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CHAPTER 71 QUALITY ASSURANCE

7101 MANAGING DOCUMENTS.

This policy applies to the Office of Forensic Sciences (SF) documents that address management system activities (e.g., manuals, handbooks, orders, etc.) and external documents that affect the management system. The quality management system policies and procedures for the laboratory system are maintained in Master List A and Master List B.

NOTE: Exhibit 1/7101 lists acronyms used in this subchapter.

7101.1 Quality System Document Management.

Top Management (see 7201):

A. Ensures management system documents posted on the SF Document Control Center (SFDCC) have the following information:

1. Unique identification.
2. Date of issue.
3. Page numbering.
4. Total number of pages or a mark to signify the end of the document.
5. The issuing authority.

B. Approves management system documents prior to posting on the SFDCC.

C. Maintains obsolete management system documents and ensures accessibility to staff.

D. Identifies revisions or summarizes changes to edited documents.

E. Reviews management system documents annually.

7101.2 Office of Forensic Sciences Document Control Center.

See PRO-7101.2A, Reviewing, Approving, and Posting Controlled Documents: Laboratories and PRO-7101.2B, Reviewing, Approving, and Posting Controlled Documents: Headquarters. See TSK-7101.2C, Posting Controlled Documents – Headquarters Document Control Officer.

A. Top Management ensures the ability to update the SFDCC is limited to the Headquarters Document Control Officer (HQDCO) and an alternate.

B. Personnel access management system documents through the SFDCC, unless specified otherwise under “Official Location” on the Master Lists.

C. The SFDCC contains the official current versions of documents.

D. Copies printed or saved from the SFDCC are not official.

E. Management system documents that were in effect when an examination was started will remain the applicable reference documents until the analysis is completed.

7102 MANAGING RECORDS.

7102.1 Quality System Record Management.

A. The Laboratory Quality Assurance Manager (LQAM) ensures management system records are stored so that they are easily retrievable and protected from damage, deterioration or loss.

B. The LQAM ensures records stored on any type of approved media (i.e., electronic media or hard copy) will be controlled.

C. Personnel will not maintain copies of management system records in any personal storage area or binder, or on any personal electronic media.

D. Personnel responsible for filing hard copy quality records will store them in appropriate facilities in the location(s) stated on the Quality Records list and DEA Records Information System (DEARIS) File Plan.

E. Responsibility for developing, revising, or completing records accurately and promptly resides with the personnel responsible for generating the quality record.

NOTE: Exhibit 1/7102 lists acronyms used in this subchapter.

7102.2 Disposing or Retaining Records.

The LQAM ensures records are disposed or retained in accordance with REDACTED.

7103 TESTING ANALYST PROFICIENCY.

7103.1 Proficiency Testing Program Types.

A. Inter-laboratory proficiency testing program (PTP) samples.

B. Intra-laboratory proficiency testing program (IPTP) samples.

C. External proficiency testing program (EPTP) samples.

D. Blind proficiency testing program (BPTP) samples.

References to PTP and BPTP apply only to drug analysis and do not apply to the latent print and digital evidence proficiency testing programs.

NOTE: Exhibit 1/7103 lists acronyms used in this subchapter.

7103.2 Proficiency Testing Program Responsibilities.

A. Office of Forensic Sciences Quality Assurance Manager (SFQAM):

1. Monitors analytical results of all types of proficiency test samples and notifies Top Management of any analytical issues.
2. Prepares the *Quarterly Proficiency Testing Program Report* which includes:

   a. A summary of results of proficiency test samples analyzed during the previous quarter
   b. Information regarding digital and fingerprint proficiency tests, when applicable.
   c. Authorization to destroy PTP and EPTP samples for which there are no outstanding issues.

3. Maintains laboratory system documentation related to proficiency testing for an accreditation cycle.

B. Laboratory Director (LD):

1. Monitors the analytical results of proficiency test samples and notifies SF of any analytical issues.

2. Includes review of proficiency test results in the management review report (see TSK-7105.3, Conducting a Management Review).
3. Authorizes destruction of IPTP samples for which there are no outstanding issues.

C. LQAM:

1. Issues a proficiency testing schedule to laboratory personnel on a rotational basis.
2. Ensures expected proficiency test results are not known to, or readily available to, the test taker.
3. Ensures that all analyses are completed and that the results and all supporting documents are forwarded to the originating laboratories, or test provider, within the deadlines.
4. Informs laboratory personnel of the results of proficiency testing.
5. Issues supplementary proficiency tests to analysts, if applicable.
6. Maintains accountability of IPTP and PTP samples.
7. Maintains documentation related to proficiency testing for an accreditation cycle, including documentation of sample destruction.

D. Quality Assurance Specialist (QAS):

1. Serves as the PTP coordinator for drug analysis.
2. Selects exhibits for reanalysis as drug IPTP samples.
3. Ensures that each forensic analyst successfully completes a minimum of one IPTP analysis by the following schedule:

   a. Forensic chemists complete a minimum of one IPTP per fiscal year.
   b. Digital examiners complete a minimum of one IPTP per fiscal year.
   c. Fingerprint examiners complete a minimum of one processing IPTP per accreditation cycle.

4. Ensures that each forensic analyst successfully completes a minimum of one proficiency testing program sample (IPTP, PTP or EPTP) for each discipline on the scope of accreditation each fiscal year.
5. Maintains proficiency test records on an annual basis.
6. Prepares summary reports of IPTP samples on an annual basis.
7. Prepares summaries for the months when the drug PTP sample originates from the laboratory and forwards results to each laboratory and SF.
8. Ensures EPTP samples are ordered annually.
9. Reviews IPTP, PTP, and EPTP results.
10. Forwards results and supporting documentation to the LQAM.
11. Ensures EPTP results are sent to the test provider within established deadlines, and notifies SFQAM.

E. Forensic analyst:

1. Completes at least one proficiency sample per fiscal year in the analyst's forensic science discipline(s).
2. Handles, secures and analyzes proficiency test samples in the same manner as evidence.
3. Maintains a sufficient sample reserve to permit additional analysis (drug analysis only), whenever possible.

7103.3 Procedures for Preparing and Conducting Proficiency Tests.

See the Analysis of Drugs Manual (ADM), REDACTED, and the Latent Print Examination Manual (LPEM) for discipline-specific proficiency test program procedures.

7104 GATHERING FEEDBACK.

NOTE: Exhibit 1/7104 lists acronyms used in this subchapter.

7104.1 Customer Satisfaction Surveys.

A. SFQAM:

1. Distributes a survey to senior-level customers that use laboratory services, at least once each year. See TSK-7104.1.A1, DEA Laboratory Customer Satisfaction Assessment of Senior-Level Customers.
2. Distributes survey to laboratory report recipients at the DEA field offices and other law enforcement organizations that use laboratory services, at least once each year. See TSK-7104.2.A2, Customer Satisfaction Assessment of Report Recipients.
3. Uses appropriate follow-up procedures to ensure that the surveys are returned.
4. Provides survey summary report to top management.
5. Notifies LD and LQAM of feedback received.

B. LD:

1. Uses feedback from the surveys to improve the laboratory's management system.
2. Attempts to resolve negative feedback.

7104.2 Managing Complaints and Recommendations for Improvement.

A. For internal and external quality management system customer service complaints and recommendations for improvement, the LQAM:

1. Resolves a complaint as a *nonconformance* and a recommendation for improvement as an *area of concern*. See 7109.
2. Discusses the issue(s) with the complainant, or the person making the recommendation, to reach a resolution.
3. Refers complaints to the SFQAM if a resolution cannot be reached if applicable.

B. See REDACTED for complaints that include harassment, Equal Employment Opportunity, Standards of Conduct, or grievances.

7104.3 Evaluating and Documenting Testimony.

A. Supervisors, or other designated technically competent analysts, will technically evaluate each expert testimonial presentation provided by employees in a criminal proceeding by either observation or transcript review.

B. Whenever possible, supervisors will also evaluate the overall presentation and professionalism of the employee's testimony through direct observation.

C. Laboratory personnel must request transcripts of their testimony when supervisor observation is not possible.

NOTE: A video or audio recording is considered equivalent to a transcript.

D. Supervisors will discuss the results of evaluations, and/or reviews, with the employee and document this activity using the Documenting Testimony Review located in the Blank Forms section of the SFDCC. This will be done within 30 calendar days of either witnessing the testimony or obtaining the transcript.

E. Laboratory management must maintain the completed reviews and evaluation forms as either hard copy or electronic file for at least one full accreditation cycle.

7105 CONDUCTING INTERNAL AUDITS AND MANAGEMENT REVIEWS.

7105.1 Utilizing Qualified Personnel.

A. Only qualified personnel may conduct audits. Qualified personnel are those that have previously participated in a management visit, an inspection with the Office of Inspections (IN), an SF coordinated evidence inventory, or completed at least six hours of auditor training internally or through an outside provider.

NOTE: This requirement also applies to 7106.

B. The LQAM maintains the names and qualifications of all individuals eligible to participate in the internal audit.

NOTE: Exhibit 1/7105 lists acronyms used in this subchapter.

7105.2 Internal Audit Responsibilities.

The LQAM:

A. Conducts or coordinates internal audits and provides the LD with the necessary documentation to conduct the management reviews. See TSK-7105.2, Conducting an Internal Audit.

B. Includes direct observation of a sampling of testing within each discipline by a qualified individual.

7105.3 Management Review Responsibilities.

The LD:

A. Conducts a management review at least annually. See TSK-7105.3, Conducting a Management Review. This review may not be delegated.

B. Forwards the final management review of the fiscal year to SFQAM.

7106 MONITORING LABORATORY COMPLIANCE.

NOTE: Exhibit 1/7106 lists acronyms used in this subchapter.

7106.1 Administering the Self-Inspection Program.

The LQAM:

A. Coordinates the completion of the Self-inspection Program (SIP) report.

B. Ensures qualified personnel complete audits. See 7105.1.

7106.2 Annual Inspections.

SFQAM:

A. Provides an annual schedule for inspections.

B. Determines the criteria and scope of the inspection and provides notification to the laboratory at least 60 days prior to the visit.

C. Selects qualified personnel to perform inspections (audits). See 7105.1.

D. Reviews the audit report and disseminates the report to laboratory management within 30 days of the close out meeting.

E. Monitors follow-up corrective actions issued to the laboratory. See 7109.

7106.3 Peer Review.

See the Analysis of Drugs Manual (ADM), REDACTED, and the Latent Print Examination Manual (LPEM) for discipline-specific peer review policy.

The LQAM:

A. Ensures that each proficiency-tested analyst is selected for peer review over the course of a calendar year.

B. Ensures the peer review is documented.

C. Reviews the results of the peer review for each exhibit.

D. Ensures the analyst and the supervisor are notified to complete any corrections.

7107 THE QUALITY ASSURANCE COMMITTEE.

7107.1 Office of Forensic Sciences Quality Assurance Committee.

A. The Office of Forensic Sciences Quality Assurance Committee (SFQAC):

1. Meets with at least the following members present:

   a. SFQAM
   b. Section Chief from the Laboratory Management and Operations Section (SFM) or the Forensic Sciences Instruction Section (SFT) or the Forensic Science Advisor (SFS)
   c. Program Manager from the Quality Assurance Section (SFQ)
   d. Discipline-specific Program Manager(s) from SFM
   e. An assigned:
      1. Associate Laboratory Director (ALD)
      2. QAS
      3. Subject Matter Expert (SME) from the discipline-specific technical advisory committee

NOTE: The ALD, QAS and the SME serve on a rotational basis.

2. Meets to review nonconformances, and recommends closure, further action, or improvements to the management system.

B. SFQAM:

1. Coordinates Office of Forensic Sciences Quality Assurance Committee (SFQAC) meeting times and prepares agendas.
2. Refers all recommendations that result from the committee meetings to SF Top Management for consideration.

NOTE: Exhibit 1/7107 lists acronyms used in this subchapter.

7107.2 Laboratory Quality Assurance Committee.

The Laboratory Quality Assurance Committee (LQAC):

A. Includes the LQAM, QAS and designated laboratory personnel.

B. Ensures operational and analytical consistency throughout the laboratory.

C. Meets at least quarterly to review pending analytical inconsistencies, nonconformances, results of peer reviews, and any additional topics.

D. Chooses a member to record meeting minutes.

E. Makes meeting minutes available for the laboratory staff and SFQAM to review.

7108 RISK MANAGEMENT.

A risk management strategy encompasses three stages: identifying risks, assessing risks, and mitigating risks. The LQAM will monitor the laboratory's ability to enhance opportunities and reduce risks.

NOTE: Exhibit 1/7108 lists acronyms used in this subchapter.

7108.1 Definitions.

Opportunity: a circumstance, or set of circumstances, that may improve the function of the laboratory, or the products received by customers.

Risk: an issue that may be detrimental to the function of the laboratory, or the products received by customers.

Risk priority: a determination of the magnitude of a risk intended to assist in addressing an area of concern or a nonconformance. The risk priority incorporates the severity, occurrence, and detection.

Severity: the impact that a nonconformance or area of concern has on a customer or customer decisions.

Occurrence: the frequency, or likelihood, of a specific nonconformance happening.

Detection: the ability of existing management and/or engineering controls to prevent a nonconformance from reaching a customer.

Analytical inconsistency: two (or more) reports of conflicting conclusions, or if reported results are unsupported by observed data.

Corrective action request: a plan or decision resulting from an identified nonconformance.

Preventive action request: a plan or decision resulting from an area of concern that has not resulted in a nonconformance.

7108.2 Identifying Risks.

Personnel identify risks through routine review, management and engineering controls, and other internal and external customer inputs (e.g., document review, LQAC, surveys, inspections and audits, complaints, recommendations, and root cause determinations, etc.).

7108.3 Assessing Risk.

Personnel assess risk by assigning relative values in three areas: severity, occurrence, and detection.

7108.31 Calculating a Risk Priority Number.

Calculate the risk priority number (RPN) from three areas: severity, occurrence, and detection. See TSK-7108.31, Calculating the Risk Priority Number. Assessing the value for each of the three areas calculates the RPN using a formula (Severity x (Occurrence + Detection)). See Exhibit 2/7108, Matrix for Calculating RPN.

NOTE: Determining the RPN can be accomplished individually by the LQAM or the SFQAM, or through majority consensus of the LQAC or the SFQAC.

7108.4 Acting on Risks.

An effectively administered risk management plan leads to consistent action in the form of system improvements. SFQAM and LQAMs correct and prevent nonconformances as described in 7109.

7109 CORRECTING AND PREVENTING NONCONFORMANCE

NOTE: Exhibit 1/7109 lists acronyms used in this subchapter.

7109.1 Using the Risk Priority Number

A. In the absence of a nonconformance, an RPN ≥ 20 calculated from a process or activity requires that the LQAM initiate, log, implement, monitor and complete a preventive action request (PAR). Instructions for completing the Office-Imposed corrective action request and preventive action request (CAR/PAR) and SF-Imposed CAR/PAR forms are within the document located in the Blank Forms section of the SFDCC.

B. In the absence of a nonconformance, an RPN < 20 calculated from a process or activity requires that the LQAM log the area of concern; however, initiation, implementation, and monitoring of a PAR is discretionary.

C. An RPN ≥ 20 calculated from a process or activity that is identified as not conforming with established policy and procedures requires that the LQAM initiate, log, implement, monitor, and complete a corrective action request (CAR). Instructions for completing the Office-Imposed CAR/PAR and SF-Imposed CAR/PAR forms are within the document located in the Blank Forms section of the SFDCC.

D. An RPN < 20 calculated from a process or activity that is identified as not conforming with policy and procedures requires that the LQAM initiate, log, and complete a correction.

E. When a nonconformance with an RPN > 50 is calculated (or a severity determined to be a 9 or a 10), the LQAM will notify SFQAM within 2 business days and the SFQAC will determine if immediate action is required for the laboratory system.

MECHANISM FOR IMPROVEMENT:	Scenario	RPN	Convene LQAC?	Root Cause Analyses	Additional Monitoring

Preventive Action Request	Any process or activity that is identified as an area of concern during routine operations, audit events, etc.	Initiate when: RPN ≥ 20, May be initiated when RPN < 20 at LQAM discretion.	At LQAM discretion	Not required unless proposed plan reveals underlying nonconforming processes or activities.	Usually no more than 6 months of monitoring from the date plan is implemented.
Corrective Action Request	Any process or activity that is identified as nonconforming with policy and procedures during routine operations, audit events, etc.	Initiate when: RPN ≥ 20 RPN > 50 requires notification to SFQAM	Convene LQAC	Conduct root cause investigation with LQAC members.	Usually no more than 6 months of monitoring from the date corrective action plan is implemented. If plan is not correcting the problem, the LQAM must take a different course of action.
Correction	Any process or activity that is identified as nonconforming with policy and procedures during routine operations, audit events, etc.	Initiate when: RPN < 20 LQAM may initiate a CAR if problem is recurrent or indicates a systemic failure despite low RPN.	Not required	Not required.	No monitoring required. Revisit correction effectiveness through laboratory internal audit.

7109.2 Nonconforming Work Products.

Corrective action results from an identified nonconformance and describes the reactive process of addressing an identified risk to the quality management system. The corrective action addresses processes or activities which led to a nonconformance. Instructions for completion of the Office-Imposed CAR/PAR and SF-Imposed CAR/PAR forms are found within the document located in the Blank Forms section of the SFDCC.

Many operational processes and laboratory programs are not directly related to the technical work products and the issuance of laboratory reports, but may impact the work product if a nonconformance occurs.

7109.21 Analytical Inconsistencies.

A. An analytical inconsistency (AI) is defined as two (or more) reports of conflicting conclusions, or if reported results are unsupported by observed data.

NOTE 1: Typographical, or other administrative errors, identified during the normal technical and administrative review process, and prior to issuance of a final report, are not considered AIs.

NOTE 2: An investigation may include evidence reanalysis of previously tested exhibits.

B. No type of analytical inconsistency is acceptable without resolution, or an attempt to determine the root cause for the discrepancy.

C. SFQAM maintains a log of AIs.

D. The SFQAC reviews all AIs with an RPN ≥ 20.

E. An AI resulting from an individual analyst's actions determined to have an RPN greater than 50 (or a severity value of 9 or 10) as calculated or determined by the SFQAC will be reported to the Deputy Assistant Administrator (DAA).

F. If an analyst has multiple analytical inconsistencies, the SFQAC will calculate a separate RPN which takes into account the history of the analyst. If the resulting RPN is greater than 50, the SFQAC will report the actions to the DAA.

7109.3 Responsibilities for Correcting or Preventing Nonconformances.

SF delegates responsibilities for resolving and preventing nonconformances as follows:

A. LQAM:

1. Logs AIs, corrective and preventive action requests on the SFQ site.
2. Manages the laboratory quality assurance program to include tracking nonconformances, establishing a reasonable timeframe for completion of corrective actions, preparing summaries, and making recommendations to the LD.
3. Investigates the root cause of nonconformances.
4. Utilizes LQAC to conduct investigations in preparing a response to the LD.
5. Proposes action to prevent, or prevent recurrence, of nonconformances.
6. Maintains the associated documentation for at least one full accreditation cycle.

B. LD:

1. Maintains overall responsibility for addressing nonconformances.
2. Approves recommendations for action to minimize or eliminate nonconformances.

C. SFQAM:

1. Manages the laboratory system quality assurance program to include tracking nonconformances, preparing summaries, and making recommendations to SF.
2. Convenes meetings to resolve pending nonconformances.
3. Recommends improvements to laboratory system policies and procedures based on successful plan implementation.
4. Maintains the associated documentation for at least one full accreditation cycle.

D. DAA:

1. Takes action to reduce risks to processes in the laboratory system.
2. In the event of analytical inconsistencies with an RPN > 50 (or a severity of 9 or 10) resulting from an individual analyst's actions, discloses the results of nonconformance root cause investigations to the

Office of Chief Counsel (CC) so that they may review the facts and determine whether there are legal and/or policy obligations to disclose the information outside of the agency.

3. Develops strategic, quality-based goals as a result of the risk assessments for laboratory system continual improvement.

7109.4 Preventing or Correcting Nonconformances.

Preventive and corrective action describes the action taken when areas of concern or nonconforming work events are identified.

7109.41 Preventive Action Requests.

Preventive action describes the proactive process resulting from an identified potential risk to the quality management system. The preventive action addresses processes or activities which may lead to nonconformances.

A. If a preventive action is required, the LQAM will develop a preventive action plan. A preventive action plan is issued to reduce the risk of occurrence of nonconformance and to improve the quality management system. The LQAM will use the CAR/PAR form located in the Blank Forms section of the SFDCC.

B. The laboratory-developed preventive action plan includes:

1. Implementation of the plan
2. Monitoring of the plan
3. Verification of plan effectiveness.

C. The LQAM will provide a detailed summary of the preventive action taken, including any supporting documentation.

7109.42 Corrective Action Requests.

If a corrective action is required, the LQAM will calculate the RPN and either convene the LQAC and investigate the nonconforming process or activity to improve the quality management system, or issue a correction. Corrective actions taken may include reissuance of work products, improvements to policy or procedure, personnel changes, or additional training. The LQAM will use the CAR/PAR form located in the Blank Forms section of the SFDCC.

A. If the RPN scores above 20, the LQAC:

1. Investigates further to determine the root cause(s) of the problem.
2. Considers all aspects of the quality management system when determining the root cause (e.g., policies, customer requirements, samples, sample specifications, methods and procedures, skills and training, critical consumables and supplies, instruments, etc.).

B. The LQAM

1. Leads the root cause analyses and implements a plan that is intended to minimize or eliminate the problem and prevent a recurrence. The corrective action plan includes:

   a. Implementation of the plan
   b. Monitoring of the plan
   c. Verification of plan effectiveness.

2. Ensures corrective actions taken are appropriate to the magnitude of the risk. Following the root cause analysis, the RPN will be recalculated to determine if further corrective action is necessary, or if the issue can be resolved as a nonconformance correction.

C. The LQAM will provide a detailed summary of the corrective action taken, including the supporting documentation.

7109.5 Correcting Nonconformances with Training.

A. If an investigation reveals that a training deficiency is the root cause of a nonconformance, the LQAC may recommend a retraining period for the personnel involved. The LQAM must initiate a course of action, assign remedial training, and document the temporary suspension of work.

B. The LQAM considers remedial training successful when the individual demonstrates compliance with policy and/or procedure. The LQAM documents permission for the resumption of work.

NOTE: In some cases, training may require an analyst to successfully complete additional competency samples.