Indiana State Department of Toxicology

Quality Assurance Manual

Contents

1. Scope

This Quality Assurance Manual describes the control procedures and practices for the Indiana State Department of Toxicology (Department or ISDT) quality system. It contains or references policies and procedures used by the Department to ensure technical competence and valid forensic results.

2. References

2.1. The format of this document is based on the requirements found in the following documents:

2.1.1. ISO/IEC 17025:2017.

2.1.1.1. General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Switzerland, 2017.

2.1.2. AR 3125

2.1.2.1. Accreditation Requirements for Forensic Testing and Calibration (2023), ANSI National Accreditation Board, Milwaukee, WI, February 1, 2023.

2.2. IAC Title 260.

2.2.1. Indiana Administrative Code Title 260 (https://www.in.gov/isdt/2335.htm).

2.3. Hyperlinks throughout this document are provided for convenience only. Document links only work when accessed through network drives when onsite or through VPN accessibility.

3. Terms and Definitions

3.1. The following words used in this document have the following interpretations:

3.1.1. shall – a requirement

3.1.2. should – a recommendation

3.1.3. may – a permission

3.1.4. can – a possibility or capability

3.2. Accreditation

3.2.1. A process by which an authoritative body, such as ANSI National Accreditation Board, gives formal recognition that an entity is in compliance with a set of criteria.

3.3. Administrative records

3.3.1. Records, electronic or hardcopy, including evidence receipts, toxicology reports, chain of custody records, description of evidence packaging and seals, service requests, and correspondence received/sent.

3.4. Administrative review

3.4.1. Review of case and breath test instrument inspection records for clerical error and consistency with Department policy.

3.5. Amended report or inspection certificate

3.5.1. An official report or certificate amended to add information not included in a previously issued report (also known as supplemental report) or certificate.

3.6. Analyst

3.6.1. A forensic scientist who conducts analyses as outlined in Laboratory Test Methods or conducts or supervises breath test instrument inspections, interprets data, reaches conclusions, and authorizes the release of a toxicology report or inspection certificate. A breath test instrument inspector who complies with or is exempt from the educational requirements outlined in ANAB accreditation documents may be considered an analyst.

3.7. ANAB Forensic Provider Accreditation Program

3.7.1. An accreditation program of ANSI National Accreditation Board (ANAB) in which any forensic laboratory may participate to demonstrate that its management, technical operations, and overall quality management system meet ISO/IEC 17025:2017 and ANAB AR 3125 accreditation requirements.

3.8. Approved test provider

3.8.1. A proficiency test provider that has complied with the test manufacturing guidelines established and approved by the ANAB Proficiency Review Committees.

3.9. Audit

3.9.1. A systematic, documented process for obtaining records, statements of fact, or other relevant information, and assessing them objectively to determine the extent to which specified requirements are fulfilled.

3.10. Breath test instrument

3.10.1. An instrument selected and owned by the Department for use for evidentiary breath testing that measures the concentration of alcohol in an exhaled sample of human breath. Also known as breath alcohol instrument.

3.11. Breath test instrument inspection (inspection)

3.11.1. Includes the procedure that confirms the accuracy and precision of a breath test instrument (calibration method), calculates the measurement uncertainty, and other testing as needed to demonstrate compliance with the requirements of 260 IAC 2.5-3-2.

3.12. Breath test instrument inspector

3.12.1. A person who performs inspections, calibration adjustments, service, and maintenance of breath test instruments under supervision of an analyst.

3.13. Breath test instrument inspection records

3.13.1. Administrative and technical records, both electronic and hardcopy, generated or received by the Department pertaining to a particular breath test instrument.

3.14. Calibrator

3.14.1. A material of known composition that is used to produce a calibration curve or adjust an instrument’s calibration. Unknowns are compared to the calibration curve to determine the quantity of the analyte in the unknown.

3.15. Calibration method

3.15.1. Confirms the accuracy and precision of a breath test instrument at 0.020 g/210L, 0.082 g/210L, and 0.150 g/210L ethanol values, at minimum, using certified reference materials.

3.16. Case records

3.16.1. Administrative and technical records, both electronic and hardcopy, generated or received by the laboratory pertaining to a particular case.

3.17. Certificate of Inspection and Compliance of Breath Test Instrument and Chemicals (inspection certificate)

3.17.1. A document (also known as calibration certificate) stating that a breath test instrument and chemicals used in the performance of evidentiary breath tests are in compliance with the requirements of IAC Title 260.

3.18. Certified reference material (CRM)

3.18.1. A purchased reference material that is certified to contain specific concentration(s) of a compound or compounds and is accompanied by a Certificate of Analysis (CoA) that contains a measurement uncertainty. A CRM may be used as a calibrator or control or to prepare calibrators and controls.

3.19. Chain of custody

3.19.1. A process that documents each transfer of evidence over which the Department has control.

3.20. Competency test

3.20.1. A test used to evaluate a person's knowledge and ability to conduct examinations in a forensic discipline or category of testing prior to that person performing independent work.

3.21. Contemporaneous revision

3.21.1. Revisions that occur while performing an activity (e.g., processing data, filling out electronic worksheets, backspacing while typing), but prior to submission for technical review (or analyst review for breath test records).

3.22. Contract

3.22.1. An agreement between the Department and a vendor or service provider to provide products, instrument maintenance, forensic testing services, and/or calibration services, products, and/or instrument maintenance; or an agreement between a customer and the Department to provide forensic testing or calibration services.

3.23. Control

3.23.1. A material of known composition that is analyzed along with unknown sample(s) to evaluate the performance of an analytical procedure. Controls

may be carried through the procedure in parallel with the unknown sample(s).

3.24. Controlled document

3.24.1. A document issued by the Department and distributed in a trackable manner (e.g., worksheets, archived documents), including management system documents.

3.25. Controlling documents

3.25.1. Management system documents: Indiana laws, rules, and policies, Quality Assurance and other manuals, Breath Test Program Methods, Laboratory Test Methods, SOPs, and applicable memorandums for record.

3.26. Correlation

3.26.1. Performing calibration or testing and comparing the result with a previously obtained result. In ISO/IEC 17025:2017 and AR 3125, this is called a verification.

3.27. Corrected report or inspection certificate

3.27.1. An official report or inspection certificate revised to correct an error in a previously issued report or inspection certificate.

3.28. Corrective action

3.28.1. A response to eliminate or reduce the likelihood of recurrent non-conforming work or unauthorized departures from approved policies and procedures.

3.29. Customer

3.29.1. For purposes of defining the customer in accordance with ISO/IEC 17025 and AR 3125:

3.29.1.1. The submitting agency and/or associated prosecutor's office, as applicable, is the customer regarding testing of toxicology specimens.

3.29.1.2. The Department is its own customer regarding inspection of breath test instruments (ref. IC 9-30-6-5 and 260 IAC 2.5-3).

3.29.2. With respect to Department duties outside the scope of its accreditation, the customer is Indiana courts, attorneys, coroners, law enforcement agencies, officials of hospitals, and the public (ref. IC 10-20-2-4 and IC 10-20-2-5).

3.30. Deviation

3.30.1. A nonconformance with a controlling document.

3.31. Document control

3.31.1. The process of ensuring that controlled documents, including revisions, are reviewed for adequacy, approved for release by authorized personnel, and distributed for use to the personnel performing the prescribed activities.

3.32. Evidence

3.32.1. An item submitted for examination (e.g., specimen such as blood, serum, or plasma), which may be packaged in a kit, envelope, bag, etc.

3.33. External proficiency test

3.33.1. A test prepared, provided by, and reported to a source external to the Department.

3.34. Laboratory supervisor

3.34.1. A forensic scientist responsible for directly overseeing the work of the analytical laboratory and personnel, including lab accreditation and quality assurance.

3.35. Management system

3.35.1. The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

3.36. Measurement Uncertainty (MU)

3.36.1. A symmetrical interval that characterizes the variation that could reasonably be attributed to a measured quantity or result within which the true value is expected to lie with some level of certainty.

3.37. Memorandum for Record (MFR)

3.37.1. Documentation used to convey information or authorize variance(s) from a test method or SOP.

3.38. Performance check

3.38.1. Verification that equipment, an instrument, or a process is working as expected. Analysis of a control may be used as a performance check.

3.39. Preventive action

3.39.1. An action to reduce the likelihood of a non-conformity in the technical operation and management system.

3.40. Proficiency test

3.40.1. An evaluation used to verify the performance (i.e., testing, calibration) of the Department against pre-established criteria to verify the continued capability and quality of the laboratory's operations. Proficiency tests may be external (prepared by an outside provider) or internal (prepared by the Department).

3.41. Quality assurance

3.41.1. Planned and systematic actions necessary to provide sufficient confidence that the Department's product or service will satisfy given requirements for quality.

3.42. Quality assurance manager

3.42.1. A person with the defined authority and obligation to ensure that the quality requirements of the management system are implemented and maintained.

3.43. Quality control

3.43.1. Internal activities, or activities conducted according to externally established standards, used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

3.44. Quality system

3.44.1. The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

3.45. Reagent

3.45.1. A substance used because of its known chemical or biological activity.

3.46. Reference material (RM)

3.46.1. A traceable material or substance having known properties. Reference materials may be used for the identification of unknown substances, performance checks of instruments, or assessments of a method (e.g., CRMs and in-house validated solutions).

3.47. Reference standard

3.47.1. A standard from which measurements are made to confirm the required accuracy of other measurement standards (e.g., barometer or thermometer traceable to National Institute of Standards and Technology (NIST)).

3.48. Subcontractor

3.48.1. An entity that conducts examinations on behalf of the Department that are within the scope of testing performed by the Department.

3.49. Supervisory personnel

3.49.1. Director, assistant director, quality assurance manager, forensic toxicologist, analytical laboratory supervisor(s), breath test program supervisor, and general counsel.

3.50. Technical review

3.50.1. Review of a laboratory analysis or breath test instrument inspection record to ensure the validity of results and conclusions.

3.51. Test method

3.51.1. A document that specifies the procedures, equipment, and materials necessary to perform a task properly and provides instruction and standardization for activities affecting quality.

3.52. Technical record

3.52.1. Hardcopy or electronic documentation of procedures followed (e.g., laboratory analysis or breath test instrument inspection worksheets, chromatograms, instrument printouts, photographs, observations, analytical results, control charts, review worksheets, toxicology reports, and inspection certificates).

3.53. Toxicology report

3.53.1. A laboratory report issued by the Department that communicates results from the analysis of evidence.

3.54. Traceability

3.54.1. A property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

3.55. Validation

3.55.1. The process of performing a set of experiments that verify the efficacy and reliability of a technique, procedure, or modification thereof.

3.56. Verification

3.56.1. A check performed by a person or an electronic procedure to confirm an action was completed correctly or a check performed to ensure an instrument is functioning properly.

4. General Requirements

4.1. Impartiality

4.1.1. Laboratory activities and breath test instrument inspections and maintenance shall be undertaken to safeguard impartiality and reduce any potential bias.

4.1.2. Department personnel shall comply with all laws, rules, and procedures regarding ethical conduct and shall avoid conflict of interest situations, including involvement in activities that would diminish confidence in their competence, impartiality, judgment, or operational integrity.

4.1.3. Commercial, financial, or other pressures shall not compromise impartiality of the testing or calibration performed by the Department.

4.1.3.1. Department personnel shall

a) comply with Code of Professional Conduct: ISDT Admin-003, Ethics and Conflicts of Interest: IC 4-2-6, Indiana Code of Ethics for the Conduct of State Business: 40 IAC 2-1, and Indiana Code of Ethics 42 IAC 1;
b) review ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel by using web-based training upon hiring and reviewing on an annual basis thereafter (ref. ISDT Mission Statement); and
c) report any concerns or claims of unethical or biased behavior to the Department ethics officer. If there is an issue with reporting to the Department ethics officer, report concerns to the Director or by submitting a report to the Office of the Inspector General at https://www.in.gov/ig/hotline/.

4.1.3.1.1. Records shall be maintained on a network drive and retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules/).

4.1.4. Department staff shall be cognizant of the importance of impartiality. Department staff shall complete web-based bias training upon hiring and review it on an annual basis thereafter

4.1.5. If a risk to impartiality is identified, the Department shall take steps to eliminate or minimize the risk (e.g., restricting access to cases or files when there is a conflict of interest).

4.2. Confidentiality

4.2.1. The Department is subject to the requirements of Indiana Code § 5-15-5.1-10 and the Indiana Access to Public Records Act (IC 5-14-3) regarding the retention, disclosure, and disposition of Department records. The Department website shall include the advisement that it is subject to these statutory requirements. Records of the Department shall only be disclosed in accordance with the statutory provisions cited in this section and the Records Management Manual.

4.2.2. When the Department is required by Indiana state or federal court rules to release information that is not subject to disclosure under the Indiana Access to Public Records Act (IC 5-14-3), the customer shall be notified of the information provided as required by the applicable rule. If the applicable rule does not require notification of the customer, the Department shall provide the notification in accordance with the Records Management Manual, unless prohibited by law.

4.2.3. Not applicable.

4.2.4. Personnel, including contractors, personnel of external bodies, and persons acting on the Department's behalf, shall keep confidential all information obtained or created during the performance of the Department activities (within the scope of the Department's accreditation), except as required by law.

5. Structural Requirements

5.1. The Department is established as a department of state government by Indiana Code §10-20-2-1.

5.2. The Director is the highest-ranking manager within the Department, with overall authority to operate and oversee the Department. The Director is appointed by the Governor and has the authority to carry out the responsibilities of the Department under Indiana Code §10-20-2-2.

5.2.1. Responsibilities and authorities of the Director are defined in the associated job description.

5.3. All testing listed on ISDT's website (https://www.in.gov/isdt/2330.htm) and breath test instrument inspections performed by Department personnel shall conform to this document, the applicable test method, IAC Title 260 (breath test instrument inspections only), ISO/IEC 17025, and AR 3125.

5.4. The Department provides forensic toxicology services as part of its duties under Indiana Code §§ 9-30-6-5, 10-20-2-4, and 10-20-2-5 and in such a way as to meet the requirements of the ANAB forensic provider accreditation program. The Department's management system shall be followed wherever activities are conducted by Department personnel, whether on-site or in the field.

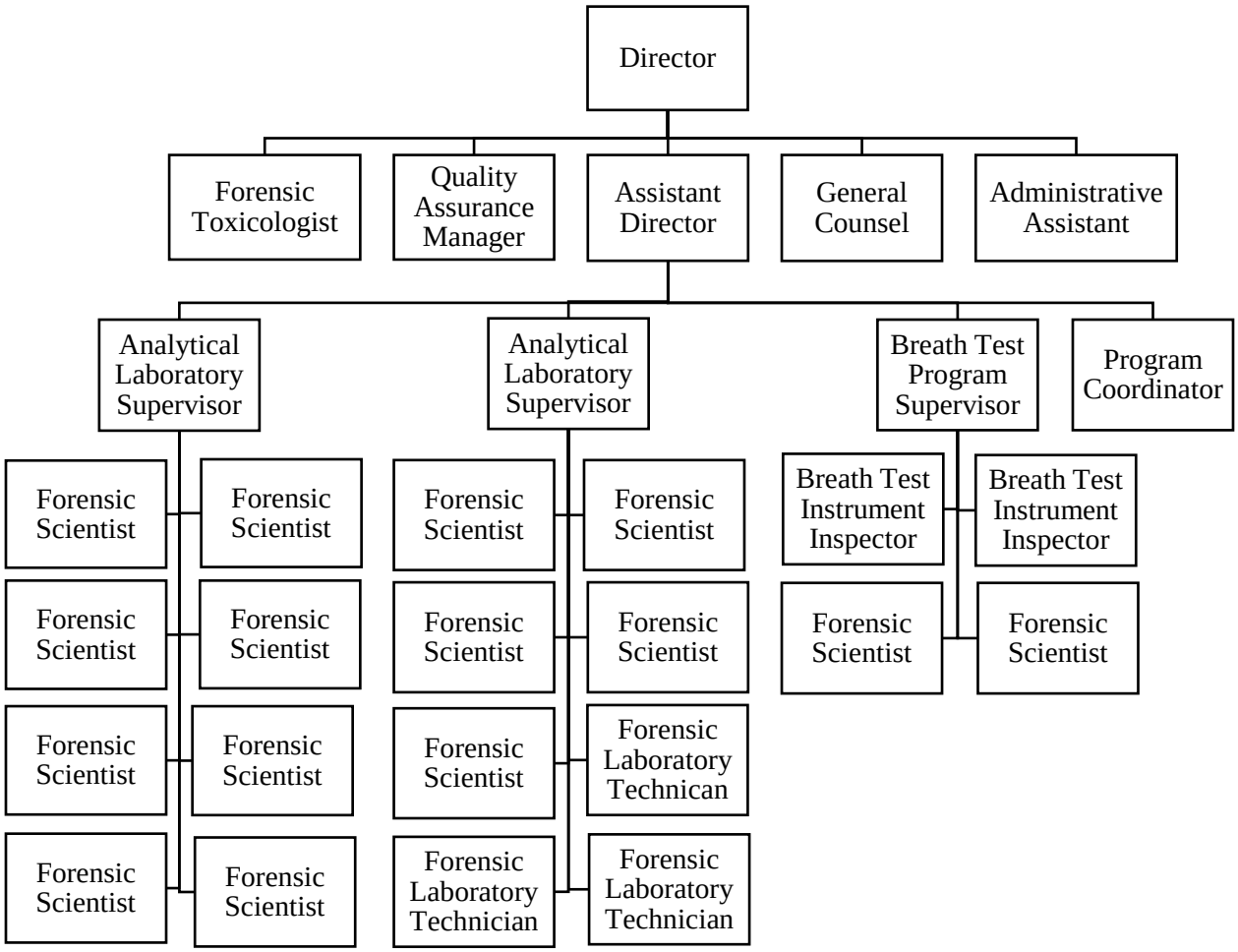
5.4.1. The Department shall conform to requirement by ANAB in PR 1018, ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status.

5.4.2. Certification of breath test instruments is performed under authority of Indiana Code § 9-30-6-5 and IAC Title 260 (http://iac.iga.in.gov/iac/iac_title?iact=260).

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

5.5. Management System

5.5.1. The Organization Chart shows the organizational and management structure of the Department. The Department is staffed with forensic scientists, inspectors, management, and administrative employees. All forensic scientists and breath test instrument inspectors have received specialized training within their disciplines. They are prepared and qualified to present expert testimony in their respective disciplines. Responsibilities and authorities of personnel are defined in the associated job descriptions.



a) The immediate supervisor shall be responsible for the supervision of subordinates, including trainees, and be familiar with methods and procedures, the purpose of each test and/or breath test instrument inspection procedure, and the assessment of test and/or inspection results. Each subordinate shall be accountable to only one immediate supervisor. The analytical laboratory supervisors & breath test program supervisor are responsible for the technical operation of the laboratory and breath test program, respectively. The analytical laboratory supervisors, breath test program supervisor, and quality assurance manager have overall responsibility for technical operations to ensure the quality of laboratory and field results through training, the performance appraisal system, casework reviews, proficiency testing, method and reagent validations, and witness evaluations. The quality assurance manager is responsible for the overall quality system of the Department, including the coordination, administration, and implementation of activities required to maintain quality.
b) Procedures for testing or inspections are documented in the respective test methods.

5.6. The quality assurance manager shall have responsibilities, authority, and resources to carry out the duties of that position, which include, but are not limited to, the following:

a) maintain and update all controlled documents;
b) monitor Department practices to verify continuing compliance with policies and procedures related to quality by monitoring the deviation log, interacting with supervisors, analysts, and inspectors, and performing audits once per calendar year and as needed;
c) oversee the evaluation of records of breath test instrument inspections, calibration adjustments, and maintenance, and laboratory instrument and equipment maintenance and quality controls;
d) ensure validation of new technical procedures by reviewing validations and authorizing methods;
e) investigate technical problems, propose corrective and/or preventive actions, and verify their implementation;
f) administer proficiency testing and evaluate results;
g) select, train, and evaluate internal auditors, as applicable;
h) schedule and coordinate management system reviews;
i) evaluate results of management system reviews;
j) ensure training records of Department personnel are maintained;
k) recommend training to enhance the knowledge of Department personnel with the goal of improving results and efficiency; and
l) propose corrections and improvement to the management system.

5.7. The Director may name Department designees. A designee list shall be maintained on a network drive and retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules/).

a) Department personnel shall be made aware of the relevance and importance of their activities and how they contribute to the achievement of Department objectives through training, staff meetings, and/or other communication. All communication, both internal and external, should be clear, concise, and professional. Supervisors shall encourage employees to use up to 2.5 hours of work time per week to read periodicals, journals, articles, books, web pages, etc., related to their disciplines to maintain their knowledge and expertise. The Director and supervisory personnel shall facilitate and encourage effective and direct communication. Supervisory personnel shall conduct staff meetings periodically to convey and discuss policies and procedures. A staff meeting shall be documented by a meeting sign-in sheet, a synopsis, and/or agenda of the discussion (ref. meetings notes and Meeting Sign-In Sheet). Meeting documentation records shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules). Department personnel shall understand the importance of responding to customer requests for analyses, breath test instrument maintenance and/or service, records of laboratory testing, breath test instrument inspections and certifications, and compliance with applicable statutory and regulatory requirements.

b) A supervisory personnel member who has approved time off of more than three (3) consecutive workdays should designate an appropriate Department staff member to act in the supervisor's stead during the absence and should notify their immediate supervisor, subordinates, and all other relevant personnel of the designation by email. In the event of an unexpected absence of a supervisory personnel member, the Director may make the designation.
c) When changes to the management system are planned and/or implemented, integrity of the management system shall be maintained by clearly indicating whether a document version is a draft or archived. New versions of controlling documents that are controlled by the Department shall be labelled with a version number, effective date, and distributed to department staff. Controlled documents are in controlled folders on a network drive.

6. Resource Requirements

6.1. General

6.1.1. The Department shall have available the personnel, facilities, equipment, systems, and support services necessary to manage and perform its activities.

6.2. Personnel

6.2.1. All Department personnel shall act impartially, be competent, and work in accordance with the laboratory's management system.

6.2.2. The Department shall list the competence requirements for each position in each job description.

6.2.2.1. Personnel trained after May 11, 2019, who authorize test reports and/or breath test instrument inspection certificates shall meet the minimum educational requirement of a baccalaureate or an advanced degree in chemical, physical, or biological science or forensic science.

6.2.2.2. The Department training program includes the following documents: New Employee Training Manual, Laboratory Training Manual, Breath Test Instrument Inspector and Analyst Training Manual, and Quality Assurance Manual. All personnel shall complete the relevant training modules that are in effect when hired or trained in the specific task to verify or gain the knowledge, skills, and abilities needed. The training shall include a general overview of forensic science. All personnel shall complete ethics training as part of new employee onboarding with regular refreshers in ethics. Retraining and maintenance of skills and expertise shall be addressed on a case-by-case basis by management. Past work experience and training may be substituted for the training program to the extent that it has been demonstrated to be relevant and sufficient.

6.2.2.2.1. All personnel shall complete the New Employee Training and applicable training in the training manuals for the laboratory or breath test program. The checklist(s) for each training manual shall act as the record that personnel performing particular tasks have been properly trained. The checklist(s) shall be reviewed and signed by the supervisor upon successful completion of training outlined in the checklist(s). A training authorization memo shall be written by the trainee's direct supervisor and approved through chain of command channels.

6.2.2.2.2. Annual computer-based training in the areas of bloodborne pathogens, bias, and review of ANAB's guiding principles and the Department's mission statement shall be conducted for all personnel.

6.2.3. The Director shall ensure the competence of all personnel who perform laboratory analyses, breath test instrument inspections, evaluation of results, and authorize test reports and breath test instrument inspection certificates. Personnel undergoing training shall be provided appropriate supervision. Personnel are trained to the Department test methods and quality control procedures to identify and evaluate deviations. All method deviations require supervisory approval and notification to the quality assurance manager. Personnel performing specific tasks shall be qualified based on appropriate education, training, experience, and/or demonstrated skills, as required.

6.2.3.1. Initial competency in testing or calibration is evaluated as part of the initial training and supervisory review of the work product (ref. 6.2.2.2.1). Continued competency is evaluated each year through relevant proficiency testing, analysis of known controls, and/or direct observation of testing or calibration.

6.2.3.1.1. A memo from the supervisor, signed by the Director, revoking the authorization to perform testing or calibration shall be written when a person has not completed the competency evaluation requirement.

6.2.3.1.2. To regain competency the person shall review current applicable test methods, participate in a proficiency test, analyze known controls, be directly observed performing testing or calibration, and/or other testing deemed appropriate by the quality assurance manager. This work shall be reviewed by a person who has maintained competency in the task.

6.2.3.2. Personnel who perform technical review of results, reports, certificates, or testimony shall meet the competency requirements specified in 6.2.3.1 for the activities being reviewed.

6.2.4. Job descriptions containing job duties and responsibilities for all personnel are maintained by the Department and are available on a network drive. Direct supervisors shall communicate changes in work expectations through routine meetings, conducting performance evaluations, and setting

individual employee objectives. As part of the annual performance evaluations, supervisors should consult with their personnel to identify training needs relevant to the present and anticipated work of the Department. Supervisors shall submit training requests to the Director.

6.2.5. The Department maintains records for:

a) competency requirements;
   - These requirements are outlined in 6.2.3.1 and training manuals.

b) selection of personnel;
   - The Department shall follow the procedures of the State Personnel Department for the hiring of personnel. These records are maintained by the State Personnel Department.

c) training of personnel;
   - Training requirements are outlined in training manuals, which are controlled documents.

d) supervision of personnel;
   - Personnel are assigned an immediate supervisor;
   - The supervisor shall follow the procedures of the State Personnel Department for conducting performance evaluations and setting individual employee objectives. Personnel records are maintained by the direct supervisor and/or the State Personnel Department. Additional information regarding personnel may be maintained by the immediate supervisor.

e) authorization of personnel; and
   - Authorizations are issued or revoked by the Director (ref. 6.2.2.2.1 and 6.2.3.1). These records are maintained on a network drive.

f) monitoring competence of personnel.
   - Competency is monitored by the direct supervisor and quality assurance manager. Competency is evaluated each year and documented on the Management System Review.

6.2.5.1. Records shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

6.2.6. Authorization letters issued for personnel shall be specific to the laboratory and/or calibration activities they are authorized to perform. These activities comprise all aspects of testing and/or calibration and include, but are not limited to, developing, modifying, verifying, and validating methods; analyzing specimens, including statements of conformity, opinions, and interpretations; the use of equipment and instrumentation; and reporting, reviewing, and authorizing of results. All forensic scientists are authorized to perform method development and validation of modified and new methods. The lead forensic scientist is the scientist that has primary

responsibility for the validation and should be an analyst trained in the type of instrumentation being used in the validation.

6.3. Facilities and environmental conditions

6.3.1. Department facilities for laboratory testing shall facilitate correct performance of analytical tests.

The Department shall ensure that environmental conditions do not invalidate laboratory results or adversely affect the required quality of any measurement. Any environmental condition observed that can affect the results of a breath test instrument inspection shall be documented in the technical record.

6.3.2. Laboratory activities shall only be conducted when there is electrical power to the building and instrumentation, proper ventilation of the workspace, and temperature within normal range.

6.3.3. The Department shall monitor, control (if possible), and record environmental conditions as required by test methods or where they influence the quality of results (e.g., temperature, electrical). Laboratory analyses and breath test instrument inspections shall be stopped when environmental conditions jeopardize the results of the analyses or inspections being performed.

6.3.4. The Department occupies a limited area of the State of Indiana Forensic and Health Services Laboratories facility.

a) Access to the Department areas (administrative area, laboratory, and walk-in refrigerator) is limited by keycard access. Visitor access to the facility shall be permitted only by authorization of a Department employee. The authorizing employee shall ensure that a complete visitor log entry is made and that the visitor is provided with a visitor tag to wear for the duration of the visit. Building custodial and maintenance staff and employees of other agencies within the facility are exempted from signing the visitor log or wearing the Department visitor tag. Exceptions to the requirements in this provision may be made by the Director or laboratory supervisor on a case-by-case basis.
The laboratory is accessible through 4 doors, which are secured by keycard access. Access is limited to Department personnel and Capitol Police (in case of emergency). Visitors are permitted in the laboratory when escorted by Department personnel. Building custodial and maintenance staff are permitted in the laboratory when Department staff are also present in the laboratory. The walk-in refrigerator is located inside the laboratory and secured by keycard access. Access is limited to the persons authorized to handle evidence. Building maintenance staff are permitted in the walk-in refrigerator for maintenance and repair work and shall be escorted and accompanied by Department staff the entire

time the walk-in refrigerator is being accessed. The Director or designee shall use a spreadsheet and other appropriate records to maintain control of all keys and access identification cards (ref. Admin-006). When the facility is unoccupied, the outer doors are locked, and external alarms activated. The entire facility is monitored by security personnel.

b) During preparation of samples, specimens shall be opened one at a time in order to prevent cross-contamination. Work areas shall be tidied and cleaned, if necessary, after completion of sample preparation. Hazardous chemical waste and biological waste shall be regularly transported from the laboratory to the location in the facility designated for such waste.

c) There shall be effective separation between neighboring areas in which incompatible activities are being performed. In order to maintain and improve the environmental conditions of the laboratory, all employees shall strive to maintain a clean, safe, and orderly laboratory.

6.3.4.1. Analysis of specimens shall occur in the laboratory. Breath test instrument inspections may occur in the laboratory, administrative area, or in the field. Review of data, technical review, and administrative review may occur in the laboratory, administrative area, or off-site.

6.3.5. Breath test instrument inspections occur off-site when instruments are installed for evidentiary use. Breath test instrument locations are inspected by a breath test instrument inspector prior to instrument installation to ensure the location is secure (e.g., inside a building with limited access to persons other than law enforcement officers and employees of the agency where the instrument is to be installed) and the environment will not interfere with the good operating condition of the instrument. An annual maintenance agreement is signed by the host agency and the Department, which states in part that the host agency shall maintain a secure area for the instrument. During instrument inspections the inspector or analyst shall evaluate instrument site environmental conditions, which shall be documented on the inspection record.

6.3.5.1. Records shall be retained on a network drive and maintained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

6.4. Equipment

6.4.1. It shall be the responsibility of management to ensure that adequate equipment and supplies (including, but not limited to, instrumentation, RMs, software, reagents, and consumables) and facilities are provided to ensure quality analyses of biological evidence and inspections of breath test instruments. Centralized Accounting and/or the Indiana Office of Technology (IOT) shall maintain the Department equipment inventory,

including laboratory and breath test instruments, computers, refrigerators, balances, and other items with an original purchase cost of over $500 and/or a serial number.

6.4.2. If the department requires the use of an instrument or equipment not in its permanent control, it shall ensure that the requirements of ISO/IEC 17025 and AR 3125 are met prior to use of the instrument or equipment.

6.4.3. Care should be taken when handling, transporting, storing, and using equipment. Planned maintenance of measuring equipment shall be performed to ensure proper functioning and in order to prevent contamination or deterioration (ref. Laboratory Test Methods and Breath Test Program Methods).

6.4.3.1. Reagents shall be labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records shall be maintained identifying who made the reagent and components used in the preparation (ref. Solution Verification/Validation section of the Laboratory Test Methods).

6.4.3.2. Not applicable

6.4.4. Before being placed into service, equipment critical for sampling and analysis shall be validated, calibrated, or checked, as applicable, to establish that it meets the Department's requirements and complies with the relevant standard specifications. When an instrument is taken out of service, performance checks (e.g., calibrations, inspections, and QC checks) shall be performed prior to returning the instrument to service (ref. Breath Test Program Methods or Instrument and Equipment Maintenance and Operation of the Laboratory Test Methods, as applicable.)

6.4.5. Equipment and associated software used for laboratory testing and/or breath test instrument inspections shall be capable of achieving the accuracy required by the applicable test method. Instruments shall be calibrated as required by the applicable test method.

6.4.6. Measuring equipment having a significant effect on the accuracy or validity of a test result or breath test instrument inspection that is used for laboratory tests and/or breath test instrument inspections shall be calibrated prior to being put into service, periodically as described in Laboratory Test Methods or Breath Test Program Methods, as applicable, or when required to establish the metrological traceability of the reported results.

6.4.7. For measuring equipment requiring calibration, the interval of calibration for equipment is in the Laboratory Test Methods or Breath Test Program Methods, as applicable.

6.4.7.1. A list of pipettes, autodilutors, and balances, identified by serial numbers, is maintained with the calibration records for the measuring equipment. This list contains the dates of calibration. Each pipette shall be calibrated at a minimum of 3 volumes that span the normal working range of the pipette. Each autodilutor shall be calibrated at the volume used in normal operation (i.e., 200 µL and 2000 µL), at a minimum. Each balance shall be calibrated at a minimum of 5 weights across the normal working range of the balance. Barometers shall be calibrated at pressures that encompass the barometric pressures across the normal range for atmospheric pressure in Indiana, at a minimum. Calibrations shall be performed by an ISO/IEC 17025 accredited calibration laboratory. Calibration certificates shall report "as found" calibrations and, if applicable, "as left" calibrations. An "as left" calibration shall be performed if adjustment or maintenance was performed.

6.4.8. All measuring equipment listed in 6.4.7.1 shall be labeled. Each label shall include the equipment serial number and clearly indicate the date of the last calibration and/or the date when calibration is due.

6.4.9. Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired, and the appropriate supervisor(s) shall be notified. A QC check or breath test instrument inspection shall be completed and documented prior to placing the equipment back into service, as applicable. The Department shall examine the effect of the defect or departure from specified limits on previous laboratory tests or breath test instrument tests or inspections and shall evaluate how to proceed (ref. 7.10).

6.4.10. Intermediate checks, including, but not limited to, accuracy checks, use of controls, QC checks, and verifications, are used to maintain confidence in the calibration status of equipment, reference standards, and RMs. These checks shall be carried out according to a defined procedure (ref. Breath Test Program Methods and Laboratory Test Methods).

6.4.10.1. A modification extending the interval between intermediate or performance checks shall be based on empirical data or an evaluation of risk.

6.4.11. If calibration and RM data include reference values or correction factors, the Department shall ensure the reference values and correction factors are updated and implemented, as appropriate. The nominal concentration or analyzed concentration (breath test program only) shall be used for all CRMss.

6.4.12. Laboratory test instruments and equipment, including hardware and software, are safeguarded from adjustments that would invalidate test results by limiting access to the laboratory and software. Instruments and equipment within the laboratory are only accessible to Department staff, and, in the event of service by a manufacturer or authorized provider, access is supervised by Department staff. Access to software for the headspace-GC is limited to staff with valid log-in credentials who have been given access by the analytical laboratory supervisor, quality assurance manager, or assistant director. Log-in credentials are provided by the IOT and require frequent password changes and password security criteria. Additionally, analysts do not have the access necessary to modify the "Master Methods" for the headspace-GC. Access to software for the GC/MS, LC/TOF, and LC/QQQ instruments is limited to Department staff who have access to the laboratory. Annual audits may include verification of software and firmware of instruments.

Breath test instruments and equipment, including hardware and software, are safeguarded from adjustments that would invalidate tests and/or inspection results by password protection of instrument adjustment functions and location of instruments in secure facilities. Password access is limited to inspectors, the breath test program supervisor, and limited administrative personnel. At a minimum, these passwords shall be changed upon termination of employment by the Department of any person with access to these passwords. Passwords used to perform inspections and calibration adjustments shall not be disclosed to any person outside the Department.

6.4.13. Each item of equipment and associated software used for laboratory testing and/or breath test instrument inspections that has significant contribution to the result shall, when practicable, be uniquely identified (e.g., by serial number or asset tag number) in the technical record.

The Department shall maintain a record for equipment and instruments and any associated software that requires scheduled maintenance or affects the MU for laboratory tests and/or breath test instrument inspections performed. These records include, but are not limited to, maintenance logs, temperature charts, instrument inventories, batch summaries, chromatograms, and breath test instrument inspection and service worksheets, as applicable. The records shall include at least the following:

a) the identity of the item of equipment and any associated software.
b) manufacturer name, model, and serial number or other unique identification.
c) checks that verify compliance with the accuracy specifications (ref. 6.4.4 and 6.4.5).
d) the current location, where appropriate.

e) dates, results, and copies of reports and inspection certificates from all breath test instrument inspections and calibration adjustments.
   1. The inspection interval and acceptance criteria are set forth in 260 IAC 2.5, which is referenced on the inspection certificate.
f) documentation of RMs used, results, acceptance criteria, and relevant dates, including expiration dates.
g) the maintenance plan, where appropriate, and maintenance carried out to date.
h) any damage, malfunction, modification, or repair to the instrument or equipment.

6.5. Metrological Traceability

6.5.1. The Breath Test Program Methods require that measurements made during a breath test instrument inspection for purposes of determining instrument calibration be traceable to the International System of Units (SI units) of measurement through use of NIST traceable RMs and a reference manometer as part of the inspection and calibration adjustment procedures.

6.5.1.1. The Department shall have its reference standards externally calibrated at least every twelve months, unless otherwise noted in the applicable test method (e.g., thermometers). Whenever possible, calibration of reference standards shall be traceable to a national measurement standard (e.g., NIST). Reference standards shall be calibrated before and after any adjustment, if possible. RMs shall be traceable to SI units of measurement or to CRMs. Internal RMs or RMs not traceable to SI units of measurement shall be validated prior to use.

a) If an external calibration service is used for either a reference standard requiring calibration or equipment (when the calibration of the equipment has a significant effect on the accuracy or validity of sampling, a test result, or the total uncertainty of a test result), the external calibration service shall be provided by a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration to be performed listed in a scope of accreditation.
b) When possible, a supplier of CRMs used to establish or maintain measurement traceability shall be an accredited RM producer that is accredited to ISO/IEC 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC-recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the CRM to be purchased.

6.5.1.2. If a RM producer described in 6.5.1.1 is not available, the laboratory shall confirm by objective evidence competence, measurement capability, and measurement traceability for the supplier and product being purchased. Records of the objective evidence shall be maintained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

6.5.1.3. Intox EC/IR II calibration

a) Instrument inspections shall be conducted by trained inspectors or analysts employed by the Department;
b) The calibration method used shall be validated or verified prior to use;
c) NIST traceable RMs shall be used in instrument inspections, and equipment used for subsidiary measurements that could affect instrument calibration (e.g., manometer) shall be calibrated within the time frame specified in the applicable test method. RMs and equipment described herein shall be traceable to SI units with the appropriate measurement uncertainty;
d) An Intox EC/IR II instrument inspection shall be performed at the location (environment) in which the instrument will be used. Manometers shall be calibrated to include barometric pressures consistent with the normal range of barometric pressures in Indiana, at a minimum;
e) All technical records generated during the inspection and/or service shall be maintained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules);
f) The MU shall be calculated for each breath test instrument inspection (ref. Breath Test Program Methods);
g) A technical review of the record of each breath test instrument inspection and/or service shall be performed by a person other than the one who performed the work (ref. Breath Test Program Methods).

6.5.1.4. CRMs may be used as is or altered to the desired concentration. When a CRM is altered, calibrated equipment (e.g., volumetric flasks, pipettes) shall be used to maintain an unbroken chain of calibrations. Records of the preparation of a solution shall document the unique number identifying the specific equipment used to dilute the CRM as well as the lot number of the CRM.

6.5.2. The Department shall ensure that measurement results are traceable to SI units through calibration by an ISO/IEC 17025 accredited laboratory,

certified values of CRM provided by an ISO/IEC 17034 accredited RM producer, or direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

6.5.3. When metrological traceability to SI units is not technically possible, the laboratory shall demonstrate metrological tractability to an appropriate reference such as certified values of CRM provided by an ISO/IEC 17034 accredited RM producer.

6.6. Externally provided products and services

6.6.1. When externally provided products and services that could affect breath test instrument calibrations or toxicology analyses are intended for incorporation into Department activities, provided directly to the customer as received from the external provider, or used to support the operations of the Department, the Department shall ensure that the externally provided products and services are suitable for use.

6.6.2. The Department shall purchase supplies, equipment, and services following State purchasing procedures, Indiana Department of Administration rules and regulations, and Requests, Invoices, and Received Funds (Admin-012). Supervisors shall identify and evaluate suppliers of critical consumables, supplies, and services that affect the quality of testing or calibration. Evaluations shall occur prior to Department use of the product or services. For example, the evaluation may be based on the accreditation to the relevant standard (e.g., ISO/IEC 17025, ISO/IEC 17034, and ISO/IEC 17043), traceability to NIST, certificate of analysis, experience with the provider, and/or in-house laboratory validation. For CRMs, RMs, and service providers used frequently throughout the year, the scope of accreditation should be verified prior to the first purchase each fiscal year or at the time the Department and the external provider enter into or amend a contract. A record of this evaluation shall be maintained and retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

Department personnel shall verify receipt of supplies to a shipping manifest and document receipt by stamp and/or signature on receipts, packing slips, and/or invoices, and, when possible, by initialing and dating chemical containers. Receipt of purchased RMs used in the laboratory shall be documented in the RM inventory. Copies of certificates of analysis of RMs shall be maintained on a network drive. If an updated certificate of analysis is obtained, the updated certificate shall be maintained, and the previous version(s) may be archived or deleted. A file should be maintained to organize the purchase and receipt of supplies and materials by the Department.

The Department shall monitor and perform evaluations of the products received or services rendered. When externally provided products or services do not conform to the laboratory's established requirements for the product or service, the provider shall be contacted to resolve the issue. If a resolution cannot be agreed upon, the laboratory may cease usage of the products or services. Records of the nonconforming products or services, correspondence with the provider, evaluations, and monitoring of the products and services shall be maintained and retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

6.6.3. The laboratory shall communicate requirements for products and services to external service providers. The requirements to be communicated, if applicable to the product or service, include acceptance criteria for the product or service and competency of personnel performing services (e.g., any required qualifications).

7. Process requirements

7.1. Review of requests, tenders, and contracts

7.1.1. Breath Test Program: The Director shall review each submitted request for installation of a breath test instrument. Only written requests shall be considered. A request should be on agency letterhead. If the Director agrees to installation of a breath test instrument at a requesting agency's location, a maintenance agreement between the requesting agency and the Department shall be completed prior to installation and yearly thereafter. The Department shall notify prospective breath test operators of the procedure for requesting enrollment in the Breath Test Operator Training Course and shall notify certified breath test operators of the procedure for accessing the recertification training and examination by posting the information on the Department website (https://www.in.gov/isdt/2333.htm).

Analytical Laboratory: The Toxicology Analysis Request (TAR) is used to submit a request for analysis. If both alcohol and drug analyses are requested in a non-priority case, alcohol analysis should be completed first. If the ethanol concentration reported is ≥0.100 g/100 mL blood, the request for drug analysis should be canceled. A subsequent request for analysis on a case that has already been received by the Department shall be in writing. Procedures for the review of requests for analysis are described in the Evidence Handling section of the Laboratory Test Methods. The procedure for submission of evidence to the Department is listed on the Department website (https://www.in.gov/isdt/specimen-collection-and-submission/). Through use of the TAR to submit evidence to the Department, the customer is notified that submission of evidence acts as approval of the Department's selection of the test method(s) to be used to analyze the evidence, including outsourcing the analysis unless requested otherwise. A list of analyses routinely outsourced shall be posted on the Department's website. The Department shall inform the customer of subcontracted testing on the toxicology report. The Department shall select the appropriate validated test method(s) to analyze submitted evidence. An agency requesting a ToxResults account or a change of ToxResults administrator shall submit a completed ToxResults Sign-up sheet to the Department prior to the Department assigning or reassigning an ToxResults administrator.

The Director shall ensure that the Department has the capability and resources to perform the services offered.

7.1.2. Not applicable.

7.1.3. IAC Title 260 establishes minimum requirements for the method used for inspections of breath test instruments. The method used for inspection of the Intox EC/IR II is included in the Breath Test Program Methods. For each inspection of an instrument deployed for evidentiary use that meets the

criteria of IAC Title 260, a statement of conformity is issued and posted on the Department's website (https://secure.in.gov/apps/isdt/recordsearch/#).

7.1.4. The Department shall follow the Laboratory Test Methods or Breath Test Program Methods, as applicable, to meet the needs of its customers. These methods and a list of analytes included in analyses are posted on the Department's website. The Department shall select the appropriate method for the category of work to be performed. The Department shall only use methods that have been validated by the Department. Deviations from a method may occur with supervisor or quality assurance manager approval, provided it does not affect the integrity of the laboratory or the validity of a result. A deviation requested by the customer shall not impact the integrity of the laboratory or the validity of a result.

7.1.5. By submitting evidence to the Department, the customer agrees to any deviations from the customer's request. Deviations shall be documented in the electronic case file, when practicable. Additional documentation of deviations may be found in batch QA/QC documents, the deviation log, and/or an MFR. Notice of this agreement is provided on the TAR and posted on the Department website (https://www.in.gov/isdt/2499.htm). If the quality or quantity of the specimen submitted is insufficient to complete testing, the customer shall be informed by release of a report for the analysis indicating the reason the analysis could not be completed. The customer shall be informed of deviations that affect the ability to quantify the analytes in the specimen by release of a report for the analysis indicating that quantitative analysis could not be performed. Qualitative analyses may be reported in these cases if all qualitative criteria are met for the applicable analyte(s).

A deviation related to an evidentiary breath test instrument maintenance agreement shall be communicated to the contact designated by the customer.

7.1.6. The Department shall work cooperatively with customers on amended requests. Case-specific communication regarding a customer request shall be documented, and a copy of any written communication shall be saved in the electronic case file for a laboratory case, in the communications folder for the Breath Test Program, and/or the appropriate location per the Records Management Manual.

7.1.7. Department personnel shall work cooperatively with customers to clarify requests, when necessary. Requests for testing outside the scope of testing performed by the Department will not be completed. Department personnel may assist the customer in finding an alternative service provider for services not included in the scope of testing performed by the Department.

Laboratory visits or tours are available upon request. Information regarding laboratory tours is available on the Department website.

7.1.8. A copy of a customer request shall be maintained in the case or breath test instrument record, as appropriate. Additional case-specific communication regarding the request shall be documented, and a copy of any written communication shall be saved either in the electronic case file for a laboratory case, in the communications folder for the Breath Test Program, and/or the appropriate location per the Records Management Manual. Subpoenas and correspondence regarding testimony shall be saved in the ISDT-Trials calendar.

7.1.9. Not applicable.

7.2. Selection, verification, and validation of methods

7.2.1. Selection and verification of methods

7.2.1.1. The Laboratory Test Methods and Breath Test Program Methods establish the procedures to be used by Department personnel when performing testing and breath test instrument inspections, respectively. These methods include procedures for handling, transporting, storing, and preparing items to be tested and inspected and, where appropriate, estimation of measurement uncertainty and statistical techniques for analysis of laboratory and/or breath test instrument inspection data. Methods not included in the Laboratory Test Methods or Breath Test Program Methods shall not be used to perform testing on evidentiary specimens or inspections of breath test instruments deployed for evidentiary testing.

7.2.1.1.1. Procedures for interpretation of screening and confirmation data are included in subsection 10 of each applicable test method in the Laboratory Test Methods.

7.2.1.1.2. Each test method that compares a known sample (calibrator or control) and unknown sample shall contain criteria for analyte identification and quantitation, if applicable.

7.2.1.1.3. The breath test instrument calibration method shall assess accuracy (bias and precision) of the breath test instrument using NIST traceable RMs across a range of ethanol values (ref. Breath Test Program Methods). A calibration adjustment of a breath test instrument shall be performed using a NIST traceable RM from a different lot than that of the dry-gas CRM used to check instrument accuracy in the inspection in which the calibration adjustment

is made. Verifications of breath test instrument accuracy during each subject test shall be performed using a NIST traceable RM from a different lot than that of the NIST traceable RM used to perform the calibration method or calibration adjustment (ref. Breath Test Program Methods).

7.2.1.2. All test methods, manuals, and reference documents relevant to the work of the Department shall be kept up-to-date and shall be made readily available to personnel (e.g., on a network drive) (ref. 8.3).

7.2.1.3. The latest valid version of a method shall be used for all calibration and testing. The current version is located on a secure drive separately from the archived versions. An issue date and version number shall be listed in the footer of each method. If the document is printed, a print date should be located in the bottom right footer. Any MFR modifying a method shall be incorporated into the main method document and signified as version #.#.

7.2.1.4. As stated on the Department website and in the footer of the TAR, by submitting evidence to the Department, the customer agrees to allow the Department to select the appropriate method for analysis of alcohols and/or the lists of drugs posted on the Department website (https://www.in.gov/isdt/2499.htm).

7.2.1.5. All methods used for testing or calibration shall be verified or validated prior to use.

7.2.1.6. When a method is developed in-house, it shall be a planned activity assigned to competent personnel equipped with adequate resources. Once development of a basic method is completed, a validation plan shall be written for the method prior to the initiation of validation experiments. Any modification to the validation plan shall be approved and authorized by the appropriate supervisor and quality assurance manager.

7.2.1.7. A deviation from a test method is permitted only when approved by the appropriate supervisor and/or quality assurance manager prior to release of the data. The deviation, technical justification, and supervisor or quality assurance manager's signature shall be documented in the laboratory case and/or batch QA/QC documents, breath test instrument inspection record, and/or an MFR. A log documenting deviations in laboratory analyses and breath test instrument inspections shall be maintained (i.e., deviation log and CAR-MFR-PAR log, however named) and

retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules). Each supervisor shall use the deviation log to inform the quality assurance manager of a deviation from a test method. As stated on the Department website and in the footer of the TAR, by submitting evidence to the Department, the customer agrees to allow the Department to determine acceptability of deviations from a test method (https://www.in.gov/isdt/2499.htm).

7.2.2. Validation of methods

7.2.2.1. The laboratory shall validate all methods prior to use for evidentiary testing. The validation shall be as extensive as necessary to meet the needs of the given testing or calibration being performed. For the analytical laboratory, the procedure for method validation for new and modified methods (ref. Method Validation in the Laboratory Test Methods) shall be used for method validation. The validation plan shall be based on the instrument type being utilized in the method and the requirements for method validation as listed in the test method. The validation process shall be performed under the direction of a supervisor and the quality assurance manager. Before their use in evidentiary testing, new methods require review and approval by the supervisor, quality assurance manager, and Director. A modification to a validated method requires review and approval by the supervisor and quality assurance manager.

Validation of a breath test instrument calibration method shall include:

a) evaluation of bias and precision using NIST traceable RMs.
b) performance of a systematic evaluation of the factors that could influence the results. Prior to starting a validation, the validation plan shall outline the experiments required, parameters to be evaluated, and the acceptance criteria required for the method to be approved for use.
c) determination of the number of replicates required for each RM is based on the desired degrees of freedom of the measurement uncertainty with a 99% confidence interval. The concentrations of the RMs evaluated shall be determined based upon Indiana statutory *per se* levels.
d) analysis of a proficiency test dry-gas cylinder to provide results to compare with other laboratories using different validated methods.
e) performance of interlaboratory comparisons using proficiency test dry-gas cylinders.

f) calculation of measurement uncertainty as described in the Breath Test Program Methods.

7.2.2.1.1. The validation summary shall:

a) include all associated data analysis and interpretation;
b) establish the data required to report a result, opinion, or interpretation; and
c) identify the limitations of the method, reported results, opinions, and interpretations.

7.2.2.1.2. A validation summary and/or validation plan shall include the following information:

1) Purpose –The purpose and a brief description of the method or method change being validated, with a summary of how the validation is to be or was conducted.
2) Experimental Setup – The instructions for performing the method or method change being validated, including the use of any required reagents, RMs, quality control samples, instruments, equipment, and performance or acceptance requirements.
3) Acceptability Criteria – The parameters being evaluated and the requirements for the parameters to pass acceptability criteria for the method, if applicable.
4) Results – A summary in text, tables, and/or graphs of the data collected during the validation process, an explanation of the data and results in relation to the method being validated, and, when applicable, measurement uncertainty.
5) Conclusion – A summary of the validation results, including a statement as to whether the method is suitable for the intended use.
6) References – A citation to any publication used in the development of the method or its validation.

7.2.2.2. Minor changes to a method may be evaluated through comparisons with the validated method. If the changes do not affect the original validation, then no further validation is required to incorporate the changes. A partial validation or complete revalidation shall be done when changes to a validated method affect the original validation. These changes include, but are not limited to, changes in sample preparation, instrument method, data analysis, and interpretation of data.

7.2.2.3. Performance characteristics (e.g., dynamic range, accuracy, measurement uncertainty, limit of detection, limit of quantification, selectivity, linearity, repeatability and reproducibility, and robustness) shall be relevant to the needs of the customer and consistent with specified requirements. Relevance to customer needs may be determined by the therapeutic range, statutory *per se* levels, or expected range of values in evidentiary specimens.

7.2.2.4. Validation plans, validation summaries, and verifications shall be maintained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

7.3. Sampling: Not applicable.

7.4. Handling of test or calibration items

7.4.1. Procedures for evidence receipt, handling, protection, storage, retention, and disposal are in the Evidence Handling section of the Laboratory Test Methods. Breath test instruments are certified and maintained in the field. The breath test instruments have password-protected functions and are required to be located in limited access areas (ref. 6.3). Procedures for avoiding deterioration, loss, or damage to evidence during storage, handling, and preparation are in the Laboratory Test Methods. Evidence in the process of analysis is maintained in the secure, limited-access laboratory. Evidence shall not be left out in the laboratory overnight, with the exception of aliquots on an instrument that are awaiting analysis. All evidence not in the process of receiving, accessioning, analysis, or transfer shall be maintained in the secured, limited-access, temperature-monitored walk-in refrigerator.

7.4.1.1. For all evidentiary test items received:

a) Evidence shall be stored in the secure walk-in refrigerator unless it is being used to perform any of the following: receiving, accessioning, analysis, or transfer. Specimen tubes shall be stored numerically in racks, when possible. When a specimen container is opened, it shall be opened individually and closed prior to opening the next specimen container.
b) Specimen and aliquot containers may only be left unattended in the secure and limited-access laboratory when placed in the sample prep area of the laboratory or when placed on equipment or instrumentation in the laboratory. Evidence in the process of receiving and accessioning may be left unattended in the secure and limited-access laboratory.
c) Chain of custody records that reflect the receipt of evidence and all internal transfers of evidence shall be maintained. Each person receiving or transferring evidence shall

document the activity in the appropriate case chain of custody record at or about the time of receipt or transfer. All evidence received shall be uniquely identified and tracked via barcode. When an aliquot is taken from a specimen container as a part of testing, the aliquot shall be tracked on an aliquot chain of custody for the batch. Transfer of evidence for testing by an external service provider shall be documented on a manifest for each container shipped.

d) The case chain of custody record shall include the Department case number and item number, the date of each receipt and transfer of evidence, the signature, initials, or secure electronic equivalent, of each person who received or transferred the evidence, and the purpose of each transfer.
e) The disposition of each item is tracked by an electronic chain of custody. Chain of custody records are available to the submitting agency and associated county prosecutor's office by request. A person other than a representative of the submitting agency or associated county prosecutor's office may request chain of custody records by submission of a non-party discovery request and subpoena.
f) Department policy for retention of evidence is listed on each TAR and each toxicology report issued. If requested in writing, evidence may be sequestered for a longer period.

7.4.2. The Department's Laboratory Information Management System (LIMS) identifies and tracks the container in which evidence is received and each individual specimen container. Evidence shall retain the same laboratory case number and item or sub-item letter/number throughout its retention by the Department. Each aliquot removed from an individual specimen container is identified by the case number and item number from which the aliquot was obtained. The transfer of aliquots in a batch is documented on an Aliquot Chain of Custody. Each record associated with a specific item of evidence shall include the case number and item number. Each breath test instrument shall be identified by a serial number. Breath test instrument records shall be identified by the instrument serial number and the date of activity. A list of instrument serial numbers and current instrument locations shall be maintained.

7.4.3. Department personnel shall document on the Evidence Description Worksheet any abnormality observed during receiving or accessioning of evidence submitted for testing (ref. Laboratory Test Methods). If a specimen is unsuitable for testing and no other specimen is available, a toxicology report shall be issued indicating the reason testing could not be completed (ref. Laboratory Test Methods). Correspondence and any additional information or instruction received from the customer shall be recorded in the case record. If a customer acknowledges a deviation from specified

conditions and requires evidence to be tested, a note shall be added to the report indicating any result that may be affected by the deviation.

7.4.4. The temperatures of refrigerators and freezers storing evidence shall be maintained within specified levels, monitored for compliance, and recorded (ref. Laboratory Test Methods).

7.5. Technical reviews

7.5.1. The Department shall retain records of data derived from each case analysis and breath test instrument inspection and/or service performed. The technical records in combination with the applicable test method shall contain the results and shall contain sufficient information to facilitate, if possible, identification of factors affecting measurement uncertainty and enable replication of the activity. Technical records shall contain the unique case number (and sub-item letter/number, if applicable) or breath test instrument serial number, specific activity performed, date(s) the activity was performed, and identify the person(s) who performed the activity. Original observations, data, and calculations shall be recorded at the time they are made and be identifiable to the specific activity and person performing the activity.

7.5.1.1. Records included in a test record are listed in the “Records” section of each test method.

7.5.1.2. Abbreviations and symbols specific to the Department shall be defined in the record or the appropriate test method, manual, or SOP.

7.5.1.3. Technical records shall contain information sufficient for another reviewer possessing the relevant knowledge, skills, and abilities to evaluate what was done and interpret the data.

7.5.1.4. Technical records created shall be maintained in electronic format.

7.5.1.5. If data from testing or a breath test instrument inspection is rejected, the reason, identity of the person(s) taking the action, and date shall be recorded in the technical review record (ref. Laboratory Test Methods and Breath Test Program Methods).

7.5.1.6. If the calibration of a breath test instrument is adjusted due to an instrument status message (e.g., fuel cell diagnostic failure) or a calibration result outside the acceptable range, results of pre-adjustment calibrations, if applicable, and post-adjustment calibrations shall be retained and reported on the inspection certificate (ref. Breath Test Program Methods).

7.5.2. Measures shall be taken to avoid loss or alteration of original data. Changes to a technical record shall be tracked. Contemporaneous revisions to a technical record are not changes. Correction of an error on a hardcopy or electronic record shall be made with a single line through the error, addition of the correct information, the date of correction, and the initials or signature of the person performing the correction. A brief comment explaining the correction should be made if the reason for the correction is not self-evident. A correction to information in a field used in a calculation contained in an electronic record may be made by changing the information in the field and adding a dated and signed note describing what information was changed and why. It is acceptable to use an asterisk and define the asterisk elsewhere on that page or another page of the document or to refer to an attached document that explains the correction. A change made to a technical record as a result of verification or technical review shall be tracked (ref. Laboratory Test Methods and Breath Test Program Methods).

7.6. Evaluation of measurement uncertainty

7.6.1. The Department shall identify the significant components of uncertainty, make a reasonable estimation of measurement uncertainty, and ensure that the manner of reporting a result does not give an inaccurate impression of its uncertainty. Reasonable estimation of measurement uncertainty shall be based on knowledge of the performance of the method and on the measurement scope and shall use, for example, previous experience and validation data.

7.6.1.1. Measurement uncertainty evaluations shall include calibration data from measuring devices (e.g., pipette, volumetric flask), if any, and/or instruments used in the testing for calibration for a reported result. The procedure for rounding and review or recalculation of the measurement uncertainty shall be listed in the appropriate test method. The coverage probability shall be 99.73 % for volatile analyses, 99% for breath test instrument calibrations, and 95.45% for drug analyses. The schedule for updating the MU is listed in the appropriate test method.

7.6.2. Measurement uncertainty is calculated for each breath test instrument from the data obtained by performing the calibration method during an inspection. The department does not calibrate measuring devices.

7.6.3. Measurement uncertainty is calculated and reported for all reported laboratory quantitative testing results. The measurement uncertainty is estimated using historical control data and control validation data, calibration data from measuring devices, and measurement uncertainty of CRMs used for calibrators and controls.

7.6.4. A measurement uncertainty record shall include statements defining the measurand and explaining how traceability is established for the measurement, list the equipment used, all uncertainty components considered, all uncertainty components of significance and how they were evaluated, data used to estimate repeatability, all calculations performed, the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty. These records may be made and maintained in multiple locations. Records of evaluations of measurement uncertainty shall be maintained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

7.7. Ensuring the validity of results

7.7.1. The Breath Test Program Methods shall include criteria for monitoring each breath test instrument inspection. Instrument status messages shall be reviewed at least once each calendar year to determine whether there are any trends in performance of a specific instrument or all instruments. The results of this analysis shall be reviewed at the time of the annual audit, at a minimum, by the breath test program supervisor and/or quality assurance manager. Records of these reviews shall be maintained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

The Laboratory Test Methods shall include quality control criteria for monitoring the validity of laboratory analyses within a test batch. Calibrators and controls used shall be monitored by reviewing QA/QC records to detect any trends for the calibrators and controls within the batch. In addition, control values may be used with statistical software to detect any trends in quality control samples. Control values shall also be used in determining measurement uncertainty of the method.

Monitoring for the laboratory and breath test program shall be planned, recorded, and reviewed and, if applicable, may include, but is not limited to, the following:

a) regular use of CRMs and/or internal quality control samples using secondary RMs;
b) comparison between instruments validated for the same method;
c) quality control checks following maintenance;
d) calibration and control charts;
e) participation in an external proficiency-testing program (ref. 7.7.4);
f) replicate tests using the same or different methods;
g) positive and negative controls;
h) fortified samples and use of internal standards; and
i) review of reported results.

Correlation:
When an analysis or inspection is repeated to confirm the original result, it shall be conducted by a person authorized to perform the activity that produced the original result. A record of the correlation shall be made and shall include identification of the person who performed the correlation, when it was performed, and the result. The resolution of any discrepancy shall also be recorded in the record.

Review of Technical Records:

1. Technical records, test reports, inspection certificates, and testimony shall be technically reviewed by a person other than the one who performed the analysis being reviewed and/or reported, and who has successfully completed competency testing in the task(s) encompassed by the review.
2. A technical review shall not be performed by the person who performed the work being reviewed.
3. All technical records, including test reports and inspection certificates, shall be technically reviewed.
4. Testimony of each analyst and breath test program inspector/analyst shall be reviewed by a peer, supervisor, or quality assurance manager at least every 3 years, if applicable, and documented on the Courtroom Testimony Evaluation. The evaluation shall be submitted to the quality assurance manager or supervisor for review and feedback.
    a. If testimony is not available, a deposition transcript may also be reviewed.
5. Technical review of technical records, including inspection certificates, but excluding test reports, shall be documented on technical review worksheets. Technical reviews of test reports are conducted as part of the administrative review and recorded in LIMS.
6. The technical reviewer shall ensure that the results, opinions, and interpretations are accurate, properly qualified, and supported by the technical record.
7. The technical reviewer shall ensure conformance with applicable methods and management system documents.
8. A discrepancy found as a result of a technical review shall be documented on the technical review worksheet or case synopsis, as applicable. A discrepancy shall be handled in accordance with the applicable test method (ref. ref. Laboratory Test Methods and Breath Test Program Methods). A discrepancy that does not affect the validity of a result, but is a deviation from the method, requires supervisory sign-off, which shall also be documented in the deviation log.

7.7.2. The Department shall monitor its performance by comparison of results from other laboratories through participation in at least one proficiency test for breath test instrument calibration and one proficiency test for laboratory testing each calendar year.

A proficiency test for calibration shall be purchased each calendar year for the Breath Test Program. On a rotating basis each year, the results of at least one breath test instrument inspector or analyst shall be submitted for comparison with the results of other laboratories. Prior to administering the proficiency test, the quality assurance manager shall determine which inspector's or analyst's results are to be submitted per the rotation schedule.

For the analytical laboratory, multiple proficiency tests shall be ordered to encompass analyses of serum/plasma and whole blood specimens, with multiple proficiency samples to aid in ensuring inclusion of a representative sample of specimens. Proficiency testing assignments shall be made each calendar year. A schedule as to which analyst is assigned each proficiency test screen shall established by the quality assurance manager each calendar year along with a rotation for who is next in line for specific confirmation testing. If an assigned analyst is unavailable to perform testing within the time provided for submission of results, the schedule may be modified with approval of the quality assurance manager.

7.7.3. Quality control data shall be reviewed for each analytical batch and each breath test instrument inspection, and, when found to be outside acceptance criteria of the test method, the action listed in the test method shall be taken. If an applicable action is not listed in the test method, the supervisor and/or quality assurance manager shall be consulted. The action resulting from the consultation shall be documented on the inspection record or appropriate batch document and deviation log, if applicable. A corrective action report or MFR may be issued (ref. 8.7).

7.7.4. Each laboratory analyst and breath test program inspector/analyst shall complete at least one intralaboratory comparison, proficiency test, or be observed completing testing in each calendar year. This performance monitoring shall occur for each discipline in the scope of accreditation in which the person is trained (i.e., analysis for drugs and/or volatiles and/or breath test instrument calibrations).

7.7.5. Monitoring performance by intralaboratory, proficiency testing, or direct observations:

a) The acceptable proficiency test result range shall not be known or readily available to the person completing the proficiency test.
b) Each laboratory proficiency test shall be conducted using an approved test method or in conjunction with validation of a new test method. External proficiency test results shall only be reported after approval of the validation of the new test method.
c) A proficiency test result shall be deemed successful by the criteria set by the external proficiency test provider. The acceptance criteria for an internal laboratory proficiency test result are equivalent to the applicable correlation acceptability requirements in the Laboratory Test Methods.

d) An internally-created proficiency test shall be verified against the target concentration within the applicable acceptance criteria for correlation in the test method. A previously-used proficiency test may be used for training purposes, correlation, or a proficiency test. The result from a previously-used proficiency test shall be compared to the reported mean of the proficiency test provider and meet the applicable acceptance criteria for correlation in the Laboratory Test Methods or be within 0.005 g/210L or 5%, whichever is greater, for breath test instrument calibration.
e) A Breath Test Program proficiency test shall be completed on a breath test instrument that has been inspected per the Breath Test Program Methods by the person completing the proficiency testing.
f) Notification to ANAB shall occur within 30 days of any monitoring activity not resulting in the expected result. This notification may be done by ISDT or the proficiency test provider.

7.7.6. A spreadsheet shall be maintained to track the instrument serial number used to analyze the dry-gas proficiency tank or the case number associated with each proficiency test received. The spreadsheet shall list the person that completed the inspection or analysis.

7.7.7. A proficiency test provider shall be ISO/IEC 17043 accredited, and results shall be submitted from the proficiency test provider directly to ANAB, if possible.

7.7.8. The following records, at a minimum, shall be maintained for each proficiency test conducted:
a) discipline tested;
b) design of monitoring activity (ref. f));
c) expected results;
d) location where proficiency test was completed, if other than the department;
e) records submitted to the proficiency test provider;
f) appropriate technical records;
g) evaluation of results and action taken in response to unexpected results; and
h) feedback provided to the person(s) who completed the proficiency test.

7.8. Reporting of results

7.8.1. General

7.8.1.1. Results shall be reviewed and authorized prior to release.

7.8.1.1.1. The preparer and authorizer of an inspection certificate is the analyst who prepared the document. The analyst shall review the technical

record of the inspection prior to authorizing the certificate. This review is documented by the analyst's signature on the certificate.

The preparer of a toxicology report is the analyst named on the report, and a toxicology report may be authored by more than one analyst. The authorizer of a toxicology report is the administrative reviewer. The administrative reviewer shall review the applicable record(s) prior to authorizing the report. This review shall be documented in LIMS and on the report.

7.8.1.2. The Department shall report results of each test, inspection, or series of tests accurately, clearly, unambiguously, objectively, and in accordance with the corresponding test method. A toxicology report or inspection certificate shall include all information required by the method used and any information necessary for the customer to relate the report or inspection certificate to the evidence submitted or affected breath test instrument.

7.8.1.2.1. Inspection certificates and toxicology reports are available electronically through links located on the Department website (https://www.in.gov/isdt).

7.8.1.2.2. When the requested analysis has been completed, the toxicology report for drug or alcohol analysis shall report the positive finding(s), if applicable, and the associated measurement uncertainty(ies) for the specimen used to perform the confirmation testing. If testing cannot be completed due to insufficient quantity or quality of the specimen submitted, a report shall be issued stating the reason testing could not be completed. If there is not a positive finding, the report shall state "None Detected." The toxicology report shall indicate each specimen tested, if any. When a request for analysis is canceled, a toxicology report shall be issued if requested or if a positive confirmation result was obtained before cancellation of the request. When all testing has not been completed but a report is issued due to cancellation of the request, a note shall be added to the report stating that testing was not completed due to cancellation of the request. If a request for analysis is canceled and a report is not issued, the request in LIMS

shall be marked as canceled, and the cancellation of the request for analysis shall be documented in the case file. An inspection certificate shall report the results of the accuracy checks performed during the inspection and the associated measurement uncertainties.

7.8.1.2.3. The Breath Test Program Methods shall state the process for reporting calibration results on the inspection certificate. When an inspection of a breath test instrument deployed for evidentiary use has been completed and the instrument is found to comply with the requirements of IAC Title 260, an endorsed inspection certificate shall be generated.

7.8.1.3. All inspection certificates shall use a simplified format with only one date listed on the certificate, which is the date of inspection. Toxicology reports shall use a simplified report format omitting deviations from the appropriate test methods that do not impact results, the statement that reported results only relate to the items tested, and the dates of screen testing performed. This simplified toxicology report is agreed to by customers upon submission of evidence to the Department for testing. Toxicology reports shall indicate the presence of an attached report, if applicable.

7.8.2. Common requirements for certificates and toxicology reports

7.8.2.1. Each toxicology report and inspection certificate shall include at least the following information, unless otherwise indicated:

a) title (e.g., Toxicology Analysis Report-Drug Analysis, Toxicology Analysis Report-Alcohol Analysis, Certificate of Inspection and Compliance of Breath Test Instrument and Chemicals);
b) name and address of the Department;
c) location of the breath test instrument inspection. Not applicable for toxicology reports;
d) laboratory case number or breath test instrument serial number, and page numbering that reflects the total number of pages of the record (i.e., “page __ of __”);
e) customer name and address;
f) method used;
    1) The instrument type listed on the report identifies the method used for the analysis. (ref. Laboratory Test Methods and Department website).
    2) The instrument type listed on the inspection certificate identifies the inspection method (ref. Breath Test Program Methods).

g) description and identification of each item submitted, and each item screened and confirmed with a positive finding (toxicology analysis reports only), or the breath test instrument serial number of the instrument inspected;
   1) The condition of each evidentiary item is documented on the Evidence Description Worksheet. If the condition of the specimen prevents the Department from completing the analysis, it shall be noted on the report.
   2) The condition of each breath test instrument is documented on the Intox EC/IR II Breath Test Instrument Inspection and Service Worksheet.
h) date of receipt of the specimen(s) or date of inspection of the breath test instrument;
i) date of sample preparation for confirmation, if any, or date of inspection of the breath test instrument;
j) report date (toxicology report only) or inspection date (inspection certificate only). A breath test instrument inspection certificate shall be effective on the date of inspection listed on the certificate;
k) not applicable;
l) test or inspection results and, where appropriate, units of measurement;
m) any deviation from the method that affects the analysis or inspection;
n) identification of the authorizer; and
   1) Laboratory: The administrative reviewer is the authorizer of the laboratory test report and is identified on the report by employee number.
   2) Breath Test Program: The analyst is the authorizer of the inspection certificate and is identified by the signature on the inspection certificate.
o) Not applicable.

7.8.2.2. With the exception of information provided by the customer, the Department shall be responsible for all information contained in a report.

7.8.3. Specific requirements for toxicology reports

7.8.3.1. In addition to the requirements listed in 7.8.2, toxicology reports shall include the following, when necessary for the interpretation of test results:

a) omitted per customer agreement.
b) not applicable.
c) estimated measurement uncertainty (ref. Laboratory Test Methods).

d) not applicable.
e) additional information required by the test method or customer.

7.8.3.1.1. Not applicable.

7.8.3.2. Not applicable.

7.8.4. Specific requirements for certificates

7.8.4.1. In addition to requirements listed in 7.8.2, inspection certificates shall include the following:

a) the measurement uncertainty for each average concentration of the NIST traceable RMs analyzed in the calibration method (ref. Breath Test Program Methods);
b) not applicable;
c) a statement that the measurements are traceable;
d) the average concentration and measurement uncertainty of the NIST traceable RMs analyzed in the calibration method before and after any adjustment or repair, if available;
e) a statement of conformity with requirements of 260 IAC 2.5; and
f) not applicable.

7.8.4.1.1. Not applicable.

7.8.4.2. Not applicable.

7.8.4.3. Not applicable.

7.8.4.4. Not applicable.

7.8.5. Reporting sampling – specific requirements: Not applicable.

7.8.6. Reporting statements of conformity

7.8.6.1. Statements of conformity shall comply with the requirements of 260 IAC 2.5.

7.8.6.2. An inspection certificate shall relate only to quantities and the results of functional tests. If a breath test instrument does not meet the requirements of 260 IAC 2.5-3-2, an inspection certificate shall not be issued. When statements of compliance are made, measurement uncertainty shall be considered.

7.8.7. Reporting opinions and interpretations

7.8.7.1. The basis of an opinion or interpretation shall be documented in the case or instrument record. Opinion or interpretation shall only be provided by authorized personnel. Additional information provided by the customer shall be saved in the case file or in the Breath Testing Communications folder.

7.8.7.2. Opinions and interpretations shall not be included in a toxicology report.

7.8.7.3. Opinions and interpretations provided that are specific to a laboratory case shall be documented in the case synopsis unless provided in recorded testimony. Opinions and interpretations provided that are specific to a breath test instrument shall be saved in the Breath Testing Communications folder unless provided in recorded testimony.

7.8.8. Corrections and amendments to toxicology reports or certificates

7.8.8.1. When an issued toxicology report or inspection certificate is amended or corrected, any change of information shall be clearly identified and, where appropriate, the reason for the change shall be included in the report or inspection certificate.

7.8.8.2. An amended toxicology report or inspection certificate shall be issued when information is added to the original toxicology report or inspection certificate. A corrected toxicology report or inspection certificate shall be issued to correct an error in the information or an analytical result in the original toxicology report or inspection certificate.

7.8.8.3. An amended or corrected report shall reference or be attached to the previously issued report and identify the information that was added or changed. Previously issued reports or inspection certificates shall be saved in the case file or instrument file and shall be maintained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

7.9. Complaints

7.9.1. *Customer/Other-Party Complaints:* The Department accepts complaints in person and by mail, telephone, and e-mail. Information regarding submission of comments and complaints is posted on the Department's website (https://www.in.gov/isdt/2492.htm). A complaint should be made by the affected person or attorney, or, in the case of a juvenile, a parent, guardian, or attorney. A complaint may be filed with the Department at any time, but the filing of a complaint close to the time of the incident at issue will facilitate the gathering of pertinent information. Complaints may also

be filed with the Office of Inspector General, 315 West Ohio Street, Room 104, Indianapolis, Indiana 46202, telephone 317-232-3850, IG: Hotline.

Employee Complaints: Employees shall advise supervisory personnel of potential quality management system deficiencies or concerns about the quality of work. Concerns or complaints should be made in writing and submitted through channels or directly to the quality assurance manager. A complaint regarding unethical behavior shall be submitted directly to the Ethics Officer or Office of Inspector General.

An employee may file a complaint regarding a personnel action following the procedures listed in the State of Indiana Employee Handbook (e.g., Anti-Discrimination/Harassment Policy, Complaints Procedures, and Working Test Period in the State Classified Service).

7.9.2. The quality assurance manager or Director designee shall investigate all complaints, except those related to ethics violations, and shall, if necessary, implement a corrective and/or preventive action (ref. 8.7). The quality assurance manager or Director designee shall respond to the reporting party in writing, when possible, regarding each non-ethics complaint received, regardless of severity.

7.9.3. When a complaint other than an ethics violation is received by the quality assurance manager, the director and appropriate supervisor shall be informed. The validity of the complaint shall be considered. Next, the circumstances surrounding the complaint shall be investigated. A response and any resulting action to be taken as a result of the complaint shall be determined by the quality assurance manager and/or Director.

The original complaint or summary of the complaint and any written response shall be saved on a network drive. If an action occurred to resolve an issue raised by a complaint, a summary of the investigation and resulting action shall be saved with the original complaint on a network drive. If an MFR or corrective or preventive action was completed in response, a shortcut containing the name of the document should be saved with the original complaint on a network drive. All records of complaints and associated records shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

7.9.4. The Department is responsible for gathering and verifying all information to determine the validity of a complaint.

7.9.5. The Department shall acknowledge receipt of a complaint and provide the complainant with a progress report and/or outcome, when possible.

7.9.6. Prior to communication of the outcome to the complainant, the outcomes shall be reviewed and approved by the Director, or person authorized by the

Director, who was not involved in the original activity that was the subject of the complaint.

7.9.7. The Department shall provide the complainant with written notice of the resolution of the complaint, when practicable.

7.10. Nonconforming work

7.10.1. All nonconforming work shall be evaluated and appropriate corrections and/or corrective actions implemented. A deviation from a method may be identified through any review of the case, including, but not limited to, technical case review, administrative case review, proficiency testing, preparation for testimony, witness evaluation, internal audit, customer feedback, or annual performance appraisal.

a) Supervisor(s) shall notify the quality assurance manager of nonconforming work. Supervisor(s) and the quality assurance manager are responsible for recommending whether a corrective action is necessary and shall inform the Director if further action is recommended.
b) The Director shall authorize the halting of casework and breath test instrument inspections and the withholding of toxicology reports and inspection certificates, etc., as necessary.
c) The quality assurance manager and supervisor(s) shall assess the nature and significance of a method deviation. If the assessment is that the problem could be systemic, previous work shall be evaluated to determine any impact.
d) Any correction shall be prompt and appropriate to the significance of the method deviation. The acceptability of the nonconforming work shall be evaluated.
e) If there is an impact on a reported result, the customer shall be notified of the method deviation, and a corrected or amended report or inspection certificate shall be issued (ref. 7.8.8).
f) If halting of work occurs, the resumption of casework and breath test instrument inspections and the release of documents previously withheld shall be authorized by the Director.

7.10.2. All records shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

7.10.3. When an evaluation indicates that the method deviation affects the quality of the test or calibration, is a systemic problem, or could reoccur or cause a future noncompliance with a method, manual, or SOP, the corrective action procedures in 8.7 shall be followed.

7.11. Control of data and information management

7.11.1. The Department shall have access to data and information needed to perform testing and calibration activities.

7.11.2. Laboratory information systems (e.g., computers and servers used for the acquisition, processing, recording, reporting, storage, and retrieval of laboratory test or breath test instrument inspection data) shall be validated for functionality before being placed into normal usage. The Department ensures that uses of computer software, templates, reports, and macros developed by the Department are validated for acceptability of use and that the validation is documented in sufficient detail. Confirmation of calculations in PDFs and reports may be performed by comparison with a previously validated worksheet or Excel sheet with the same calculations or manual calculations and do not require a validation plan or summary. Whenever there is a change, including laboratory software configuration or modification to commercial software, it shall be authorized, documented, and validated prior to implementation.

7.11.2.1. If computer software is developed by the Department, it shall be validated according to an approved validation plan, and records of the validation shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

7.11.3. Laboratory information management systems shall be protected from unauthorized access by requiring a username and password for access or located in areas limited to access by approved staff. Department computers are maintained by the IOT to ensure proper functioning. IOT is required by agreement to provide environmental and operating conditions necessary to maintain the integrity of laboratory test and breath test instrument inspection data. The integrity and security of data entry, collection, storage, transmission, and processing are maintained and protected by IOT (ref. Records Management Manual). When a system failure occurs it shall be recorded, and appropriate immediate and corrective action shall be taken to restore the system to proper function.

7.11.4. For servers maintained off-site, the Department shall ensure that IOT complies with all applicable requirements of ISO/IEC 17025:2017 and AR 3125.

7.11.5. The Department shall ensure that instructions, manuals, and reference data relevant to the laboratory information system(s) are readily available to personnel.

7.11.6. Calculations and data transfers that are not part of a validated electronic process shall be subject to appropriate checks. The breath test instrument inspection or service record shall be technically reviewed in accordance

with the Breath Test Program Methods. Laboratory records shall be reviewed in accordance with the technical and administrative review processes outlined in the Laboratory Test Methods. During the technical review of records for either the Breath Test Program or the laboratory, data transfers shall be checked by the technical reviewer for accuracy. Data transfers that are secure and not subject to human error need not be verified.

7.11.6.1. The technical record shall include a record of the check(s) performed and identify the person performing the check(s). When practicable, a check shall be conducted by a person other than the one who performed the calculation or data transfer.

8. Management System Requirements

8.1.1. The Department shall establish, document, implement, and maintain a management system that can support and demonstrate the consistent achievement of the requirements of ISO/IEC 17025:2017 and AR 3125 and ensure the quality of Department results.

8.2. Management system documentation

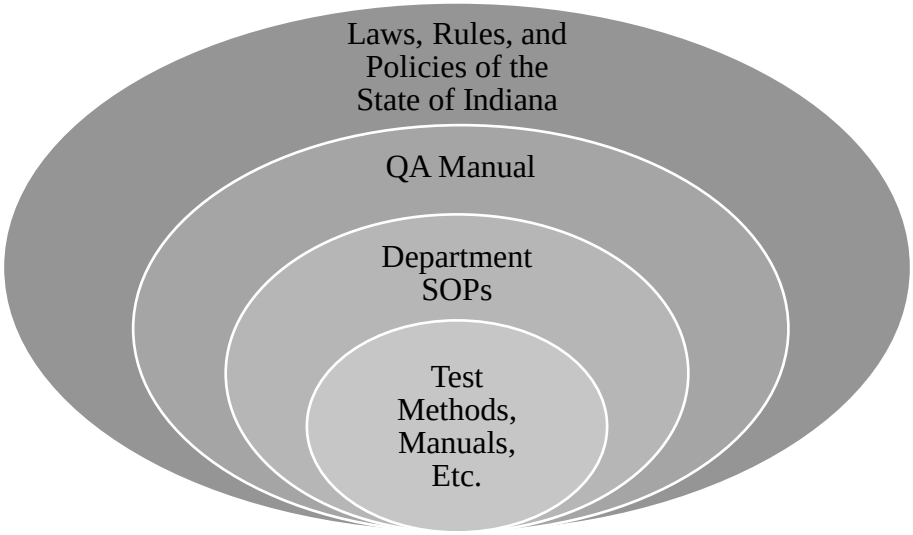
8.2.1. Department personnel shall familiarize themselves with relevant management system documents and adhere to manuals, SOPs, and test methods in the performance of their work.

8.2.1.1. When any of the following terms (including any variation thereof) are used in this document, written documentation is required: agreement, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, or specify.

8.2.2. The Department is committed to following sound professional practices and maintaining or improving the quality of forensic services it provides to its customers (ref. Admin-003, Mission Statement, Objective, and Values).

8.2.3. The Department shall comply with ISO/IEC 17025 and the ANAB forensic provider accreditation program. The Department has developed and implemented the management system described in this Quality Assurance Manual and is committed to continually improving its effectiveness by conducting internal audits, performance evaluations, forensic scientist upgrade interviews, and, as necessary, corrective and/or preventive actions.

8.2.4. The controlling documents of the Department include the Quality Assurance Manual and other manuals, Department SOPs, and test methods. The hierarchy of the Department's controlling documents is as follows:



8.2.5. The official version of a controlling document is maintained on a controlled network drive. Employees shall have access to network drives when onsite or through VPN accessibility, when practicable. A printed version of an electronic controlling document (e.g., test method, SOP) is an uncontrolled copy and may be made for reference purposes but shall be destroyed when the immediate use of the copy is no longer necessary. The Director or designee shall notify appropriate personnel of changes to controlling documents. Department personnel shall review and familiarize themselves with the controlling documents pertaining to their work.

8.3. Control of management system documents

8.3.1. The Department controlling documents provide administrative and technical operational instructions. Controlling documents are adopted to ensure the quality of the Department's work product. Approved and disseminated controlling documents shall be followed by all Department personnel through use of the versions saved in the controlled network folders labeled Manuals, Methods, SOP, and CAR-MFR-PAR (for MFRs or PARs that modify Manuals, Methods, or SOPs). Electronic versions located outside these folders or hard copies of controlling documents are uncontrolled copies.

Equipment and software manuals, textbooks, and journal articles maintained for general reference purposes are not subject to document control requirements. In this context, "general reference purposes" means that personnel are not required by the Department to read or follow specific procedures or instructions contained within the reference documents.

8.3.2. Controlling Documents procedures:

a) The Director and quality assurance manager shall review and approve all controlling document revisions. The Director is the issuing authority and controls the management system by formulating and enforcing written policies and procedural requirements.
b) Appropriate personnel shall review the Department's controlling documents each calendar year to verify their continued suitability. When an employee identifies the potential need for a new or revised manual, test method, or SOP, the proposed revision should be brought to the attention of the immediate supervisor or quality assurance manager. Prior to implementation, the Director shall review and approve a new or revised test method or manual and authorize its release by email to the quality assurance manager. For test methods and manuals with an effective date after January 1, 2019, a change shall be listed in a document history at the end of the new version of the document. The Director shall review and approve any other revision to a controlling document and authorize its release by email to the quality assurance manager. These revisions shall be tracked through comparison with previous versions.

c) Revisions to controlled documents shall be submitted for review with revised text identified in the document (e.g., Track Changes or use of colored or highlighted text). The current approved version of each controlling document is located in the following controlled electronic folders: Manuals, Methods, SOP, and CAR-MFR-PAR.
d) Access to controlled documents is available through VPN access or network access with a Department employee username and password.
e) The name of the document, date of issue or revision, page numbering, total number of pages, and issuing authority shall be included on each page of a controlling document except the title page.
f) When a controlling document revision is approved, the previous version shall be moved to the appropriate folder in the Archives folder on a network drive. A previous version of a controlling document shall be marked as archived. The document name of an electronically archived document version should include the beginning and ending effective dates of the document. Archived documents shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

8.4. Control of records

8.4.1. Quality records, laboratory technical records, and breath test instrument inspection, service, and certification records shall be maintained in an electronic format or as hardcopies.

8.4.2. The Records Management Manual describes the general policies of the Department regarding the retention, disclosure, and disposition of Department records. Breath test instrument service, inspection, certification, and measurement uncertainty records shall be indexed by instrument serial number and date of the record. Laboratory records shall be indexed by case number or sequence name of the batch. Records shall be legible and stored in a manner to prevent damage, deterioration, and loss. (ref. 7.5 for additional requirements for technical records)

8.4.2.1. All records shall be retained as required by state records retention and disposition schedules (i.e., General Records Retention and Disposition Schedule and Department of Toxicology Records Retention and Disposition Schedule https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

8.4.2.2. When an original record on paper or other media is captured as an electronic record and the original record is destroyed, the Department shall ensure that the electronic record is complete prior to destruction of the original record (ref. Records Management Manual sections 4.5 and 5).

8.4.2.3. All records shall be maintained in a secure location and shall only be released in compliance with Records Management Manual section 7.

8.4.2.4. Records stored electronically are on network servers that are backed up regularly by IOT. Electronic records of the Department are only accessible to department personnel and authorized users. Amendments to LIMS records are tracked by an audit trail. Electronic signatures using LIMS login IDs or digital IDs stored in the Windows Certificate store and protected by individual Windows logins shall be used to track amendments to electronic documents after the date of signature.

8.4.2.5. All records shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

8.5. Actions to address risk and opportunities

8.5.1. The Department shall continually improve the effectiveness of its management system through the use of the quality policy and objectives (ref. 8.2.2), analysis of data (ref. 7.7.3), evaluating for improvements (ref. 8.6), performing corrective actions (ref 8.7), auditing results (ref. 8.8), and performing management reviews (ref. 8.9). Continual assessment of its calibration and testing activities allows the Department to ensure the management system achieves its intended purposes, find opportunities for improvements in the fulfillment of its mission, and prevent or reduce undesired impacts or potential failures in accomplishment of its mission.

8.5.1.1. The Safety Manual shall be reviewed and updated as appropriate as the risks and opportunities related to the health and safety of Department personnel are considered.

8.5.2. Potential risks and opportunities for improvement shall be evaluated each calendar year as part of the Management System Review. This may be accomplished through feedback from Department personnel or other means. Any change made as a result of the evaluation of risks and opportunities shall be evaluated for effectiveness the following year as part of the Management System Review. The effectiveness of a corrective action shall be evaluated as part of the Management System Review, as appropriate.

8.5.3. An action taken to address a risk or opportunity shall be proportional to the potential impact on the validity of Department results.

8.6. Improvement

8.6.1. Department personnel shall identify needed improvements and potential sources of deviation (e.g., in upgrade interviews, performance of an annual audit, proficiency test feedback, direct observation, and input from customers and personnel). When a needed improvement and/or potential source of deviation is identified, it shall be reported to the supervisor(s) and/or quality assurance manager. The supervisor(s) and/or quality assurance manager shall evaluate the information to determine whether any action is appropriate (ref. 7.10 and 7.9). When warranted, the supervisor(s) and/or quality assurance manager shall develop, implement, and monitor an action plan to make improvements and/or reduce the likelihood of occurrence of deviations. Action taken shall be documented in a Corrective and/or Preventive Action Report following the same procedure used for 8.6 or 8.7, issuing an MFR, and/or by a method update, if applicable. If action is not warranted, the reporting personnel shall be notified and provided with an explanation for this determination.

8.6.2. The Department shall seek feedback from customers through surveys, feedback, complaints, and evaluations of testimony to improve the management system, testing, breath test instrument inspections, testimony, and customer service.

8.7. Corrective actions

8.7.1. The Department policy regarding corrective actions is as follows:

Supervisor(s) and/or the quality assurance manager are responsible for implementing corrective actions. When a deviation from a method, manual, or SOP has been identified, a corrective action shall be considered.

Supervisor(s) shall notify the quality assurance manager of a deviation from a method, manual, or SOP. Supervisor(s) and the quality assurance manager are responsible for recommending whether a corrective action is necessary, based on discussions with the reporting party, personnel, and supporting documentation, and shall inform the Director if further action is recommended.

Each Corrective Action Report, Preventive Action Report, and/or MFR shall be named using the following convention: yyyy_[Report Type]_mmdd Subject of the Report, where the month and day correspond to the date of the issuance (e.g., 2018_MFR_0101 Instrument Parameters Updated). A supplemental report shall be named the same as the original report with the addition of a letter in the name (beginning with “A”) after the date and stored with the original report.

A deviation that occurred prior to but was discovered after the approval of a Corrective and/or Preventive Action Report may be addressed by adding a

supplemental Corrective and/or Preventive Action Report to the previous Corrective and/or Preventive Action Report.

If the supervisor(s) and/or the quality assurance manager determine(s) a corrective action or MFR is appropriate, a Corrective and/or Preventive Action Report or MFR shall be completed and listed in the CAR-MFR-PAR Log.

The final review and approval of a corrective action shall be by the quality assurance manager and Director. Resumption of casework or inspections, if necessary, shall be authorized by the Director. Preventive actions and MFRs shall be reviewed and approved by the quality assurance manager and Director before being issued.

a) When nonconforming work occurs, the Department shall respond to the nonconformity by taking action to control and correct it and/or address the consequences, as applicable (ref. 7.10).
b) Corrective action shall begin with identification of the extent of the deviation and any past or future impact on the quality of Department work product or objectives. A cause analysis shall include review of the processes involved, identification of factors that contributed to the deviation, and an audit of the associated past and current records. The deviation, investigation findings regarding the cause(s) of the deviation, and solution(s) to address the deviation and reduce the risk of future occurrences shall be summarized in the Corrective and/or Preventive Action Report or MFR, as applicable. If the deviation does not impact the validity of the results and is not included in a corrective/preventive action report or MFR, it shall be documented in the deviation log.
c) When corrective action is appropriate, the Department shall select and implement the action(s) most likely to mitigate the consequences of the deviation and reduce the risk of recurrence. Corrective action shall be appropriate to the magnitude of the problem. The Department shall document and implement any required change identified in a corrective action investigation.
d) The quality assurance manager and/or supervisor(s) shall monitor the results to ensure that the corrective action taken has been effective. The proposed monitoring should be outlined in the Corrective and/or Preventive Action Plan section of the Corrective and/or Preventive Action Report. The effectiveness of each Corrective and/or Preventive Action shall also be evaluated, when practicable, as part of the management system review for the year in which it was implemented. The effectiveness of a Corrective and/or Preventive Action may also be evaluated during subsequent management system reviews. When warranted, the Department shall conduct additional audits of operations to confirm effectiveness of a corrective and/or preventive action. Such an audit may be combined with the annual internal audit or management system review.

e) Any updated information regarding risks or opportunities shall be considered (ref. 8.5.2).
f) A corrective and/or preventive action may include changes to the management system.
g) The timeframe for completion of a corrective action shall be related to the severity of the deviation and depth of investigation required. After the deviation has been identified, action to correct the initial deviation should be completed in 30 days. Investigation and cause analysis of the deviation (ref. 4.11.2) should be completed in 90 days, but may exceed this timeframe (e.g., if an additional deviation was found during the investigation and incorporated in the corrective action). Implementation of a change to the management system as a result of the corrective action should be completed within 6 months, but may take longer, depending on the extent of the change needed.
h) ANAB shall be notified within 30 days of any nonconformance that affects the results.

8.7.2. A corrective action shall be appropriate as related to the effect of the nonconforming work.

a) A corrective action shall be implemented when the nature or cause of the deviation raises immediate concern about the quality of the work being performed.
b) A corrective action and/or MFR shall be implemented when the nature or cause of the deviation may affect the quality of the work but is not persistent or serious enough to raise immediate concern about the overall quality of the work product.
c) An MFR may be issued when the nature or cause of the deviation is of minimal effect or significance, is unlikely to reoccur, is not systemic, and/or does not significantly affect the fundamental reliability of the work product.
d) A deviation may be addressed by supervisory personnel and shall be documented in the technical record and deviation log.

8.7.3. The Department shall retain records of a nonconformity, including information regarding the nature of the nonconformity, cause(s), any subsequent action taken, and any results of a corrective action. Records shall be retained as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

8.8. Internal audits

8.8.1. The internal audit shall provide information regarding whether the management system conforms to the Department's controlling documents, ISO/IEC 17025:2017, and AR 3125. The internal audit shall be used as a tool to evaluate the effectiveness and maintenance of the management system.

8.8.2. The quality assurance manager shall plan and organize annual internal audits to ensure that the Department complies with the requirements of the ANAB forensic provider accreditation program and the management system. The annual internal audits shall include direct observation of a sampling of breath test instrument inspections and laboratory testing and review of the audit trail of at least one inspection, one drug analysis, and one volatiles analysis. The activities of the internal audit may span the entire calendar year, but at least one report shall be submitted summarizing the findings of the annual internal audit per calendar year.

The quality assurance manager shall ensure that internal audits are carried out by personnel who are trained and qualified and who are, wherever resources permit, independent of the activity to be audited. During an internal audit, the auditing personnel shall consult with other personnel to ensure that all significant changes made in the past year to personnel, facilities, services, or procedures are documented in the audit report. Internal audit reports shall be forwarded to the Director for review.

If nonconforming work is found, the supervisor of the work shall be informed of the nonconformity and shall work with the quality assurance manager in the implementation of effective and prompt corrective action. Each internal audit report shall define the criteria and scope for each audit. A deviation from standards or established criteria discovered as a result of an internal audit shall be documented. This documentation shall describe any remedial action to be taken and the timeline for completion. An affected customer shall be notified in writing when an internal audit indicates the validity of an analytical result may have been affected by a deviation.

Follow-up audit activities (e.g., management system review of the following year) shall verify and record the implementation and effectiveness of any corrective and/or preventive action taken. Copies of internal audit reports shall be retained on a network drive as required by state records retention and disposition schedules (https://www.in.gov/iara/divisions/records-management/state-retention-schedules).

8.9. Management system reviews

8.9.1. The quality assurance manager shall organize management reviews, which shall be conducted to review the Department's management system, laboratory testing, and breath test instrument inspection activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

8.9.1.1. The Department shall conduct a management system review at least once each calendar year.

8.9.2. A management system review shall take account of:

a) changes in internal and external conditions relevant to Department work;
b) fulfillment of Department objectives;
c) suitability of SOPs, manuals, and test methods;
d) status of actions taken as a result of a previous management system review (as appropriate);
e) outcomes of recent internal audits;
f) corrective and preventive actions;
g) assessments by external bodies;
h) changes in type or volume of work;
i) customer and personnel feedback;
j) complaints related to quality assurance;
k) effectiveness of any changes made to improve workflow or performance of calibrations or testing;
l) adequacy of resources;
m) results of risk identification;
n) outcomes of measures taken to assure validity of results; and
o) other relevant factors, such as quality control activities, resources, and personnel training.

8.9.3. The record of a management system review shall list any actions taken related to effectiveness of the management system or its processes, improvements to laboratory activities related to fulfilment of the requirements of ISO/IEC 17025:2017 and AR 3125, provision of required resources, and any need for change. The Director shall ensure that any plan of action is completed in an appropriate timeframe.

9. Document History

Effective Date	Version	Description of Activity or Revision	Approved By
10/23/18	1	Initial issue	Ed Littlejohn Sheila A. Arnold, PhD
03/15/19	2	Update definitions: 3.6.1, 3.10.1, 3.11.1, 3.17, 3.25.1, 3.27.1, and 3.48.1 Added definition: 3.15.1 and 3.27.2 Modified: 4.3.2.2 b) & c), 4.3.3.4, 4.11.1, 4.11.4, 4.11.5, 4.12.2, 5.1.4, 5.4.2.2, 5.4.7.2 a), 5.6.3.1, 5.6.3.4 a) & b), 5.8.1.1 g), 5.10.1.1, 5.10.2 e) 1. & 2., and 5.10.4.3.	Ed Littlejohn Sheila A. Arnold, PhD
03/26/19	3	Updated page numbering, added "Uncontrolled Document" watermark, and print date.	Ed Littlejohn Sheila A. Arnold, PhD
04/29/19	4	Added: 2.3 Modified: 5.9.4 and 5.10.2. e) j)	Ed Littlejohn Sheila A. Arnold, PhD
02/24/20	5	Updated to comply and follow the format of ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories and ANAB Forensic Science Testing and Calibration Laboratory Accreditation Requirements, AR 3125	Ed Littlejohn Sheila A. Arnold, PhD
03/01/21	6	Updated 260 IAC citations in 3.11.1, 3.29.1.2, 6.4.13 e) 1., 7.8.4.1, 7.8.6.1, 7.8.6.2, to IAC 2.5 instead of IAC 2. Modified: 7.1.5, 7.5.2, 7.7.1 8., 7.8.1.2.2, 7.8.7.3, 7.9.3, 7.9.4, 7.9.6, 7.9.7, and 8.5.1	Ed Littlejohn Sheila A. Arnold, PhD
02/10/22	7	Modified: 4.1.3.1 c), 6.5.1.1 b), and 7.8.1.3	Ed Littlejohn Sheila A. Arnold, PhD
2/15/23	8	Updated to reflect new organizational chart, including switching "quality control coordinator" to "quality assurance manager" and amend naming of CAR/PAR/MFR	Christina Beymer Kathleen Toomey
12/22/23	9	Incorporated 2023 MSR draft and MFRs 2023_MFR_0630 and 2023_MFR_0831. Updated documentation regarding method modifications from MFRs.	Christina Beymer Kathleen Toomey
4/12/24	10	Incorporated AR 3125, 2023 revision. Improved consistency of abbreviations. Updated organizational chart. Minor grammatical edits throughout.	Christina Beymer Kathleen Toomey