QUALITY MANUAL

ILLINOIS STATE POLICE

Division of Forensic Services

Forensic Sciences Command

QUALITY MANUAL
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Last Date Reviewed: July 2025
QM Rev. 93 (09/01/2025)

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The Illinois State Police (ISP), Division of Forensic Services (DFS), Forensic Sciences Command (FSC) is mandated to provide forensic science services for Illinois law enforcement agencies in criminal investigations under the authority of Illinois State Statute 20 ILCS 2605-40. The FSC is committed to provide world-class forensic service to our customers by ensuring that accurate, complete, and timely analyses are conducted by highly trained employees who take pride in producing a quality product. Quality services begin with the initial agency contact, continue through the analysis, and end with providing testimony in court.

To meet customer requirements and provide world-class forensic analysis, the Forensic Science Command established a quality management system consisting of the necessary policies and procedures that ensure quality services are provided. This quality management system complies with the requirements of the ISO 17025:2017 standards and the ANAB accreditation requirements for quality as well as those required by the Federal Bureau of Investigation (FBI) DNA Quality Assurance Standards.

Employees of the FSC are committed to complying with the guidelines and measures of the quality management system in all areas - from the administrative aspects through the analytical procedures, to the report issued and the testimony given in support of the findings – so a quality product is achieved. This commitment to quality is spearheaded by FSC's executive management. We will strive for continuous improvement of the quality management system to ensure that the ideals established by the FSC are met.

The FSC Quality Manual serves to inform all FSC employees of the guidelines and measures associated with a quality product - not only in the work itself, but in all areas, from the administrative aspects through the analytical procedures, to the reports issued and testimony given in support of the findings. These directives, issued under the authority of the Director of Quality Assurance, outline the necessary actions to assure that quality services are provided. Emphasis is placed on the improvement of quality and on prevention of and correction of concerns. Since the FSC holds the individual producing the results accountable for the accuracy of the report, progressive and corrective disciplinary action may occur when there is inaccurate analysis. The Forensic Sciences Command closely monitors all situations which could result in inaccurate, incomplete, or untimely analysis.

All properly submitted evidence relinquished to the FSC will be handled with extreme care to ensure evidential integrity and that a proper chain of custody is maintained. During the process of evaluating and analyzing evidence, the FSC will employ due diligence and reasonable procedures to preserve the evidence; however, certain analytical techniques may require consumption and/or alterations such that the evidence can no longer be utilized for its intended purpose. The FSC will select and utilize appropriate, validated scientific techniques of our choice to include outsourcing of analytical services to provide our user/client agencies with accurate, complete, and timely forensic science services. By submitting evidence to the FSC, the user/client agency agrees to the conditions and terms expressed in this "Pledge to Provide Quality Services" notification.

The FSC will initiate various checks to monitor the quality of services. Input from agencies and other sources will be solicited to improve the quality of service. Forensic scientists are encouraged to share their

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experiences, both positive and negative, to assist in improving quality. The quality of casework is directly related to the care taken in both choosing an appropriate analytical scheme and in performing the analysis. These actions involve following the established standards and controls and incorporating good scientific practices. While a self-checking process is a fundamental aspect of quality assurance, external checks and reviews are necessary to monitor the overall quality of work performed. These checks and reviews involve at least yearly audits of laboratories by FSC personnel or independent third-party assessors. Periodic reevaluation of the FSC's standards and controls considering advances in technology, results of proficiency testing, and review of a representative sampling of casework is also mandated. An ongoing review of the Quality Assurance Program will be conducted by the Director of Quality Assurance.

In the event of a work stoppage, the lab(s) will be considered officially closed and routine quality checks will be suspended.

Tranellie Collins

Tranellie Collins – Acting Director of Quality Assurance
Forensic Sciences Command

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- *Administrative Documentation*
  1. Records such as case related conversations, evidence receipts, description of evidence packaging and seals, and other pertinent information.
  2. These include all administrative case information that is not considered part of the examination documents but are relevant to the laboratory case number and the evidence received and having no other pre-determined storage location. Examples include evidence receipts, laboratory reports, subpoenas duces tecum and responses, phone conversation records, custody and location history records, investigative reports, and xerographic copies of evidence.

- *Annual Term*
  Yearly events (calibrations, audits, etc.) which must occur within 30 calendar days from the date they were conducted in the previous year. Examples: 1) Calibration of an instrument occurs on June 4.The next calibration must be conducted by July 4 of the next year. 2) An audit was conducted on March 31. The annual audit must be conducted by April 30 of the next year to be in compliance.

- *Blind Proficiency*
  Cases made up by the Quality Review Coordinator, and with the assistance of the submitting agencies, are sent through as an actual case by the agency for the receiving analyst to work.

- *Case File Reviews*
  Reviews of cases for analytical procedures and adherence to standards and controls, such as reportwording, utilized by the analyst/examiner.

- *Case Reanalysis*
  Cases that are randomly selected, if possible, and reworked by the Quality Review Coordinator.

- *Equipment*
  Items including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results

- *Examination Documentation (See also the term Notes)*
  1. Includes reference to procedures followed, tests conducted, standards and controls used, diagrams,printouts, audio radiograms, photographs, observations and results of examinations.
  2. These include all analytical notes and documentation generated in the laboratory and used by the analyst to draw and support his/her conclusions. Examples include but are not limited to: work notes,spectra, charts, references to routine and non-routine procedures, photographs, and any other documentation required by the Procedures Manual.

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- *External Proficiency Test*
  Tests made by an outside testing agency which are submitted to, and worked by, Forensic SciencesCommand analysts/examiners/technicians; results are graded by the testing agency to ascertain theproficiency in area of analysis.

- *ANAB (ANSI-ASQ NAB)*
  American National Standards Institute-American Society for Quality National Accreditation Board

- *Internal Proficiency Test*
  Specific tests made by the Quality Review Coordinator and worked by the analyst/ examiner/technician to test his/her proficiency in area of analysis.

- *ISO/IEC*
  International Organization for Standardization/International Electrotechnical Commission

- *Issues Affecting Case*
  Issues that would deter or have an effect on the adjudication process.

- *Major Error*
  An error in a proficiency test or casework which not only is in opposition to what has been determined as a correct answer, but has been worked in such a manner as to cast doubt about an analyst's/section's abilities to perform casework in the particular area or discipline.

- *Master File*
  The original file folder created at the time the case is first signed in at the originating laboratory. It isstored in the laboratory's file storage room numerically, and contains all examination and administrative documentation required for that uniquely identified case, including completed Working Files. Cannot include any physical evidence.

- *Measurement Uncertainty*
  The doubt that exists about the result of any measurement; parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to themeasurand (item being measured).

- *Minor Issues*
  Issues found during case review/reanalysis which do not deter nor have an effect on the adjudicationprocess.

- *Monthly*
  Events that occur once a month and not less than 24 days from the date the event was conducted

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in the previous month.

- *Notes (See* also the term *Examination Documentation)*
  Documentation of procedures, standards, controls and instruments used, observations made, results oftests performed, charts, graphs, photos, and other documents generated which are used to support the examiner's conclusions.

- *On-Site Visit (non-DNA section)*
  A visit made by the Quality Review Coordinator to the analyst's/examiner's laboratory to observe the analyst/examiner working cases in their home laboratory environment.

- *Qualified Analyst*
  A qualified analyst is an analyst who has successfully completed training in a specific area, passed an appropriate test, and has been approved to perform independent casework. An individual released from a training program will be considered qualified as of the date listed on the memorandum notifying him/her of the release from training.

- *Quality*
  Accurate, complete and timely analysis of casework; the totality of features and characteristics of aproduct or service that bear on its ability to satisfy stated or implied needs; conformance to requirements.

- *Quality Assurance*
  The measures which determine that the quality system is performing properly and also provide a course of action to improve analysis and the resulting information provided to the criminal justicesystem.

- *Quality Committee*
  Committee composed of the Director of Quality Assurance, Quality Review Coordinators, and Laboratory Quality Managers. Meets at least annually to discuss the quality program.

- *Quality Control*
  The action of following standards and controls and following valid methods and procedures. Properquality control mandates that the individual Forensic Scientist uses and documents the proper functioning of all tests performed. A well-defined set of standards and controls for the Forensic Scientist to use as a basis for producing quality work is a cornerstone of quality.

- *Quality Documents*
  All documents utilized by the Command to provide quality forensic services such as manuals, forms,and procedures. These are maintained in the Command Directives, Command Quality Manual, Procedures Manuals, Training Manuals, Command Safety Manual and the Facility Operations Manuals.

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- *Quality Improvement*
  Actions taken throughout the organization to increase the effectiveness and efficiency of activitiesand processes in order to provide added benefits to both the organization and its user agencies.

- *Quality Issue*
  Potential nonconforming work or a departure from the policies and procedures in the quality systemor technical operations; after investigation it will be determined whether the issue is substantiated

- Q*uality Manager*
  The individual responsible for ensuring that the quality system is implemented and followed at alltimes for the laboratory or the Forensic Sciences Command. The command quality manager is designated as the Director of Quality Assurance. The Laboratory Quality Manager oversees the quality system for the respective laboratory.

- *Quality Measures*
  To assure that results are of the highest quality and that the system is performing as it is designed,information will be obtained through both direct and indirect means.
  a. *Direct Means* consist of routine checks, both periodic and random, which are initiated within thecommand.
  b. *Indirect Means* consist of input from individual analysts/examiners, administrators, qualityreview or training coordinators or others as designated.

- *Quality Review Coordinator*
  A bench analyst, selected from one of the analytical sections, who reviews case files, performs reanalysis of cases, creates and grades proficiency tests for the other members of that analytical section, and performs other assigned quality assurance duties.

- *Working File*
  Minimally contains documents pertaining to a particular analyst's work such as examination documentation, analytical reports and pertinent administrative documentation (e.g., copies of evidence receipts, CALMS property inventory sheets, documentation of agency requests).

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I. GOALS

A. The Forensic Sciences Command (FSC) is committed to providing quality scientific analysis of evidence to the law enforcement community. Quality services begin with the initial agency contact, continue through the analysis, and end with providing testimony in court. To this end, Command is committed to good professional practice and the quality of its forensic testing activities in servicing its customers via these objectives:

II. OBJECTIVES

A. Conducting forensic analyses that are accurate, relevant, complete, timely, impartial and satisfy customer requirements,

B. Interpretation of analytical results without bias and free of internal and external influence,

C. The presentation of the results of analyses and examinations in reports and testimonies that are clear, objective, balanced and easily understood by its customers,

D. The ongoing development of the skills and expertise of its personnel,

E. Establishing an integrated quality management system, as set forth in in the FSC/CSSC Directives, Procedures Manuals, Quality Manual, and Command Training Manuals.

F. The conformance of laboratory policies and procedures with the accreditation requirements of the Division's accrediting body under ISO 17025 guidelines, National DNA Index System (NDIS) Operational Procedures Manual, FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, and the FBI Quality Assurance Standards for DNA Databasing Laboratories,

G. Continuous improvement of the effectiveness of the management system and quality of forensic science provided to customers, using this quality policy, audit results, analysis of data, corrective and preventive actions, and management review. Ensuring that when changes are made, they do not impact the integrity of the management system.

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H. To develop principles and performance standards that validate and advance the strategies and techniques associated with forensic analysis,

I. To heighten the awareness of all Forensic Sciences Command personnel regarding the importance of quality assurance and encourage suggestions for improvement of analysis and service,

J. Identifying risks and opportunities on an ongoing basis, including risks that arise from laboratory activities, including but not limited to, relationships of personnel, corrective actions, testimony reviews, health and safety, or commercial and financial pressures. Laboratory management and Command Quality Assurance shall be immediately notified once it has been determined a nonconformity exists. The risks, corrections, and opportunities shall be investigated and documented as required in QM-8, QM-17, or by the Division of Internal Investigation.

K. Adherence to the Code of Ethics as described in Command Directives – ADM 01.

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I. COMMAND ORGANIZATIONAL STRUCTURE

The Division of Forensic Services, Forensic Sciences Command, contains the forensic laboratory function of the Illinois State Police. Authority for the establishment of the forensic laboratories is set forth in the Illinois State Statute 20 ILCS 2605-40. The Director of the Illinois State Police, appointed by the Governor of the state of Illinois, appoints the Deputy Director of the Division of Forensic Services. The Deputy Director has responsibility and authority for oversight of the Forensic Sciences Command. The Deputy Director, through the Assistant Deputy Director, directs the Command executive management through theCommander of the Forensic Sciences Command.

The Forensic Sciences Command organizational structure can be found in the Command Directives (ORG 1).

A. The Commander is responsible for the overall administration of the Forensic Sciences Command.

B. The Bureau Chiefs administer the laboratories and programs. The various laboratories and/or specialties will be divided among the Bureau Chiefs and periodic rotation of one or more functions may occur. A designated Bureau Chief will perform the duties of the Commander in his/her absence.

C. The Director of Quality Assurance is responsible for the daily operations of the quality assurance program. Through delegated authority, the Assistant Director of Quality Assurance will perform various activities for which the Director of Quality Assurance is responsible. In the absence of the Director of Quality Assurance, the Assistant Director of Quality Assurance will assume the duties for administering the quality assurance program.

D. Laboratory Directors are responsible for the daily operation of the laboratories, with Assistant Laboratory Directors or Deputy Laboratory Directors in place who are authorized to assume their duties in their absence.

E. Key personnel outside of the Forensic Sciences Command that have influence on the operation of the Command include the Director of the Illinois State Police, who is influential in the budget process and strategic planning, and the First Deputy Director who assists the Director in managing the Illinois State Police.

II. INDIVIDUAL LABORATORY ORGANIZATIONAL CHARTS

The organizational charts for individual Forensic Sciences Command laboratories can be found on the Command intranet site.

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The Forensic Sciences Command will provide and maintain quality forensic services by utilizing a quality assurance program/quality management system in accordance with ISO 17025:2017 Option A. All items in ISO17025:2017 (and supplemental accrediting body requirements) designated with the words *agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, or specify* shall be addressed in one of the Command controlled documents (Command Directives, Quality Manual, Section Procedures Manual, Laboratory Facility Operations Manual, Safety Manual, Training Manual).

I. QUALITY MANAGER

The Quality Manager for the Illinois State Police, Forensic Sciences Command is the Director of Quality Assurance. The Director of Quality Assurance will manage the daily operations of the Quality Assurance Program. Through delegated authority, the Assistant Director of Quality Assurance will perform various activities for which the Director of Quality Assurance is responsible. The Director of Quality Assurance is responsible for, but not limited to:

A. Coordinating and implementing each section's quality assurance program and monitoring subsequent activities;

B. Supervising the distribution and monitoring the results of the Command's proficiency testing program;

C. Supervising the reporting of external proficiency tests;

D. Administration of the Command's Quality Review Coordinator program, which includes a case reanalysis program;

E. Maintaining and reviewing the Command Quality Manual;

F. Ensuring compliance with ISO/IEC 17025:2017, supplemental accreditation provider requirements, and the FBI DNA Quality Assurance Standards;

G. Administration of the Command's Safety Program;

H. Conducting laboratory audits and quality system reviews, and arranging for external audits/reviews;

I. Overseeing the corrective action process for quality issues;

J. Serving as administrative aide to the Commander and Bureau Chiefs as appropriate;

K. Serving as the evidence custodian for the Command;

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L. Ensuring FSC fulfills the objective of testimony review per QM-5; and

M. Ensuring ANAB is notified when an event or nonconformity occurs that could substantially affect the integrity of laboratory activities and is related to an accreditation requirement.

II. LABORATORY QUALITY MANAGER

Each laboratory will designate an individual as the Laboratory Quality Manager. This individual, in conjunction with the Laboratory Director, will be responsible for facilitating the quality program at the laboratory. This individual will be responsible for working directly with the Director of Quality Assurance and Laboratory Director on all quality matters involving their assigned laboratory. Specific duties for the Laboratory Quality Manager include, but are not limited to:

A. Coordinating, implementing, and monitoring the laboratory's quality assurance activities;

B. Monitoring laboratory practices to verify continual compliance with ISO/IEC 17025:2017, supplemental accreditation provider requirements, and the FBI DNA Quality Assurance Standards;

C. Coordinating and monitoring proficiency test participation for the laboratory;

D. Coordinating and monitoring reanalysis and case file review activities in the laboratory;

E. Participating in an annual internal (in-house) laboratory audit and assessing requirements according to the appropriate accrediting body and Command criteria;

F. Participating in Command audits of the quality management system;

G. Monitoring and participating in resolving any quality issues within the laboratory;

H. Proposing corrections and improvements in the quality system of the laboratory and the Command;

I. Conducting an annual review of the laboratory's quality system and submitting documentation of the review through the chain-of-command to the Director of Quality Assurance;

J. Documenting that each testifying employee in the laboratory had their testimony monitored, and verifying and documenting those analysts without feedback did not testify in the calendar year in accordance with QM-5;

K. Recommending training to improve the quality of laboratory staff.

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III. DNA TECHNICAL LEADER

This individual will be responsible for working directly with the Director of Quality Assurance on all quality matters (all documents on reviews, proficiency tests, continuous improvement projects, reanalysis, etc.) involving DNA. They will provide input on corrective actions, recommend changes as necessary for continuous improvement of DNA quality assurance, and have access to all documents relating to quality assurance measures in DNA.

IV. PROGRAM MANAGERS

These individuals will be responsible for working directly with the Director of Quality Assurance on quality matters assigned to them (e.g. revisions to quality documents, continuous improvement projects, preventive actions, etc.) that involve their program areas. They will recommend corrective action to address identified quality issues including the remediation of any ISO assessment nonconformity as applicable. They will request input from the Director of Quality Assurance to ensure laboratories continue complying with policies, procedures, and accreditation standards within the assigned areas. The Program Managers will provide input to the Director of Quality Assurance on improving quality assurance measures.

V. QUALITY DOCUMENTS

In addition to those contained in the Quality Manual, other quality documents are contained in the Command Directives, the Safety Manual, Procedures Manuals, Training Manuals and Facility Operations Manuals. Specific quality-related topics such as type and extent of laboratory examinations, disclosure of information and facilities (location and contact information) are listed in the Command Directives; all safety items are discussed in the Command Safety Manual and Facility Operations Manuals; Facility Operations Manuals discuss the specific operations for a particular laboratory; while Procedures and Training Manuals content is discussed elsewhere in this manual.

VI. MINIMUM STANDARDS AND CONTROLS

Minimum standards and controls have been established to ensure the integrity of analysis and to provide consistency of analysis among laboratories. The standards and controls have been designated to cover the majority of analyses performed within the Forensic Sciences Command. However, it is not possible to establish controls for every eventuality that might arise during the examination of a case by a forensic scientist. The absence of standards and controls does not negate the responsibility of the forensic scientist to perform examinations in accordance with sound scientific principles and according to good laboratory practice. Nor will the adherence to the standards and controls always ensure that additional examinations are not necessary. If the nature of the evidence warrants further examination, preservation, etc. than is indicated by the standards and controls, the forensic scientist is expected to take that action and document the extent of the actions in the case notes.

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VII. QUALITY ASSURANCE ACTIVITIES

The activities defined below serve as a resource to Command administration by allowing forensic analysts to act in an advisory capacity to review emerging analytical technology/instrumentation, training needs, casework trends and to improve or revise standards and controls for analytical casework.

A. Quality Review Coordinators - Quality Review Coordinators will be selected from each forensic science discipline.

1. Qualifications

An individual serving as a Quality Review Coordinator must meet the following qualifications:

a. Authorized to perform analyses under the Command's scope of accreditation (e.g. Component/Parameter, Item, Key Equipment/Technology) for the forensic discipline
b. Has extensive experience in the specific discipline and produces quality casework
c. Has a thorough awareness of the interrelationships between the forensic disciplines
d. Demonstrates an interest in improving the work product of those individuals working in their forensic discipline
e. Can objectively evaluate situations, identify problems, and recommend solutions

2. Selection Process

Interested employees will send a request for consideration as a Quality Review Coordinator to their Laboratory Director through the appropriate chain of command. The Laboratory Director will provide input to the Director of Quality Assurance about the employee's capabilities. The selection of the Quality Review Coordinator is made by the Commander and the Director of Quality Assurance.

3. Term

Term of the Quality Review Coordinator is three years in the forensic biology, microscopy, trace chemistry, footwear/tiretrack, Y-STR DNA, Indexing, and toxicology sections, and is considered a part-time assignment, with casework production still a duty.

Term for the Quality Review Coordinator in, drug chemistry, latent prints, and firearms/toolmarks is two years. The term for DNA is three years. These positions

are considered as full-time, with limited casework done as time permits.

The DQA may extend terms when necessary.

4. Responsibilities include, but are not limited to, the following duties:

   a. Provide technical assistance to each section member;
   b. Conduct quality assurance visits as requested by the Laboratory Director or the Director of Quality Assurance including an evaluative report provided to the Laboratory Director and Director of Quality Assurance;
   c. Address the analytical capabilities of each section member by conducting case reanalysis, technical reviews, and internal proficiency testing (as needed). Notifications of these activities will be issued to the Director of Quality Assurance and respective Laboratory Quality Manager, with all matters to be handled in a confidential manner;
   d. Review the section's procedures and standards and controls as needed, and forward potential procedural concerns and recommendations for changes to the Director of Quality Assurance;
   e. Review all external proficiency tests for analysts which fall under their discipline in accordance with QM-6;
   f. Select Technical Review and Reanalysis cases for each analyst, notifying the respective quality managers in a timely fashion to transfer cases as needed;
   g. Provide the Director of Quality Assurance with a year-end report of section quality assurance activities, to include a review of the section's adherence to policies and procedures, as well as detailing areas of improvement identified;
   h. Participate in Command Quality Assurance Committee Meetings; and
   i. Maintains a high level of quality work and serves as an example to others.

B. Quality Assurance Committee - A Quality Assurance Committee composed of all Quality Review Coordinators, the Director of Quality Assurance, the Assistant Director of Quality Assurance, and Laboratory Quality Managers that assess the quality assurance activities in the Command.

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POLICY

Quality documents used in the Forensic Sciences Command Quality Management System are controlled to ensure that only current, up-to-date documents are being utilized.

I. DEFINITION

Forms – The document templates used for recording information related to monitoring and operating the Quality Assurance Program and/or forensic science laboratory system. They are Quality Documents and are controlled. Forms are in the manuals listed below as Quality Documents.

Quality Documents - All documents utilized by the Command to provide quality forensic services such as manuals, forms and procedures. These are maintained in the Command Directives, Command Quality Manual, Procedures Manuals, Training Manuals, Command Safety Manual and the laboratories' Facility Operations Manuals (FOM).

Worksheet Templates– A software or document (hardcopy or electronic) that is the frame for entering analytical data during casework. These are Quality Documents and are controlled. These are stored in LIMS.

II. CONTROL

A. Only approved quality documents may be utilized.

B. Approved documents may not be customized or altered.

C. Control of manuals and dissemination is discussed in ADM 18, Electronic Manuals, of the Command Directives.

D. Authorization/approval for the manuals is as follows:

1. Command Directives - Commander

2. Quality Manual - Director of Quality Assurance

3. Procedures Manual - Appropriate Bureau Chief or Program Manager

4. Training Manuals - Director of Training

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5. Command Safety Manual - Director of Quality Assurance

6. Laboratory FOMs - Laboratory Director

F. Reviews

1. The Command Directives, Quality Manual, Safety Manual and Laboratory FOMs are reviewed annually, at a minimum, and all new policies are reviewed prior to implementation.

   a. Reviews for adequacy are overseen by the person designated as having authorization/ approval for the manual.

   b. Reviews can be conducted by committees of individuals picked by the review overseer, with any necessary additions or changes noted for implementation.

   c. Review dates and version number will be noted in each manual.

   d. Changes to the Command Directives, Safety Manual, Quality Manual, and FOM's will be communicated to staff via email, using a solid bar next to any changes.

2. Section Procedures Manuals review policy is covered in Command Directives – ADM 11.

III. LIST OF QUALITY DOCUMENTS

A. The Director of Quality Assurance controls a legal edition of ISO/IEC 17025:2017.

B. In lieu of a list of approved documents distributed to Command personnel, an equivalent process is implemented in which each manual will contain:

1. Table of contents, which lists the document or policies within;

2. Revision/acceptance date of documents to demonstrate the most current version;

3. Date of last review, or for Procedures/Training Manuals, date of next review;

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4. Authorizations for transmittal and use of the documents by the person identified in II.E of this directive.

C. A version of the Quality Assurance Standards for Forensic DNA Testing and Databasing laboratories can be obtained from the Federal Bureau of Investigation website (refer to QM-9 for the exact location of the documents).

D. When a section's Procedures Manual states Forensic Sciences Command analysts must rely on an equipment operating manual for a procedure (e.g. conducting analysis or performing maintenance), then the manual is defined as a "controlled document." The relevant edition/version of the operating manual must be listed in the approved procedure manual.

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POLICY

It is the responsibility of the Forensic Sciences Command to ensure that testimony in each forensic discipline is technically reviewed annually to ensure that the expression of any result, interpretation and/or opinion is accurate and supported by the technical record from which it is derived.

It is also the responsibility of the laboratory management to ensure each individual analyst's testimony is evaluated. This may be accomplished by a technical review of testimony, a non-technical evaluation of testimony, reviewing court surveys submitted by attorneys and judges, through conversation with the attorneys and judges involved for feedback, or by reviewing transcripts.

I. PROCEDURE

A. Technical Review of Testimony

1. Testimony must be technically reviewed annually for each discipline in the Forensic Sciences Command's scope of accreditation (e.g. Seized Drugs, Fire Debris, Trace (Materials), Footwear/Tiretrack Impressions, etc.).

2. A Testimony Reviewer must be selected that is:
   a. Competency tested in the discipline for which the testimony is being given, and
   b. Trained in the techniques which were utilized to form the foundation of the scientific opinion.

2. It is preferred that the Testimony Reviewer:
   a. Be currently participating in proficiency testing in the relevant discipline,
   b. Not have been the original technical reviewer of the case, and
   c. Not work in the same laboratory as the analyst which will testify.
   d. Be a manager or Quality Review Coordinator (QRC) as available.

3. Prior to a live testimony, the Testimony Reviewer will familiarize themselves with the case file and discuss any questions if needed with the testifying analyst. The Testimony Reviewer will document their review through a Post-Review within LIMS. If a Post-Review has already been done by another individual, the review will be documented as a Case Event in the LIMS.

4. The Testimony Reviewer will record all observations in Appendix 5.1.1 – Testimony Evaluation Form.

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5. Upon completion, Appendix 5.1.1 will be provided to the Quality Manager from the analyst's laboratory. The Laboratory Quality Manager will review the form and document the Testimony Reviewer in the activity log for the court testimony. If the review is free of issues, Appendix 5.1.1 will be forwarded to appropriate Command personnel for attachment to the activity log entry in LIMS. The analyst and supervisor review the feedback and document appropriately in LIMS. In addition, the respective Bureau Chief will be provided a copy for review. Any unexpected results and/or issues will be communicated to the Director of Quality Assurance, Technical Leader (if applicable) and respective Bureau Chief by the Lab Quality Manager to determine if any corrective actions are needed per QM-8.

6. In lieu of witnessing a live testimony, transcripts of a testimony can be reviewed by the Testimony Reviewer and evaluated using Appendix 5.1.1.

B. The testimony of each Forensic Biology and DNA analyst must be evaluated annually. This may only be accomplished by technical review of testimony (I.A) or any of the options listed below.

1. Evaluation of Live Testimony (Non-Technical)

a. Evaluation of a live testimony (non-technical) does not need to be performed by an individual previously competency tested in the discipline for which the testimony is being given.

b. It is preferred that the Testimony Reviewer:
   i. Be a manager or an analyst
   ii. Not have been the original technical reviewer of the case

c. Appendix 5.1.1 will be utilized; however, it is not required to fill out the "Pre-Testimony" and "Technical Review of Testimony" sections.

d. Upon completion, Appendix 5.1.1 will be provided to the Quality Manager from the analyst's laboratory. The Lab Quality Manager will review the document. If the review is free of issues, Appendix 5.1.1 will be forwarded to appropriate Command personnel for attachment to the activity log entry in LIMS. The analyst and supervisor will review the feedback and document appropriately in LIMS. The Testimony Reviewer should be consulted as needed. Any unexpected results and/or issues will be communicated to the Director of Quality Assurance, Technical Leader (if applicable) and respective Bureau Chief by the Lab Quality Manager to

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determine if any corrective actions are needed per QM-8.

2. External Court Testimony Feedback

   a. All personnel will ensure that a witness critique survey (Appendix 5.2.1) is made available to both the prosecuting and the defending attorneys for cases in which they provided testimony. In addition, whenever possible, a survey should be given to the judge hearing the case. Alternative means such as providing a link via e-mail to the web portal for the survey are also acceptable.

   b. The witness critique survey may also be completed through verbal conversations with the attorneys and judges involved.

   c. All court testimony will be documented using the activity log in LIMS.

   d. Testimony feedback received from an external source will be attached to the particular activity log entry in LIMS and reviewed by both the analyst and their supervisor.

   e. If the feedback is negative in nature the laboratory will notify the Director of Quality Assurance, and corrective action will be taken as needed in accordance with QM-8.

3. Review of Transcripts

   The appropriate Laboratory Director may obtain a transcript of the analyst's testimony to conduct the annual review. A laboratory manager and/or QRC will review the transcript and complete the Testimony and Technical Review sections of the Appendix 5.1.1 form. The form will be provided to the appropriate Laboratory Quality Manager for attachment to the activity log entry in LIMS. If there are no issues, the analyst and supervisor will review the feedback and document appropriately in LIMS. The Laboratory Quality Manager will communicate any unexpected results and/or issues to the Director of Quality Assurance, Technical Leader (if applicable), and respective Bureau Chief to determine if any corrective actions are needed per QM-8.

C. If the analyst did not testify during the calendar year, this information must be documented in the LIMS Activity Log.

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D. Effective January 1, 2024, the testimony of each analyst and evidence technician in all forensic disciplines must be evaluated annually. This may only be accomplished by the options listed in I.A and I.B above.

ILLINOIS STATE POLICE
DIVISION OF FORENSIC SERVICES
FORENSIC SCIENCES COMMAND

QUALITY MANUAL – APPENDIX 5.1.1 - TESTIMONY EVALUATION FORM

General Information	
Analyst Name	
Date of Review	
Testimony Reviewer	
Case Number	
Venue (Live, Video, Transcript)	

Pre – Testimony (only required for Technical Review of Testimony QM-5.I.)	YES	NO	N/A
Did the Testimony Reviewer review the case file? (if so, document the review in LIMS in accordance with QM-5)			
Did the Testimony Reviewer understand and agree with the scientific basis for which any result, opinion and/or interpretation was made?			
Did the Testimony Reviewer discuss with the analyst about any questions or issues identified from the attorneys?			

Personal Impressions/Demeanor	SATISFACTORY	UNSATISFACTORY
Voice (adequate volume, tone, fluency)		
Eye contact		
Posture		
Facial Expressions		
Gestures		
Dress		
Etiquette		
Confidence		

Testimony	YES	NO	N/A
Clear and Concise?			
Responsive to questions?			
Understandable?			
Limited to area of expertise?			
Asks for clarification when needed?			
Referred to notes when necessary?			
Was the evidence handled properly?			
Were visual aids clear and used effectively?			

Technical Review of Testimony	Yes	No	N/A
Were the results, interpretations, and/or opinions conveyed consistent with the analytical results and report issued to the agency?			
Were visual aids consistent with the findings conveyed on the report?			
Was the evidence sealed as described on the notes, apart from any explainable differences?			

Comments (required for any unexpected result or issue indicated above)

Corrective Action (to be completed by Quality Manager)	YES	NO
Is corrective action necessary?		
If yes, please list the QIR #		

Appendix 5.2.1 - Witness Critique Survey Questions

The Illinois State Police (ISP) value the comments of officials of the court to ensure our forensic services staff provide effective courtroom testimony. Your open communication and cooperation with us will help us to achieve service excellence.

Please provide the following case information

1. Prosecuting County/Jurisdiction
2. Date of Testimony
3. ISP Case Number
4. Submitting Agency
5. ISP Employee

The witness was prepared for trial

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

The witness was responsive to subpoena requests and/or appropriate pretrial communications

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

The witness was objective

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

The witness was responsive

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

The witness was professional

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

The testimony was clear

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

The technical content of the testimony was understandable

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

Rank your overall level of satisfaction with the testimony of the witness

1. Strongly Satisfied
2. Somewhat Satisfied
3. Neutral
4. Somewhat Unsatisfied
5. Strongly Unsatisfied

Comments on testimony / Suggestions for improvement

Comments

Would you like someone to contact you regarding this witness testimony?

1. Yes
2. No

Thank you for your assistance. Please contact us if you have any questions or concerns.

Email: DFS_Quality_Assurance@Illinois.gov

Contact information for person completing survey

1. Name and Title
2. Phone Number
3. Email Address

Case Involvement

1. Judge
2. States' Attorney
3. Defense
4. Other (please specify)

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POLICY

The Forensic Sciences Command has four types of performance tests that may be used as quality assurance measures. These are competency tests, external proficiency tests, internal proficiency tests, and blind proficiency tests. Proficiency testing will be used either as an assessment of the analyst's ability to obtain accurate results and interpret them properly or as a measure and comparison of reproducibility between laboratories, as in quantitative analysis. When incorrect analysis or non-concordant result(s) (including an Inconclusive conclusion) occurs in proficiency testing, the corrective action process (QM-8) will be initiated.

I. COMPETENCY TESTS

A. Frequency and Purpose

1. The purpose of the competency test is to establish that an analyst has demonstrated the achievement of technical skills and knowledge necessary to perform specific forensic analyses. It is also used to ensure that new techniques are instituted in the Command in a uniform manner. A competency test may consist of a written test and/or sample analysis.

   A competency test must be given to an analyst, including but not limited to the following situations, unless otherwise directed by the Director of Quality Assurance, DNA Technical Leader, Bureau Chief or Commander:

   a. During initial training, prior to performing supervised casework.

   b. When an analyst is assigned to a different laboratory and has not operated the type of instrumentation found at the destination laboratory, or there are sufficient differences in testing between the two laboratories (i.e. an analyst transferring from a laboratory that does not perform toxicology blood drug quantitation to one that does).

   c. When new techniques are instituted in the Command.

2. A competency test (or a proficiency test in substitution) must be given to an analyst who has not performed analyses for a significant period or has been on leave that takes them out of the proficiency test cycle. The Laboratory Director may request retraining of an analyst based upon the length of the leave, which will be approved by the Commander. If the request for retraining is for a DNA analyst, the Technical Leader must assess the extent and approve the retraining plan which must include competency testing.

3. For all other situations, the decision to give a competency test rests with the Laboratory Director or Laboratory Quality Manager.

B. Administering the Test

1. The Training Coordinator is responsible for directing the creation, administration and evaluation of the competency test. However, it is the responsibility of the Laboratory Director to request the test and ensure that the examiner has taken and passed the test before performing specific forensic analyses.

2. If the test involves sample analysis, samples will consist of a set of unknowns which the analyst is to analyze utilizing the designated technique.

3. The time allotted to complete the test is to be established by each Laboratory Quality Manager and the analyst involved; however, it will not exceed four (4) weeks.

4. All samples will be kept until notification of successful completion of the tests is received.

C. Evaluating the Results

1. The analyst must submit the test in LIMS. The completed test will include a report along with the supporting notes to the Training Coordinator or designated reviewer for technical review.

2. The analyst must report all findings in concordance with the responses anticipated in preparation of the test. Inconclusive answers are acceptable if anticipated by test design or if acceptable as a part of the section's protocols.

3. When the test involved sample analysis and the analyst did not pass the first test, laboratory management will notify Statewide Training or the Director of Quality Assurance immediately depending on the purpose of the test. The results of the test will be communicated to the analyst and the individual shall be retested. The analyst may not be responsible for an error since the test samples may have been mislabeled, the person being tested may not have understood the instructions, or the sample being submitted may have deteriorated. To accommodate these possibilities, the analyst will receive a second sample, different from the first, but on the same subject matter. This second sample is to be analyzed upon receipt with results due within two (2) weeks. If there is an error in the results of the second test, the Director of Quality Assurance or Statewide Training will inform Command Administration and the appropriate DNA Technical Leader (for DNA issues).

Laboratory management, Command Administration, the Director of Quality Assurance, and the appropriate DNA Technical Leader (for DNA issues) will discuss the appropriate actions to be taken. A review of the test by another analyst may also be warranted.

4. When the test did not involve sample analysis (i.e., written tests) and the analyst did not pass the first test, laboratory management will notify Statewide Training or the Director of Quality Assurance immediately, depending on the purpose of the test. Laboratory management, Command Administration, the Director of Quality Assurance, and the appropriate DNA Technical Leader (for DNA issues) will discuss the appropriate actions to be taken.

5. Upon satisfactory completion, the designated tester will send a report to the appropriate Laboratory Quality Manager and the Director of Quality Assurance. The Laboratory Quality Manager will communicate successful completion of the test to the analyst.

D. Maintaining Test Records

Test records will be maintained in each analyst's laboratory training file as specified by the Command Directives.

II. EXTERNAL PROFICIENCY TESTS (EPT)

A. Frequency and Purpose

1. All laboratory personnel assigned to do casework in a specific laboratory activity will be required to pass an external proficiency test every year in their specific discipline(s) for which a test has been developed unless otherwise indicated below. This includes all DNA analysts that participate in casework, as designated by the Technical Leader(s). External proficiency tests are required to be passed annually for the testing activities listed below, unless otherwise indicated:

   a. Body Fluid Identification – one (1) test per year; may be combined with a DNA test
   b. Casework & Indexing DNA – two (2) tests per year, per the FBI QAS requirements

   c. Toxicology:
      i. Blood Alcohol/Volatile analysis
      ii. Blood Drug analysis

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iii. Urine Drug Analysis
iv. Quantitative Beverage

d. Firearms/Toolmarks
   i. Firearms Comparison
   ii. Serial Number Restoration
   iii. Toolmarks Examination

e. Drug Chemistry
   i. Cannabis Identification
   ii. Drug Identification

f. Latent Print
   i. Latent Print Comparison

g. Footwear/Tiretrack
   i. Footwear/Tiretrack comparison (alternate years)

h. Micro/Trace
   i. Arson
   ii. Primer Gun Shot Residue
   iii. Paint
   iv. Fiber Comparison
   v. Physical Match

2. A Laboratory Director may, with the approval of the appropriate Bureau Chief, request an additional proficiency test for any individual at any time.

3. Proficiency testing may be used either as an assessment of the analyst's ability to obtain accurate results and interpret them properly following all ISP policies and procedures, or as a measure and comparison of reproducibility between laboratories, as in quantitative analysis.

4. Proficiency tests shall be purchased from providers accredited to the ISO 17043 standard. If no test exists, an approved alternative test will be used as approved by the current laboratory accrediting body. Prior to the purchase of the external proficiency test, DNA tests will be approved by the Casework or Indexing DNA Technical Leaders, respectively.

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5. For the Casework and Indexing DNA tests, the received date of the proficiency test will be considered as the performance date of the test, with the next test to be performed not less than four months nor greater than eight months after this date.

B. Administering the Test

1. A test will be administered every year to certify the analyst for the following period, i.e., completion in 2019 will certify casework in 2020. Analysts who recently completed training will participate in the next external proficiency test that is available after the completion of training (no more than 8 months from the release of training for DNA analysts). For example, in all sections but DNA, if training is completed in March 2020, and the external proficiency test was administered in January 2020, the first proficiency test the analyst will participate in will be for January 2021.

2. All analysts working cases must be proficiency tested for those casework areas for which a test is available.

   a. Analysts will treat the proficiency test as normal casework, except as otherwise noted in II.B. Testing will be performed with adherence to the relevant minimum standards and controls using LIMS to record all notes and to generate a report.

   b. If an answer sheet requires an answer that is not normally reported in casework (for instance, an answer sheet that includes a scale of similarity) the most appropriate answer will be chosen on the answer sheet, while the mock "report" generated in LIMS will reflect how the analyst would report the results of testing if it were an actual case.

   c. The Laboratory Quality Manager will assign analysts the external tests using LIMS. Proficiency tests take precedence over casework. DNA tests are required to be completed in six (6) weeks and all other tests are required to be completed in one (1) month, unless approved by the laboratory management.

   d. EPTs will be worked independently and will not be subject to peer review prior to submission to the Quality Review Coordinator (QRC). If no approved verification is being conducted on the test, a supervisor that is not participating in the test will initial the verification field in LIMS to allow submission of the test.

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e. When complete, the analyst will submit the answers to the test provider and route the assignment in LIMS to the QRC (with provider answer sheet attached in the image vault).

3. For DNA proficiency tests:

a. For Casework DNA proficiency tests, the autosomal typing test kit will be used for each semi-annual test in the calendar year. Additionally, analysts qualified in a Y-STR typing kit will need to conduct this analysis in one of the semi-annual tests in the respective calendar year.

b. For Indexing DNA proficiency tests, analysts that are qualified in both autosomal and Y-STR typing kits will need to use each of these typing kits on one of the semi-annual tests in the calendar year. However, it will only be necessary to use the autosomal typing kit for each semi-annual test in the calendar year if the analyst is only qualified in the autosomal typing test.

c. For Casework and Indexing DNA proficiency tests, each analyst will perform at least one method in each methodology for which they are qualified at least once per year. For the definitions of method and methodology refer to the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and Databasing Laboratories.

d. For Casework DNA proficiency tests, the LIMS notes packet shall contain documentation of the number of contributors for each unknown sample and all mixture samples will need to be differentiated as appropriate following ISP Interpretation procedures.

e. If a quality issue occurs with the analytical processes for Casework DNA proficiency tests, the appropriate DNA Technical Leader must be notified that the issue being documented with the Incident Report contains proficiency test samples. This notification must occur prior to the submission of the results to the test provider.

f. The Statewide CODIS administrator must also be notified in the event of non-administrative discrepancies that affect the typing results and/or conclusions.

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4. For Toxicology proficiency tests:

   a. All samples must undergo full volatile and/or drug analysis as warranted by sample type/request of the proficiency test vendor, and no analysis will be deferred. For example, a urine drug proficiency test would require EMIT and confirmatory testing for all positives, and a general drug screen. Additional testing for GHB and lorazepam should also be performed when the provided case history indicates that a drug facilitated assault is suspected. Analysts will only be responsible for drugs listed in the toxicology drug panel (See Toxicology PM).

C. Evaluating the results

1. Upon receipt of the results from the test provider, the QRC will review the test using the Proficiency Test Checklist in LIMS. Once complete, the analyst, Laboratory Quality Manager, the appropriate DNA Technical Leader (for Casework and Indexing DNA proficiency tests) and Director of Quality Assurance will be notified of the results. If the answer is concordant with the proficiency test provider's results and follow ISP procedures, the test will be considered satisfactory.

2. For quantitative toxicology samples:

   a. Expected results are limited to analytes within the laboratory's scope of quantitative testing with an established measurement uncertainty.

   b. When a grand mean is provided, an analyst's test will be deemed concordant if the reported value and its uncertainty range is inclusive of the test provider's reported grand mean.

   c. If the reported value and its uncertainty range is not inclusive of the test's grand mean, however the reported value is within 2 SD of the grand mean, the test will be considered expected and concordant. The QRC will notify the Technical Leader to review the analyte's measurement uncertainty budget.

   d. When a grand mean is provided, and a reported value is outside 3SD of the grand mean, a Quality Issue Report will be issued. The Technical Leader will review the test including the analyte's measurement uncertainty budget.

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e. When a grand mean is provided, and a test provider reports an analyte where 3SD of the grand mean is outside the quantitative limit established by the procedure's calibration range, the QRC will review the analyst's proficiency test to ensure proper reporting policies were followed. If so, the test will be deemed concordant. If proper policies were not followed, the test result will be deemed unexpected and non-concordant.

f. When a test provider does not provide sufficient information to evaluate test results, the QRC or Technical Leader will determine an assessment criterion. This assessment may include a statistical analysis that includes all laboratory participants test results if necessary.

3. Non-Concordant Results

All non-concordant results will be documented using a Quality Issue Report (QM-8). Laboratory management should immediately notify the appropriate Bureau Chief and Command Quality Assurance once a determination that a non-concordant external proficiency test result exists. The Director of Quality Assurance will notify the accreditation body of all non-concordant proficiency test results within thirty (30) days of becoming aware that expected results were not attained.

a. Administrative Issues

If the QRC can determine that the non-concordant answer is due to an administrative (typographical) error, the QRC will notify the Laboratory Quality Manager. The laboratory will document this issue using a Quality Issue Report (QM-8) and notify the appropriate Bureau Chief and Command Quality Assurance. It must be clear from the supporting data that the analyst would have arrived at the correct response but filled out the answer sheet incorrectly. This must be documented in the QIR, and then commensurate actions will be taken.

b. Reporting Limitations

If the QRC can determine that the non-concordant answer is due to a reporting limitation, the QRC will notify the Laboratory Quality Manager. Reporting limitations are instances in which the section's policies and procedures preclude the analyst from submitting a concordant answer. The laboratory will document this issue using a Quality Issue Report (QM-8) and notify the appropriate Bureau Chief and Command Quality Assurance. It must be clearly documented

in the QIR the conclusions submitted to the proficiency test provider adhered to Illinois State Police procedures, and then commensurate actions will be taken.

c. Technical Issue

i. If the QRC determines that the non-concordant answer is technical in nature, the QRC must ensure the appropriate discipline's Technical Leader concurs (if applicable). Then, the QRC will notify the Laboratory Quality Manager. The laboratory will notify the appropriate Bureau Chief and Command Quality Assurance. Issues that arise that are technical in nature will be documented using the Quality Issue Report (QM-8). The Laboratory Quality Manager will conduct a cause analysis and develop a course of action. All corrective actions will be approved by the discipline's Technical Leader (if applicable) and the Director of Quality Assurance.

ii. In addition to any other corrective actions that result, the analyst will be required to pass a second test for the same testing activity. An additional external proficiency test may be procured, or the QRC or appropriate Training Coordinator will prepare an internal test for the analyst, in consultation with the Director of Quality Assurance and subject to Section III. of this policy.

iii. Should the results of the second test be non-concordant, the analyst will be suspended from casework until competency in the testing activity can be re-established.

4. The notification to Command Quality Assurance should include the type of non-concordant result, associated employee(s), and a description of the quality issue preferably citing the non-compliant procedure.

5. If the Director of Quality Assurance or the Laboratory Quality Manager becomes aware of any discrepancies or inappropriate results, he/she will immediately brief the appropriate Laboratory Director and Bureau Chief. If necessary, corrective action will be initiated and documented per QM-8.

6. If an error appears to be systemic, the Director of Quality Assurance will notify the Commander and take any additional necessary actions, which may include recommending the appropriate Program Manager or Bureau Chief to determine the

appropriate course of action which may include remedial training and/or method modification.

7. If a major error is identified, the Commander or DNA Technical Leader, as appropriate, may require that casework in a particular area be suspended in a laboratory or the Command until appropriate remedial actions are taken.

D. Maintaining Record and Samples

1. All proficiency tests, except for those listed in II.D.2., will be given an ISP case number and all data, notes and reports will be maintained in LIMS. All samples may be discarded once the analyst has successfully completed the proficiency test as indicated by the test provider, or through the quality assurance mechanisms listed in II.C. above. Whenever possible, the Laboratory Quality Manager will contact the Director of Training (or designee) prior to disposal of the tests to determine if there is a training need for the samples, and forward tests as appropriate.

2. The DNA Indexing Laboratory does not utilize LIMS to perform sample analysis at this time, therefore these tests will not be assigned a LIMS case number, nor stored in LIMS. The tests will be stored in a secure, limited access location on the network.

III. INTERNAL PROFICIENCY TESTS (IPT)

A. Internal proficiency tests will be prepared by appropriate staff in consultation with the Director of Quality Assurance. Internal tests will be used only as a supplement to external testing, or for testing activities that do not have a suitable external test. All applicable requirements listed in Section II. for external tests will apply for internal tests.

1. Additional requirements of internal proficiency tests

a. The Director of Quality Assurance will assign an appropriate analyst to analyze a prepared test prior to its distribution to verify the samples(s). Any exceptions to verifying the test will be approved by the Director of Quality Assurance.

b. Samples will be marked appropriately to allow identification and are to be varied, where practical, to ensure that all analysts at the same laboratory do not receive the same samples.

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c. Exceptions to this might include samples which are for quantitation, for evaluation of techniques, or as indicated in the section's quality assurance protocol.

d. An answer key for samples will be sent to the Director of Quality Assurance prior to issuing the test to the analyst(s).

2. Test Preparation

a. If the test is prepared for use as a second test as indicated in section II.C.2.c. above, the samples prepared will assess the same testing activity.

b. If the test is prepared for a testing activity where no suitable external test exists, the test should mimic casework samples as closely as possible.

c. If the internal test is to be taken after a non-concordant test as indicated in II.C.2.c. above, the analyst will have two (2) weeks to complete the analysis. Any extension must be submitted through chain and be approved by the Director of Quality Assurance. Extension requests must be made no later than three (3) working days before the due date.

IV. ALTERNATIVES TO PROFICIENCY TESTING

Testing activities that are monitored through case file reviews or reanalysis instead of proficiency testing:

1. Firearms and Toolmarks
   - Make/Model Determination, Determination of Functionality, and Barrel Length Measurement
   - Individual Characteristic Database
   - Muzzle to Clothing Contact Examination

2. Latent Prints (Friction Ridge)
   - Enhancement
   - Individual Characteristic Database

3. Footwear
   - Enhancement

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V. BLIND PROFICIENCY TESTS

A. Frequency and Purpose

The Command may periodically submit blind proficiency testing samples to its employees. This serves as an assessment of the analyst's ability to obtain accurate results.

B. Administering the Test

1. Command Administration and the Director of Quality Assurance, sometimes utilizing other units within the Command, will prepare samples for distribution.

2. The samples will be prepared in duplicate and will resemble actual case material. One set of samples will be maintained by the Director of Quality Assurance for comparison purposes. Careful notes will be taken as the tests are prepared.

3. Blind proficiency testing will require the cooperation of user agencies. The user agency will submit the test, which shall be carefully disguised as an actual case submitted by that agency. Officers will be aware that the purpose of the test is to ensure that quality laboratory service is being rendered to their agency. The Laboratory Director will be the designated contact for the involved agency. The agency will be instructed to return test materials to the Director of Quality Assurance after analysis by the laboratory.

C. Evaluating the Results

1. Upon satisfactory completion, the Laboratory Director or designee will send a memorandum of successful completion to the Director of Quality Assurance. The memorandum will be maintained by the Director of Quality Assurance as documentation of the blind proficiency testing.

2. If there is an error in the results, a Quality Issue Report will be issued. It will be the responsibility of the appropriate Bureau Chief to notify the Laboratory Director and analyst.

a. The submitting agency will not be advised of any errors.

b. A thorough review of the "case" with the analyst and Laboratory Quality Manager will be conducted so that all the notes can be reviewed for possible sources of error.

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i. If the integrity of the sample tested is in question, the reference sample will be examined by the preparer in the presence of the examiner to determine if the original sample is valid.

ii. If valid, every effort will be made to determine the source of the analyst's error.

D. Maintaining Test Records

All test materials (photos, notes, spectra, etc.) will be retained as quality records per the Command Directives.

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I. MEASURING SERVICE TO ASSURE QUALITY

A. Quality Service

The Forensic Sciences Command is committed to providing high quality services to the law enforcement community. These directives outline the necessary actions to ensure that quality services are provided.

B. Monitoring Our Service

The Command will initiate various checks to monitor the quality of services.

1. Input from agencies and other sources will be solicited to improve the quality of service.
2. Forensic Scientists are encouraged to share their experiences, both positive and negative, with the Director of Quality Assurance to assist in improving quality.
3. The quality of casework is directly related to the care taken in both choosing an appropriate analytical scheme and in performing the analysis. This will involve:
    a. Following the established standards and controls
    b. Incorporating good scientific practices
4. While a self-checking process is a fundamental aspect of quality assurance,external checks and reviews are necessary to monitor the overall quality of work performed.
    a. These checks and reviews involve at least yearly audits of laboratories by audit teams authorized by Command administration.
    b. Periodic reevaluation of the Command's standards and controls in light of advances in technology, results of proficiency testing and review of a representative sampling of casework is also mandated.
5. An ongoing review of the Quality Assurance Program will be conducted by the Director of Quality Assurance.

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II. QUALITY MEASURES

A. The Laboratory will monitor the validity of testing using quality control procedures.Each discipline's procedure manual will outline the quality control procedures for that specific discipline. The following are examples of quality control procedures:

- Use of reference collections;
- Use of certified reference materials;
- Use of positive and negative controls;
- Participation in proficiency testing programs;
- Performance Checks on instruments and equipment;
- Review of reported results and verifications.

Each discipline's procedure manual will specify the controls and standards utilized in each method or procedure. All controls and standards utilized in casework will be documented in the examination documentation. The laboratory will perform technical review on 100% of scientific examination documentation and test reports prior to release. Verifications are performed as specified in each discipline's Procedure Manuals. The technical review process ensures the conclusions are reasonable within the constraints of the validated technical knowledge and supported by the examination documentation. Technical reviews are documented in LIMS.

B. Quality Assurance Reviews

The quality service of both the laboratory as a whole and the individual analysts will be monitored continually through administrative reviews. Various checks will be conducted at both the laboratory and Command level. Minimum requirements for this review will be utilization of court cards, file and testimony reviews, the use of agency questionnaires, reanalysis of selected cases as appropriate, and other reviews as described in the Command Directives. The adherence to quality assurance measures will be noted in an analyst's annual performance evaluation.

C. Case Reanalysis

1. Frequency and Purpose

a. The Commander, Bureau Chiefs, the Director of Quality Assurance, Laboratory Directors or their designees may select a case for re-examination.

b. In each discipline, a minimum of two cases per analyst per calendar year will be reanalyzed, except for drug chemistry, which will have three cases reanalyzed, and Indexing, where hit verifications will serve as reanalysis in place of having samples reanalyzed.

c. Casework DNA will not routinely use reanalysis as a quality control measure due to the nature of the samples and the potential for consumption.

d. In some instances, the number of cases worked by a given analyst does not warrant or permit this amount of reanalysis. The Director of Quality Assurance will determine the appropriate number of cases to be reanalyzed in those situations.

2. Coordinating the Analysis

a. The case will be re-examined by the Quality Review Coordinator; however, there may be certain situations where a Training Coordinator, DNA or Toxicology Technical Leader, or a Command approved designee may also perform this analysis.

b. For Indexing, hit verifications will serve as reanalysis in place of having samples reanalyzed. The procedures for hit verifications are in the Indexing Procedures Manual, and those procedures will be followed.

3. Evaluating the Results

a. If there is no disagreement with the results of the original analysis, a reanalysis report will be issued to the submitting agency.

b. If non-conforming work is identified, the Director of Quality Assurance will be immediately notified. The course of action to be followed will be determined in conjunction with the appropriate Bureau Chief and Commander (See QM-8 and QM-17). A course of action involving a technical DNA or Toxicology issue will be implemented upon the approval of the DNA or Toxicology Technical Leader. All issues will remain confidential. A reanalysis report will be issued to the submitting agency upon resolution of the discrepancy.

4. Maintenance of Reanalysis Records

   a. All documentation from the reanalysis will be maintained in LIMS.

D. Case File Reviews

1. Author Review

   Prior to the administrative and technical review, the author of the report is responsible for reviewing the case file and accompanying report for editorial correctness, technical accuracy, and completeness. At the completion of the Author review, the analyst will submit the case for technical review, which will apply the analyst's signature to the report. This signature serves as authorization of the results.

2. Technical and Administrative Review

   a. Prior to releasing the laboratory report, LIMS requires that technical and administrative reviews of case files and their accompanying laboratory reports are completed by an individual who did not conduct the laboratory activity. The reviewer is usually a currently qualified analyst in the discipline of testing but may be any individual previously qualified in the area the reviews are encompassing. The reviewer is responsible for confirming technical accuracy of the conclusions from supporting data within the case notes, that appropriate policies and scientific procedures are followed and for editorial correctness.

   b. The reviewer will utilize the technical review checklist in LIMS to document the review. If calculations are made that are subject to human error, this task will be added to the technical review checklist, and the calculations will be reviewed. Upon successful completion, the reviewer will mark the case as "REVIEW COMPLETE" in LIMS. The technical reviewer will contact the analyst if there are questions or clarification is needed. When corrections are necessary, the case will be "rejected" back to the analyst in LIMS, and the reasons documented in the comments section. The analyst will make any necessary corrections and re-submit the case for technical review.

   c. For non-routine or novel procedures, the reviewer will make every effort to verify the original work of an analyst. This will include checking sources of information i.e., literature references and analytical accuracy.

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d. Technical/Administrative reviews and verifications of identifications will not be performed by individuals who have a real or apparent conflict of interest due to a known relationship (including but not limited to household, family, or financial) with the forensic scientist who performed the analysis.

e. Should there be a disagreement with the verification of an identification or the technical/administrative review of a report, information will be presented to laboratory management who will then take appropriate action by contacting the Director of Quality Assurance for input in resolving the disagreement. The appropriate Technical Leader will be contacted for all DNA and Toxicology issues in dispute.

f. Any forensic scientist who observes quality concerns with the work of another laboratory employee has the ethical obligation to inform the Laboratory Director through the appropriate chain of command. It is the Laboratory Director's responsibility to investigate and document the situation.

g. The minimum number of reports that requires administrative/technical review is as follows:
   1) Personnel in training regardless of position titles - 100%
   2) Forensic Scientists, regardless of position titles - 100%

3. Supervisory Review (Management Review)

   a. Each Laboratory Director will ensure that laboratory management reviews three cases per month for each case working analyst in all sections. If a case working analyst did not complete three cases during the month, then laboratory management will review all the cases that are available (e.g. The laboratory manager reviews the single case that is completed in April and then reviews three of the five cases completed in May).

   b. The cases reviewed will be documented using the management review checklist in LIMS. Any discrepancies will be addressed through the appropriate process and documented.

4. Quality Review Coordinator Case File Reviews

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a. The Quality Review Coordinator will review a portion of the case files generated by each analyst for completeness and accuracy. Efforts will be made to ensure a representative sample of the analyst's work is selected for review in each calendar year that the analyst worked. If the coordinator or management feels that further review is needed based on laboratory circumstances, additional case files may be reviewed. The review will be documented in the same fashion as technical review indicated above, except for Indexing, which will utilize Appendix 7.1.

b. The type and amount of DNA cases selected for annual review will be determined by the DNA technical leader.

c. The number of cases selected for QRC technical review varies per discipline, and is as follows:

Discipline	Amount/Analyst
Biology	5
DNA: autosomal	5
DNA: Y-STR	3
Drug Chemistry	7
Firearms/Toolmarks	5
Latent Prints	5
Toxicology	5
Footwear/Tiretracks	2
Micro/Trace	5
Indexing	5

i. If a particular analyst did not work a sufficient number of cases in a given year (i.e., extended leave, change in assignment) these numbers can be modified with the approval of the DQA.

ii. If an analyst works within multiple disciplines (for instance trace, physical match, and firearms), a total of 5 cases per analyst only need be reviewed incorporating an appropriate sampling of cases from each discipline.

d. The types of cases selected for QRC technical review varies per discipline, and is as follows:

Discipline	Case Types to be Reviewed
Biology	Any
DNA	Autosomal STR cases selected will have unknown evidentiary sample(s) which have been profiled. Cases in which there are only sample(s) that have been stopped at quantification or cases that only have reference standards profiled shall not be reviewed. At least three of the cases shall have sample(s) in which a mixture was differentiated. Y-STR cases selected will have at least one unknown evidentiary sample which has been profiled along with a reference standard for comparison.
Drug Chemistry	Any
Firearms/Toolmarks	Bullet/Cartridge case comparisons, Muzzle to Clothing Contact Examination, Toolmarks, Physical Match
Latent Prints	Mix of lifts, porous, and non-porous, 2 cases should have prints that have been compared but not identified (exclusions and/or inconclusives), and two cases should have ABIS/NGI searches that did not result in hits
Toxicology	At least one quantitative result, one blood alcohol, one drug analysis, and one Criminal Sexual Assault Analysis, if possible.
Footwear/Tiretracks	May supplant file reviews in Latent Prints and/or Firearms.
Micro/Trace	GSR, Fiber, Paint, Materials, Arson, Physical Match
Indexing	Indexing Analytical files

E. Laboratory Visits

1. Frequency and Purpose

The purpose of the visit is to give the Quality Review Coordinator the opportunity to observe the analyst at work in his/her home laboratory and to discuss various aspects of casework. The visits will be at the direction of the Director of Quality Assurance and when the need arises as demonstrated by issues with case reanalysis, proficiency tests, file reviews or from findings made during internal or external audits.

2. Conducting the Visit

a. The Quality Review Coordinator will:

i. Meet with the Laboratory Director or designee initially to discuss the visit;
ii. Meet with each analyst, if possible;
iii. Review and summarize the visit with the Laboratory Director and the analysts in a close-out session to discuss strong points and concerns and make recommendations;
iv. Provide a document (memo or form) after the close-out session summarizing the results of the visit.

b. Extent of the Visit

As time and circumstances permit each Quality Review Coordinator will observe the following areas, along with items described in each section's quality assurance protocol:

i. Safety procedures
ii. Evidence receiving, handling, and storage procedures
iii. casework, including the case approach followed and procedures used
iv. Supplemental activities, such as preventive maintenance, reagent preparation, etc.
v. Interaction of the section with laboratory management and other sections
vi. Court testimony observations, if possible
vii. Standard reference files, if applicable
viii. Instrument maintenance and calibration records

c. Close-Out Session

During the close-out session, an attempt will be made to resolve any questions that may have arisen during the visit, defining which items are concerns for correction and which are suggestions. Recommendations for corrective action will be presented for any deficiencies.

d. Report of Laboratory Visit

The results of the laboratory visit, including the close-out session, will be summarized in either a memorandum or on the Report of On-Site Visit form (Appendix 7.2). The original report will be sent to the Director of Quality Assurance; copies will be sent to the analysts, Laboratory Director, and Laboratory Quality Manager. This will include the

recommended follow-up action plan to ensure that any deficiencies are corrected.

e. Analyst Response
Each analyst must complete the Analyst's Response Form (Appendix 7.4) and return it to the Quality Review Coordinator within one (1) week after receiving the Quality Review Coordinator's report; copies will also be sent to their Laboratory Quality Manager, Laboratory Director, and the Director of Quality Assurance. If the analyst agrees with the recommendations, this will be so indicated. If the analyst disagrees with the Quality Review Coordinator's recommendations, a request for a peer review may be made. Specific areas of contention will be included with the request.

f. Quality Assurance Response
After the Quality Review Coordinator completes the exit interview with the Laboratory Director and the analysts, the coordinator will complete the Quality Review Coordinator Response Form (Appendix 7.4) and forward it to the Director of Quality Assurance. The Director of Quality Assurance will evaluate the comments and advise Command administration when appropriate.

III. PREVENTIVE ACTION

A. Preventive action is a proactive process to identify opportunities for needed improvements and potential sources of nonconformities, either technical or concerning the quality system. If, during casework analysis or the performance of any quality assurance measure, a Forensic Sciences Command employee identifies a need for improvement in procedures or a potential source of non-compliance, the individual will inform the immediate supervisor, the Command Advisory Board Chairperson, or the Director of Quality Assurance.

B. Preventive Action Processes

When preventive action is required, the Forensic Sciences Command will utilize various methods for developing and implementing action plans to take advantage of the opportunity for improvement. These methods include, but are not limited to, the following:

1. Recommendations from the Command Advisory Boards are reviewed and approved per policies documented in Command Directives ADM 11.

2. Research projects are coordinated by the Research and Development Laboratory per policies documented in Command Directives ORG 4

3. Preventive Action Tracking (PAT)
   a. The Preventive Action Tracking (PAT) form (Appendix 7.5) may be utilized to document and follow the progress of an action plan.

   b. Once a need for improvement in procedures or a potential source of non-compliance is confirmed, an action plan will be created and implemented to remedy the situation.

   c. After implementation of the action plan, the results of the action plan will be reviewed for effectiveness and may be repeated as necessary.

   d. Upon receiving the final information regarding completed actions, the Director of Quality Assurance or designee will note the date received. The appropriate DNA Technical Leader will approve the completed actions for DNA-related issues. The Director of Quality Assurance will approve the action plan is complete and appropriate. The PAT will then be forwarded to the appropriate Bureau Chief and the Commander for review and signature.

C. Monitoring Results of Preventive Action

1. Command Advisory Board

   The Command Advisory Board is responsible for reviewing and communicating issues of section concern to Command Administration. This includes reviewing any revisions to procedures resulting from preventive actions.Command Advisory Board discussions occur at least once a year.

2. Quality Assurance Measures

   For preventive actions affecting case analysis, quality assurance measures(e.g. administrative/technical reviews, cases reanalysis, proficiency tests, etc.) ensure the procedures implemented for preventative actions are effective.

3. Laboratory management

   As applicable, laboratory management will review and document the effectiveness of any preventive action when conducting the laboratory's annual management review.

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V. ANNUAL PERFORMANCE EVALUATION

Laboratory management will comment on the employee's adherence and performance regarding quality assurance guidelines, tests, and standards and controls during the reporting period. This is to be done in the narrative portion of the employee performance evaluation.

Illinois State Police
Division of Forensic Services
Forensic Sciences Command

Case File Review Results Summary

YEAR: _____

Date: _____

Discipline: Indexing

Analyst: _____

Quality Review Coordinator: _____

File Numbers:

Results:

DNA Indexing Data Analysis File Review Checklist

Analyst		Extraction Plate Name	
Evaluator		Amplification Plate Name	
Type of Analysis		Date of Review	

Administrative	Results	Comments
Project saved to designated Location		
Controls		
Negative Control-Primer Peaks present/documented		
Positive Amplification Control		
Orientation Control		
Ladder		
Technical		
Correct Software/Analysis Parameters		
Interpretation rules followed		
Paper Review Table Present		
Yield Gel Worksheet Present		

Comments

Add Page | Save | Print | Reset Form

REPORT OF ON-SITE VISIT

SECTION: _____ PURPOSE OF VISIT: _____

LABORATORY: _____ DATES OF VISIT: _____

ANALYST: _____ DATE OF REPORT: _____

SUMMARY OF GENERAL REVIEW (Include both strong & weak points.):

SUMMARY OF _____FILES REVIEWED: _____(Include both strong & weak points.):

SUGGESTED ACTION(S) TO BE TAKEN:
CORRECTIVE:

FOLLOW-UP:

Evaluator _____ Date_____

ANALYST'S RESPONSE

DO YOU WISH THIS REPORT REVIEWED BY A QUALITY ASSURANCE REVIEW BOARD? Y ☐ N ☐

IF YES, WHICH RECOMMENDATIONS DO YOU WISH REVIEWED?

OTHER COMMENTS:

Analyst's Signature:_____Date:_____

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DIVISION OF FORENSIC SERVICES
FORENSIC SCIENCES COMMAND

Quality Review Coordinator Response Form

1. Was the laboratory director courteous and patient?

2. Did the laboratory director allow enough time for the exit interview (cancel interruptions; i.e., phone calls, other business)?

3. Did the laboratory director properly address recommendations and issues concerning the Quality Assurance visit?

4. Did the laboratory director utilize the Quality Assurance review as a management tool?

5. Was the assistant laboratory director in attendance?

6. Other comments?

Quality Review Coordinator signature_____ Date_____

ILLINOIS STATE POLICE
DIVISION OF FORENSIC SERVICES
FORENSIC SCIENCES COMMAND

PREVENTIVE ACTION TRACKING

PAT_____

Part I: Issue Statement

Reported By:_____ Date:_____

Laboratory/Program:_____

Description of Issue: _____

_____

_____

_____

_____

_____

_____

_____

Part II: Action Plan Assignment/Development

Preventive Action Plan to be developed by _____
(Attach completed plan)

Targeted completion date of action plan _____

Reviewed by _____ _____
Signature Date

Part III: Results of Action Plan

Brief description of what occurred as a result of implementation of the action plan:

_____

_____

_____

_____

_____

_____

_____

_____

_____

Part IV: Review

Results Received: Date: _____

QA Review: Signature_____ Date:_____

Bureau Chief: Signature_____ Date:_____

Commander: Signature_____ Date:_____

Comments:_____

_____

_____

_____

_____

_____

_____

Illinois State Police
Division of Forensic Services
Forensic Sciences Command

Indexing
Proficiency Test Review

YEAR: _____

Date: _____ Test Name: _____

Analyst: _____

Quality Review Coordinator: _____

Checklist:

Are all reported inclusions correct?

Are all reported exclusions correct?

Are all reported genotypes/haplotypes correct?

Are all uninterpretable results compliant with written laboratory guidelines?

Have all discrepancies or errors been corrected (select N/A if there were no discrepancies or errors)?

Have all administrative errors been corrected (select N/A if there were no discrepancies or errors)?

Are the final reports satisfactory (i.e., no analytical errors in the DNA profiling data)?

Comments:

Technical Leader Approval: _____

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I. POLICY

To monitor potential and/or confirmed quality issues requiring corrective action, the Quality Issue Report Form (Appendix 8.1) is used. The Quality Issue Report (QIR) Form is utilized to assess the risks associated with the issue, document cause analysis, and serve as a record of the corrective actions taken to prevent recurrence. Quality issues or situations requiring corrective action include, but are not limited to, the list in Appendix 8.3. As necessary, the Bureau Chief (BC), Command Quality Assurance (Director of Quality Assurance and/or designee), or Commander may direct the laboratory manager to initiate corrective action for any quality issue. The Effectiveness of Corrective Actions and Management System Review form (Appendix 8.4) is used afterwards to evaluate the effectiveness of any corrective actions taken.

II. PROCEDURE

A. Within two business days after the discovery of the quality issue, the Laboratory Quality Manager or designee will notify the Laboratory Director, the Bureau Chiefs, Director of Quality Assurance, and/or their designee. The DNA and Toxicology Technical Leaders will be included in the notification, as necessary. If the DNA quality issue affects the DNA profiles entered into CODIS, the State CODIS administrator will be notified. The notification shall specify the quality issue as listed in Appendix 8.3, list the involved personnel, and the immediate actions that will be taken.

B. Command Quality Assurance (QA) will assign a QIR number and indicate in LIMS the involved cases are associated with a QIR. QA maintains a log of all QIRs assigned and tracks their progress accordingly.

C. The Laboratory Quality Manager and applicable laboratory management will implement any Immediate Corrective Actions that will temporarily halt or adjust processes to prevent recurrence of the quality issue. They will document these actions in Part I of the QIR.

D. Command Quality Assurance will monitor the progress of the QIR from steps II.C through II.I below and grant extensions as necessary.

E. The reporting person (a member of laboratory management) will enter information into Part I and the Cause Analysis of the QIR form. Within 15 working days of notification, the Laboratory Quality Manager or designee will electronically provide the form to the appropriate Bureau Chief. While the QIR must be sent in a timely fashion after notifying Command Headquarters, a thorough, accurate communication of facts in the laboratory draft is expected.

F. Laboratory management will conduct the cause analysis. While conducting cause analysis,

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the six factors below must be investigated. It is possible some of the factors do not apply to the quality issue. Laboratory management will determine which factors do apply and investigate them.

1. Policies/procedures
2. Personnel
3. Equipment
4. Standards/controls
5. Material/sample
6. Working conditions

G. After the factors causing the quality issue have been identified, the corrective action(s) most likely to eliminate the problem and prevent recurrence will be developed by laboratory management, the Bureau Chiefs, the Commander, the Director of Quality Assurance (or designee), the appropriate Technical Leader, or any combination thereof. This step may occur in any stage of the process before the QIR is finalized and approved.

The DNA or Toxicology Technical Leader must approve corrective action items prior to their implementation for their respective quality issues.

H. The individual(s) assigned to oversee completing the corrective action(s) will have no longer than 60 days to complete the action(s). A member of laboratory management will update Parts II and III of the QIR as the action items are completed.

I. Once all parts of the QIR are completed, it will be routed to the Laboratory Director for review and approval. The Laboratory Director will then route the QIR to the personnel listed on the form. Once all required approvals are obtained, QA will store the form and related attachments in a secure server location.

J. Using Appendix 8.4, the LQM and QA must determine the plan for reviewing the effectiveness of corrective actions listed in the completed QIR form.

1. The LQM and any appropriate laboratory personnel will review the effectiveness of the corrective action plan at the agreed frequency and document the results of the review.

2. The Bureau Chief and appropriate Technical Leader will be notified if the review indicates that the actions were not effective. Additional corrective action steps may be implemented as necessary and documented via a QIR.

3. QA will store the completed Appendix 8.4 form in a secure server location once all

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reviews are completed.

4. Laboratory and Command management will review the completed Appendix 8.4 forms during the annual management review.

III. Notifications and Review of Documentation

A. The BC and QA must evaluate the initial notification from the laboratory to triage the severity of the issue. If the issue represents a potential significant risk to the laboratory, the Commander, and Technical Leader and CODIS Administrator, as appropriate, must be immediately notified to determine whether work must be suspended promptly until the emergent issue can be resolved.

B. Any event or nonconformity that could substantially affect the integrity of laboratory activities and is related to an accreditation requirement or the requirements of regulatory authorities shall be disclosed to ANAB within 30 calendar days of the occurrence. If the event or nonconformity is identified more than 30 days after the occurrence, it shall be disclosed to ANAB immediately.

C. The DQA will provide status updates and gather feedback at regularly scheduled meetings with top Command management.

D. The following personnel will be notified of the completed QIR document and provided access to the final version.

- Personnel involved in the quality issue
- Laboratory Director and Quality Manager
- Technical Leaders
- Bureau Chiefs and Commander

Illinois State Police
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Appendix 8.1 – Quality Issue Report and Corrective Action Plan

QIR #

Part I:

Issue Information			
Type:		Date Discovered:	
Location:		Date Command Notified:	
Section:		Date of Issue:	
Discovered By:		Date of Amended Report:	
Part I Completed By:		Date Part I Rec'd by QA:	
Personnel Involved:		Date Personnel Notified:	
Tech Reviewer (TR):		Date TR Notified:	
Agency:		Date Agency Notified:	
Case(s)/Items(s):			
Offense:			

Describe the Quality Issue
What is the issue:
How the issue was discovered:
Why it is an issue:
What data was used to deem the situation an issue:

Immediate Corrections Taken	
Action	Date Completed
	Date

Case Review/Reanalysis

Are Reviews Warranted/Possible?	
Type of Review:	
Date Sent for Review:	

Part II:

Case Review/Reanalysis Results		
Date Completed:		
Case Number	Date Original Analysis Completed	Results of Review
	Date	

Consequences/Effect of the Discrepancy
Impact to the case(s):
Impact to other cases in the laboratory:
Impact to the customer:

Cause Analysis (Staff Interviews, 5 Whys analysis, Failure Modes Effects Analysis, fishbone diagrams, as appropriate)

Containment/Corrective Action Plan:

Action 1

Individual overseeing action:	
Technical Leader Approval (if required):	
Date Corrective Actions Due:	
Date Completed:	
Results:	

Timeframe	
Estimated Completion Date of Corrective Action Plan:	
Identify any impediments to completion in this time frame:	
Plan to mitigate impediments:	

Part III:

Additional Risks and Opportunities Analysis
Additional risks identified/actions taken:
Opportunities identified/actions taken:

Final Review		
Title	Signature	Date
Director of Quality Assurance:		Date
Bureau Chief:		Date
Commander:		Date

[This form will be printed on colored paper so it can be differentiated from the other administrative documents]

Quality Issue Report / Laboratory Quality Flag Notification

A Quality Issue Report □ Laboratory Quality Flag □ is associated with this case:

_____

See QIR or
Flag number _____

APPENDIX 8.3

Quality Issues or Situations that Require a QIR

1. If analysis requested of the laboratory can no longer be performed or results cannot be reported due to quality issue (e.g. no latent prints analysis possible because glass item has shattered or DNA contamination prohibits reporting the results)
2. External and internal audit non-conformities
3. Concerning technical competence (e.g. DNA mixture interpretation, suitability of latent impression, AFIS tracing)
4. Proficiency test results are different from expected answer (including "inconclusive" results or administrative errors, except as provided for in QM-17, Appendix 17.2)
5. Requiring QRC reanalysis or additional cases need to be reanalyzed
6. Involving or affecting entire section, laboratory, or statewide operations
7. Review of an external expert report that upon completion, necessitates a revision of the original analytical conclusions.
8. Upon individual's third, similar quality issue (unless otherwise directed by a Bureau Chief)
9. If situation or quality issue results in a known, significant impact to the case (e.g. the SAO communicated that the case was dropped because of the quality issue)
10. If a new or revised Command policy/procedure must be developed to address the quality issue.
11. Missing evidence
12. Missing case file that was needed for court, supplemental case analysis, CODIS, etc.
13. DNA contamination and the following criteria are met:
    a. The blank is consumed, the sample is consumed, or it is not possible to re-swab parent exhibit (essentially exhibit is rendered unusable and another parent exhibit will need to be analyzed for results)
    b. DNA for the exhibit is unsuitable, the result is Inconclusive/cannot be reported because the contamination affects the interpretation, or the interpretable profile is not eligible for NDIS entry due to contamination associated to the exhibit
    c. Upon multiple documented incidents (Incident Reports) of contaminations for an individual

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Division of Forensic Services
Appendix 8.4 – Effectiveness of Corrective Actions and Management System Review

QIR #

Plan	
Action(s) to be taken to review the effectiveness of the corrective action plan:	
Frequency of the review:	
Duration of the review:	

Results	
Has the issue re-occurred(Y/N)?	
Date of Reviews and Results	
Were the corrective actions effective (explain if necessary)?	

Management System Review	
Actions taken to improve management system, if necessary:	
Action	Date Completed

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I. Purpose

A. The Forensic Sciences Command conducts internal audits and participates in external assessments to ensure the laboratory system is executing operations in accordance with the stated goals and objectives outlined in QM-1.

II. Internal Audits

A. The Forensic Sciences Command is responsible for conducting at least one internal management system and operational audit per year at each laboratory. A successful internal audit involves a critical evaluation of each of the standards by knowledgeable personnel to ensure conformance to each relevant standard.

B. The Internal Audit will ensure compliance with the following standards, as applicable:

1. Forensic Science Command Audit Checklist (Appendix 9.1)

2. FBI DNA QAS Guidelines
   a. Casework
   https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=15744

   b. Indexing
   https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=15741

3. ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories:
   - Official Copy maintained by DQA, Audit Spreadsheet available on ISPPortal

4. ANAB - AR 3125, ISO/IEC 17025:2017 Forensic Testing and CalibrationLaboratories Accreditation Requirements
   - https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=12371

5. A report with the findings of the internal audit is then sent to the appropriate Bureau Chief and the Director of Quality Assurance within 60 days from the beginning of the audit unless an extension is granted by the Director of Quality Assurance. The Director of Quality Assurance will retain records of eachlaboratory's audit report.

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For laboratories conducting "on-going" audits throughout the year, the audits conducted during the calendar year will be summarized in that calendar year's annual management review.

6. The laboratory will document the direct observation of any new procedures implemented (those requiring in-service training and management authorization in accordance with Command Directives TRN 15) since the date of the last internal audit and include this information with the internal audit report. In addition, the laboratory management will observea sampling of the accredited services from each discipline in the laboratory.

7. When necessary, corrective actions for the internal audit will be documented in a Quality Issue Report (QIR) form. Command Administration and the appropriate DNA Technical Leader will review the audit documents and, wherever applicable, approve the corrective action(s).

8. Completed DNA audit documentation and, if applicable, corrective actions(s) will be provided to the CODIS administrators and appropriate Technical Leader. Receipt of this information will be documented in the LIMS Activity Log.

III. Command Audit

A. When necessary, the Director of Quality Assurance is responsible for conducting a Command Audit of a laboratory, using trained auditors where practical. A list of trained auditors is maintained by the Director of Quality Assurance.

B. The Command Audit is conducted using the guidelines in II.B. above (as applicable). Whenever necessary (e.g., travel restrictions, operational needs, etc.), the Director of Quality Assurance is responsible for appropriately modifying the scope of the Command Audits. Any modifications will be discussed with the laboratory's chain of command and documented in the Command Audit Nonconformity Summary form (Appendix 9.2).

C. Findings from the Command Audit will be documented using the Command Audit Nonconformity Summary form (Appendix 9.2). The Director of Quality Assurance

or designee (lead assessor) will provide this document to laboratory management and appropriate personnel in Command Administration.

D. Laboratories may appeal the nonconformities observed in the Command Audit.

E. To begin the appeal process, the laboratory must complete the Command Audit Appeal Form (Appendix 9.3) and send it to the Director of Quality Assurance within 10 business days after receiving the laboratory's Command Audit Nonconformity Summary document.

F. The Commander and an independent committee composed of scientific management personnel from Command Administration will then evaluate the laboratory's Command Audit Nonconformity Summary document and appeal. The committee's decision will be documented on the Command Audit Appeal Form. The Commander will determine which Command Administration personnel is appointed to the committee.

G. The Command Audit Nonconformity Summary document will be appropriately updated, if necessary, after the committee's decision. The Director of Quality Assurance or designee(lead assessor) will provide laboratory management with the completed Command Audit Appeal Form and updated Command Audit Nonconformity Summary document (if applicable).

H. Corrective actions for the Command Audits will be documented using the Quality Issue Report (QIR) form. Command Administration and the appropriate DNA Technical Leaderwill review the audit documents and, wherever applicable, approve the corrective action(s).

IV. External Audit

A. The Director of Quality Assurance is responsible for coordinating external audits with independent, third-party assessors.

B. The third-party assessor will document findings from an external audit in a report.

C. The third-party assessor will prescribe the format for documenting the laboratories' responses to the findings. Regardless of the format, the laboratory will ensure:

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1. Corrective actions for an external audit are documented using the Audit Nonconformity Form (Appendix 9.4).

2. The DNA Technical Leader will review DNA audit documentation and approve corrective actions, if any. The review and approval will be documented.

3. DNA audit documentation and corrective actions will be provided to the State and Local (casework) CODIS administrators. Receipt of this information will be documented.

4. The Director of Quality Assurance will submit external audit documentation and laboratory responses or corrective actions to the FBI within 30 days of receiving the audit document, or immediately upon completion.

V. Annual Reviews

A. The Director of Quality Assurance is responsible for completing a management review summary report for the Command. This summary report will describe all quality assurance activities and issues during the previous year and include a summary of laboratory activities based on the annual laboratory management reviews.

B. Each Quality Manager is responsible for conducting an annual management review of the quality system in place at the laboratory. This review is important for ensuring the continued suitability and effectiveness of the system and for ensuring all measures are being taken to provide the highest quality service. The review should include information obtained from various internal and external audits and how the audits were used to continue/improve quality. The review will address, but not be limited to, the following topics that shall be documented:

1. Changes in internal and external issues that are relevant to the laboratory such as:
   - New programs/procedure/objectives initiated to improve quality and their effect;
   - Legal issues and their effect;
2. Fulfilment of objectives;
3. The suitability of policies and procedures;

4. Status of actions from previous management reviews;
5. Outcome of internal audit and DNA TL onsite visit schedule for the following year;
6. Status of QIRs and Quality Flags;
7. Results of ISO 17025 accreditation assessments, DNA QAS audits, and other assessments from external bodies;
8. Changes in the volume, type of work, or laboratory scope;
9. Customer feedback and court testimony survey;
10. Reports and feedback from managerial and supervisory personnel;
11. Complaints;
12. Effectiveness of any implemented improvements
13. Adequacy of resources;
14. A review of any risks and/or opportunities associated with laboratory activities, including how to integrate and implement the results of this review, ensuring the effectiveness of these actions, and that they are proportional to the potential impact on the validity of the laboratory results;
15. Outcomes of the assurance of the validity of results such as:
    - Status of QRC reviews
    - Results of inter-laboratory comparisons or proficiency tests;
16. Any other relevant factors such as staff training and personnel feedback.

C. These reviews are due to the Director of Quality Assurance by March 31st of the following year.

D. Forensic Sciences Command management will determine the appropriate actions to be taken in response to concerns noted in the management review. Actions arising from the management reviews shall be recorded or a plan and time frames for completion will be noted. Forensic Sciences Command will select opportunities from the laboratory management reviews, and implement any actions deemed necessary statewide.

E. Corrective actions for quality issues noted in the management review will be documentedusing the Quality Issue Report (QIR) form. Command Administration and the appropriate DNA Technical Leader will review the audit documents and, wherever applicable, approve the corrective action(s).

VI. Evidence Vault Audits

A. The method and frequency of evidence vault audits is described in the following

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paragraphs. Audits may also be necessary for specific instances as noted elsewhere in the Illinois State Police Operations Directives.

B. All evidence vault audits will be recorded by the Laboratory Quality Manager. Documentation must include who conducted the audit, the date(s) conducted, the amount of evidence reviewed (number and percentage) and any discrepancies noted. The results of the evidence vault audits must be communicated to the Laboratory Director.

C. Evidence vault audits will include the physical inventory and inspection of evidence, including the verification of any applicable items or containers, laboratory case numbers on the evidence, custody handling initials/identity and dates, and evidence seals. The results of the physical inventory and inspection of evidence must be compared and verified to records prior to making corrections in LIMS

D. The following routine audits will be conducted:

1. Monthly Audits

   a. At least once each month, each Laboratory Director (or designee) will conduct an unannounced audit of laboratory evidence.

   b. At least 2% of the cases/exhibits (as defined by the laboratory's Facility Operations Manual) in the laboratory must be inspected.

   c. The monthly audits can be supplanted by the semi-annual audits or annual 100% audit. Appropriate notation must be made by the Laboratory Quality Manager.

2. Semi-Annual Audits

   a. Each Laboratory Director (or designee) will arrange to have semi-annual audits of all evidence handling records, disposition records and evidence storage facilities maintained at their laboratory.

   b. The person or persons conducting the audit must not be from the inspected laboratory.

   c. At least 10% of the cases/exhibits (as defined by the laboratory's Facility Operations Manual) in the laboratory must be inspected.

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d. Semi-annual audits can be supplanted by the annual 100% audit. Appropriate notation must be made by the Laboratory Quality Manager.

3. Annual 100% Audit

a. At least once every year, each Laboratory Director (or designee) will conduct a complete (100%) audit of laboratory evidence.

4. Unannounced audits by others

a. In the instance external assessors conduct a vault audit, this audit can supplant the semi-annual or monthly audits if the percentage of evidence inspected meets the minimum requirements described above. Appropriate notation must be recorded by the Laboratory Quality Manager.

Appendix 9.1 - INTERNAL AUDIT CHECKLIST

SCOPE:

The internal audit consists of three elements:

1. **ISO 17025:2017 Requirements.** This checklist incorporates the necessary laboratory review elements of the ISO17025:2017 standard including the ANAB AR3125 supplemental requirements as well as other FSC policies and procedures that require review. No additional checklist is necessary.
2. **FBI DNA QAS Requirements**. For the DNA Section, the relevant casework and/or databasing audit document must be completed as well. Links to these documents are located in QM-9.
3. **Safety Audit**. The laboratory will conduct an audit of the safety program using Safety Manual Appendix 1.1. This audit may be a substitute for one of the regular quarterly safety audits.

DIRECTIONS:

Please mark the appropriate column as Conforming (C), Nonconforming (N), or Not Applicable (N/A) for each criterion listed below.

All Nonconforming marks must be described in the comments section at the end of the document. The Director of Quality Assurance must be notified to initiate a QIR and assign a tracking number in accordance with QM-8. This notification can take place as soon as possible and does not require that the audit itself is complete.

When the audit is complete, this checklist, the applicable QAS Checklist(s), and the Safety Audit Checklist, shall be sent to the Director of Quality Assurance, with a courtesy copy to the Bureau Chief. A cover memo will also be included, which will include at a minimum a summary of any findings and any immediate corrections taken upon submission of the document. Cause analysis and corrective actions shall be documented in the assigned QIR for any Nonconforming criteria.

The format of the final document should be one document, signed electronically by the Quality Manager and the Laboratory Director.

ADMINISTRATIVE

Criteria	Result
Is a procedure developed that assures all memos/directives, and policy manual updates are communicated to all affected employees?	
Are the following licenses/permits posted?	
DEA DRUG LICENSE	
STATE DRUG LICENSE	
FEDERAL ALCOHOL PERMIT	
STATE ALCOHOL PERMIT	
IEMA X-RAY/LASER REGISTRATION	
Does each section and/or analyst maintain court qualifying questions?	
Have all laboratory complaints been addressed as required in QM-16?	
Does the laboratory perform required audits of paper archive master files on site?	

Are all sections following the appropriate case management strategies (i.e. deferral policies, etc.)?	
Does the laboratory have method for tracking priority cases in each section?	
Have all employees completed the CODE of ETHICS review within 1 year of this audit?	
Is the scope of accreditation online at anab.org accurate for the laboratory?	
Is the online organizational chart accurate for the laboratory?	
Does the laboratory have on site and available worksheets for each discipline to record analytical results in the event that LIMS is unavailable for an extended period of time?	
Has all court feedback received been reviewed by management staff in a timely manner? Mark Nonconforming if any review of feedback took longer than one month to complete.	
Was the laboratory Annual Management Review completed prior to March 31st in the subsequent calendar year?	
Have potential quality issues been reported to the Director of Quality Assurance (DQA), Bureau Chief, and Technical Leader (if applicable), within two working days of their discovery, as required in QM-8?	
Have all QA supplements been added to LIMS for case related QIRs and laboratory quality flags?	
Did the CODIS administrator document in the LIMS Activity Log that internal and external audit documentation were provided in the subsequent calendar year?	

AUDITS

Criteria	Secured (Y/N)	Result
Drug Standards		
Alcohol		
Key/Access Card	N/A	
Vendor Evaluation	N/A	
Firearms Reference Collection		
Evidence (in accordance with QM-9)		

EQUIPMENT

Criteria	Result
Are performance checks performed for all instruments/equipment that are repaired/serviced (not including calibration) before the instruments/equipment are returned to service, when applicable?	
Are performance checks conducted on any instrument/equipment that goes outside the direct control of the laboratory for calibration before the instrument/equipment is returned to service?	
Have all instrument logs been verified to be accurate and complete?	
Has each reagent in use in the laboratory been performance checked, labeled appropriately, and unexpired?	
For balances that require traceability, have the relevant calibration certificates been reviewed and been found to be valid?	
For balances that do not require traceability, have the balances been checked with traceable weight sets and in accordance with section procedures manuals?	
For traceable standard weights, have the calibration certificates been reviewed and found to be valid?	

For traceable pipettors, have the calibration certificates been reviewed and found to be valid?	
For traceable measuring equipment have the calibration certificates been reviewed and found to be valid?	
For any traceable equipment/instruments that exceeded its required calibration period, were the appropriate actions taken in accordance with QM 11?	
For any new equipment that possibly impacts measurement uncertainty (e.g. balance, ruler, etc.) were the appropriate data points/measurements collected in accordance with the section's procedures prior to using the new equipment?	

EVIDENCE CONTROL/STORAGE

Criteria	Result
Is written authorization obtained from the submitting agency prior destroying evidence?	
Are all analyzed evidence returned in a timely fashion? If any evidence is in a return location over one year and has not been addressed with the user agency, mark Nonconforming.	
Are evidence lockers properly utilized?	
Is evidence received in the mail secured upon receipt?	
Is each refrigerator/freezer housing evidence or analytical consumables being checked with a traceable thermometer at an established frequency (e.g. per Procedures Manual or Facility Operations Manual) and are the checks recorded?	
Is evidence properly stored at analyst workstations?	
Does effective separation exist between areas of the lab with incompatible activities?	

EVIDENCE HANDLING

Inspect 10 items of evidence in each of the applicable sections' vaults for Proper labeling, marking, and seals. For one item in each section, is the packaging accurately reflected in LIMS?

Case/Item Number	Section/Location	Labels (C/N)	Initials (C/N)	Seals (C/N)	LIMS (C/N)
	Section				
	Section				
	Section				
	Section				
	Section				
	Section				
	Section				
	Section				

CHAIN OF CUSTODY

Inspect the chain-of-custody report for 5 laboratory cases. For one of the cases, all disciplines must have handled at least one item. Does each chain-of-custody report accurately identify (for all items received and/or created):

1. the individual(s) or location(s) receiving or transferring the item(s);
2. the item(s) being transferred; and
3. the chronological order of all transfers, including the date

Case Number	Discipline(s)	Result
	Section	
	Section	
	Section	
	Section	
	Section	

SERVICE REQUESTS

For five (5) completed cases in the laboratory, review the service request submitted by the agency. Did the laboratory complete all the required services?

Case Number	Result

PERSONNEL

Criteria	Result
Are all forensic scientist and evidence technician training files accurate and current, to include documentation of existing competencies, as well as any new methods, as applicable, that have been instituted since the last audit?	
Does the laboratory have access to the relevant job description for each type of position at the laboratory?	
Do all employees have a current CV uploaded to LIMS?	
Has any staff on a leave of absence that caused them to miss an external proficiency test successfully completed a competency test prior to resuming casework?	

PROFICENCY TESTS

Criteria	Result
Has the laboratory reviewed the proficiency test plan, and verified that all disciplines on the scope of accreditation are accounted for?	
Have all proficiency tests been received, distributed, and submitted to the test provider?	

REPORTS

Criteria	Result
Do all technical employees in a trainee position have their reports approved by the applicable training coordinator?	
Are all amended reports reviewed by management?	
If an agency requests a copy of the laboratory report(s) for a case that was submitted by another agency, did the laboratory obtain permission from the submitting agency and document the approval?	

NEW PROCEDURES/METHODS

DIRECT OBSERVATION: List any new procedures implemented and observed since the last internal audit.

Procedure	Date Implemented	Date Observed
	Date	Date

DOCUMENTATION:

Criteria	Result
Has a validation study and/or performance check been completed for each new method listed above, and is it available to staff via the ISP Portal?	

DIRECT OBSERVATION OF EXISTING PROCEDURES

Auditors must observe at least one procedure per discipline on the scope of accreditation for the laboratory. Every attempt should be made to observe different procedures each year and include different equipment/technologies.

Procedure	Discipline	Date Observed
	Section	Date
	Section	Date
	Section	Date
	Section	Date
	Section	Date
	Section	Date

OVERALL CONDITION OF SECTION

Section/Location	Condition
Drug Chemistry	
Toxicology	
Trace/Microscopy	
Forensic Biology	
Firearms/Toolmarks	
Latent Prints	
Clerical/Evidence Receiving	
Chemical Storage	
Other	

CHEMICAL STORAGE

Criteria	Result
Is a master list maintained of all chemicals in the laboratory?	
Is the chemical storage area continuously vented?	
Are all chemicals and reagents properly labeled and dated?	

Are all chemicals in storage reviewed periodically so unstable or unused chemicals are disposed of?	
Is the light within an explosive proof fixture and switched outside the chemical storage room (if applicable)?	

SECURITY

Criteria	Result
Is the laboratory security system periodically checked for functionality?	
Does the laboratory record access into the facility by non-laboratory personnel (e.g. visitor log book)?	
Do all employees have proper identification and laboratory access?	
Are all confidential documents shredded when appropriate?	

COMMENTS

FINAL REVIEW

Please sign below to certify that the audit was completed and reviewed by the laboratory.

Date Audit Completed:	Date

Name	Title	Signature	Date
	Quality Manager		Date
	Laboratory Director		Date

The following personnel performed actions or provided information related to this internal audit:

AUDIT TEAM:

Audit Team Member(s)	Title

Command Audit Nonconformity Summary

Laboratory: _____

Assessment Dates: _____

Lead Assessor: _____

Scope of Assessment: _____

NC / OFI / Comment	NC/OFI #	Repeat Finding?	Quality Standard and Clause #	Description of Finding
		Y☐ N☐		
		Y☐ N☐		
		Y☐ N☐		
		Y☐ N☐		
		Y☐ N☐		
		Y☐ N☐		

Command Audit Appeal Form

Appellant	
Laboratory:	
Date of appeal:	
Nonconformity	
Nonconformity being appealed (#):	
Quality Standard and Clause #:	
Description of nonconformity:	
Description of appeal (attach any relevant information)	

Committee decision	
Date of response:	

Illinois State Police
Division of Forensic Services

ISO/IEC 17025:

Describe the Quality Issue
Requirement:
Nonconformity:
What data was used to deem the situation an issue:

Cause Analysis

Corrective Action Plan:	
Action 1	
Individual overseeing action:	
Technical Leader Approval (if required):	
Date Corrective Actions Due:	
Date Completed:	
Results:	
Action 2	
Individual overseeing action:	
Technical Leader Approval (if required):	

Date Corrective Actions Due:	
Date Completed:	
Results:	

Case Review/Reanalysis	
Are Reviews Warranted/Possible?	
Type of Review:	
Date Completed	

Reviewed Case Number	**Date Original Analysis Completed**	**Results of Review**
	Date	

Consequences/Effect of the Discrepancy
Impact to the case(s) / to other cases in the laboratory:
Impact to the customer:

Illinois State Police
Division of Forensic Services
Forensic Sciences Command

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Revision Transmittal Number: QA 23-03	

POLICY

It is the policy of the Forensic Sciences Command to establish the minimum facility and environmental requirements for laboratories where testing activities occur.

REQUIREMENTS

I. Laboratory facilities will be appropriate to facilitate performance of all aspects of testingand provide for storage of records, supplies, space for equipment and instruments and shall not adversely affect the validity of results.

II. Normal laboratory environmental conditions shall be controlled and monitored by the laboratory. All testing activities require normal laboratory environmental conditions unless noted in a procedure. Examinations will be stopped when the environmental conditions could jeopardize the results. If environmental conditions could affect the quality of an examination, the conditions will be recorded in the appropriate case records.

III. The laboratory will ensure that effective separation exists between incompatible laboratory activities (e.g. drug chemistry and toxicology sample prep in different rooms). This will be monitored and reviewed during the laboratory internal audit. Any changes to the laboratory layout shall ensure that effective separation still exists.

IV. Laboratory activities will not be routinely performed at sites or facilities outside its permanent control. When applicable, the laboratory will ensure the facilities and environmental conditions are suitable for performing laboratory activities at sites or facilities outside its permanent control.

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Revision Transmittal Number: QA 24-02	

I. USE, REPAIRS AND MAINTENANCE

A. A list of vendors approved to provide consumables or services (e.g., calibration or maintenance) in support of a laboratory's operation will be maintained by the Laboratory Quality Manager (or designee).

1. The Laboratory Quality Manager (or designee) will ensure the list is periodically reviewed to confirm the competence, capability, and traceability (as necessary) of the vendors. Also refer to III.E below, QM-14 II.B and Command Directives FIS 2.
2. The laboratory must ensure new vendors added to the list conform to the laboratory's established specifications/requirements before they are used. Also refer to Command Directives FIS 2.
3. Any quality issues arising from the review or performance monitoring of specific vendors must be forwarded to all laboratories and Command.
4. Command's pre-approved manufacturers/vendors/suppliers include the following, and they do not need to be added to a laboratory's list of vendors: Agilent Technologies, AirGas, ANSI-ASQ National Accreditation Board, Bode Technology, Collaborative Testing Services, Fisher Scientific, Foray Technologies, Forensic Assurance, Forensic Testing Services, Leeds Precision Instruments, Life Technologies, Logsdon Office Supply, Mettler-Toledo (including its subsidiaries), nanoScience, Novamed, Nuhsbaum, Porter Lee, Promega, Tecan, W.W. Grainger.

B. Equipment will not be used at facilities outside of the laboratory's permanent control.

C. Monitoring of equipment maintenance and any associated problems is the responsibility of each Laboratory Director. Current procedures are found in the Command Directives Manual.

D. General service equipment not directly used for making measurements (e.g., hot plates, stirrers, non-volumetric glassware, cameras, refrigerators) will be maintained by visual examination, safety checks, and cleaning as necessary.

E. High quality flasks and cylinders are used for measuring volumes and reagent preparation; volumetric equipment is maintained by visual examination, cleaning, and performance checks.

F. Instruments/equipment that is repaired/serviced (not including calibration) will have performance checks made before the instrument/equipment is returned to service, when applicable. Repairs/service will be recorded in LAM. The procedures for the Biology/DNA/Indexing critical instruments/equipment are located in the

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Biology/DNA/Indexing Procedures Manual.

G. Equipment will be handled, transported, and stored in accordance with manufacturer's specifications in order to prevent contamination and/or deterioration. If the equipment is moved to a new location, or stored for an extended period of time, a calibration/performance check will be performed as provided in III below.

II. DISPOSAL

A. All disposable equipment and/or items used when performing analyses shall be disposed of appropriately.

III. CALIBRATION/PERFORMANCE CHECKS

A. Instruments identified by the laboratory which require calibration or performance checks will use labels which signify the status of the instrument - **green** for "In-Service for Analytical Use" - **red** for "Not-In-Service, Do Not Use."

B. Instruments will be protected from unintentional changes to the operating status by following the standards and controls for operating the instruments found in the Procedures Manual for that discipline.

C. Calibration and performance check records are maintained in logs or LIMS LAM for each instrument.

D. Performance checks will be conducted on any instrument/equipment that goes outside the direct control of the laboratory for calibration before the instrument/equipment is returned to service. This excludes equipment sent to an ISO 17025 accredited calibration service provider.

E. For calibration services, only ISO 17025 accredited calibration vendors will be used. If necessary, a calibration vendor may be approved by the Director of Quality Assurance after the competence, capability, and traceability of the vendor are confirmed using objective evidence. This information will be kept in the instrument log. Laboratories will review the validity of the vendor's accreditation, whenever applicable, prior to use. Accrediting bodies that will be accepted include those that are members (or signatories) of the International Laboratory Accreditation Cooperation (ILAC), the European Cooperation for Accreditation (EA), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), or the Inter-American Accreditation Cooperation (IAAC).

F. If required to establish traceability in a method the equipment must be calibrated by an ISO

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17025 accredited calibration vendor prior to utilization and adhere to the calibration certificate's expiration date or the schedule below for successive calibrations. The date of calibration on the certificate will serve as the initial calibration date in LIMS. The laboratory will ensure that these items are replaced or scheduled for recalibration at the appropriate calibration interval.

1. The equipment listed below must be calibrated at the calibration intervals listed:
   a. Drug Chemistry, Toxicology and Trace balances – every 6 months
   b. Pipettors – annually
   c. Gage blocks – every five years
   d. NIST traceable rulers/tape measures – every five years
   e. DNA temperature verification system for thermal cycler ("Temperature Verification Kit") – annually
   f. Microscope stage micrometers – every ten years
   g. Weight sets – every six years
   h. Volumetric glassware – every ten years
   i. NIST traceable thermometers – calibration certificate's expiration date

2. Prior to a calibration vendor being selected:
   a. The vendor must be ISO/IEC 17025 accredited by an appropriate accrediting body (i.e. A2LA, ANAB, ILAC MRA signatory)
   b. The vendor's scope of accreditation must be reviewed to ensure the specific calibration service is listed.
   c. It must be determined if the vendor is accredited to perform the calibration on-site at the laboratories and/or at the vendor's location. Equipment will be calibrated at the proper location.
   d. A sample calibration certificate must be reviewed to ensure traceability. Required elements include:
      i. ISO 17025 accreditation to perform the service
      ii. Identification of equipment being calibrated
      iii. Stated uncertainty
      iv. Reference material used
      v. Calibration expiration date (consistent with the stated calibration interval)
      vi. Name and address of calibration vendor
      vii. Signature of responsible party
      viii. Where applicable, "as found" and "as left" data

3. For the following equipment, specific parameters must be adhered to during

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calibration:

a. Drug Chemistry, Toxicology, and Trace Balances – 1% tolerance and safety factor of 2
b. Toxicology Repeat Pipettors – three tip sizes should be used to cover a range of 2-1000uL
   i. 0.1 mL covers 1-20uL
   ii. 0.5 mL covers 5-100uL
   iii. 5.0 mL covers 50-1000uL
c. Gage Blocks – the size range, grade, and number of block must be known
d. Weight sets – all weights must be calibrated to Class 1 tolerance (if required to establish traceability in a method)

G. The balance acceptability checks below are the recommended course of action for analytical work; however, it is recognized that the prescribed masses may not fit with a section's normal practices. In those instances, refer to the Minimum Standards and Controls of each analytical section's Procedures Manual for the appropriate masses, acceptability ranges, and exact procedures to use.

1. Balance Check Acceptability
   a. **Capacity less than 5 kg:** Balances that have a capacity of less than five kilograms will be checked according to the following parameters at the frequency prescribed by the section's Procedures Manual. When each balance is in use, it will be checked with a minimum of three masses across the range of the balance which must include 100 mg, 1 g, and 10 g. The numerical balance reading will be recorded in the log. For each mass used, the balance must read within ±2 readability units. Higher additional masses may be used with a balance reading within ±5 readability units. The readability unit of a balance is the smallest numerical readout increment (in grams) on a digital display. If the mass is out of range, a second mass set will be used to verify all balance readings. If the mass is still out of range, adjustments (such as cleaning and/or rebalancing) will be performed. If the mass is still out of range, the balance may need servicing by an outside vendor. The laboratory will not perform any type of calibration (either manual or auto) in an attempt to return the balance to service unless the NIST traceability of the internal standard weight has been established by the calibration service provider.
   b. **Capacity greater than or equal to 5 kg:** Balances that have a capacity of five kilograms or more will be checked according to the following parameters at the frequency prescribed by the section's Procedures Manual. When each balance is in use, it will be checked with a minimum of three masses which must include 5kg and 0.5kg. The numerical balance reading

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Date of Revised Issue: 08/29/2024	Compliant with ISO 17025 standards and the ANAB accreditation requirements.
Revision Transmittal Number: QA 24-02	

will be recorded in the log. For the three masses used, the balance must read ±0.01 kg. If the mass is out of range, a second mass set will be used to verify all balance readings, if possible. If the mass is still out of range, adjustments (such as cleaning and/or rebalancing) will be performed. If the mass is still out of range, the balance may need servicing by an outside vendor. The laboratory will not perform any type of calibration (either manual or auto) in an attempt to return the balance to service unless the NIST traceability of the internal standard weight has been established by the calibration service provider.

2. Balance acceptability checks are performed using reference materials.

H. Should the parameters for calibration/performance checks not be met, the instrument/ equipment will be taken out of service until it meets those parameters by adjustments or repairs. If it is determined that the instrument/equipment was used on casework while not meeting these parameters, corrective action will be initiated to document the issue and ensure the validity of reported results.

I. If the calibration interval has been exceeded (due to administrative issues, such as procurement or vendor issues), but the instrument/reference materials is free from defects and in working order, the laboratory may continue to use the item, provided that:

1. The laboratory implements an acceptable interim strategy that has been approved by the appropriate technical leader/command coordinator if applicable.
2. The period of the interim strategy does not exceed the calibration interval in III.F above.
3. The issue and interim strategy are documented using a quality flag, per QM-17.

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I. CASE DOCUMENTS

A. All worksheets, case notes, analytical records/reports (client test reports) and administrative records (evidence receipts, conversation records, etc.) must be of a permanent nature and be maintained in a case file or in the Laboratory Information Management System (LIMS).

B. Handwritten notes regarding casework must be in ink, never in pencil. For all cases worked after January 1, 2018 (including applicable CALMS cases) the item will be scanned into the image vault for the case in LIMS.

C. Observations, data, and calculations will be recorded at the time they are made and be identifiable to the tests run.

1. Notetaking must be entered into LIMS contemporaneously with the examination being done. If there is a situation that does not allow LIMS to be contemporaneously used, any other notes generated (e.g. handwritten) will be uploaded (e.g. scanned) to LIMS and included in the case file after the information is entered into LIMS.
2. LIMS will include the start date, end date, and the identity of the individual performing each laboratory activity including checking data and results.
3. Observations will include sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty.
4. The notes will enable the repetition of the laboratory activity under conditions as close as possible to the original.
5. In addition, data will be recorded such that, another reviewer possessing the relevant knowledge, skills and abilities could evaluate what was done and interpret the data.

D. Manual calculations and data transfers will be checked by a second analyst during technical review.

E. The laboratory case number and examiner's initials must be on each page of the examination documentation in the case record. Every page of all other documents in the case file must bear the laboratory case number.

F. If an analyst performs testing for another analyst, the date of testing and the identity of the analyst performing the testing will be documented in LIMS.

G. Handwritten/Printed Records: All corrections to handwritten/printed notes, worksheets and other case documents must be made by making a single line out, dating, and initialing

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(see example).

Example: Human ~~bloood~~ ab 4/1/14 blood indicated.

Handwritten/printed notes, worksheets and other case documents will be considered "permanent" at the point they are submitted for Administrative/Technical Review. After worksheets and/or other case documents are considered "permanent," interlineations (inserted text) will be initialed and dated by the examiner making them.

H. Electronic Records: Notes, worksheets and other case documents in LIMS will be considered "permanent" at the point they are submitted for technical review. After that point, all changes will be recorded in LIMS. A new notes packet will be generated with the alterations, and the date of the change and person responsible for the change will be stored in the audit log.

I. In general, case documents will not be removed from case files or LIMS for the purpose of disposing those documents. Documents may be removed from LIMS if they are duplicates, and of poor image quality/readability, provided a suitable replacement/original is uploaded. If any other documentation is removed, a description and reason for removal will be documented on the worksheet in LIMS for that case.

J. If/when a test result or observation is rejected, the reason(s), date, and individual taking the action shall be recorded. This includes rejection by the analyst, reviewer, or verifier

K. Instrument Tracking

Items of equipment that are used for testing will be identified in the case notes if they are significant to the result or used to provide a measurement of some quantity critical to the result. This would include instruments such as GC/MS, IR, CEs, Thermocyclers, etc. In addition, balances and pipettors must be identified to allow for tracking of work and reproducibility of results.

If necessary, general service equipment (e.g., hot plates, stirrers, non-volumetric glassware, cameras, refrigerators) will be identified in the case notes in accordance with the requirements outlined in the section's Procedures Manual.

L. Any technical abbreviations used in the matrix will be defined in the section specific procedures manual.

II. LABORATORY CASE REPORTS

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A. Current policies and requirements are delineated in the Command Directives Manual (EVH 31).

B. Reporting Measurement Uncertainty

1. For every procedure where measurement uncertainty is applicable, it will be documented in the respective discipline's Procedures Manual.

2. A statement on the estimated uncertainty of measurement will be included in the laboratory case reports in accordance with the procedures outlined in the section's Procedures Manual.

C. Amended Laboratory Case Reports

1. Current policies and requirements are delineated in the Command Directives Manual (EVH 31).

III. REPORTS FROM LABORATORIES EXTERNAL TO THE COMMAND

Whenever a Command laboratory must send evidence to any other laboratory (i.e. the FBI Laboratory) for analysis, a cover letter will be sent with the evidence which will include a request that any report generated be sent to the original agency which submitted the evidence to the Forensic Sciences Command. A copy of the report is to be sent to the submitting laboratory. If the agency refuses to send the laboratory a copy, documentation of the refusal will be placed in the case file.

IV. CASE INFORMATION

Local agencies need not go further than their local Illinois State Police laboratory to obtain assistance on any type of laboratory examination.

A. A local agency may call a laboratory to obtain information concerning any type of examination.

B. The laboratory will check the appropriate source and get back to the agency.

C. The agency may submit any type of evidence according to evidence submission guidelines currently in effect and the receiving laboratory will forward the evidence to a laboratory that can perform the requested examination if the receiving laboratory cannot comply with the request.

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D. The submitting agency will be able to call their regional laboratory and check on the status of any case submitted to that laboratory.

V. DOCUMENTATION OF PHONE CALLS OR CONVERSATIONS

A. Current policies and requirements are delineated in the Command Directives Manual (EVH 20).

VI. SIGNATURE REQUIREMENTS

A. Current policy and requirements are delineated in the Command Directives Manual (EVH 17).

VII. PAGINATION OF EXAMINATION DOCUMENTATION

A. Laboratory generated examination documentation will be paginated by numbering the individual pages upon creation of a notes packet in LIMS.

Date of Original Issue: 03/01/97	Policy: **QM-13 Procedures Manuals/ Training Manuals** Page 1 of 1
Date of Revised Issue: 09/10/19	Compliant with ISO 17025 standards and the ANAB accreditation requirements.
Revision Transmittal Number: QA 19-01	

I. POLICY

It is the policy of the Forensic Sciences Command to create and maintain procedures and training manuals for each analytical section. The electronic version of the procedures and training manuals located on-line. These manuals are the sole source of the Forensic Sciences Command's latest valid version of methods, procedures, and supporting documentation relevant to laboratory activities. If the method or procedure is inappropriate or not possible to use, the Command will take corrective action in accordance with QM-8.

II. PROCEDURES MANUALS

Procedures manuals, which contain the standards and controls for performing the procedures, are produced for each section. A detailed description of the manuals and their make-up, mechanism for changes, pilot projects, validation studies, and use of non-routine procedures is found in the Command Directives Manual.

III. TRAINING MANUALS

Training manuals are produced for each section by Statewide Training. A detailed description of the manuals and their function is found in the Command Directives Manual.

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Revision Transmittal Number: QA 25-01	

I. POLICY

The Forensic Sciences Command's commitment to providing high quality services is based upon several factors. One of these is having a number of checks to monitor the quality of service. A part of quality monitoring is to ensure that appropriate reference materials and reagents are adequate for the procedures used and are traceable to primary sources.

II. Reference Materials

A. Definition - Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties *(ISO Guide 30:1992(E) Amendment 1:2008, JCGC 200:2008*).

1. "Reference material" is a generic term that is applicable to all materials that meet the definition and includes, but is not limited to, certified reference materials, reference standards, calibration standards, standard reference materials, and quality control materials. Reference materials will have certificates or other statements on the value of its specific property.

2. Reference materials will be used for identification, quality control, and performance checks of instruments.

3. Examples of reference materials include analytical "drug standards;" NIST traceable weight sets; NIST traceable gage blocks, or polystyrene and PFTBA used for function checks.

B. Subcategories of reference materials relevant to Forensic Sciences Command include, but are not limited to, “certified reference materials,” "reference standards" or "internal reference materials."

1. Certified reference materials are used for quantitation. They are characterized by a metrological value and accompanied by a certificate that verifies the specified value, associated uncertainty, and metrological traceability. Example of certified reference materials are toxicology “standards” and “controls” used for volatile analysis.

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2. Reference standards are reference materials that shall be used for calibration activities as defined by the ISO 17025 quality standard (e.g. calibration of balances or pipettes) and for no other purpose. Forensic Sciences Command does not perform such calibrations.

3. Internal reference materials are typically acquired from case samples or prepared in the laboratory. Examples of internal reference materials include semen positive controls, secondary "drug standards," or qualitative drug controls in blood or urine.

   a. Internal reference materials shall be checked against traceable reference materials unless they are obviously from a known source (e.g. blood sample collected from personnel for forensic biology analysis).

   b. Each section will follow the steps outlined in its Procedures Manual for meeting traceability criteria for internal reference materials.

C. Traceability

1. Reference materials shall, where possible, be traceable to accredited reference material producers (e.g. Cerilliant, Cayman Chemical or other ISO 17034 certified provider) or the International System of Units (SI) certified by nationally/internationally recognized metrology institutes (e.g. NIST, BCE, or NME).

2. If applicable, each section will follow the steps outlined in its Procedures Manual for meeting traceability criteria.

3. Where no such traceability exists and alternative reference materials are used, the competence and metrological traceability of the supplier must be fully documented so the origin, accuracy, stability, and/or uncertainty factors of the reference material is confirmed.

4. Chemicals that are reference materials will be purchased from reputable distributors, with supplier and lot number information maintained.

D. The following policies pertain to reference materials that are used for chemical or biological instrumental analysis (e.g. toxicology "calibrators," toxicology "controls," PFTBA, or polystyrene):

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1. When the laboratory receives or opens a new reference material, it will be authenticated prior to, or concurrent with, casework examination.

2. For quantitative analysis, expiration dates for reference materials will be supplied by the manufacturer or assigned in the laboratory. These reference materials will not be used in casework after their expiration dates.

3. Reference materials used strictly for qualitative purposes do not require expiration dates unless required by a specific Procedures Manual.

4. Reference materials that are analyzed daily during casework will not need to be assigned expiration dates. Each section must list these reference materials in its Procedures Manual.

E. Upon becoming aware that an expired reference material was used for casework, the laboratory management will refer to sections QM-8 and QM-17 of the Command Quality Manual to determine the appropriate course of action.

F. Records Retention

All reference materials will be entered into LAM upon receipt and the records will be updated as the materials are moved or consumed. The following information will be recorded:

- Asset type (reference material name)
- Lot number, if applicable
- Assigned section
- Quantity and units received (example: Quantity: 4, Units: Liters)
- Received by
- Date received
- Expiration date
- Verification/Authentication information, to include:
  - Analytical results of authentication
  - Certificate

G. Handling and Storage

Access to reference materials will be limited to section members and laboratory

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management. The items will be handled and stored to maintain their integrity and security. When necessary, storage conditions will be outlined in the Command Directives or the section's Procedures Manual.

III. Reference Collections

A. Definition - Groups of data, items, or materials encountered in casework which are maintained for identification, comparison, or interpretation purposes.

1. Typically, reference collections are used to assist in determining the class characteristics of evidence.

2. Examples of reference collections include firearms, ammunition, ignitable liquids, mass spectral libraries, wood fragments, fibers, paints and polymers, or hairs.

B. Reference collections shall have each entry in the collection fully documented, uniquely identified, and properly controlled.

1. Fully documented - Description of pertinent characteristics such as make/model; source (e.g. cocaine reference material with date or alphanumeric code); or specifications shall be documented on the item itself, packaging, or as part of a database record.

2. Uniquely identified - Individual data, items, or materials may be identified with a unique name (e.g. *Mass Spectral and GC data of Drugs, Poisons, Pesticides, Pollutants, and their Metabolites* by Pfleger, Maurer, and Weber; *GCMS S1/Fentanyl/480DC5094-1*; Amoco E-85 gasoline; or gray squirrel hair) or a laboratory generated alphanumeric code.

3. Properly controlled - Access to the reference collection will be limited to section members and laboratory management. Expiration dates are not applicable because visual examinations can verify the integrity of the item and/or the stability of the item is known.

Date of Original Issue: 03/01/97	Policy: **QM-15 Personnel Records** Page 1 of 1
Date of Revised Issue: 12/13/10	Compliant with ISO 17025 standards and the ANAB accreditation requirements.
Revision Transmittal Number: QA 10-01	

I. JOB DESCRIPTIONS

Job descriptions are a general explanation of the distinguishing features of work, illustrative examples of work and desirable requirements for all job classifications. Job descriptions for specific individuals are maintained by the laboratory to which the individual is assigned and are based on the scope of the work performed.

Position descriptions are defined on the Illinois State Form, CMS-104, for all personnel positions in the Command. These list the various positions and a description of the duties and responsibilities of the position.

More detailed performance standards and objectives for each employee are documented in an annual performance review to include information for the next reporting period.

II. TRAINING RECORDS

Initial training records are kept by Statewide Training. Subsequent training records for all employees (such as schools, seminars, workshops, etc.) are maintained by the individual laboratories. A curriculum vitae for each professional employee shall be maintained by the individual laboratories.

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Date of Revised Issue: 09/01/2023	Compliant with ISO 17025 standards and the ANAB accreditation requirements.
Revision Transmittal Number: QA 23-03	

I. OBTAINING USER AGENCY FEEDBACK

A. The Quality Assurance Survey

The Quality Assessment Survey (Appendix 16.1) is designed to elicit continuous feedback about the user agency's satisfaction with the provided services and the quality of the services. Since the actions and attitudes of personnel affect the opinion of user agencies, a careful evaluation of user agency observations will assist in identifying strong points and areas where improvements are needed. A survey link will be included with every DFS Report email notification issued in order to obtain general feedback from user agencies.

The Director of Quality Assurance will be responsible for reviewing and distributing surveys to the relevant laboratory director, bureau chief, program manager and/or technical leader as appropriate. If corrective action is required, the process will be documented in accordance with QM-8.

1. Positive feedback will be shared with appropriate staff, and laboratory management will ensure this communication is documented in an Activity Log entry.

2. Complaints

   a. All complaints will be evaluated, and the results will be documented in accordance with QM-8 and/or QM-17.

   b. Upon completion of cause analysis and corrective actions (as appropriate), or at regular intervals prior to the completion of the investigation if necessary, the laboratory director (or designee) will contact the complainant to discuss the results and notify them of the formal end of the complaint review. This will be documentedin the quality issue report.

   c. The laboratory director or designee will ensure that no individuals cited in the complaint are responsible for the evaluation.

   d. The complaint may also be investigated by the Department of Internal Investigationshould the conditions of the complaint warrant it as determined by the Commander.

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e. Defense expert reports that address specific analytical conclusions of a Forensic Sciences Command Employee shall be treated as a complaint and evaluated by Quality Assurance with the assistance of subject matter experts (Technical Leader, Quality Review Coordinator, and/or Training Coordinator as appropriate) to determine if corrective action is necessary. This review will be documented in accordance with QM-8 if the issue is deemed legitimate and impacts the reported findings in any way, or in accordance with QM-17 if there is no technical issue or change in reported findings.

B. Direct Interaction with Agencies

a. Law Enforcement Organization Membership

Law enforcement organization meetings will be utilized to provide feedback on laboratory performance and possible areas of improvement. Laboratory Directors should maintain membership in associations for law enforcement officials and/or police chief associations within their service area.

a. Memberships will be maintained in good standing. Regular attendance is expected. Regular attendance will be defined through agreement between each Laboratory Director and their respective Bureau Chief.

b. Agency feedback will be communicated to the laboratory's Bureau Chief. Attendance and feedback will also be summarized in the annual management review of the laboratory's quality system.

c. If there are no appropriate organizations within the service area of a laboratory and the Laboratory Director is unable to identify an organization nearby, the Laboratory Director will develop a meeting opportunity for the agencies. The meeting will be defined through agreement between each Laboratory Director and the respective Bureau Chief.

b. Agency contacts made by laboratory personnel either at the laboratory when agencies are present or during professional association meetings may be utilized to provide feedback. Feedback received must be forwarded through laboratory management to Command administration.

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II. UTILIZING USER AGENCY FEEDBACK

Feedback obtained from questionnaires or other means will be reviewed by Command Administration. Any changes or improvements which are derived from this review will be implemented and communicated.

Appendix 16.1

Illinois State Police Forensics Services Quality Assessment Survey Questions

The Illinois State Police (ISP) Division of Forensic Services is requesting your assistance in improving the high level of service we strive to provide. Please take the time to complete this survey. This will be used solely to assess the quality of services provided to your agency.

1. Agency
2. Name
3. County
4. Email Address

Are you providing feedback on Crime Scene for Forensic Laboratory Services?

1. Scene and Evidence Services
2. Forensic Laboratory Services

Please select the Illinois State Police Laboratory this survey is directed towards.

1. Decatur Forensic Science Laboratory
2. Forensic Science Center at Chicago
3. Joliet Forensic Science Laboratory
4. Metro East Forensic Science Laboratory
5. Morton Forensic Science Laboratory
6. Rockford Forensic Science Laboratory
7. Springfield Forensic Science Laboratory
8. Overall ISP Forensic Laboratory Services

Please select a category for your feedback

1. A Specific Case/Event
2. An Employee(s)
3. General Comments

Services rendered meet investigative and/or trial requirements

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

Our Agency is satisfied with the timeliness of results

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

ISP staff maintained professionalism in all interactions with our agency

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

Communication with ISP Forensic Services staff is effective and timely

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

Reports generated by ISP Forensic Services are clear and comprehensive

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

Our agency is satisfied with the quality of service provided by ISP Forensic Services

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

ISP Forensics Services accommodates rush requests in a timely manner

1. Strongly Agree
2. Somewhat Agree
3. Neutral
4. Somewhat Disagree
5. Strongly Disagree

If you answered "Strongly Disagree" or "Disagree" to any of the evaluative statements above, please provide a response as to why you came to that conclusion.

Comments

Would you like to provide a response to any of the other evaluative statements?

Comments

What is one improvement ISP Forensic Services could make to better service your agency, other law enforcement agencies, or the citizens of Illinois.

Comments

Please provide comments regarding situations of when your agency was particularly satisfied with services rendered.

Comments

Please provide comments regarding situations of when your agency was dissatisfied with services rendered.

Comments

Does your agency have a need for services that ISP Forensic Services does not offer?

Comments

Do you have any additional comments regarding The Illinois State Police Division of Forensics Services?

Comments

Thank you for your assistance.

If you have questions or concerns and would prefer to contact us, please email your message to **DFS_Quality_Assurance@Illinois.gov**

If you prefer to have a representative from The Illinois State Police Division of Forensic Services contact you for additional follow-up regarding any concerns or suggestions made, please provide your Name, Phone Number, and Email Address in the following field

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Date of Revised Issue: 09/01/2025	Compliant with ISO 17025 standards and the ANAB accreditation requirements.
Revision Transmittal Number: QA 25-01	

I. POLICY

The Laboratory Quality Flag form (Appendix 17.1) is used for documenting the actions laboratory management take to remediate quality issues that do not warrant corrective action. In these instances, there is no justification for root cause analysis or developing a corrective action plan. Unless otherwise specified by the Bureau Chief, Director of Quality Assurance, or Commander, Appendix 17.2 lists the quality issues for which laboratory managers will remediate and then document with the Laboratory Quality Flag. Laboratory management will maintain their issued Laboratory Quality Flags in a centralized location, which may be used to investigate a recurring issue.

II. LABORATORY QUALITY FLAG FORM

A. Assigning the Laboratory Quality Flag Identification Number

1. The Laboratory Quality Manager will maintain a centralized log/database of all issued Laboratory Quality Flag forms by number and will track their progress accordingly.

2. Once notified of a quality issue requiring a Laboratory Quality Flag, the Laboratory Quality Manager will assign an identifying number to the issue.

3. Flag numbers are generated sequentially, beginning with “1" and progressing until the end of the calendar year. Flag numbers are identified to a particular laboratory and year by the prefix preceding the sequential number. Laboratory designators are as follows:

FSCC– Forensic Science Center at Chicago
CMD – Forensic Sciences Command
JOL– Joliet Forensic Science Laboratory
MET– Metro-East Forensic Science Laboratory
MOR– Morton Forensic Science Laboratory
RD– Training & Applications Laboratory
ROC– Rockford Forensic Science Laboratory
SPR– Springfield Forensic Science Laboratory
DEC – Decatur Forensic Science Laboratory

Therefore, an example of the first flag number issued at the Joliet Forensic Science Laboratory in 2013 is JOL-13-01.

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B. Procedure for the Laboratory Quality Flag Form:

1. Upon discovery of a quality issue, the Laboratory Quality Manager will be notified. The Laboratory Quality Manager will review Appendix 8.3 to determine whether a Quality Issue Report (QIR) must be initiated. If a QIR is not required and the quality issue is listed in Appendix 17.2, then the Laboratory Quality Manager assigns a Laboratory Quality Flag identification number.

   Laboratory management will contact the appropriate Bureau Chief should there be special circumstances that warrant a QIR when a Laboratory Quality Flag would normally be initiated. Quality issues or situations that are not clearly listed in Appendix 8.3 or Appendix 17.2 will be discussed with the appropriate Bureau Chief to determine whether a QIR or Laboratory Quality Flag is required.

2. Within two business days after discovery of the quality issue, the Laboratory Quality Manager or designee will notify the Laboratory Director, the Bureau Chiefs, Director of Quality Assurance, and/or their designee. The DNA and Toxicology Technical Leaders will be included in the notification, as necessary. The notification shall specify the quality issue as listed in Appendix 17.2, list the involved personnel, and the actions that will be taken to remediate the quality issue.

3. Appropriate laboratory management will finalize their evaluation of the situation and take action(s) to remediate the quality issue.

4. Appropriate laboratory management will complete the Laboratory Quality Flag form fields and inform his/her Laboratory Quality Manager. While the form must be completed in a timely fashion, a thorough, accurate communication of facts in the form is expected.

5. The Laboratory Quality Manager will approve the Laboratory Quality Flag form once determining all the actions taken are appropriate and complete. This signed document is a completed Laboratory Quality Flag.

6. The Laboratory Quality Manager will maintain the original, completed Laboratory Quality Flag indefinitely in approved secure server locations.

C. Monitoring the Actions Taken

1. Laboratory management will review the appropriateness of the actions taken and the completion of the Laboratory Quality Flags when conducing the laboratory's annual management review. Command management will review the Laboratory

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Quality Flags when conducing the laboratory's annual management review. Command management will review the Laboratory Quality Flags periodically when investigating a recurring issue and approving the laboratory's annual management review.

D. Communicating Laboratory Quality Flags

1. Laboratory management will give access to the completed Laboratory Quality Flag to all Command employees directly involved in the quality issue and appropriate management staff.

2. After a Laboratory Quality Flag identification number for a quality issue has been assigned, all cases affected will be flagged in LIMS. For any cases generated before December 2018, with physical paper files, a Quality Issue Report / Laboratory Quality Flag Notification form (Appendix 8.2) has been placed within the administrative documentation of each case involved in the quality issue. This is only applicable for Laboratory Quality Flags that involve cases.

3. Refer to Command Directives EVH 22 for responding to prosecution or defense requests of a Laboratory Quality Flag

ILLINOIS STATE POLICE
DIVISION OF FORENSIC SERVICES
FORENSIC SCIENCES COMMAND

LABORATORY QUALITY FLAG FORM

Flag Number: _____ Reported By: _____

Date Reported: _____

Laboratory: _____

Section: _____

Quality Flag: _____

Date of Occurrence: _____

Employee(s) Associated: _____

Case(s) Associated: _____

Actions Taken:

Laboratory Quality Manager Approval: _____

Date Completed: _____

APPENDIX 17.2 – Approved Quality Flag List:

1. Consumed evidence without obtaining permission – if permission granted afterwards
2. Contamination or compromised evidence due to missed agency request
3. Delayed analysis of evidence
4. DNA CODIS - Improper CODIS search resulting in hit
5. DNA CODIS - Improperly including sample into CODIS database
6. DNA extraction issue
7. DNA sample switch
8. DNA one locus mismatch
9. Equipment failure
10. Evidence returned to incorrect agency
11. Evidence with incorrect barcode label so incorrect laboratory report mailed
12. Expired reagent, standard, or control used in casework, however it is demonstrated that there is no change in the reaction of the chemical.
13. Failed performance check that was unnoticed, however it is demonstrated that the instrument is operating correctly.
14. Improperly disposed evidence or broken evidence
15. Incomplete analysis (missed examining an item)
16. Incorrect reporting due to non-technical (e.g. typographical or administrative) error
17. Missed performance check/calibration, however it is demonstrated that the instrument is operating correctly.
18. Missing case file unless impacting court proceeding or further case analysis
19. Original evidence packaging mis-handled
20. Unidentified or unsecured evidence
21. Unsubstantiated agency "complaint" of analysis results
22. Reanalysis results in a change in findings when the original analysis was conducted appropriately and following all ISP policies and procedures. (i.e. originally reporting an inconclusive result for a latent print when a subsequent analysis indicates a more definite conclusion, a low concentration seized drug item that is reanalyzed and results in an identification). The quality flag must document that the QRC and/or discipline technical leader has reviewed the finding and deemed it to be within the acceptable range of conclusions.

23. |Reanalysis results in a change in findings when the original analysis was conducted appropriately and following all ISP policies and procedures. (i.e. originally reporting an inconclusive result for a latent print when a subsequent analysis indicates a more definite conclusion, a low concentration seized drug item that is reanalyzed and results in an identification). The quality flag must document that the QRC and/or discipline technical leader has reviewed the finding and deemed it to be within the acceptable range of conclusions.

24. Review of a "defense expert" report by the Director of Quality Assurance with the assistance of subject matter experts (Technical Leader, Quality Review Coordinator, and/or Training Coordinator) that addresses specific analytical conclusions by a Forensic Sciences Command analyst but does not result in the need for corrective action.

Illinois State Police
Division of Forensic Services
Forensic Sciences Command

Date of Original Issue: 12/09/2020	Policy: **QM-18 Measurement Uncertainty** Page 1 of 1
Date of Revised Issue: 12/01/2023	Compliant with ISO 17025 standards and the ANAB accreditation requirements.
Revision Transmittal Number: QA 23-06	

I. Measurement Uncertainty Calculations will be performed for the following activities
   a. Firearms – Length Measurements
   b. Drug Chemistry – Weights
   c. Drug Chemistry – Quantitative Determinations
   d. Toxicology – Quantitative Determinations

II. Relevant sections will have a procedure for calculating Measurement Uncertainty

III. All budget tables, uncertainty calculations, and reviews will be stored in the LAM.

IV. The following events will be evaluated for their impact on Measurement Uncertainty. The evaluation will be documented in LAM, and if warranted, a new uncertainty calculation and review will be performed.
   a. Inclusion of new equipment
   b. Inclusion of new staff
   c. New calibration certificates

V. A full calculation and review of measurement uncertainty will occur at least once per interval:

Activity	**Maximum Interval**
Firearms – Length Measurements	4 Years
Drug Chemistry – Weights	2 Years
Drug Chemistry – Quantitative Determinations	2 Years
Toxicology – Quantitative Determinations	2 Years

Date of Original Issue: 09/01/25	Policy: **QM-19 Stock Chemicals and Reagents** Page **1** of **6**
Date of Revised Issue:	Compliant with ISO 17025 standards and the ANAB accreditation requirements.
Revision Transmittal Number: QA 25-01	

I. POLICY

The Forensic Sciences Command's commitment to providing high quality services is based upon several factors. One of these is having several checks to monitor the quality of service. A part of quality monitoring is to ensure that stock chemicals and reagents which can impact case results will perform correctly when used in procedures. See also Appendix 19.1 for a quick reference guide.

Note, a stock chemical or reagent is not usually used as a reference material. In the rare instance that a stock chemical or reagent is also a reference material, then that chemical substance will be subject to the additional requirements in QM-14. In this situation, if there is a conflict between the policies in QM-14 and QM-19, then the stricter requirement takes precedence.

II. Definitions

A. Stock chemical - An element, chemical compound, or a mixture of chemical compounds purchased from a vendor and which is stable over time. It is usually used as a solvent or as an ingredient for in-house reagents. This term is not synonymous with "stock solution" or "stock standard" which are defined in each section's Procedures Manual if applicable.

Examples of stock chemicals include methanol, sodium acetate, acetic acid, Rhodamine 6G (solid), or cobalt thiocyanate (solid).

B. Reagent - A chemical substance that is being actively used in casework for any of the following purposes:

- A chemical substance used because of its chemical or biological activity (e.g. EMIT Reagents 1 and 2)
- A chemical substance used in chemical analysis (e.g. bicarbonate buffer), chemical reactions (e.g. cobalt thiocyanate color test), physical testing, or physical examination (e.g. Fry's Reagent or dyes such as the KPIC #1 and Rhodamine 6G solutions).

1. In-house reagents - A chemical solution, chemical mixture, or dilution that laboratory personnel prepared by combining two or more chemical compounds.

Examples of in-house reagents include combining the stock chemicals glacial acetic acid, sodium acetate, and deionized water for AP Buffer or 40% formaldehyde and

concentrated sulfuric acid for Marquis color test.

2. Purchased reagents - A chemical solution, chemical mixture, or dilution that a manufacturer created by combining two or more chemical compounds and which is purchased by the laboratory.

   Examples of purchased reagents include 10X Genetic Analyzer Buffer with EDTA or EMIT Reagent 1.

3. Critical reagents - In-house or purchased reagents determined by empirical studies or routine practice to require testing on established samples before use on evidentiary or casework reference samples.

4. DNA "Commercial reagents" - A term only used in the Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories and not in this Quality Manual. It pertains to the substances Forensic Sciences Command categorized as stock chemicals and purchased reagents (see definitions listed above).

III. Expiration Dates for Stock Chemicals and Reagents

A. EXPIRED STOCK CHEMICALS OR REAGENTS WILL NOT BE USED IN CASEWORK.

B. For stock chemicals and reagents, the expiration dates provided by the chemical suppliers must be followed.

C. If the chemical suppliers do not provide expiration dates, the following policies must be followed:

1. For stock chemicals, there are no expiration dates.

2. For in-house reagents, the expiration date will be one year from the preparation date or earlier (e.g. one of the components in the chemical solution expires sooner than one year).

3. For purchased reagents, each section will follow the steps outlined in its Procedures Manual for assigning expiration dates.

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Date of Revised Issue: Revision Transmittal Number: QA 25-01	Compliant with ISO 17025 standards and the ANAB accreditation requirements.

D. Frozen in-house or purchased reagents will have an expiration date of one year from the date they are thawed and put into use, which will be noted on the reagent container.

IV. Extending Expiration Dates

A. When the expiration date was originally assigned by the laboratory, in-house or purchased reagents will not be used in casework after their expiration dates until they have been re-authenticated.

B. Expired in-house or purchased reagents must be re-authenticated prior to, or concurrent with, casework examination. When re-authenticating, the results must meet the originally defined criteria, or it may be compared with data obtained from the first authentication. After re-authenticating, the in-house or purchased reagents will be given a new expiration date that is one year from the re-authentication date.

C. In-house or purchased reagents that were thawed will not be re-authenticated.

D. Upon becoming aware that an expired reagent was used for casework, the laboratory management will refer to sections QM-8 and QM-17 of the Command Quality Manual to determine the appropriate course of action.

V. Verifying and Authenticating Stock Chemicals and Reagents

A. The following minimum measures will be taken to verify the purchased chemical substance prior to use in casework:

1. The laboratory will verify the appropriate item was received.

2. The item will be inspected for damage that could affect its performance.

3. If applicable, the certificates will be reviewed.

B. In-house reagents will be authenticated to ensure their reliability and quality for casework analysis.

1. For DNA analysis, only the critical reagents are authenticated.

2. Reagents which are only prepared as components of other reagents will not be

authenticated until combined to make the final product (e.g. stock detergent solution for Physical Developer or surfactant stock solution for Small Particle Reagent).

3. The authentication will be conducted using one of the methods described below and recorded in the LAM. Any additional required documentation is outlined in the respective procedures' manuals.

   a. Authenticated when prepared prior to use in casework.

   b. Authenticated concurrently in casework utilizing controls.

C. Critical Reagents

1. As applicable, a list of critical reagents must be maintained in the section's Procedures Manual.

2. Each section will follow the steps outlined in its Procedures Manual for authenticating critical reagents. Critical reagents must be routinely tested on established samples before using on evidentiary or casework samples.

3. Lot numbers of critical reagents authenticated must be recorded.

VI. Labeling Stock Chemicals and Reagents

A. Stock chemicals must be labeled with the following information when received into the laboratory:

- Identity of personnel receiving the chemical
- Date of receipt
- Expiration date or a clear notation that there is no expiration date
- Hazard label or appropriate pictogram

B. In-house reagents must be labeled with:

- Name of reagent
- Concentration, where appropriate
- Date of preparation and expiration date
- The identity of the preparer

- Storage conditions, if relevant
- A hazard warning, where necessary

C. Purchased reagents must be labeled with:

- Identity of personnel receiving the reagent
- Date of receipt
- Expiration date or a clear notation that there is no expiration date

VII. Records retention

A. Stock Chemicals will be entered into the Laboratory Asset Manager (LAM) upon receipt and the record will be updated as chemicals are moved or consumed. The following information will be recorded:

- Asset Type (chemical name)
- Lot Number
- Assigned Section
- Quantity and units received (example: Quantity: 4, Units: Liters)
- Received by
- Date Received
- Expiration Date, if applicable
- Storage location

B. In-house reagents (including those that are critical reagents) will be entered into the LAM upon preparation and the record will be updated as reagents are re-authenticated or consumed. The following information will be recorded:

- Asset type (reagent name)
- Lot/Batch number (date prepared)
- Assigned section
- Quantity and units prepared (example: Quantity: 4, Units: Liters)
- Prepared by
- Date prepared
- Expiration date
- Components of the reagent including lot numbers when appropriate
- Verification/Authentication information
- Storage location

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C. Purchased reagents (including those that are critical reagents) will be entered into the LAM upon receipt and the record will be updated as reagents are moved or consumed. The following information will be recorded:

- Asset type (chemical name)
- Lot number
- Assigned section
- Quantity and units received (example: Quantity: 4, Units: Liters)
- Received by
- Date received
- Expiration date
- Verification/Authentication information, when applicable
- Storage location

VIII. Handling and Storage

Access to stock chemicals and reagents will be limited to section members and laboratory management. The items will be handled and stored to maintain their integrity and security. When necessary, storage conditions will be outlined in the section's Procedures Manual.

Appendix 19.1. Quick Reference Guide for Stock Chemicals and Reagents

	Testing Required?	Expiration Policies	Must Be Labeled With
Stock chemical	No. Perform visual examination	• Follow expiration date provided • If no date provided, will not expire	• Identity of personnel receiving • Date of receipt • Expiration date or clearly noted there is no expiration date • Hazard label or pictogram
Reagents:			
In-house reagent	• Yes, for non-DNA reagents • Testing occurs before or concurrently with casework • If a critical reagent, then also see critical reagent category	• Expire in one year. May confirm the quality of the reagent and give new expiration date • Frozen in-house reagent expires one year after thawing. Do not re-authenticate.	• Name of reagent • Identity of preparer • Preparation and expiration date • If needed or relevant: o Concentration o Storage conditions o Hazard label or pictogram
Purchased reagent	• No, unless a critical reagent; then, see critical reagent category	• Follow expiration date provided • If no date provided, follow Procedures Manual • <u>If laboratory assigned the date</u>, may confirm the quality of the reagent and give new expiration date	• Identity of personnel receiving • Date of receipt • Expiration date or clearly noted there is no expiration date
Critical reagent	Yes, <u>before</u> using in casework	• Follow applicable in-house reagent policies • Follow applicable manufactured reagent policies	• Follow applicable in-house reagent policies • Follow applicable manufactured reagent policies