Indiana State Police
Laboratory Division

Quality Assurance Manual

INDIANA STATE POLICE LABORATORY DIVISION
QUALITY ASSURANCE MANUAL

Table of Contents

1.	Scope	Page 3
1.1	Laboratory Division History	Page 3
2.	References	Page 5
3.	Terms and Definitions	Page 6
4.	General Requirements	Page 7
4.1	Impartiality	Page 7
4.2	Confidentiality	Page 8
5.	Structural Requirements	Page 10
6.	Resource Requirements	Page 13
6.1	General	Page 13
6.2	Personnel	Page 13
6.3	Facilities and Environmental Conditions	Page 18
6.4	Equipment	Page 21
6.5	Metrological Traceability	Page 25
6.6	External Products and Services	Page 25
7.	Process Requirements	Page 28
7.1	Review of Requests, Tenders, and Contracts	Page 28
7.2	Selection, Verification, and Validation of Methods	Page 29
7.3	Sampling	Page 32
7.4	Handling Evidence Items	Page 33
7.5	Technical Records	Page 34
7.6	Evaluation of Measurement Uncertainty	Page 36
7.7	Ensuring the Validity of Results	Page 37
7.8	Reporting of Results	Page 43
7.9	Complaints/Quality Concerns	Page 47
7.10	Nonconforming Work	Page 48
7.11	Control of Data and Information Management	Page 49
8.	Management System Requirements	Page 50
8.1	Options	Page 50
8.2	Management System Documentation	Page 50
8.3	Control of Management System Documents	Page 50
8.4	Control of Records	Page 52
8.5	Actions to Address Risks and Opportunity	Page 52
8.6	Improvement	Page 53
8.7	Corrective Actions	Page 53
8.8	Internal Audits	Page 54
8.9	Management Review	Page 55

1. Scope

This Quality Assurance Manual (QAM) contains or references the policies and procedures of the Indiana State Police Laboratory Division's quality management system that facilitates meeting accreditation requirements.

The numbering of this QAM corresponds to numbering of the accreditation requirements in the ISO/IEC 17025 standard and the accrediting body's supplemental requirements.

1.1 Laboratory Division History

The Indiana State Police Laboratory Division was established in 1936 as the Department became aware that its proficiency in investigating criminal cases was dependent upon professional collection and analysis of technical evidence. It was a forensic service designed to benefit all criminal justice agencies within the state and continues to this day to assist various units of government, towns, counties, cities, military police, and federal agencies.

The Department has long been aware that criminal or crash investigation is best augmented by laboratory analysis, exposing as it does details obscure or deliberately concealed. Today every police officer in the State is charged with the proper and meticulous collection of evidence, its preservation, and transportation to a laboratory in a manner conforming to the rules of evidence.

It is axiomatic in law enforcement work that there are no perfect crimes, only imperfect investigations. The Indiana State Police Laboratory Division has been a part of the Department's investigative teams since its inception, assisting investigators through crime scene processing and the analysis of physical evidence.

The system has grown from a small room in the Capitol basement to a highly sophisticated system of four strategically placed facilities. Prior to 1977 all forensic examinations had to be performed at the Indianapolis facility, but in that year the Department began to extend its service by establishing the first Regional Laboratory at Lowell, in northern Indiana. Now there are regional laboratories at Fort Wayne and Evansville as well. The present system employs more than 180 police and civilian personnel, all trained in the various phases of evidence identification and examination.

On June 1, 1991, the Regional Laboratories achieved accreditation from the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB®). The Laboratory Division's continuing participation in the accreditation process demonstrates its commitment and adherence to nationally recognized quality related standards and procedures.

In 2012, the four Regional Laboratories of the Indiana State Police Department attained ISO/IEC 17025 accreditation under the ASCLD/LAB-International program. During

2016, ASCLD/LAB became part of American National Standards Institute (ANSI) National Accreditation Board (ANAB).

In 2019, District facilities and crime scene investigations services attained ISO/IEC 17025 accreditation with ANAB.

Return to Table of Contents

2. REFERENCES

2.1 International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC), ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories©

2.2 American National Standards Institute (ANSI) National Accreditation Board (ANAB) – AR 3125, ISO/IEC 17025:2017 Forensic Science Testing and Calibration Laboratories Accreditation Requirements

Return to Table of Contents

3. Terms and Definitions

3.1 ANAB – ANSI - National Accreditation Board or the American National Standards Institute (ANSI) National Accreditation Board

3.2 Annual – Once during the calendar year (January 1 - December 31)

3.3 Management System Documents – Laboratory Division policies and procedures which includes, but are not limited to, Quality Assurance Manual, Policies, Physical Evidence Bulletins (PEB), Test Methods, Crime Scene Investigation Procedures Manual, and Training Manuals

3.4 Record – Documentation that provides evidence of work performed, activities conducted, and/or quality tasks for archival purposes.

3.5 QAM – Quality Assurance Manual

3.6 Quarterly – Once during the quarter (January – March, April – June, July – September, and October – December)

3.7 Shall – A word used when an element of the management system is required.

3.8 Should – A word used when an element of the management system is recommended, but not required, and is intended to be done unless a valid reason exists to not do it.

3.9 Subcontracting – A non-Laboratory Division entity conducting crime scene investigation, digital forensic, or laboratory activities normally performed by the Laboratory Division.

Return to Table of Contents

4. General Requirements

4.1 Impartiality

The Indiana State Police (ISP) Laboratory Division provides crime scene investigation, forensic laboratory, polygraph, and evidence storage services in an impartial and objective manner and in accordance with requirements of an ISO/IEC 17025 accreditation program and the Laboratory Division's management system documents.

The Laboratory Division's objectives are described in the Mission and Operating Statements. Each facility shall post the Mission and Operating Statements, which are based upon needs of our customers and the criminal justice system within the State of Indiana. Employees shall understand the content of these documents.

All Laboratory Division personnel shall be free from any undue internal and external commercial, financial, and other pressures that may compromise the quality of their work.

All members of the Laboratory Division have an ethical and professional responsibility to base their investigations and examinations on the physical evidence available. Investigations, analyses, and other job duties performed shall be impartial, free from bias or preconceived conclusions, political pressure, or other outside influences. If at any time a member of the Laboratory Division perceives pressure to conduct an investigation, analysis, or perform other job duties in a manner that is not independent, impartial, or objective, the situation shall be brought to the attention of a first line supervisor or the Laboratory Division management staff.

Laboratory Division personnel shall avoid conflict of interest situations including involvement in activities that would diminish confidence in their competence, impartiality, judgment, or operational integrity. Laboratory Division personnel shall be aware of risks to impartiality due to their own personal activities and relationships.

In order to avoid involvement in activities that would diminish confidence in the operational integrity, Laboratory Division personnel shall comply with all relevant rules for ethical conduct that includes Laboratory Division General Policy #041 Code of Professional Conduct, ISP Regulation 1: Code of Professional Ethics, and Ethics Rules from the Indiana State Code of Ethics. Laboratory Division personnel shall annually review General Policy #041. The records of these annual reviews shall be maintained on the network drive. Laboratory Division management staff shall ensure appropriate actions are taken when necessary.

All members of the Laboratory Division shall strive to identify risks to independence and impartiality. Risks to impartiality may be present; therefore, it is incumbent on everyone to be aware of those risks, to be able to recognize them and be obligated to report them, when present, to a first line supervisor or the Laboratory Division management staff for resolution.

Management staff shall ensure that Laboratory Division personnel are never instructed to alter or falsify analytical data. Laboratory Division personnel shall never use confidential information for any purpose beyond the scope of employment. Personnel involved in dishonest activities shall be subject to discipline according to Department policies and procedures.

The organizational structure, as shown the Laboratory's Division Organization Chart, helps to insulate staff from influences that could potentially compromise the quality of services provided. Management has the responsibility and authority to investigate and take appropriate action on employee concerns within the Laboratory Division. The potential for a conflict of interest shall be reported to a first line supervisor or the Laboratory Division Management.

4.2 Confidentiality

The Laboratory Division personnel shall protect all confidential information obtained from our customers or generated during the crime scene investigation or laboratory examination including paper records, electronic storage, and transmission of results.

Each employee has the responsibility to safeguard all confidential information obtained in an official work capacity, regardless of the source of the information, and shall not access or disclose any confidential information regarding investigations or casework, except while conducting official Department business.

All information obtained or created during the performance of crime scene investigation and laboratory examination duties are considered investigatory records of a law enforcement agency, which under Indiana Code (IC) 5-14-3-4 (b) (1), are confidential and not subject to public disclosure without due process of law.

Confidential information shall only be released in accordance with the Laboratory Division's procedure. When needed for official business, ISP personnel can access the Crime Scene Investigator's (CSI) Case Reports in the Records Management System (RMS) and may distribute a report to a criminal justice agency who has a need and right to know or with a valid court order.

The Digital Forensic Report and Forensic Scientist's Certificates of Analysis shall be maintained in the Laboratory Information Management System (LIMS). An electronic copy shall be available to the customer via the secure I-Results website

portal. Information may be released in written, electronic, or verbal form to a member of a criminal justice agency who has a need and right to know or with a valid court order. When the information from a Certificate of Analysis is released, a Record of Dissemination shall be completed in the LIMS. A Record of Dissemination is not required if the information is provided to the customer through I-Results.

A copy (paper or electronic) of the Case Report or the Certificate of Analysis and associated case records may be provided to former Laboratory Division employees subpoenaed to testify. The respective Laboratory Manager or designee should upload a copy of the subpoena to the appropriate case file in LIMS and shall add a Record of Dissemination in LIMS. The Crime Scene Investigation (CSI) Supervisor or designee should upload a copy of the subpoena to the appropriate case file in the CSI Archive folder. The Laboratory Manager or the CSI Supervisor shall instruct the former Laboratory Division employees to destroy all the records provided when no longer needed.

The written, electronic, or verbal dissemination of confidential information related to a criminal investigation or laboratory examination to persons outside of the criminal justice system (e.g., defense attorneys, news media, a victim, victim's family, etc.) is prohibited without written authorization (e.g., letter, email, etc.) from the prosecutor of the case or a valid court order.

Inquiries from the public shall be brought to the attention of the Laboratory Manager or Crime Scene Investigations Supervisor. The Laboratory Manager or Crime Scene Investigations Supervisor shall forward the request to the ISP Legal Office via email to the following email address, PublicRecords@isp.in.gov. The email shall include the date the request was received and copies of the relevant Case Report(s) or Certificate(s) of Analysis and other relevant Laboratory Division records. The Legal Office is responsible for responding to the request. The Laboratory Manager or designee shall add a Record of Dissemination in the LIMS.

Return to Table of Contents

5. Structural Requirements

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The Indiana State Police Department (ISP) was established in 1933 by Indiana Code (IC) 10-11-2. The Laboratory Division's position within ISP is shown in the Department's Organization Chart. The Superintendent is appointed by the Governor and serves as the agency head. The Superintendent provides guidance and vision for the entire Department. Second in command is the Assistant Superintendent/Chief of Staff, a Colonel. Within the Department, the Laboratory Division is part of the Investigations and Intelligence command under the leadership of a Deputy Superintendent/Assistant Chief of Staff, a Lieutenant Colonel. ISP is structured in manner that the Laboratory Division is independent from other investigative functions within the ISP as shown in the Department's Organization Chart.

Laboratory Division's Organization Chart shows the organizational structure and the relationships between various sections and units with the Division. The Laboratory Division is organized into five sections: Biology, Chemistry, Comparative Science, Crime Scene Investigations, and Management Support. The Laboratory Division also includes the Crime Scene Investigations Quality Assurance (CSI QA), Digital Forensic Unit (DFU), Laboratory Information Management System/Information Technology (LIMS/IT), and Polygraph Units. The Laboratory Division Commander, a Major, has overall leadership and authority of the Laboratory Division. The Laboratory Division Deputy Commander, a Captain, oversees the Crime Scene Investigations and the Management Support Sections, and the DFU, Polygraph, and LIMS/IT Units. The Director of Forensic Analysis manages the Biology, Chemistry, and Comparative Science Sections. The Laboratory Division structure separates the crime scene processing activities from the forensic testing services provided at the regional laboratories as shown in the Laboratory Division's Organization Chart, which safeguards the impartiality of both the crime scene investigations and laboratory examinations. The responsibilities, duties, and authorities of all personnel are defined in the Job Descriptions.

The Crime Scene Investigations Section is commanded by a Lieutenant and is divided into five Areas within the State. Each Area consists of a First Sergeant Crime Scene Investigations Supervisor, Sergeant Crime Scene Investigators (CSI), and District Evidence Specialists (ES). The CSIs work out of all 14 ISP Districts and the District ESs securely maintain evidence at 11 of the ISP Districts. The other three ISP Districts (Evansville, Fort Wayne, and Lowell) have a Regional Laboratory within their building, and the evidence at these locations is maintained by the Laboratory ESs. The Crime Scene Investigations Section, when requested by local, state, and federal law enforcement agencies, responds to crime scenes, 24 hours a day, seven days a week. Services provided at the crime scenes

includes scene documentation, evidence collection and packaging, presumptive testing, and bloodstain pattern analysis. The CSI QA Unit supports the Crime Scene Investigations Section by annually performing Complete Evidence Inventory Audits or Off-Year Evidence Audits at all Laboratory Division facilities, semi-annual technical assessments of CSI's work, administrating CSI proficiency testing program, and other quality related duties.

The Laboratory Division operates four regional laboratories in Evansville, Fort Wayne, Indianapolis, and Lowell, which consist of a Laboratory Manager, Forensic Scientists, Laboratory ESs, and, at the Indianapolis Regional Laboratory only, Forensic Technicians. All the Regional Laboratories provide services in Biology, Drugs, Firearms/Toolmarks, and Latent Prints disciplines. Microanalysis (Fire Debris, Footwear/Tire Impressions, and Materials/Trace) and Document examinations are only performed at the Indianapolis Regional Laboratory. Unit Supervisors are responsible for the technical operations and quality management system of their respective unit. The Biology Section has one Technical Leader for all four Regional Laboratories, who is responsible for and oversees the Section's technical operations.

The Digital Forensic Unit is commanded by a Lieutenant and provides services in the five Areas within the State. The Unit includes both sworn and civilian personnel who perform digital forensic and audio/video examinations.

Crime scene, digital forensic, and laboratory activities meets or exceeds the requirements of an ISO/IEC 17025 accreditation program. The Laboratory Division's management system documents shall be sufficiently detailed to ensure the consistent application of crime scene, digital forensic, and laboratory activities and validity of investigations and analytical results.

Laboratory Division personnel have the authority and resources needed to carry out their duties, including:

- implementation, improvement, and maintenance of the management system;
- identification of deviations from the management system documents;
- initiation of actions to prevent or minimize such deviations;
- reporting to the Laboratory Division management on the performance of the management system and any need for improvement; and
- ensuring the effectiveness of crime scene, laboratory, and evidence management activities.

A deviation is a variance, addition to, or exclusion from a documented policy, procedure, or method. Requests for a deviation from this Quality Assurance Manual (QAM) or a Laboratory Policy shall be made in writing through channels to the Laboratory Division Commander. The request shall include the reason for the

deviation and the alternate approach to be used and the anticipated duration that the deviation will be needed. The Laboratory Division Commander shall notify the employee and respective chain of command in writing of the decision. A copy of the deviation request and approval or denial shall be forwarded to the Accreditation and Quality Assurance Manager for the QA records.

The requirements in the Laboratory Division's management system documents shall be followed regardless of where work is conducted by the Laboratory Division personnel. The integrity of the management system shall be maintained when changes to the management system are planned and implemented.

Return to Table of Contents

6. Resource Requirements

6.1 General

The Laboratory Division shall have available the personnel, facilities, equipment, systems, and support services necessary to manage and perform crime scene, digital forensic, and laboratory activities.

6.2 Personnel

Staffing of the Laboratory Division shall follow the procedures in the Indiana State Police (ISP) Standard Operating Procedures (SOPs) and the direction of the ISP Human Resources Division. The Laboratory Division's specific procedures for determining the competence, training of personnel, authorization of personnel, etc. are described in QAM-6.2.

It is the desire and intent of the Laboratory Division to employ only the highest qualified personnel. All personnel shall be aware of the competencies and specific duties required in their position. Job descriptions include requirements for education, duties, responsibilities, and authorities. Personnel shall meet the minimum educational requirements specified in the job descriptions. Management and supervisory personnel shall communicate to personnel their duties, responsibilities, and authorities.

All Laboratory Division personnel shall act impartially, be competent, and work in accordance with the Laboratory Division's management system. Personnel performing specific tasks shall be qualified based on education, training, experience, and/or demonstrated skills, as required. Personnel shall have relevant knowledge of the technology used in their discipline. This knowledge is obtained and enhanced by attending training, seminars, webinars, literature review, etc.

All communications, both internal and external, shall be clear, concise, and simply stated. Tact and diplomacy are a must in communications. Laboratory Division management shall ensure that communication takes place regarding the effectiveness of the management system and importance of meeting customer's requests for services.

Training and Competency

Unit Supervisors, including the Technical Leader (TL) in the Biology Section, shall coordinate and oversee the training of Digital Forensic Examiners (DFE), Forensic Scientists (FS) and Forensic Technicians (FT) within their respective units. The Crime Scene Investigations Section Commander shall coordinate and oversee the training of Crime Scene Investigators (CSI). Laboratory Managers or Crime Scene

Investigations Supervisors shall coordinate and oversee the training of Evidence Specialists.

The training programs shall be structured to provide the employees the skills, technical knowledge, and abilities required to perform their job duties for which they will be responsible. Each training program shall comprehensively cover all work performed within the discipline, include practical exercises encompassing the examination of a range of samples routinely encountered in casework, and require competency testing either throughout the program and/or upon its conclusion. Specific disciplines shall list any special educational class requirements or certification in the training manual or in the job description.

The Laboratory Division's documented training programs shall be described in the training manuals and shall be used to instruct staff in the technical knowledge, skills, and abilities needed to perform the assigned duties and to satisfy competency requirements. The scope and duration of the training necessary for each new employee shall be determined by the assignment as well as the employee's education and experience. The training manuals shall be reviewed at a minimum annually, following the procedure described in QAM-8.3, to ensure the documents are kept up to date. The Biology Section training program shall be annually reviewed, and revisions approved by the TL prior to submitting to the Laboratory Division Commander for final approval.

Ethical practices in forensic sciences and a general knowledge of forensic science shall be components of the New Employee Orientation Training Program. Applicable criminal and civil law and legal procedures shall be included in the discipline training manual(s).

The Laboratory Division shall ensure and document the competence of all personnel who perform crime scene investigations, digital forensic examinations, laboratory analysis, and evidence handling activities. The knowledge, skills, abilities, education, and experience of personnel are essential to achieving quality results. All Laboratory Division personnel shall have the ability to make professional judgments, conform to general requirements, and use written methods to achieve quality results and reports.

All work performed by trainees and interns shall be monitored and supervised by trained and experienced employees who are qualified in that discipline.

Documentation shall be sufficiently detailed to demonstrate that employees performing tasks were properly trained and that their subsequent ability to perform these tasks was formally assessed by written examination, practical exercises, observation, and/or competency testing. The acceptance criteria to determine competence, including examinations/quizzes, practical exercises, and competency

tests, shall be established in the training manual, and documented in the training records.

All personnel who conduct crime scene, digital forensics, and laboratory activities shall successfully complete a competency test prior to performing the activity on evidence. Competency testing shall include practical examination(s) that cover the spectrum of anticipated job duties. Personnel who make interpretations, provide opinions, issue reports, or perform technical review of technical records or testimony shall meet the competency requirements specified in this section.

Retraining

When retraining of personnel is necessary, the existing training manual may be used, or a new training module developed as required. Competency tests may be incorporated into the retraining.

Mock Trial

It is the responsibility of Laboratory Division personnel to understand the principles, methods, and techniques of the employee's position and be able to effectively communicate this knowledge in the courtroom. All trainees shall successfully complete at least one mock trial during training prior to assuming crime scene investigative or laboratory casework responsibilities.

The mock trial shall simulate a real courtroom experience. The witness (trainee) and the primary participants shall dress and act accordingly. Prior to the mock trial, the trainee shall provide a complete copy of all records requested to the acting prosecutor and defense attorney. The trainee shall have completed the examination of mock evidence and have generated a discipline relevant report.

The trainee's supervisor or trainer is responsible for the coordination of the mock trial and ensuring a representative cross section of Laboratory Division personnel are present by giving at least 24 hours advance notification. Attendance requires preapproval from attendee's first line supervisor.

The mock trial shall consist of, at a minimum, the swearing in of the witness, direct examination, cross-examination, and witness critique/feedback. To be considered successfully completed, the trainee shall receive a minimum of a satisfactory rating on the Courtroom Evaluation Rating Sheet by the trainee's supervisor or trainer and two other experienced personnel who have also testified in court. These three rating sheets shall be retained with the training records.

The mock trial and subsequent witness critique should be video recorded. After the mock trial, the trainee's supervisor and/or trainer and the trainee should review

the video recording and rating sheets. The video recording may be discarded after successful conclusion of the mock trial training and the review with the trainee.

Authorization

The Laboratory Division Commander authorizes qualified and trained personnel to conduct crime scene investigations, digital forensic examinations, laboratory analysis, and/or evidence handling, technical reviews of results, and/or issue reports. No employee shall perform a procedure in which they have not been trained and authorized to perform. Trainees shall not perform crime scene investigations, digital forensic examinations, laboratory casework, and/or evidence handling until the relevant competency test has been successfully completed and they are authorized by the Laboratory Division Commander.

After training is completed in the Biology Section, the TL shall review and approve the training records of newly qualified FSs, FTs, and technical reviewers prior to beginning casework. The Biology TL shall also review, verify, and approve the academic transcripts for newly qualified FSs and technical reviewers.

Following the successful completion of a training program, a supervisor shall make written recommendations, through channels, to the Laboratory Division Commander, following the procedure in Laboratory Division General Policy 002, as to the employee's status to perform crime scenes investigations, conduct laboratory case work, and/or handle evidence. The authorizations shall include activity and the individual being authorized, beginning date of the authorization, and the Laboratory Division Commander approving.

The Laboratory Division Commander may authorize an employee to perform crime scene investigations, digital forensic examinations, laboratory analysis, and/or handle evidence that includes:

- Conducting testing and examination of evidence samples;
- Operating instruments/equipment as required by a Test Methods or a Procedures Manual;
- Analyzing, reviewing, and providing (i.e., authorize and express) results, opinions, and interpretations;
- Performing verifications, when applicable;
- Issuing (i.e., authorizing) reports; and
- Providing expert testimony.

The Laboratory Division Commander shall notify the employee and the respective chain of command in writing of the decision in this regard.

At the end of a training program, the Laboratory Division Training Record spreadsheet shall be completed by the trainer or the respective supervisor and

forwarded to the Laboratory Division Commander following the procedure in Laboratory General Policy 002. The Laboratory Division Commander shall maintain these records in the Laboratory Division's administrative files throughout the employment of the individual and ten (10) years after the person has left the employment with the Department.

Copies of the Laboratory Division Training Record forms and all the remaining records of the training program shall be submitted to the appropriate Unit or Section Supervisor. The training records shall be maintained as hardcopies or electronically on a network drive for at least five (5) years after which the file may be disposed.

For CSIs, following the successful completion of the mentoring working period, the respective Crime Scene Investigations Supervisor shall make written recommendations, through channels, to the Laboratory Division Commander as to the CSI's status to perform independent crime scene investigations.

The process for authorizing personnel to perform development, modification, verification, and validation of methods is in the Validation of Methods section of QAM-7.2.

Continuing Education, Training, and Skills

Opportunities for professional development and continuing education, such as updates on the latest developments in technology and methods, include, but are not limited to:

- Attendance at training courses (internal and external) and professional meetings;
- Completing college courses;
- Online resources such reading journal articles or viewing professional instructional videos;
- Participation in online training courses and webinars;
- Participation in technical working groups;
- Preparation and submittal of journal articles for publication; and
- Presentation at professional meetings.

The Department may pay annual membership dues, if funds are available, for any employee eligible for membership in one forensic related professional organization. The request of payment for membership dues in a forensic related professional organization shall be made through channels to the Director of Forensic Analysis or the Laboratory Division Deputy Commander, who shall ensure the requests for payments are submitted to the Fiscal Division.

Employees are encouraged to attend professional meetings and seminars related to their job responsibilities. If sufficient funds are available, the employee may be

reimbursed for the cost of attending a professional meeting to include, but not limited to, registration fees, travel, per diem, and lodging.

Each calendar year, Biology Section FSs and Unit Supervisors shall attend and maintain documentation of at least eight hours of continuing education.

The following procedure shall be used to identify training needs and provide training to Laboratory Division personnel. Each fiscal year (July 1 to June 30), Section Supervisors shall consult with the Unit Supervisors to identify the relevant training needs within their respective Section and submit a list of requested training to the Laboratory Division Commander. The Laboratory Division Commander shall formulate the essential training priorities for the Laboratory Division. Training requests should be prepared by supervisory staff and shall be submitted through proper Department channels as part of the line items included in the essential training priorities. Personnel attending external training should submit in writing or give an oral evaluation of the training. The supervisor shall retain any written evaluations in the attendee's personnel files.

Supervisors shall allow and encourage employees to take up to three hours of their normal work time per week to read periodicals, journals, articles, books, web pages, etc. related to their duties to maintain their knowledge and expertise. The review of scientific periodicals and journals is an important step in the continuing education and professional development of employees. The Biology Section shall have, follow, and document a program, approved by TL, for review by FS of scientific literature applicable to the DNA analysis.

Each CSI, DFE, FS, and FT, as well as supervisory and management staff, shall maintain a Statement of Qualification (SOQ) or similar document that, at a minimum, includes academic and professional qualifications, external and internal courses attended, relevant training attended, testimony provided, professional affiliations, and forensic work experience. The SOQs shall be updated annually and submitted to the Accreditation and Quality Assurance Manager (A&QAM), who shall upload the SOQs to the network drive.

Laboratory Division employees shall maintain documentation of continuing education for at least five years.

6.3 Facilities and Environmental Conditions

The Department shall provide adequate, safe, and secure facilities for its personnel, equipment, supplies, and evidence storage. The Laboratory Division shall ensure the continued suitability of the facilities and equipment used to carry out all work activities in a competent and safe manner. The facilities and environmental conditions shall be suitable for the examination activities and shall

not adversely affect the validity of results. Incompatible work activities shall be performed in separate areas.

Facility Access

The following procedure addresses security and access to operational areas within the Laboratory Division. Operational areas are rooms used to perform crime scene, digital forensic evidence, and laboratory analysis and examinations or store evidence areas. Offices, general supply storage room, break room, or other administrative spaces are not considered to be operational area.

Access to the operational areas of the Laboratory Division shall be limited and controlled. All exterior access/egress points to the facility shall be controlled with a lock and/or a card reader system to prevent access by unauthorized personnel. When an operational area is unoccupied, the outer doors shall be locked and, where available, the alarm activated. Alarms shall be verified monthly and documented in a log. The alarm verification records shall be maintained for a minimum of five years as hardcopies at each facility or electronically on a network drive. The use of facilities and equipment by unauthorized persons is prohibited.

Visitors shall not have unrestricted access to the Laboratory Division's operational areas. Access to the operational areas by non-Laboratory Division personnel shall be under the observation of Laboratory Division personnel. All visitors shall sign in and out on the Visitor's Log, which shall be located at or near the main entrance.

For ISP facilities, the Laboratory Managers, the CSI Supervisors, and/or first line supervisor shall cause the Visitor's Logs from the previous calendar year to be scanned and uploaded to a network drive after January 1st each year. The Visitor's Logs shall be retained for at least five years.

Personnel assigned to work at a non-ISP facility shall maintain a Visitor's Log to document access to the evidence storage areas by non-Laboratory Division personnel. The first line supervisor shall cause the Visitor's Logs from the previous calendar year to be scanned and uploaded to a network drive after January 1st each year.

ISP personnel assigned to or conducting business at a Laboratory Division facility, wearing a recognizable uniform or prominently displayed identification badge, or are known and recognizable by Laboratory Division personnel do not need to sign the Visitor Log but shall be escorted. Custodial and maintenance personnel granted access by Laboratory Division personnel may be permitted limited access to the Laboratory Division administrative and laboratory areas of a facility but shall always be escorted in evidence storage areas.

Special visitors (e.g., external auditors, approved vendors performing facility repairs, maintenance, or equipment installation, etc.) may be granted limited access to a Laboratory Division facility or operational area. These visitors shall sign in and may access administrative areas of the facility without an escort but should be kept under general observation. The visitors shall always be escorted in evidence storage areas and evidence examination rooms and laboratories.

If an evidence storage area must be accessed after hours, a Property Officer shall be called in. The normal procedures for accessing operational areas by other Department personnel shall be followed. If a Laboratory Division operational area is accessed after hours during an emergency (e.g., fire, flood, intrusion alarm, etc.), the Laboratory Manager/Property Officer shall be notified.

Evidence Storage

Evidence storage conditions shall be such as to prevent loss, deterioration, and contamination, and to maintain the integrity and identity of the evidence. The conditions of stored items shall be assessed at appropriate intervals to detect deterioration, e.g., a Complete Inventory Audit or an Off-Year Inventory Audit, Quarterly Spot Checks, and Property Area/Evidence Room Inspections.

Facilities shall be designed and equipped to ensure the proper safekeeping of physical evidence and records. All keys and access identification cards for the evidence storage system and building access shall be controlled through the use of signature cards and other appropriate records (see Laboratory Division General Policy #004 Security of Evidence Keys).

Evidence storage areas shall be controlled areas with limited access to prevent theft or interference and ensure the integrity and preservation of the evidence stored. The evidence storage area(s) shall be equipped with controlled access locks and shall be properly secured when not in active use. Except for empty lockers, all secure storage area keys shall remain in the appropriate lock box. See the Laboratory Division Evidence Policies for evidence storage procedures.

Environmental Conditions

To maintain the environmental conditions of the Laboratory Division facilities, all employees shall maintain the physical appearance of the facility in a clean, safe, and orderly manner.

Each employee is responsible for the appearance of assigned desk, work area, and other areas, which shall be maintained in a safe and orderly manner by applying good housekeeping practices.

Laboratory Division facilities shall facilitate proper performance of the examinations, including, but not limited, to energy sources, lighting, and environmental conditions. Staff shall ensure that the environmental conditions do not affect the results of work to call into question the reliability of results. Care shall be taken to ensure quality when examinations are undertaken at sites other than the permanent facilities such as at crime scenes. The technical requirements for accommodation and environmental conditions that could affect the results of examination shall be included in the Procedures Manuals or Test Methods and properly monitored and documented. The temperature of the evidence storage refrigerators and freezers shall be monitored following the procedures in Laboratory Division Evidence Policy 002.

6.4 Equipment

Laboratory Division management shall ensure that the Laboratory Division is furnished with, or has access to, all items required for the proper performance of crime scene investigations, digital forensic examinations, laboratory analysis, and evidence storage and are suitable for the methods used. A procedure for handling, transport, storage, use, and planned maintenance of equipment shall be specified in a Procedures Manual and Test Methods in order to ensure proper functioning and to prevent contamination or deterioration.

All instruments and equipment affecting the accuracy or validity of crime scene investigations, digital forensic examinations, or laboratory analysis results shall be uniquely identified, properly maintained, and calibrated and/or performance checked. Requirements for and documentation of maintenance, calibrations, and/or performance checks shall be specified in a Procedures Manual and Test Methods. Staff shall verify that equipment conforms to specified requirements before being placed or returned into service.

When performance checks are needed to maintain confidence in the proper functioning of the equipment, these checks shall be carried out according to procedure in the in a Procedures Manual and Test Methods.

Practical measures shall be taken to prevent unintended adjustments of equipment that would invalidate results. Equipment that has gone outside of the direct control of the Laboratory Division (e.g., for repair or preventive maintenance) shall be performance checked to ensure that its performance is satisfactory before being returned to service.

Equipment in which an employee has not yet been trained or authorized to use shall not be operated until proper authorization is granted by the Laboratory Division Commander for use in crime scene investigations, digital forensic

examinations, and laboratory case work. The use of equipment by trainees during training exercises shall be overseen by a qualified and authorized trainer.

Any equipment or instrumentation that has been subjected to overloading or mishandling, gives questionable results, defective, or outside specified requirements shall be taken out of service and the respective Unit Supervisor, or the TL in the Biology Section, or the Crime Scene Investigations Section Commander shall be notified. The equipment or instrumentation shall be either prominently labeled as out of service and/or physically placed in a secure area to prevent use. The equipment can be placed back into service after repair and verification of accurate results are obtained. The effect of the defect or deviation from specified requirements shall be reviewed and the nonconforming work procedure (QAM-7.10) initiated.

An infrequently used instrument may be placed in an inactive status and the normal performance check procedures suspended. The instrument shall be clearly labeled as inactive (out of service). The date the instrument was placed in inactive status and the date the instrument was returned to service shall be recorded in the instrument's maintenance records. A performance check shall be conducted on the inactive instrument prior to returning it to service and using it in crime scene investigations, digital forensic examinations, or laboratory analysis.

Equipment Inventory and Records

Equipment which can influence the quality of the crime scene investigations, digital forensic examinations, and laboratory analysis shall be uniquely identified. The respective Crime Scene Investigations Supervisors, Laboratory Managers, and Digital Forensic Supervisors shall maintain an Equipment Inventory List and Maintenance Logs for the equipment for each Laboratory Division facility. All equipment issued to the CSIs, including the unissued equipment, shall be recorded on an Equipment Inventory List maintained by the Crime Scene Investigations Section Commander, who shall keep a Maintenance Log. For equipment at non-ISP facility, the first line supervisor shall maintain an Equipment Inventory List and Maintenance Logs. All Equipment Inventory Lists shall be maintained on a network drive and shall be reviewed annually to ensure that they are kept up to date.

Records shall be maintained for each item of equipment which can affect the quality of crime scene investigations, digital forensic examinations, or laboratory analysis. The record of equipment and/or instrumentation shall include the following, where applicable:

- identify the equipment/instrumentation and its software;
- name of manufacturer, model, and serial number and/or other unique identification;

- performance checks that equipment complies with the specified requirements;
- location of or individual assigned to the equipment/instrumentation;
- calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
- documentation of reference materials, results, acceptance criteria, relevant dates, and period of validity;
- the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; and
- details of any damage, malfunction, modification to, or repair of, the equipment.

Equipment Calibration

The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. Measuring equipment shall be calibrated when the measurement accuracy or measurement uncertainty affects the validity of the reported results and/or calibration of the equipment is required to establish the metrological traceability of the reported results.

The Laboratory Division shall establish a calibration program, which shall be reviewed and adjusted as necessary to maintain the status of calibration. All equipment requiring calibration shall be labelled to readily identify the status of calibration or period of validity. The Laboratory Division shall maintain a list of the equipment requiring calibration, the specification for the calibration laboratory, requirements for the calibration, and the interval of calibration.

When calibration and reference material data include reference values or correction factors, the Laboratory Division shall ensure the reference value and correction factors are updated and implemented, as appropriate, to meet specified requirements.

Reagents

A reagent is a chemical substance that is used to create a reaction in combination with some other substance. The Procedures Manual, Test Methods, or other Unit specific manual shall include procedures to prepare, verify the reliability, and use of the reagents.

The quality of the reference materials and reagents shall be adequate for the procedure used. The lot/batch numbers of reference materials and critical reagents shall be recorded on a reagent log.

The reagent reliability testing shall be performed and evaluated prior to use on evidence and on a routine basis thereafter. Reagent preparation and reliability testing records shall be maintained including the following:

- Reagent name;
- Date of preparation;
- Date of expiration, if applicable;
- Preparer;
- Lot number of chemical/materials used in preparation;
- Reliability testing; and
- Reagent worked as expected.

Reagent logs shall be maintained for at least five years.

Reagent containers shall be labeled with, at a minimum, reagent name and date of preparation or lot number. In the Biology Section:

- Commercial reagents shall be labeled with identity of the reagent and the expiration date as provided by the manufacturer or as determined by the Biology Section.
- In-house reagents shall be labeled with identity of the reagent, the date of preparation and/or expiration, and the identity of the individual preparing the reagent.

When transporting reagents (e.g., in CSI's vehicles) due diligences shall be exercised to prevent contamination and to ensure quality and safety. Reagents should be stored in a secondary container to a control a spill if a breakage of the reagent container occurs.

Reference materials, chemicals, or reagents used for crime scene investigation or in laboratory analysis shall not be used beyond their expiration date. The reliability of expired reference materials, chemicals, and reagents can be retested, and a new expiration date established.

When handling reference materials, chemicals, and reagents, the safety precautions described in the Laboratory Division's safety manuals and policies shall be followed. The reference materials, chemicals, reagents, and other laboratory consumable materials shall be stored in a manner to ensure quality and safety. Due regard shall be given to the manufacturer's recommendations on storage and shelf life.

Reference Collections

Reference collections of data or item/materials which are maintained for identification, comparison, or interpretation purposes shall have each entry in the collection documented, uniquely identified, and handled properly to protect the characteristic(s) of interest.

6.5 Metrological Traceability

The Laboratory Division shall establish and maintain metrological traceability of its measurement results by means of documents unbroken chain of calibrations linking them to an appropriate reference provider, such as, the National Institute of Standards and Technology (NIST). The Laboratory Division does not calibrate any of its own equipment or instruments. Each Unit shall maintain a list of equipment/instrument requiring calibration on a network drive or in the Test Methods.

Measuring equipment and/or reference standards shall be traceable to International System of Units (SI) of measurement. Suppliers of external calibration services shall be accredited to ISO/IEC 17025, with scope of accreditation covering the calibration requested. The calibration certificates provided shall contain the measurement results in SI units, measurement of uncertainty, evidence of ISO/IEC 17025 accreditation, and traceability to NIST.

Certified reference materials shall be from a reference material producer accredited to ISO 17034, where available.

In situations where a vendor cannot be found that meets the requirements specified above, the competence, capability, and metrological traceability for the vendor and the external product or service being purchases shall be verified. Objective evidence of the verification shall be maintained.

When traceability of measurement to SI units is not possible, the Laboratory Division shall ensure metrological traceability to an appropriate reference.

6.6 External Products and Services

The Laboratory Division shall ensure only suitable external products and services are used that could affect the quality of crime scene investigations, digital forensic examinations, and laboratory analysis.

The following procedure shall be used when ordering supplies, equipment, and services. The Laboratory Division staff shall follow the Indiana Department of Administration and ISP Fiscal Division rules and regulations.

A description of the supplies, equipment, and/or services to be purchased, as well as product specifications and competency requirements, shall be described in the Statement of Justification (SOJ) and/or the supporting documentation. The individual requesting the purchase of supplies, equipment, and services, shall review the SOJ and any attached supporting documentation for technical accuracy prior to forwarding it to a Laboratory Manager, Unit Supervisor, or Section

Supervisor. A Laboratory Manager, Unit Supervisor, or Section Supervisor shall review and approve or reject SOJs prior to forwarding to the Fiscal Division.

When supplies and equipment are received, the staff receiving the item(s) shall document the inspection of the item(s) to ensure that they meet specifications and quantity described in the SOJ. This quality control check can be done by comparing the packing slip and the purchase order request against what was received to ensure all agree. The incoming item(s) shall not be used until conformance with specification has been verified. Any order discrepancies shall be brought to the attention of a Laboratory Manager, Unit Supervisor, or Section Supervisor, who will work with the Fiscal Division to resolve the matter.

This quality control check shall be documented by initialing and dating the packing slip and/or purchase order request that is submitted to the Fiscal Division. This can also be accomplished via e-mail correspondence with Fiscal Division. The SOJ, purchase order, and other purchasing records are maintained in the electronic system designated by the Fiscal Division.

Subcontracting (also called Outsourcing)

The Laboratory Division shall strive to perform all crime scene investigations, digital forensic examinations, and laboratory analysis which have been agreed to be completed. However, if circumstances are encountered or assistance is needed, the Laboratory Division shall follow these policies and procedures for subcontracting work.

The A&QAM shall maintain a list of approved subcontractors. Records establishing competence of each subcontractor shall be maintained on the network drive.

During the appropriate step(s) in the contract process, the respective Unit Supervisor, the Biology Section TL, or the Crime Scene Investigations Section Commander shall review and approve the technical specifications in a subcontracting or outsourcing agreement.

The customer shall be notified in writing of any subcontracting arrangement and obtain written approval, when appropriate, or verbal approval. Written notification may be either a separate communication, or incorporated into a Physical Evidence Bulletin, or be included in a Case Report and/or Certificate of Analysis.

The Laboratory Division is responsible for ensuring that the crime scene investigations, digital forensic examinations, or laboratory analysis conducted by the subcontractor adequately meets the customer’s needs. Any customer request for the use of a specific subcontractor removes the Laboratory Division’s responsibility for that subcontractor’s competence.

Each subcontractor shall be evaluated to establish competency using one or more of the following methods:

- Recognized technical accreditation, such as American National Standards Institute (ANSI) National Accreditation Board (ANAB) or other ISO/IEC 17020 or ISO/IEC 17025 programs that covers the scope of activities to be subcontracted;
- Satisfactory completion of a competency test as determined by the A&QAM with input from the appropriate technical supervisory staff;
- Audit of the subcontractor by Laboratory Division personnel overseen by the A&QAM; or
- Other requirements specific for the activities to be subcontracted, such as third-party audits, regulated government agencies, or other qualifications establishing competency, which shall be documented and reviewed by the A&QAM and approved by the Laboratory Division Commander.

Subcontracting of DNA testing shall comply with all outsourcing requirements in the Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories and/or the QAS for DNA Databasing Laboratories.

When a customer sends samples to a non-ISP laboratory for DNA analysis, the Biology Section taking ownership of the profiles for the purpose of entry into Combined DNA Index System (CODIS) is not considered to be subcontracting but is outsourcing under the FBI's DNA QAS requirements.

Return to Table of Contents

7. Process Requirements

7.1 Review of Requests, Tenders, and Contracts

The Laboratory Division Commander shall ensure that the Laboratory Division has the capability and resources for the services offered. The following are the procedures for review of requests for crime scene investigations, digital forensic examinations, and laboratory services.

Crime Scene Investigations

A request for crime scene investigation services by a criminal justice agency serves as a contract for service. The Crime Scene Investigator (CSI) shall review the request for the work to be conducted and shall ensure that the Laboratory Division has the capabilities, including appropriate procedures and equipment, to meet the needs of the requesting agency.

When needed, the CSI shall work with the requesting agency to clarify their request. Requests which are not covered by the Crime Scene Investigation Procedures Manual shall be discussed by the CSI and an agency representative. The CSI shall create and maintain in the technical record, documentation of the discussion and changes to the agency's request. The requesting agency shall be informed of any deviations beyond their original request.

Laboratory Services

The policies and procedures for submission of evidence to the Laboratory Division are in the Physical Evidence Bulletins (PEB), Evidence Policies, and Information for Customers.

The customer shall indicate, on the Request for Laboratory Examination Form the type of evidence submitted and examination(s) requested. Evidence Specialists or Property Officers shall ensure that the Laboratory Division offers the appropriate test method for the customer's request prior to accepting the evidence. Any differences between the requested services shall be resolved before the Laboratory Division accepts the evidence.

The Laboratory Division reserves the right to decline acceptance or not conduct analysis of evidence deemed unsuitable, insufficient in quantity/quality, or of limited value. If evidence is accepted but not analyzed, the customer shall be informed on the Certificate of Analysis that an item of evidence was not analyzed.

By submitting evidence to the Laboratory Division, the customer(s) agrees to allow the Laboratory Division to select the test methods or procedures to be used to

analyze the evidence. The Laboratory Division's review of submission documentation shall also cover any subcontracted cases.

A copy of the Request for Laboratory Examination Form shall be maintained in the technical record. Pertinent discussion and communication regarding the customer's request shall be documented in the technical record.

Laboratory Division staff shall determine the test method or procedures to be performed, the scope of analysis, and the items to be analyzed according to the Laboratory Division's Procedure Manuals and Test Methods. The Laboratory Division acknowledges that each case is unique and shall conduct the most appropriate analysis possible. The Laboratory Division may conduct testing beyond the type of forensic examinations requested.

The Laboratory Division shall work with the customer if an amendment is needed to the type of testing requested. Any amendments to the requested analysis shall be communicated to the customer.

Depending on the caseload of the Laboratory Division and the needs of the customer, evidence may be sent to a competent outside laboratory for analysis. The customer shall be informed by a Certificate of Analysis when cases are subcontracted.

The extent of database searches (e.g., Automated Fingerprint Identification System/Next Generation Identification [AFIS/NGI], Combined DNA Index System [CODIS], and National Integrated Ballistic Information Network/Integrated Ballistics Identification System [NIBIN/IBIS]) shall be described in the relevant PEB or in the Certificate of Analysis.

7.2 Selection, Verification, and Validation of Methods

Selection and Verification of Methods

All crime scene investigations, digital forensic examinations, and laboratory activities shall be described in the Procedures Manuals or Test Methods including procedures for quality control, where appropriate, and instructions for the interpretation and reporting of results. By requesting crime scene investigations, digital forensic examinations, or laboratory analytical services, the customer(s) agrees to allow the Laboratory Division personnel to select the methods and procedures used to examine the scene and/or evidence.

The Laboratory Division shall use appropriate methods and procedures for crime scene investigations, digital forensic examinations, and laboratory activities. All management system documents, including the Procedures Manuals and Test Methods, shall be kept up to date following the procedures in QAM-8.3 and shall

be available on the network drive. The current version of the Procedures Manual or Test Methods shall be used.

When working at a scene, CSIs can access documents via a data plan on their Department issued cell phones. Laboratory Division staff working remotely can access documents via a virtual private network (VPN).

All Test Methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, statistical rarity calculations, prior to comparison to a known item(s).

Realizing the variation in crime scenes and submitted cases, minor deviation from the Procedures Manual or Test Methods may be utilized with the approval of the respective Unit Supervisor, or when applicable, the Technical Leader (TL) in the Biology Section, or a Crime Scene Investigations Supervisor. The minor deviation, justification, and supervisor's or TL's approval shall be documented in the technical record. Significant deviation from a method shall be validated prior to use in casework.

Minor deviation is a variance, addition to, or exclusion from a Procedures Manual or Test Method, that is not expected to alter the test result, and generally will not have an extended duration. Examples include, but are not limited to, modifying instrument parameters, using known samples or quality controls not specified in the test method, use of an alternate sample preparation process, etc.

A deviation is not requesting the approval from or a notification to the Unit Supervisor or Biology Section TL when it is required in the Procedure Manual or Test Method.

Validation of Methods

The following procedure shall be used for method validations. Validation ensures that new or substantially modified methods provide accurate and reliable results prior to being used to analyze and evaluate physical evidence. Methods utilized by the Laboratory Division shall be validated as extensive as necessary to meet the needs of the given application. Method validations shall include associated data interpretation, establish the data required to report a result, opinion, or interpretation, and identifies limitation of the method, reported results, opinions, and interpretations.

When changes are made to a validated method, the changes shall be evaluated and, where they are determined to affect the original validation, a new method validation shall be performed. When changes are made to the associated data interpretation, a revalidation shall be performed.

The performance characteristics evaluated during the method validation can include, but are not limited to, measurement range, accuracy, measurement uncertainty of results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample, and bias. The performance characteristics assessed shall be relevant to the customers' needs and consistent with specified requirements.

When method development, modification, verification, or validation is required, it shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. Prior to beginning a method development, modification, verification, or validation, the respective Unit Supervisor, or the Biology Section TL, or the Crime Scene Investigations Section Commander shall submit a Method Validation Plan through channels to the Laboratory Division Commander for approval of the plan and authorization of personnel performing the validation. After approval, the supervisor who submitted the plan shall quarterly review the validation, using the Method Validation Quarterly Review Form, until completed to ensure the satisfactory progress is being made and needs of the customer are still being fulfilled. Any modifications to an approved plan, including changing the personnel conducting the validation, shall be submitted through channels to the Laboratory Division Commander for approval. The original Method Validation Plan, and, when applicable, quarterly reviews and modification approval shall be retained by the supervisor and copies provided to the Accreditation and Quality Assurance Manager (A&QAM).

If a validation will not be completed, the respective Unit Supervisor, or the Biology Section TL, or the Crime Scene Investigations Section Commander shall submit written notification with reason(s) why through channels to the Laboratory Division Commander. A copy shall be provided to the A&QAM for the QA records.

When the validation is completed and prior to implementation in the casework, the respective Unit Supervisor, or the Biology Section TL, or the Crime Scene Investigations Section Commander shall submit the Method Validation Report through channels to the Laboratory Division Commander for approval. The Biology Section TL shall review and approve the validation studies in the Section prior to the submission for the Laboratory Division Commander's final approval. The Method Validation Report shall include the following sections:

- Introduction – State the purpose and a brief description of the method validated or the change(s) to an existing validated method.
- Method – Include instructions for performing the method validated or changes to existing validated method including reagents, reference materials, quality control samples, instruments and equipment, and its performance or acceptance requirements.

- Validation Process – Describe how the validation was performed including determination of the performance characteristics of the method.
- Results – Summarize in text, tables, or graphs, the data collected during validation process. Discuss the meaning of the data and results in relation to the method validation. When applicable, determine the uncertainty of measurement.
- Conclusion – Summarize the results of the validation and include a statement on the validity of the method, detailing its fitness for the intended use.
- References – List any publication(s) used in the development of the method or its validation.

The original Method Validation Report with the Laboratory Division Commander's approval and all supporting data shall be maintained as a hardcopy or on a network drive by the respective Unit Supervisor, or the Biology Section TL, or the Crime Scene Investigations Section Commander. A copy of the Method Validation Report shall be provided to the A&QAM for the QA records.

Relevant management system documents such as the Training Manual, Procedures Manual, and/or Test Methods shall be updated to reflect new or changed methods and/or equipment. Staff shall be notified when a new or revised method is approved for use.

7.3 Sampling

When sampling may be performed, the Unit shall include in their Test Methods the sampling plan and method. The sampling method shall be available on a network drive, based upon appropriate statistical methods, and include the following:

- Describe the selection of samples;
- Address factors to be controlled to ensure the validity of the subsequent test results;
- Require an evaluation of the selected population for homogeneity;
- Require the population to have a reasonable expectation of homogeneity to use the sampling plan;
- Require that the sample plan use of probability and provides an opinion or interpretation with a minimum confidence level of 95.45% (i.e., two standard deviations);
- Require each item selected to meet the sampling plan level of confidence to be tested completed; and
- Provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity.

The technical record shall include:

- Reference to the sampling method used;
- Date and time of sampling;
- Data to identify and description the sample (e.g., number, amount, name);
- Identification of the individual performing the sampling;
- Identification of the equipment/instruments used; and
- Deviations, additions to, or exclusions from the sampling method and sampling plan.

7.4 Handling Evidence Items and Samples

Procedures for handling, protection, packaging, sealing, transportation, receipt, storage, retention, and disposal or return of evidence items are in the Laboratory Division's Evidence Policies (EVID), Laboratory Division's Physical Evidence Bulletins (PEBs), and Indiana State Police (ISP) Standard Operating Procedures (SOPs).

Procedures for protecting the integrity of all evidence and avoiding deterioration, contamination, loss, or damage to the evidence during handling, transporting, storing, and examination are found in the Evidence Policies and PEBs. Evidence items shall be re-sealed after examination as soon as practical.

All evidence received into the Laboratory Division shall be properly labeled (EVID-006 and PEB-20) and properly sealed (EVID-005 and PEB-20) when accepted and stored.

When evidence is received that departs from conditions specified in the Evidence Policies and PEBs, it shall be documented in the technical record. Substantive and significant errors in the item description, inclusive of non-reported valuables, i.e., money, jewelry, precious metals, etc., and other items having potential evidentiary value, shall be corrected in the LIMS and on the Certificate of Analysis. Forensic Scientists (FS) should avoid minor non-substantive changes but may use a more specific item description when necessary.

When an item is unsuitable for testing, the customer shall be informed on the Certificate of Analysis that an item of evidence was not analyzed.

A chain of custody shall be maintained for all evidence items collected at a crime scene or received into the Laboratory Division per the requirements in SOP-LAB-001 and EVID-001.

Subitems collected or created and preserved in the Laboratory Division for possible future testing shall be tracked through a documented chain of custody record to the same extent as the original item (EVID-025) and the existence of subitems shall be communicated to the customer in the Certificate of Analysis.

The disposition of all items received from a Regional Laboratory shall be communicated to the customer in the Certificate of Analysis or, when all items of evidence are routinely returned to the customers, a notification statement in the respective PEB.

The procedure in EVID-001 shall be followed to secure unattended evidence which is in the process of being examined.

When evidence needs to be stored in a refrigerator or freezer, the proper temperature shall be maintained, monitored, and recorded following the requirements in EVID-002.

7.5 Technical Records

Documentation in a technical record (also called field notes or case notes/case file) may include records of telephone conversations, evidence receipts, descriptions of evidence packaging and seals, subpoenas, records of observations and test/examination results, reference to procedures used, diagrams, printouts, photographs, etc. The technical record shall contain sufficient detail of the results, opinions, and interpretations that a technically qualified peer could review the documentation, could evaluate what was done, and interpret the data.

The technical record shall contain all the results of examinations and observations, including visual examination, as well as the findings, results, opinions, and interpretations. The technical records shall include which equipment, having a significant influence on the results of the investigation/examination, was used for each activity.

When an observation, data, calculation, or examination result is rejected, the reason for the rejection, along with the initials or name of the individual taking the action, and the date shall be recorded in the technical record.

All records shall be stored indefinitely in a secure network drive and the information contained therein maintained in strict confidence. Technical records shall only be destroyed with authorization by the Laboratory Division Commander.

All administrative case related records, both hardcopy and electronic, shall be identified with the Records Management System (RMS) case number for CSIs or laboratory case number. Submitted records received bundled and/or stapled may be considered a single record and may be identified with the laboratory case number on the front page of the record. Item number(s) shall be recorded where appropriate.

The RMS case number or laboratory case number and original handwritten CSI, DFE, FS, or Forensic Technicians (FT) initials or signature shall be on each page

of the hardcopy of technical records. When both sides of a page are used for hardcopies, each side shall be treated (identified with case number and initials or signature) as a separate page.

Each page of technical records generated electronically shall have the case number and CSI's, DFE's, FS's, or FT's typed initials or name. When the typed case number and/or initials/name are omitted, the correction can be typed or handwritten.

The file name of the digital images shall, at a minimum, have the RMS case number or laboratory case number and CSI's, DFE's FS's, or FT's initials, name, or permanent employee (PE) number. Whenever practical, the RMS case number or laboratory case number and item identifier should be placed in photographs. Digital images shall not be deleted from the memory card until after the files are verified to have been uploaded properly.

Technical records shall be permanent in nature. Notes, worksheets, and other writings in a technical record shall be made in ink or electronically. A Procedures Manual or a Test Methods may permit exceptions to using ink.

The technical record shall include a description and identification of evidence items, as well as the condition when it could affect examination/analytical results or integrity of the evidence. Item number(s) shall be recorded where appropriate. The technical record shall accurately record and maintain observations, data, and calculations made during the crime scene investigations, digital forensic examinations, and/or laboratory analysis of evidence samples. The technical record shall specify the method(s) and/or technique(s) used to process and/or analyze the evidence.

Examinations, analyses, observations, data, and calculations shall be recorded contemporaneous to the time the actions are performed, i.e., nearest to the time as reasonable possible. The original recordings shall be maintained in the technical record. Dates shall be recorded in the technical record when the work is performed. It is recommended that a page numbering system be used (e.g., page of) for each technical record.

When instrumental analyses are conducted, operating parameters shall be recorded in the Test Methods, instrument logbook, or in the technical record.

When a correction needs to be made to a hardcopy record, a single line shall be drawn through the text, initialed, and the correct value entered nearby. In addition, corrections shall be dated when not contemporaneous to the date on the record.

When technical records are prepared by an individual(s) other than the FS who interprets the findings, prepares the report, and/or testifies concerning the records,

the handwritten initials (or secure electronic equivalent) shall be on the page(s) of examination records representing their work. When multiple CSIs work at the same scene, each CSI shall generate field notes and a report for the work performed. The CSI shall include all forensic work performed at a crime scene in the case report.

When data from multiple cases are recorded on a single printout, the case number of each case shall be appropriately recorded on the printout.

Abbreviations may be used when universally recognized or a key is provided in a management system document or the technical record.

At a minimum, both hardcopy and electronic cases records shall be labeled with the RMS case number or laboratory case number. Technical records shall be retained in an electronic format and stored in the Laboratory Information Management System (LIMS) or on an approved network drive. Access to the network drives is limited to authorized users only and the information contained therein maintained in strict confidence. Any printouts generated from the electronic records shall be destroyed when use is no longer needed. General Policy #037 Laboratory Information Management System shall be followed.

Technical records shall be considered complete when submitted for administrative and/or technical review. Any changes made to completed technical records generated and/or maintained in an electronic format shall be tracked by saving the changed page(s) of the technical records in LIMS or approved network drive. Both the original and the amended technical records shall be maintained.

Old hardcopy records, prior to the requirement to maintain records electronically, shall be stored in a secure location within the Department. Electronic and hardcopy technical records shall be maintained indefinitely and can only be destroyed with written authorization from the Laboratory Division Commander.

7.6 Evaluation of Measurement Uncertainty

Measurement uncertainty shall be evaluated, or estimated when applicable, for all reported quantitative results. Where appropriate, the Units shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be considered using appropriate methods of evaluation. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be based on an understanding of the theoretical principles or practical experience of the performance of the method.

The method for evaluation of measurement uncertainty shall:

- Require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;
- Include the process of rounding the expanded uncertainty;
- Require the coverage probability of the expanded uncertainty to be minimum of 95.45% (i.e., two standard deviations); and
- Specify the schedule to review and/or recalculate the measurement uncertainty.

The following records shall be maintained for each evaluation and estimation of measurement uncertainty:

- What is being measured;
- How traceability is established for the measurement;
- The equipment used (e.g., measuring devices or instruments);
- All uncertainty components considered;
- All uncertainty components of significance and how they were evaluated;
- Data used to estimate repeatability, intermediate precision, and/or reproducibility;
- All calculations performed; and
- The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

7.7 Ensuring Validity of Results

Crime Scene Investigations Section, Digital Forensic Unit, and the analytical laboratory Units shall have instructions in the Procedures Manuals and Test Methods for monitoring the validity of the results. The data shall be recorded in such a way that trends are detectable and, where practical, shall be applied to the review of results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not limited to:

- use of reference materials or quality control (QC) materials;
- use of alternative instrumentation that has been calibrated to provide traceable results;
- performance check(s) of measuring and testing equipment;
- use of check or working standards with controls charts, where applicable;
- intermediate checks on measuring equipment;
- replicate tests using the same or different methods;
- retesting of retained items;
- correlation of results for different characteristics of an item;
- review of reports results;
- intralaboratory comparisons; and
- testing of blind samples.

The Laboratory Division shall monitor its performance by comparison with results of other laboratories via participation in external proficiency testing.

Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the Laboratory Division's activities. If the results of the analysis of data from monitoring activities are found to be outside criteria specified in the Procedures Manual or Test Methods, appropriate action shall be taken to prevent incorrect results from being reported.

Verification

When a verification is performed it shall be conducted by an individual currently authorized to perform the examination. The technical records shall include the verifier's name, the date verification was performed, and the result of the verification. The resolution of any discrepancy shall be documented in the technical record. The verifier may also perform the technical review.

Technical Review

The following procedure shall be used for technical review of technical records including reports. The CSI, DFE, or FS shall review the technical records for compliance with Laboratory Division policies and procedures and technical accuracy prior to submitting for administrative and/or technical review. An individual shall not technically review their own casework.

The technical review ensures the results, interpretations, and opinions, are accurate, properly qualified, and supported by the technical record and the Procedures Manual, Test Methods, and other management system documents were followed. Technical reviews shall be conducted by an individual currently or previously authorized, including competency testing, in the area(s) that the review encompasses.

The Procedures Manual or Test Methods shall specify the number of technical reviews to be completed in each discipline. A Technical Review Checklist shall be completed to document the review and shall be uploaded to LIMS or network drive.

The technical reviewer shall work with the CSI, DFE, FS, or FT to make any necessary corrections or changes. The A&QAM shall be notified through channels of any substantive nonconformance related issues identified during a technical review.

Technical and administrative reviews may be conducted at the same time and/or by the same individual. Technical reviews should be conducted before the report is published.

Resolution of Technical Variations and/or Conflicts of Opinion

Substantive technical variations and/or conflicts in the results, interpretations, and/or opinions reached during a verification and/or case review shall be resolved prior to release of the report.

Once a verification and/or technical review has begun, the same verifier and/or reviewer, if available, shall complete the process. If the CSI, DFE, or FS and the verifier/reviewer disagree, the CSI, DFE, or FS shall not seek a second verifier/reviewer. The respective Crime Scene Investigations Supervisor or the Unit Supervisor(s), and/or, when applicable, the TL in the Biology Section, shall be notified of substantive variations of opinions.

The CSI, DFE, or FS, the verifier/reviewer, first line supervisor, and/or when applicable the TL in the Biology Section, shall discuss the examination results, interpretation, opinions, and conclusions. The technical disagreement, discussion, and resolution shall be documented in the technical record.

If the difference of opinion cannot be resolved, the first line supervisor(s), and/or when applicable the TL in the Biology Section, shall meet with the Director of Forensic Analysis or Laboratory Division Deputy Commander, the respective Section Supervisor, and the A&QAM to determine a plan of action. If a corrective action is necessary, the procedures in QAM-8.7 shall be implemented.

Administrative Review

All reports with crime scene investigations, digital forensic examinations, analytical laboratory results, and withdrawals shall be administratively reviewed prior to release. Reports for cases that are outsourced to a qualified forensic laboratory do not have to be administratively reviewed. The CSI, DFE, or FS shall not administratively review their own casework. The administrative review shall be documented in the RMS for CSI's Case Reports and in LIMS for FS's Certificates of Analysis. The administrative reviewer is responsible for the verification of information and release of the report after the administrative review is satisfactorily completed. At a minimum, the administrative review shall include:

- A review of the report for spelling and grammatical accuracy;
- A review of the report to ensure that all key information fields are completed; and
- A review of all documentation records associated with the report to ensure that the records are properly and uniquely identified.

In Biology Section, the administrative or technical review shall include a review of the chain of custody and disposition of evidence.

Testimony Monitoring

Testimony may be monitored during deposition, trial, or other legal proceeding.

The following procedure shall be used for technical review of testimony. At a minimum, the testimony of at least one CSI, DFE, or FS in each discipline shall be evaluated annually by another technically qualified individual. The first time a CSI,DFE, or FS testifies after completing a discipline training program, their first line supervisor should observe and evaluate the testimony. If the first line supervisor is not available to observe their first testimony, the supervisor should assign another technically qualified individual to monitor the testimony.

To facilitate scheduling of court testimony monitoring, personnel shall inform their first line supervisor of scheduled testimony. The evaluator should observe employee's testimony by attending the proceeding, viewing virtually, or review of a transcript and shall complete the Testimony Evaluation Rating Sheet. A qualified member of the Laboratory Division may also review written depositions, when available, of testimony and shall complete the Testimony Evaluation Rating Sheet.

Any Laboratory Division employee may observe testimony for other purposes, e.g., a trainee as part of their training program. The observer should complete the Testimony Evaluation Rating Sheet.

Witness Critique Cards should be provided for each testimony to prosecutors, defense attorneys, or judges to evaluate the testimony of expert witnesses. These monitoring cards elicit feedback from judicial officers on the effectiveness of testimony, objectivity, and the clarity of communication by the witness.

Any deficiencies found by a testimony evaluation shall be appropriately addressed. If a corrective action is necessary, the procedures in QAM-8.7 shall be implemented.

In the Biology Section, each testifying FS and FT shall attempt to be monitored at least once during the calendar year. When a Biology Section FS or FT testifies during the year and does not receive at least one annual testimony evaluation, the FS or FT shall attempt at least three times, with at least one week between attempts, to obtain a completed Witness Critique Card from an officer of the court. If the three attempts fail, the testifying Biology Section FS or FT shall provide documentation of all the failed attempts to the A&QAM. The A&QAM shall upload the documentation to a network drive and shall add a comment to the Biology Section's Testimony Evaluation Log that the FS or FT was unsuccessful in obtaining the testimony evaluation documentation.

Testimony evaluation documentation shall be forward to the witness's first line supervisor. The supervisor shall review testimony evaluation documentation with the testifying employee, and both shall initial the document as evidence of this review. The Section Supervisor and A&QAM should also review the testimony evaluation documentation. The initialed testimony evaluation documentation shall

be submitted to the A&QAM, who shall save testimony evaluation documentation in a PDF format on a network drive.

A Testimony Evaluation Log shall be completed by the A&QAM. It shall be documented on the Log when an individual did not testify during the calendar year.

The Logs and testimony evaluation records shall be maintained on a network drive for at least five years.

Proficiency Testing

Proficiency tests are given to ensure that CSIs, DFEs, FSs, and FTs remain competent and skilled in the relevant areas of crime scene investigation, digital forensic examination, and/or laboratory analysis. The A&QAM shall have responsibility for overseeing the administration of the Laboratory Division proficiency testing program. In the Biology Section, the TL shall also review, approve, and oversee the DNA and body fluid identification proficiency testing program. The Director of Forensic Analysis or designee shall administer the bloodstain pattern analysis proficiency testing program.

The individual taking the proficiency test shall not participate in its preparation and shall not know the answers prior to completing the test.

Proficiency tests are not required to be verified, technically reviewed, or administratively reviewed by Laboratory Division staff. However, when a verification, technical review, or administrative review is performed by Laboratory Division staff on a proficiency test, the participant may verify or review a test only after completing and submitting their own test results.

When participating in a proficiency test, the analytical testing or examination procedures from the Procedures Manual and/or Test Methods shall be followed as closely as possible. In addition, proficiency testing shall comply with requirements for technical records in QAM-7.5 with the following exceptions:

- a Certificate of Analysis or Report is not required for a proficiency test;
- a proficiency test identifier shall be used instead of a RMS or laboratory case number; and
- proficiency test records storage, retention, and file naming shall follow the procedure in this section.

The individual preparing internal tests shall ensure the quality of the tests and establish criteria for determining the successful completion prior to the test being distributed to the participant(s). Successful completion of a proficiency test means the results are consistent with the expected results. If there is a discrepancy in the results obtained, the discrepancy shall be accounted for or a correction/corrective action appropriate to severity of the discrepancy implemented (QAM-8.7).

The Crime Scene Investigations QA Unit is responsible for the preparation, assignment, and evaluation of the crime scene investigation related proficiency tests for CSIs. The Unit Supervisors, or, when applicable, the TL in the Biology Section, are responsible for the preparation, assignment, and evaluation of the proficiency tests for the DFEs, FSs, and FTs within their respective Unit.

When available and appropriate for the casework conducted, external proficiency tests shall be from a provider accredited to ISO/IEC 17043 with the applicable proficiency test(s) in its scope of accreditation. External proficiency tests shall be sent to the A&QAM. An internal due date shall be set for the external proficiency test at least one week prior to the test provider's due date. The proficiency test shall be forwarded through channels to the respective Unit Supervisor, or the Biology Section TL, or the Crime Scene Investigations Section Commander.

External proficiency test results shall be sent to the A&QAM, who shall submit the test results to the test provider prior to the due date. In the Forensic Biology Section, a Unit Supervisor and/or the TL is responsible for reviewing and submitting results to the test provider before the due date.

Each CSI, FS, and FT shall successfully complete at least one internal or external proficiency test per calendar year in each discipline(s) in which they perform crime scene investigation or conduct laboratory casework. When appropriate, an observation based proficiency test may be used and shall be documented on an Forensic Scientist Observation Form or CSI Observation Checklist.

DNA FSs and FTs shall comply with proficiency test requirements in the Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories and QAS for DNA Databasing Laboratories.

The A&QAM shall maintain a documented schedule for proficiency testing on the network drive, which shall be followed by the Laboratory Division. During the accreditation cycle, a representative sample of the components/parameters, methods, and key equipment/technologies within each discipline listed on the scope of accreditation shall be included on the proficiency testing program.

At least one external proficiency test from an accredited test provider shall be completed annually at each Laboratory Division facility for each discipline in which it provides services. If no accredited proficiency test provider is available in a discipline, the A&QAM shall request approval from the accrediting body to use an alternate approach.

Proficiency test records shall include:

- Proficiency test number;
- Discipline;
- Location where the test was completed;
- How samples were obtained or created;

- Expected results;
- Identity of the person taking the test;
- Originals or copies of all data and notes supporting the conclusion (full details of the analyses/examinations undertaken and the results and conclusions obtained);
- Evaluation of the results with any discrepancies from expected results noted;
- An indication that the performance was reviewed, and feedback provided to the participant;
- Details of the corrective actions taken, when necessary; and
- Records submitted to the proficiency test provider, when applicable.

The proficiency testing records shall be retained on the network drive for a minimum of five years. The Unit Supervisors, or, when applicable, the Biology Section TL, and the QA CSIs shall complete a Proficiency Test Log. The Logs shall be retained on a Laboratory Division's network drive.

The results of the proficiency test shall be reviewed by the respective Unit Supervisor, or, when applicable, the Biology Section TL, or a QA CSI and feedback communicated to the CSI, DFE, FS, or FT with the use of the Proficiency Test Report Form.

At the completion of a proficiency test, the test documentation shall be saved in a PDF file format. The file name shall clearly identify the individual completing the test and the proficiency test number.

The A&QAM shall review and approve all proficiency related correspondence with the accrediting body prior to being sent. A copy of all correspondence shall be maintained on the network drive.

When an individual missed a regularly scheduled proficiency test due to extended period of leave, the individual shall successfully complete a competency test prior to returning to casework.

7.8 Reporting of Results

The CSI report is a Case Report, the FS report is a Certificate of Analysis, and the DFEs utilize a Digital Forensic Report. Hereafter in this sub-section (QAM-7.8) all are referred to as a report. The report for cases that are outsourced to a qualified forensic laboratory is an Outsource Notification. The Laboratory Division is responsible for all the information provided in the reports. The following procedure shall be used for reporting of results:

The results of crime scene investigations, digital forensic examinations, and laboratory analysis shall be reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the Procedures

Manuals and/or Test Methods. The report shall contain information necessary for the interpretation of the results. Case Reports are retained in the RMS and the Certificates of Analysis are maintained in the LIMS.

The CSI, DFE, or FS shall review the technical records, which is documented by their name on the report, prior to submitting for technical and/or administrative review. In the ISO/IEC 17025 language, the CSI, DFE, or FS is the authorizer of the report.

A written report shall be generated for all crime scenes investigated and all items received and examined or tested at a Regional Laboratory and in the Digital Forensic Unit. This shall include cases withdrawn in which no work was performed, items collected or created and preserved for future testing, and for all (partial and complete) work performed. An Outsource Notification report shall be issued for all cases that are outsourced to a qualified forensic laboratory.

Opinions and interpretations shall be in the Results/Opinions/Interpretations section of the Certificate of Analysis. Only personnel authorized shall provide opinions and interpretations in a report. The technical record shall document the basis of the opinion and interpretations including the results obtained from item(s) tested. When opinions and interpretations are directly communicated verbally to the customer, a record of this communication shall be retained, e.g., a record of dissemination in LIMS or a note in the technical record.

The significance of associations shall be properly qualified in the report either by a statistic or a qualitative statement.

When results are inconclusive the reason(s) shall be documented in the technical record and clearly communicated in the report.

The initial database entry (e.g., AFIS/NGI, CODIS, and IBIS/NIBIN) shall be reported. An association resulting from a database search shall also be reported.

Each report shall include at a minimum the following information:

- title (Case Report or Certificate of Analysis);
- date of the report;
- the name and address of the District or Regional Laboratory location;
- the location of the performance of crime scene, digital forensic, or laboratory activities;
- the RMS case number for CSI's reports or laboratory case number and request number for Certificates of Analysis;
- page number (e.g., page 1 of) on each page and a signature, or electronic equivalent, that indicates the end of the report;
- the name and contact information of the customer;
- identification of the method(s) used;

- a description, unambiguous identification, and where necessary, the condition of the item(s);
- since the date that evidence items are received is not critical to the validity or application of the results, this date may not be included on the Case Reports or the Certificates of Analysis (this date shall be recorded on the Property Record and Receipt Form (PR&R) and/or in LIMS);
- the date(s) of performance of the crime scene, digital forensic, or laboratory activities (on Certificates of Analysis these dates are the date the evidence is assigned to the DFE, FS or, when utilized, the FT to the report date);
- sample plan and sampling method used;
- a statement to the effect that the results relate only to the item tested;
- the results with the units of measurement, where appropriate;
- additions to, deviations, and exclusion from the method;
- identification and title of the person authoring or issuing the report; and
- clear identification when results are from external provider (subcontractor).

Reports shall, where necessary for the interpretation of results, include the following:

- information on specific test conditions, such as environmental conditions;
- the measurement uncertainty when it impacts the evaluation of a specification limit stated in a statute, case law, or other legal requirement;
  - The measured quantity value (y) shall be included with the associated expanded uncertainty (U), and the coverage probability in the format of y $\pm$ U.
  - At most two significant digits shall be used unless there is documented rational in the measurement uncertainty study for reporting additional significant digits.
  - Measurement uncertainty shall be reported to the same level of significance as the measurement results.
- where appropriate, opinions, and interpretations; and
- additional information that may be required by specific method, authorities, or customer(s).

When the Laboratory Division conducts sampling, in addition to the requirements listed above, reports shall include the following, where necessary for the interpretation of results:

- the date of sampling;
- item number(s) of the items sampled;
- the location of the sampling, including any diagrams, sketches, or photographs;
- reference to the sampling plan and sampling methods including the confidence levels and corresponding inference(s) regarding the population;

- details of any environmental conditions during sampling that affect the interpretation of the results; and
- information required to evaluate measurement uncertainty.

When items from different cases are used in an examination, a separate Certificate of Analysis shall be issued for each case associated with the examination. The following shall also be required:

LIMS

- The cases shall be related in the LIMS.
- The items requested to be used for comparison from the additional case(s) may, at the FS's discretion, be listed under the Items Submitted for Analysis. These items shall be uniquely identified.

The FS may place a hold designation via LIMS on items that are going to be used in cross comparison to ensure that the items are not inadvertently returned to the customer. If the FS places a hold on any items, they shall remove the designation when the analysis is completed.

Reports

- Cross case comparison items referred to in the Results/Opinions/ Interpretations area of the Certificate of Analysis shall be clearly identified (e.g., Indiana State Police Laboratory Division Item Number and Case Number, and Agency Case Number).
- Results/Opinions/Interpretations of the examination of relevant case items, which were selected for cross comparison, shall be listed or referenced in the Certificate of Analysis of all the cases cross compared.

Notification to Involved Agencies

- While issuance of a Certificate of Analysis provides notification to an agency that their items have been used in a forensic examination, additional contact, such as a phone call, shall be made when appropriate.

Amended Reports

A report that needs to be changed or reissued shall have AMENDED REPORT typed after the laboratory case number in bold print. Amended Reports shall only be issued when a substantive error is found in the original report. Reports that require amending shall contain a Remarks section at the end that states the reason(s) for the amendment.

A case that was re-examined shall have RE-EXAMINATION REPORT typed after the laboratory case number in bold print.

If additional testing is performed on a previously examined item, within the same Discipline, an additional Certificate of Analysis shall be issued indicating the

supplemental results. The new report shall have SUPPLEMENTAL REPORT typed after the laboratory case number in bold print.

Amended, Re-examination, and Supplemental Reports shall meet all other requirements for reports in the Quality Assurance Manual and shall reference the original report.

7.9 Complaints/Quality Concerns

All complaints or quality concerns received from an employee, customer, or other parties concerning the quality management system shall be investigated using the following procedure.

In the event an employee identifies a potential quality management system deficiency or a concern about the quality of the crime scene investigations, digital forensic examinations, laboratory analysis, or evidence storage areas, the employee shall advise supervisory staff of the concerns or issues. When possible, supervisory staff, and/or when applicable TL in the Biology Section, shall evaluate and resolve complaint or quality concern.

When quality management system complaints or quality concerns is significant or cannot be resolved by the supervisors, and/or when applicable, the Biology Section TL, they shall submit the complaint or quality concern in writing through channels, to the A&QAM, who shall acknowledge its receipt and, if necessary, provide progress reports.

In the event an employee receives a written complaint or quality concern from a customer or other party, the employee shall forward it through channels to the A&QAM. If a verbal complaint or quality concern is received from a customer or other party, the employee shall fully describe it in an email, including the name and contact information, through channels to the A&QAM who, whenever possible, shall acknowledge its receipt and, if necessary, provide progress reports.

The A&QAM shall ensure all complaints and quality concerns received are investigated, all necessary information is verified to validate it, and the appropriate actions are taken. The investigation and decisions shall not involve individuals in the original activities in question. When necessary, the A&QAM shall implement a corrective action (see QAM-8.7).

Regardless of the severity of the complaint or quality concern, the A&QAM shall prepare a written summary, including actions undertaken to resolve the complaint, to the Laboratory Division Commander for each complaint received. After the Laboratory Division Commander's review, the A&QAM shall ensure, whenever possible, the complainant is advised of the outcome of the complaint.

The records of the complaint or quality concern, investigation, response, and communications shall be maintained on a network drive for a minimum of five years.

Upon request, the procedure for the complaints or quality concerns shall be made available to any interested party. The investigation and resolution shall not result in any discriminatory actions.

7.10 Nonconforming Work (also called Corrections)

The following procedure shall be implemented when any aspect of crime scene investigations, digital forensic examinations, or laboratory activities do not conform to the Laboratory Division's management system:

- Crime Scene Investigations Supervisors, Unit Supervisors, and/or, when applicable, the Biology Section TL are responsible for non-conforming work within their area of responsibility. The Supervisors shall notify the A&QAM of the non-conforming work. The A&QAM is responsible for the overall management of non-conforming work.
- The Laboratory Division Commander, with input from supervisory staff including, when applicable, the Biology Section TL, shall authorize the halting or repeating of work and withholding of reports for the Unit or an individual based upon the risk levels established by the Laboratory Division.
- The A&QAM, working with supervisory staff, including, when applicable, the Biology Section TL, shall evaluate the nature and significance of the non-conforming work, including the impact on previous results, and decide on the acceptability of the nonconforming work.
- When necessary, the customer(s) shall be notified of the non-conforming work and the corrective measures taken.
- The Laboratory Division Commander, with input from supervisory staff, including, when applicable, the Biology Section TL, shall authorize the resumption of case work.
- Non-conforming work may be identified and brought to the attention of Laboratory Division management through a variety of activities, including but not limited to, technical and administrative case review, proficiency testing, testimony evaluation, annual internal audits, etc.

Records of nonconforming work and action taken shall be retained in the technical record or in the quality assurance records on a network drive.

When the evaluation indicates that the nonconformance could reoccur or there is doubt about the compliance with Laboratory Division's management system documents, the corrective action procedures in QAM-8.7 shall be implemented.

7.11 Control of Data and Information Management

The Laboratory Division shall have access to the data and information needed to perform crime scene, laboratory, and evidence storage activities.

The Laboratory Division uses a commercial off the shelf LIMS. Any modifications to LIMS shall be documented, validated, and authorized by the Laboratory Division Commander before implementation.

LIMS shall be maintained in a manner that ensures the integrity of the data and information. A password shall be required to access Department computers and LIMS. The LIMS Unit Manager shall maintain a record of system failures and the corrective actions. The additional requirements in Laboratory Division General Policy #037 shall be followed.

The instructions and manual are available within the help feature of LIMS.

Records stored on network servers are backed-up by the Indiana Office of Technology (IOT).

Calculations and data transfers shall be checked in an appropriate and systematic manner. The technical record shall indicate the check performed and who conducted the check. When possible, this check shall not be conducted by the person who performed the calculation(s) or data transfers.

Return to Table of Contents

8. Management System Requirements

8.1 Options

The Laboratory Division's management system facilitates meeting accreditation requirements of the ISO/IEC 17025, as well as the supplemental requirements of the accreditation body, in accordance with Option A as described in the ISO/IEC 17025 standard.

8.2 Management System Documents

The Laboratory Division management and supervisory staff shall establish, document, and maintain policies and objectives for fulfilment of the ISO/IEC 17025 standard. The policy and objectives shall address the competence, impartiality, and consistent operation of the Laboratory Division. They shall ensure the policies and objectives are acknowledged and implemented by all personnel in the Laboratory Division.

The Laboratory Division Commander, Laboratory Division Deputy Commander, Director of Forensic Analysis, and Accreditation and Quality Assurance Manager (A&QAM) shall provide evidence of its commitment to the development, implementation, and continually improving the effectiveness of the management system.

The A&QAM shall:

a) ensure that processes and procedures needed for the management system are established, implemented, and maintained; and
b) report to the Laboratory Division Commander, Laboratory Division Deputy Commander, and Director of Forensic Analysis on the performance of the management system and any need for improvement.

All policies and procedures related to fulfilment of the requirements of the ISO/IEC 17025 standard are included in the management system documents available on the network drive, which all Laboratory Division personnel have access to.

8.3 Control of Documents

The Laboratory Division management system provides administrative and technical policies and procedures to assure quality work is performed. Management system documents, once approved and disseminated, shall be the controlling influence for all Laboratory Division employees to adhere to.

The Laboratory Division's Management System documents include, but are not limited to, Laboratory Policies, Quality Assurance Manual (QAM), Physical Evidence Bulletins (PEBs), Crime Scene Investigation Procedures Manual, Test

Methods, and Training Manuals. The current approved version of the management system documents shall be listed in either the Index of Management System Documents, Table of Contents of General Laboratory Policies, Table of Contents of Unit Policies or the Physical Evidence Bulletin Index, which all shall be maintained on a network drive.

The Laboratory Division's management system documents shall be reviewed at least annually, and updated as necessary, by the appropriate personnel assuring their continued suitability and adequacy. The Technical Leader (TL) shall annually review the Biology Section related documents and the Laboratory Division Quality Assurance Manual and approve the revisions prior to submitting for final approval.

The Laboratory Division Commander shall review and approve all new and revised documents that includes policies, procedures, and instructions (e.g., Laboratory Policies, QAM, PEBs, Procedures Manuals, Test Methods, and Training Manuals, etc.).

The Section Supervisor shall review and approve all new and revised forms (i.e., worksheets, checklists, logs, forms, etc.) used within their respective Section. The Chemistry Section Supervisor shall review approve new and revised safety related forms. The A&QAM shall approve new and revised quality related forms and Laboratory Division forms used by more than one Section. Note: The issuing authority in the footer of the forms will remain the Division Commander until the next revision of the form when it will be changed to the appropriate Section Supervisor.

The review and approval of any new or revised management system documents shall be documented on the Document Control Ledger. The Document Control Ledger shall be maintained securely on a network drive.

Revisions and/or new text shall be identified in the document by using, for example, red lettering. The A&QAM shall notify Laboratory Division personnel of document changes. Laboratory Division staff shall review and familiarize themselves with the management system documents pertaining to their work.

The official version of a management system document shall be securely maintained electronically on a network drive by the A&QAM. When working at a scene, Crime Scene Investigators have access to the network drive via Department issued cell phones with data plans and laptops.

Printed versions are uncontrolled copies made for reference purposes only that shall be destroyed when the immediate use of the copy is no longer necessary. When it is necessary to post a document in a Laboratory Division facility, only the current version of a controlled document shall be posted. When a posted

document is revised, the old version shall be promptly replaced with the new version.

To ensure documents are legible, all management system documents shall be typed and maintained electronically. The document title, date of issue or revision, page numbering, the total number of pages, and the issuing authority shall be affixed to the document. Previous versions of a document shall be stored in secured archive folders on a network drive and identified as an Archive Copy by the A&QAM.

External Documents

Controlled external documents shall be reviewed and approved for use by the Laboratory Division Commander. The current approved version of external documents shall be listed on the Index of External Controlled Documents or incorporated and/or referenced in an appropriate management system document.

Electronic version of external documents may be available on a network drive when legally permitted by copyright laws. Paper copies and other electronic storage devices (e.g., CDs, DVDs, etc.) shall be labeled Controlled Copy and properly tracked to ensure that obsolete versions are not used.

8.4 Control of Records

Field notes, laboratory case notes, reports, and other related records (i.e., technical records) are investigatory records of a law enforcement agency. Under Indiana Code (IC) 5-14-3-4 (b) (1), investigatory records of law enforcement agencies are confidential and not subject to public disclosure without due process of law.

8.5 Actions to Address Risk and Opportunity

The Laboratory Division shall consider risks and opportunities associated with crime scene, laboratory, and evidence handling activities to:

- give assurance that the management system achieves its intended results;
- enhance opportunities to achieve the purpose and objectives of the Laboratory Division;
- prevent, or reduce, undesired impacts and potential failures in Laboratory Division activities; and
- achieve improvement.

The Laboratory Division shall plan actions to address these risks and opportunities, integrate and implement these actions into the management system, and evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of crime scene and laboratory results.

8.6 Improvement

The Laboratory Division shall identify and select opportunities for improvement and implement any necessary actions.

The Laboratory Division shall seek feedback from our customers through periodic surveys. The feedback shall be analyzed and used to improve the management system, crime scene investigations, digital forensic examinations, and laboratory activities, and customer service.

8.7 Corrective Actions

Non-conforming work may be identified and brought to the attention of management through a variety of avenues including, but not limited to, technical and administrative case review, proficiency testing, witness critique, annual internal audits, etc. The A&QAM shall be notified through channels of the potential need to implement a corrective action.

When a nonconformity has been identified and a corrective action is warranted, the corrective action procedure shall be implemented. The A&QAM working with the reporting party and supervisory staff, including, when appropriate, the Biology Section Technical Leader (TL), shall:

- respond to the nonconformity and, as applicable:
  - take action to control and correct it;
  - address the consequences;
- evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - reviewing and analyzing the nonconformity;
  - determining the cause(s) of the nonconformity;
  - determining if similar nonconformity exist, or could potentially occur;
- implement action(s) needed, including, when applicable, preventative measures to minimize its reoccurrence;
- review the effectiveness of any corrective action taken;
- update risks and opportunities determined during planning, if necessary; and
- make changes to the management system, if necessary.

Corrective actions shall be appropriate to the effect of the nonconformities. The corrective action process shall establish a reasonable time frame for completion for each corrective action. In Biology Section, corrective action plans shall also be approved by the TL prior to implementation. The Combined DNA Index System (CODIS) State Administrator shall be notified when the nonconformity impacts DNA records in CODIS.

A Corrective Action Report shall be completed by the A&QAM. The records retained shall include the nature of the nonconformity, cause(s), any subsequent actions taken, and the result of the corrective action. The Laboratory Division Commander shall review and approve the corrective action. The Corrective Action Report and supporting documentation shall be maintained for a minimum of five years on a network drive.

8.8 Internal Audits

At least annually, internal audits shall be conducted to verify that operations of the Laboratory Division are meeting the requirements of the ISO/IEC 17025 standard, accreditation body requirements, and to ensure the management system is effectively implemented and maintained.

The annual internal audit shall be planned by the A&QAM, assisted by Laboratory Division personnel, who are, whenever resources permit, independent of the activity to be audited. The planning and scope shall take into consideration the work performed and areas to be audited, as well as results of the previous audits. The annual internal audit shall include review of case files and direct observations of the work conducted. In Biology Section prior to the audit, the TL shall determine a representation sample of the cases worked that will be reviewed.

At a minimum, internal audits shall be conducted annually. The frequency of internal audits may be adjusted depending on the importance of the activities concerned, changes affecting the Laboratory Division, and the results of previous audits.

The Biology Section shall be audited annually with the Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories and QAS for DNA Databasing Laboratories and shall follow the requirements in the QAS audit documents.

Any nonconformance found during the internal audits shall be documented and the appropriate correction and/or corrective action implemented including a timeline for completion. Opportunities for improvement should be identified and implemented.

Checklists or other records shall be produced by the internal auditors. A summary report shall be prepared by the A&QAM and reviewed by the Laboratory Division Commander.

Internal audit documentation and external audit reports from accrediting body and DNA audits shall be maintained on the network drive for a minimum of five years.

8.9 Management Reviews

A management review shall be conducted annually to ensure continuing suitability, adequacy, and effectiveness of the policies, procedures, and objectives related to the fulfilment of the ISO/IEC 17025 standard and accreditation body requirements. The following procedures shall be used to conduct the annual management review of the Laboratory Division.

At a minimum, the Laboratory Division Commander, Laboratory Division Deputy Commander, Director of Forensic Analysis, A&QAM, and the Biology Section TL shall annually review the management system operations. A management review shall be independent of the annual internal audit and include, at a minimum, the following topics:

a) changes in internal and external issues that are relevant to the Laboratory Division;
b) fulfilment of objectives (Mission & Operating Statements);
c) suitability of policies and procedures;
d) status of actions from previous management reviews;
e) outcomes of recent internal audits;
f) corrective actions;
g) assessments by external bodies;
h) changes in the volume and type of the work or in range of crime scene investigations, digital forensic examinations, and laboratory activities;
i) customer and personnel feedback;
j) complaints;
k) effectiveness of any implemented improvements;
l) adequacy of resources;
m) results of risk identification;
n) outcomes of the assurance of the validity of results; and
o) other relevant factors, such as monitoring activities and training.

Documentation from a management review shall include decisions and actions related to at least the following:

a) the effectiveness of management system and its processes;
b) improvement of the Laboratory Division activities related to the fulfilment of the ISO/IEC 17025 standard and accrediting body's requirements;
c) provision of required resources; and
d) any need for changes.

The Laboratory Division Commander shall ensure action items from the management review are completed in an appropriate time. Records of the management review shall be maintained on the network drive for a minimum of five years.

Return to Table of Contents