit Technical Management, or a Program Manager identifying a situation or condition will notify the Quality Manager at the time the situation or condition is determined to be adverse to quality. This notification will be recorded. The Quality Manager or a QA Specialist will assist the unit in determining if a *Corrective Action Request* or a *Follow-Up Action Request* is appropriate and, if so, ensure that one is initiated. The Quality Manager does not need to be notified when a situation or condition is determined to be a concession or a correction, or has progressed to a personnel performance issue, unless the situation also involves steps taken in accordance with these practices.

4.4 Completing a *Corrective Action Request* or a *Follow-Up Action Request*

The *Corrective Action Request* and the *Follow-Up Action Request* are used to record and track corrective actions and their ensuing resolutions. A *Corrective Action Request* is used to record a Level 1 corrective action. It may also be used for a repeat Level 2 corrective action. A *Follow-Up Action Request* is used to record a Level 2 corrective action. These forms identify the situation or condition, the requirement source, the individual who is responsible for managing the corrective action, the root cause(s) of the situation or condition, the action step(s), and the expected date of completion of the action step(s). The *Corrective Action Request* and the *Follow-Up Action Request* will be initiated using the FASU-CAR database or the FASU Audit Application. Refer to the Forensic Analysis Support Unit (FASU) Procedures for Entering Data in the Quality Assurance Corrective Action Request (CAR) Database or the FASU Procedures for Entering Data in the Quality Assurance Audit Application for completing the steps listed below.

4.4.1 Root Cause Analysis

Root cause analysis (RCA) is important in detecting and correcting nonconformities. The individual responsible for managing a corrective action will investigate and determine the root cause(s) as well as record how the root cause(s) was determined. The record of how the root cause was determined will be maintained by the FASU.

RCA can be determined by following a cause and effect model (e.g., 5 whys, fishbone diagram, cause map) that evaluates potential causal factors. Potential causal factors should be evaluated, as appropriate, in the broad areas of equipment, personnel (e.g., work schedules, deployments, staffing), methods, environment, evidence, materials and supplies, budget, previous occurrences, and/or customer complaints. Refer to Appendix B for an example of recording the evaluation of the potential causal factors.

4.4.2 Action Steps

Depending on the nature of the nonconformity, appropriate action steps may include:

- Notifying the contributor(s) or the casework laboratory.
- Review of, and correction to, any relevant casework and/or DNA databasing.
- Supplemental review of work before release of reports and/or DNA match confirmation letters.
- Issuing amended and/or supplemental reports and/or DNA match confirmation letters.
- Reassignment of duties to another individual.
- Remedial training.
- Revisions to policies, practices, procedures, and/or forms.
- Adoption of additional quality control measures.
- Indefinitely removing the individual(s) from casework or DNA databasing.

Prior to the resumption of independent casework or DNA databasing, a sufficient quantity of casework or DNA databasing, determined by the appropriate Technical Management, will be reviewed to ensure the quality of the individual's work. An appropriate Technical Leader or when appropriate, a Unit Chief, is authorized to permit the resumption of casework or DNA databasing.

4.4.3 Accepting Corrective Action Steps

The Quality Manager or a QA Specialist will review the *Corrective Action Request* or *Follow-Up Action Request* to determine its adequacy, acceptability of the planned action step(s), and the stated time frame. If the request is determined to be less than adequate, the individual responsible for managing the corrective action will be required to amend the request. If the Quality Manager or QA Specialist determines the *Corrective Action Request* or *Follow-Up Action Request* is not appropriate given the level of corrective action, it may be changed. If accepted, the Quality Manager will sign and date the bottom of the form in the space labeled "Reviewed and Accepted By" and forward a copy to the individual responsible for managing the corrective action. When applicable, the appropriate Technical Leader in the unit responsible for managing the corrective action will sign and date the form in the space labeled "Steps Approved By Unit Technical Leader (TL) (when applicable)" indicating unit approval of the action steps listed.

4.4.4 Completed Corrective Action Steps

The assigned QA Specialist will liaise with the individual responsible for managing the corrective action to determine if the action step(s) is complete. If the action step(s) has been completed, the assigned QA Specialist will review objective evidence in support of its completion. The assigned QA Specialist will sign and date the bottom of the form in the space labeled "Actions Completed."

4.4.5 Verification of Effectiveness of a Corrective Action

The assigned QA Specialist will ensure that the effectiveness of the corrective action(s) is verified. This verification may be accomplished by reviewing the objective evidence of completion, or it may be necessary to verify the effectiveness by other methods, which may include a review of affected work or additional audits. When the effectiveness has been verified, the assigned QA Specialist will sign and date the bottom of the form in the space labeled "Verified Effectiveness." For some corrective actions, the effectiveness of the action steps cannot be verified. The assigned QA Specialist will mark the space labeled "Verified Effectiveness" as not applicable. A brief summary of what records were reviewed to determine verification of effectiveness or why the effectiveness was not verified will be entered in the FASU-CAR Database or the FASU Audit Application, as appropriate, by the assigned QA Specialist.

4.4.6 Closing Out a Corrective Action

4.4.6.1 *Corrective Action Request*

The Unit Chief and/or when applicable, the appropriate Technical Leader in the unit responsible for managing the corrective action, will sign and date the bottom of the *Corrective Action Request* in the space labeled "Unit Approved" indicating unit approval for close out of the *Corrective Action Request*.

The Quality Manager will sign and date the bottom of the *Corrective Action Request* in the space labeled "Approved" indicating approval for close out of a corrective action. The AD will sign and date the bottom in the space labeled "Closed Out" thereby closing the *Corrective Action Request*. The original *Corrective Action Request* will be retained in the FASU. A copy of the *Corrective Action Request* will be forwarded to the person responsible for managing the corrective action.

4.4.6.2 *Follow-Up Action Request*

The Unit Chief and/or when applicable, the appropriate Technical Leader in the unit responsible for managing the corrective action, will sign and date the bottom of the *Follow-Up Action Request* in the space labeled "Unit Approved" indicating unit approval for close out of the *Follow-Up Action Request*.

The Quality Manager will sign and date the bottom of the *Follow-Up Action Request* in the space labeled "Approved/Closed Out" thereby indicating approval for close out and closing the

Follow-Up Action Request. The original *Follow-Up Action Request* will be retained in the FASU. A copy of the *Follow-Up Action Request* will be forwarded to the person responsible for managing the corrective action.

4.5 Tracking Progress on *Corrective Action Requests* and *Follow-Up Action Requests*

QA Specialists will track the progress of *Corrective Action Requests* and *Follow-Up Action Requests.* The Quality Manager or a QA Specialist will notify the affected Unit Chief(s) when delinquencies are identified.

4.6 Monitoring

After a *Corrective Action Request* or a *Follow-Up Action Request* is completed and closed out, the Quality Manager will ensure that periodic monitoring is performed if necessary to assess the continuing effectiveness of corrective actions. The monitoring may be accomplished by subsequent audits.

5 Records

The following records will be generated and/or retained by the FASU unless specified otherwise for at least the current ASCLD/LAB-*International* Accreditation cycle or five years, whichever is longer, as a result of these practices:

- *Corrective Action Requests* with associated records.
- *Follow-Up Action Requests* with associated records.
- Root Cause Analysis records.
- Unit concession or correction records will be maintained by the unit.

6 References

ASCLD/LAB-*International* Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, NC, 2011.

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

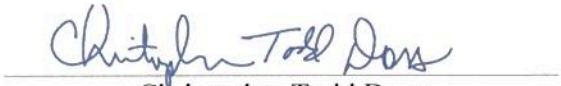
ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2005.

Okes, D., *Root Cause Analysis The Core of Problem Solving and Corrective Action*, American Society for Quality, Quality Press, Milwaukee (2009).

Robitaille, D. *Root Cause Analysis Basic Tools and Techniques*, Paton Professional, Chico (2004).

Rev. #	Issue Date	History
6	09/10/12	Updated section 3.1 to include signing 7-254/7-255. Added new sections 3.4 and 3.5 for consistency. Added second sentence to section 4.2.1.1c. Updated wording in section 4.2.1.4o. Clarified unit approval in sections 4.4.4.1 and 4.4.4.2. Deleted 7-261 from sections 4.1.3.2 and 5. Updated Appendix A - 7-254 and 7-255.
7	03/13/13	Revised wording in bullet 1, section 3.1 from initiate to ensure and in section 3.2 revised wording to require notification at time condition/situation/nonconformity are identified. Added reference to QAM in section 4.2. Updated wording to require notification at time nonconformity/condition/situation identified in sections 4.1.1.1, 4.1.2.1, 4.1.2.2.1, 4.1.4.1, and 4.1.4.2.1. In section 4.1.3.1, added option of notifying appropriate management and that this will be done in a timely manner. Clarified where preventive action records will be maintained in section 4.1.3.2. Added form numbers as appropriate. Added Unit Chiefs to section 4.5 and updated references in section 6.
8	09/08/14	Updated entire document to reflect current and new processes, including introducing the concepts of nonconformity, correction, concession, and corrective action and adding a section on the concept of root cause analysis and requiring the individual responsible for managing a corrective action to record how the root cause(s) was determined. Updated references. Updated Corrective Action Request and Follow-Up Action Request.

Approval

Laboratory Director  Date: 08/25/2014

Christopher Todd Doss

Quality Manager  Date: 08/25/2014

Robin M. Ruth

Appendix A: *FBI Laboratory Corrective Action Request* (7-254)

7-254 Revised (09-08-14)	FEDERAL BUREAU OF INVESTIGATION **Corrective Action Request**

Corrective Action: A Level I corrective action is an action to eliminate the cause of a situation or condition that directly affects and has a fundamental impact on the quality of the work or testimony, the integrity of the evidence, or the reliability of the testimony.

Refer to LOM - Practices for Addressing a Nonconformity and the FASU Procedures for Entering Data in the Quality Assurance CAR Database or the FASU Procedures for Entering Data in the Quality Assurance Audit Application.

Section A Tracking #: Date Entered: _____

Situation/Condition (may also include effect of the nonconformity):

Requirement Source:

Individual(s) Responsible for Managing Action: _____

Response Due Date: _____

Section B

Root Cause of Situation/Condition:

Section C

List the action(s) used to address the situation/condition, and the expected completion date for the steps.

Action Step(s):

Expected Completion Date:

Step(s) Approved By Unit Technical Leader (TL) (when applicable): _____ Date: _____

Section D

Reviewed and Accepted By: _____ Date: _____

Actions Completed: _____ Date: _____ Verified Effectiveness: _____ Date: _____

Unit Approved: _____ Date: _____
(TL when applicable) Signature of UC or TL

Approved: _____ Date: _____
Signature of Quality Manager

Closed Out: _____ Date: _____
Signature of AD

Appendix A: *FBI Laboratory Follow-Up Action Request* (7-255)

7-255 Revised (09-08-14)	FEDERAL BUREAU OF INVESTIGATION **Follow-Up Action Request**

Follow-Up Action: A Level 2 corrective action is an action to eliminate the cause of a situation or condition that may affect the quality of the work or testimony but does not, to any significant degree, affect the fundamental reliability of the work or testimony, or the integrity of the evidence.

Refer to LOM - Practices for Addressing a Nonconformity and the FASU Procedures for Entering Data in the Quality Assurance CAR Database or the FASU Procedures for Entering Data in the Quality Assurance Audit Application.

Section A Tracking #: Date Entered: _____

Situation/Condition (may also include effect of the nonconformity)

Requirement Source:

Individual(s) Responsible for Managing Action: _____

Response Due Date: _____

Section B

Root Cause of Situation/Condition:

Section C

List the action(s) used to address the situation/condition, and the expected completion date for the steps.

Action Step(s):

Expected Completion Date:

Step(s) Approved By Unit Technical Leader (TL) (when applicable): _____ Date: _____

Section D

Reviewed and Accepted By: _____ Date: _____

Actions Completed: _____ Date: _____ Verified Effectiveness: _____ Date: _____

Unit Approved: _____ Date: _____
(TL when applicable) Signature of UC or TL

Approved/Closed Out: _____ Date: _____
Signature of Quality Manager

Appendix B: Example of Potential Causal Factors for Root Cause Analysis

Potential Causal Factors	Comment
Documentation	
Work Schedules/Deployments	
Equipment	
Personnel	
Materials/Supplies	
Environment	
Communication	
Previous Occurrence	
Customer Complaint	

Other Factors considered:	