QUALITY/PROCEDURE MANUAL

Contents

REVISION HISTORY

Revision #	Description of Changes
1	Original Qualtrax version- updated quality policy and objectives, scope, normative references, definitions, org chart, and sections 14.1.5.f, 14.2.1.2, 4.2.2-4.2.8, 4.3.2.1, 14.3.2.1, 4.3.2.2, 4.3.3.1, 4.3.3.3, 14.3.3.4, 14.4.1.1, 14.4.4.1, 4.5.1, 4.5.4, 14.6.1.1.3, 14.6.3.5, 14.6.5.1, 14.6.5.2, 14.9.1a, 14.9.1b, 14.9.1c, 4.9.2, 14.11.1.1, 4.11.2, 14.11.3.1, 14.11.3.2, 14.11.3.3, 14.11.3.4, 14.11.3.5, 14.11.4.1, 14.11.4.2, 4.11.5, 14.12.2, 14.13.1.2.4, 14.13.1.2.7, 14.13.1.4, 4.13.2.3, 14.13.2.4, 4.13.2.5, 14.13.2.13.1, 14.14.1.1, 14.14.1.6, 14.14.1.7, 14.14.1.9, 14.14.1.11, 4.14.1.2, 4.14.4, 14.15.2, 4.15.1.1, 4.15.1.2, 5.1.3.1, 15.2.1.1.1, 15.2.1.1.2, 15.2.1.1.3, 15.2.2.1, 15.2.2.8, 5.2.6.2.4, 5.3.6, 15.4.1.2, 15.4.3.3, 15.4.3.5, 15.4.3.11, 15.4.5.2.4, 15.4.5.3, 15.4.6.2.2, 5.4.7.2, 5.5.6, 5.5.9, 15.6.3.2.1.2, 5.6.3.3, 15.8.1.f, 15.9.3.4, 15.9.3.1.1, 15.9.3.1.2, 5.9.3.2, 5.9.3.4, 15.9.4.2.2, 15.9.6.2, 15.9.6.5, 5.9.6.7. 5.9.7, and Appendix A
2	Updated definitions, org chart, and sections 14.1.4.3, 14.1.5.c.8, 4.1.5j, 14.6.5.1, 14.13.1.2.2, 14.13.1.2.3, 4.13.2.2.1, 4.14.1, 14.14.1, 15.2.2.1, 15.2.6.1.4, 15.2.6.1.3, 15.2.6.1.4, 15.3.4.1a1.1, 15.4.2, 15.8.1.b, 15.8.4.7, 15.8.4.1.6, 5.8.4.5, 15.8.4.6.1.3, 15.9.3.1.1, 6.2.2, 6.3.2, 6.3.3
3	Updated to comply with ISO 17025:2017 standards and numbering. Miscellaneous clarification updates throughout
4	Updated scope, 5.3, 15.5b.2, 15.7a.1, 16.2.5b.2, 16.2.5e.2.9, 16.2.5c.3.6, 6.2.5e, 6.2.6a, 6.4, 16.6.2b, 16.2.2d.2. 17.1.1.2, 17.2.1.7.2.2, 7.2.2.1, 17.2.2.1.2.2, 17.4.1.10, 17.4.4.9.1, 17.4.4.10
5	Updated definitions of correction and corrective action, quality objectives, normative references, 15.5b.2, 7.1.1, 17.1.1.1, 7.1.8, 7.4.1, 17.4.1.12, 17.4.2.4, 17.4.5, 17.5.1.1, 17.5.1.2.8, 17.8.1.1.2.2, 17.8.1.1.2, 7.9.3, 17.11.3 e), 18.3.1.1, 18.3.2.f1, 9.2.3
6	Updated formatting throughout for consistency, and sections 4.2.1.5, 14.2.1.11, 15.5b.2, 15.5c, 16.2.5b.2.4.5, 16.2.5f.3.3, 16.6.2a.4, 17.1.1.1, 17.1.1.2, 7.4.1, 17.4.4.7, 17.4.4.9.4, 17.4.4.11, 17.7.2.2, 17.7.2.3, 17.7.2.7.1, 7.8.1.2, 17.8.1.2.1, 17.8.1.2.2, 17.8.1.2.3, 7.8.1.3, 17.8.1.3, 8.9.2, 18.9.2.1
7	Updated Quality Objective 4, normative references, sections 15.5b.1, 15.7a.1.3, 16.2.5c.2.10, 17.2.1.7.2, 17.2.1.7.2.1,

	17.2.1.7.2.2, 17.4.1.10.1, 17.4.4.7, 17.7.1.3, 17.7.1.3.2, grammatical changes made throughout

MISSION STATEMENT

Providing public safety across the State of Idaho through law enforcement excellence.

QUALITY POLICY

Idaho State Police Forensic Services will provide analysis and testimony regarding those examinations to the people of Idaho that meets or exceeds the expectations and requirements of its customers free of bias due to external or internal influence and will establish, maintain and adhere to a management system that is compliant with recognized national and international standards for analytical laboratories for the purpose of achieving the highest level of quality possible.

Idaho State Police Forensic Services will review its established management system at least annually for compliance with national and international standards and for its capability to continue to meet established goals for customer satisfaction and achievement of management system objectives.

Idaho State Police Forensic Services will ensure that all personnel within the organization are aware of the management system requirements, including the individuals' responsibility to adhere to the management system, and will provide the resources necessary to implement, maintain, and continually improve the management system.

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The commitment to implement a successful Quality policy begins with the organization's executive management and is strengthened by a commitment from laboratory and discipline-level management. The Laboratory System Director affirms their commitment to this policy by the documented approval of this manual.

Quality Objectives

1. To receive customer feedback, analyze, consider, and respond to the feedback as part of the review of the management system.

2. To meet agency adopted turnaround times 90% of the time for each discipline as outlined in the current Idaho State Police Strategic Plan.

3. To comply with established ISO 17025 accreditation standards.

4. To review and evaluate current Organization of Scientific Area Committees (OSAC) Registered Standards and implement, as appropriate.

5. To provide training to all staff in the requirements and responsibilities of the quality management system.

6. To maintain staff, facilities, and equipment capacity to satisfy turnaround requirements and effectively and efficiently meet demands.

7. To establish key initiatives (including quality objectives) for Forensic Services for the coming year after annual review.

8. To annually establish, review, and measure individual employee's goals and objectives and their employee development plan to determine consistency in meeting Forensic Services and Idaho State Police strategic plans.

9. To undergo periodic third-party evaluations for compliance with national and international standards and the internal management system.

10. To provide forensic laboratory analysis to the criminal justice system of Idaho and appropriate court testimony regarding the examinations performed, support programs within police agencies that have Forensic Services involvement, and provide training to the criminal justice system.

1 Scope

Idaho State Police Forensic Services, hereafter identified as Forensic Services provides assistance at crime scenes, laboratory examinations, and interpretation and presentation of the findings in legal proceedings or for use in investigative and intelligence purposes.

This Quality Manual is applicable to the following examinations:

The laboratories of Forensic Services offer examinations in the following disciplines and subdisciplines:

Coeur d'Alene Lab	Meridian Lab	Pocatello Lab
Drug Analyses, Quantitative Analyses of Meth, Cannabis Typification	Drug Analyses, Cannabis Typification	Drug Analyses, Cannabis Typification
Blood and Urine Toxicology		Blood and Urine Toxicology
Alcohol and Volatile Analysis, Breath Alcohol Calibration	Alcohol and Volatile Analysis, Breath Alcohol Calibration	Alcohol and Volatile Analysis, Breath Alcohol Calibration
Firearms/Toolmarks		
	DNA Casework, Body Fluid Identification, DNA Database Analyses	
Ignitable Liquids		
	Latent Print Processing and Comparisons	

This Manual contains both quality policies and administrative policies for Forensic Services. These policies are applicable to both testing and calibration activities and staff is expected to follow them whenever Forensic Services staff is performing any job related function regardless of laboratory location or duty. However, the administrative policies are not part of the quality management system and are neither audited for nor enforced as part of the quality management system.

2 Normative References

A2LA R101 - *General Requirements: Accreditation of ISO/IEC 17025 Laboratories*, November 4, 2021

A2LA R102 - *Conditions for Accreditation*, March 19, 2021

A2LA R103 - *General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories*, June 24, 2021

A2LA R105 - *Requirements When Making Reference to A2LA Accredited Status*, October 5, 2020

A2LA R205 – *Specific Requirements: Calibration Laboratory Accreditation Program,* October 5, 2020

A2LA R221 - *Specific Requirements - Forensic Examination Accreditation Program – Testing and Calibration*, October 5, 2021

A2LA P102 – *Policy on Metrological Traceability*, September 13, 2021

A2LA P103 - *Policy on Estimating Measurement Uncertainty for Testing Laboratories*, October 5, 2019

A2LA P103b – *Policy on Estimating Measurement Uncertainty for Life Sciences Testing Labs,* March 16, 2021

A2LA P103e - *Annex: Policy on Estimating Measurement Uncertainty for Forensic Conformity* Assessment Bodies, November 12, 2020

A2LA P115 – *Technical Consensus Decisions from the Forensic Examination Advisory Committee,* February 1, 2021

International Organization of Standardization (ISO) / International Electrochemical Commission (IEC), ISO/IEC17025 - *General requirements for the competence of testing and calibration laboratories*, 2017. (ISO/IEC 17025:20017 (E))

U.S. Department of Justice (DOJ), Federal Bureau of Investigations (FBI), *Quality Assurance Standards for DNA Databasing Laboratories*, 2020.

U.S. Department of Justice (DOJ), Federal Bureau of Investigations (FBI), *Quality Assurance Standards for Forensic DNA Testing Laboratories*, 2020.

3 Terms and Definitions

These definitions apply when the following words or phrases are used in this Quality Manual.

- **Administrative documentation (records)** – documentation either received or generated by the laboratory. Administrative documentation includes records such as case related conversations, evidence receipts, description of evidence packaging and seals, investigative reports and other pertinent information.
- **Administrative review** – a procedure performed to ensure that the examination reports issued by the staff of Forensic Services are editorially correct and to ensure that the examination reports and their documentation are compliant with Forensic Services policies and procedures.
- **Agency** – ISP Forensic Services customers (submitting agency).
- **Amended Report** – a report that supersedes the original report to add or correct administrative or technical information.
- **Analytical methods** – written or electronic scientific methodologies approved for use by ISP Forensic Services staff for performing analyses (previously referred to as SOPs).
- **Audit** - a review conducted to compare the various aspects of the laboratory's performance with a standard for that performance.
- **Bench standard** – A limited quantity of a compound that is traceable back to a manufacturer and that is authenticated by comparing a spectrum from GC/MS or FTIR with literature, library, or a previously authenticated standard. Some old bench standards may not be completely traceable back to a manufacturer as traceability of standards is a recent policy for ISPFS.
- **Calibration** – A set of operations which establish under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.
- **Case record –** all administrative records and technical records pertaining to a case that are received or generated by the laboratory. This may include, but is not limited to, the administrative and examination documentation maintained in the case file, electronic case file, electronic data, digital images, instrument maintenance and verification documentation, and reagent and standard quality control documentation.
- **Chain of custody** – documented trail of possession or location of evidence.
- **Complaint** – an expression of concern regarding some aspect of the management system, casework analysis or other work product, a report of analysis either written or presented in testimony, or the behavior of a staff member. While it is preferred to have a complaint received in written form; verbal complaints, anonymous complaints, or complaints from persons who wish their names to be held in confidence are accepted.
- **Contract** – a request is made when evidence is submitted to Forensic Services anticipating that specific examinations will be performed. A tender is made when Forensic Services agrees/disagrees to provide the examination subject to its conditions. The contract is the agreement, whether written, electronic, or verbal, by both parties to the examination(s) that will be performed.
- **Correction (immediate action)** – measures taken to address immediate concern; not to be confused with corrective action.

- **Corrective action** – action that is reactive to eliminate the cause of a current nonconformity, or other undesirable situation, taken to prevent recurrence.
- **Critical supply/service** – Foundational to the examination performed. Supplies, consumables or services which can't be internally verified during the course of the analysis. The user determines that they are acceptable by virtue of the dependability of the supplier or by verifying them through some analytical process different from routine analysis. (They are not critical if they are part of an analytical process and their reliability is verified as part of that analysis.)
- **Customer –** organization or person that receives a product or service.
- **Cycle of accreditation –** the time period between one accreditation to the next.
- **Department -** Idaho State Police (ISP), a functional or administrative division of Idaho State Government.
- **Document (hard copy or electronic) –** any policy, quality or analytical method, form, normative reference, etc. providing information on some aspect of the management system of Forensic Services.
- **Examination documentation** – see technical record.
- **Executive management (top management) –** person or group of people who direct and control Forensic Services at the highest level. This would include the ISPFS Management Assistant, laboratory managers, the quality manager and the Laboratory System Director.
- **Forensic Services – (ISPFS or FS)** the entity comprised of three forensic laboratories (located in Coeur d'Alene, Meridian, and Pocatello), all related laboratory staff and functions with its overall headquarters in Meridian. The three laboratories are regulated by common policies, procedures and management.
- **Frozen –** At or below zero degrees Celsius.
- **Idaho State Police –** a department within the Idaho State Government consisting of various units (one of which is Forensic Services) with the designated role of handling certain aspects of law enforcement and business regulations on a statewide basis.
- **ILIMS –** Idaho Laboratory Information Management System (ILIMS) also referred to as the Laboratory Information Management System (LIMS). The electronic system used to maintain chain of custody and case record information.
- **Individual Characteristic Database --** A collection, in computerized, searchable form, of features associated with an object or person uniquely or with a high degree of probability.
- **Intermediate checks** – checks needed to maintain confidence in calibration.
- **Laboratory developed method –** an analytical method that is developed within a Forensic Service laboratory.
- **Nonconforming work –** work that does not meet one or more requirements of the quality system.
- **Non-standard analytical method** – analytical methods developed by technical organizations, published in relevant scientific texts or journals, provided by instrument or reagent manufacturers, or analytical methods obtained from other laboratories.
- **Normative references** – these are the external quality documents upon which the Forensic Services management system is based. Forensic Services complies with the quality standards in these documents

- **Performance verification** – a set of operations to determine if a piece of equipment, instrumentation, reagent, or control is working correctly within manufacturer's specifications or ISP specified parameters.
- **Preventive action –** action that is proactive and identifies potential nonconformities
- **Pre-Log** – The secure webpage used by ISPFS for agencies to register case and item information. Pre-Log is the customer interface with the laboratory for case information such as submission, lab process, and lab reports.
- **Primary standard** – A compound that is traceable back to a manufacturer and that is authenticated by comparing with literature, library, or a previously authenticated standard.
- **Proper seal –** a seal that prevents loss, cross-transfer, or contamination while ensuring that attempted entry is detectable.
- **Quality –** adhering to generally recognized standards of good laboratory practice and policies and procedures set forth in the management system.
- **Quality record -** written or electronic text that is used to demonstrate compliance with the management system.
- **Reagent –** a substance used because of its chemical or biological activity or because it takes part in or brings about a particular chemical or biological reaction.
- **Record –** an electronic or paper document that provides evidence of: a condition, work performed, activities conducted, and/or quality for archival purposes.
- **Reference collections –** groups of items intended to assist in determining the class or individual characteristics of a piece of evidence.
- **Reference material–** Material or substance, one or more of whose property values are sufficiently homogenous and well-established to be fit for its intended use in measurement or in examination of nominal properties.
- Example 1. Some reference materials used for measurement: The gauge blocks in firearms, the matrix controls in blood alcohol, the simulator solutions used to calibrate breath testing instruments.
- Example 2. Some reference materials used for nominal properties: Drug standards in controlled substances, non-extracted reference material in urine toxicology, DNA with a specific nucleotide sequence.
- **Reference standard –** Standard with highest metrological quality available in a laboratory of Forensic Services from which measurements made in a laboratory are derived. Reference standards are used to calibrate equipment with output in SI or U.S. customary units of measurement. ISPFS does not currently use reference standards.
- **Refrigerated –** At a temperature above -2 degrees Celsius and below 12 degrees Celsius.
- **Request –** the analysis asked for by the submitting agency on evidence received in the laboratory.
- **Reset Report** – a laboratory analytical report that contains incorrect or incomplete administrative or technical information and has been removed from electronic distribution.
- **Root cause analysis** – a process of fact finding used to evaluate all aspects of testing or the management system to identify the basis of the nonconformity.

- **Sample selection** – the process used to choose the evidence or portions of the evidence that will be examined. Sample selection involves such considerations as amount of evidence available, significance of the evidence, number of specimens available for analysis, etc. Sample selection is not sampling, which is a statistical process of inferring properties of substances without performing analysis.
- **Sampling/Sampling plan –**Sampling is a process whereby examining a portion of a substance allows the analyst to make inferences about the properties of the whole. A sampling plan is documented in an analytical method and describes how the representative sample is collected, and the inferences that can be made by the analyst about the properties of the whole.
- **Secondary standard** – A laboratory produced or casework derived sample that has been compared to a primary or bench standard by utilizing GC/MS or FTIR.
- **Standard analytical method –** an officially recognized analytical method published in international, regional, or national standards. Examples of standard analytical methods are contained in *Official Methods of Analysis of AOAC INTERNATIONAL.*
- **Subcontract –** to engage an outside laboratory to perform examinations, which Forensic Services, by an implied or explicit contract, previously agreed to perform. (This definition applies only when Forensic Services has an approved analytical method(s) and a qualified analyst to perform the examination but chooses to forward the sample to a laboratory, which is not a part of Forensic Services, for analysis.)
- **Technical records (examination documentation) –** written or electronic text or data that result from carrying out examinations. It includes examination notes, reference to analytical methods followed, standards and controls used, diagrams, printouts, photographs, observations, and results of examinations.
- **Technical review –** a review of the case notes and the report to ensure that proper technical procedures were used and documented and that the analytical findings and documentation support the conclusions in the report.
- **Technical verification** – a process of independently performing a comparison or analyzing evidence to determine if the reviewer comes to the same conclusion regarding the analysis as the analyst.
- **Tender –** an offer of denial or acceptance of a request to complete work.
- **Traceability** – property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. (International Vocabulary of Basic and General Terms in Metrology, second edition 1993)
- **Uncertainty of measurement –** an estimated value, within a specified confidence limit, that depicts a value of variability that can be attributed to the result or test.
- **Undue influence or pressure –** any action or communication by an individual or individuals, either employed with Forensic Services or external to it, whose purpose or impact is to affect the technical judgment of Forensic Services staff, to adversely impact the compliance of Forensic Services with its normative references, to adversely affect the quality of work, or to unduly influence the expert opinion of personnel within Forensic Services.

- **Unique identifier –** the laboratory case and item number assigned to a piece of evidence that distinguishes it from all others.
- **Validation –** a process for acquiring the necessary information to assess equipment/instrumentation, a technique, and/or analytical method to determine if the equipment, technique, and/or analytical method is fit for the intended use.
- **Verification –** confirmation, through supporting data, that the requirements for a specific intended use or application have been fulfilled.
- **Work instructions –**specific steps for performing a procedure or operating a piece of equipment/instrumentation.

4 General Requirements

4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management is committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

14.1.3.1 Undue Influence: The Idaho State Police Forensic Services shall not engage in activities that may diminish confidence in the laboratory's operational integrity, competence, impartiality or judgment. Forensic Services strives to ensure that there is no inappropriate influence on the professional judgments of its management and personnel, including any internal or external pressures that may adversely affect the quality of their work. In order to insulate staff from undue influence, the following procedures are in place:

14.1.3.1.1 ISP Conduct Expectations 01.02 (Conduct Expectation in ISP Employee Handbook) which contain 18 specific directives, (e.g. honesty, integrity, customer service, not accepting gratuities, not using one's position to favor any segment of the community, etc.).

14.1.3.1.2 ISP outside Employment procedure 03.06 (Outside Employment in ISP Employee Handbook), which prohibits secondary employment that constitutes a conflict of interest with their ISP position.

14.1.3.1.3 ISP Forensic Services, in accordance with ISP and Idaho Department of Human Resources procedures, conduct annual performance evaluations and provides annual performance expectations for each of its employees. Managers/Supervisors evaluate each employee on their individual performance based on the established performance competencies/criteria.

14.1.3.1.4 The Forensic Services procedure 17.9 (Complaints in ISP Employee Handbook), ISP procedure 03.01 (Incident Review and Administrative Investigation in ISP Employee Handbook), 03.02 (Complaints in ISP Employee Handbook) and 03.10 (Problem Solving in ISP Employee Handbook) and 03.13 (Progressive Discipline and Disciplinary Due Process in ISP Employee Handbook) provide remedies for conflict resolution for employees, supervisors, managers, and customers.

14.1.5.1.5 The Idaho State Legislature sets the annual budget for each state agency. A budget is appropriated to each division within ISP. The Police Services Major is responsible for building the budget for Forensic Services in consultation with the Laboratory System Director. The Laboratory System Director is responsible for allocation and distribution of the FS budget.

14.1.3.1.6 Casework prioritization is the responsibility of the analyst with direction and authorization from their supervisor. Intersession from Lab Managers and/or the Laboratory System Director may be requested or imposed if undue pressure is exerted upon any analyst to improperly adjust casework.

14.1.3.1.7 Rush Cases: While both are important, ISP Forensics values the quality of analysis more than the turn-around-time. An analyst who accepts a rush case is responsible for ensuring that the time frame given will not compromise established processes and procedures that safeguard quality analysis. Supervisors are also responsible to ensure that quality procedures are maintained and may adjust the time frame of a rush case if it becomes evident that technical requirements demand additional time in order to ensure a quality product. Analysts and supervisors are under no obligation to complete any rush cases by the defined deadlines if adequate time cannot be dedicated to the case in order to ensure quality standards are being met.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel.

14.1.4.1 Top management will assess and identify risks to impartiality annually in the management review.

14.1.4.2 If a complaint is received it will be evaluated for risks to impartiality.

4.1.5 If a risk to impartiality is identified, the laboratory shall demonstrate it eliminates or minimizes such risk.

14.1.5.1 If a risk to impartiality is identified, a "Quality Action Report" (QAR) will be initiated if appropriate, or actions will be defined and initiated in the management review.

4.2 Confidentiality

4.2.1 The laboratory is responsible for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall notify the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory

and customer, all other information is considered proprietary information and shall be regarded as confidential.

14.2.1.1 *Employees of forensic services are required to keep confidential all information obtained in their official capacities. Employees will not disseminate, access, or disclose any confidential information obtained in their official capacities except where legally authorized or per ISP and Forensic Services procedures and policies. Unauthorized distribution of confidential information is forbidden.*

14.2.1.2 *The Public Records Act, Idaho code 9-338 through 9-349 in conjunction with rules established by this agency governs the release of all department documents and records to the general public.*

14.2.1.3 *The procedure for release of information through discovery in criminal cases is contained in the Idaho Criminal Rules, 16 (b)*

14.2.1.4 *The procedure for the release of information through a court order in criminal cases is contained in the Idaho Criminal Rules, 16 (b)(8)*

14.2.1.5 *Results of examination shall only be released to the submitting agency or the prosecutor having jurisdiction over the case if the case was submitted by a police agency. Unless they are the submitting entity, the results shall be released to the defense attorney or other entity through a discovery, court order, or the permission of the prosecutor or a representative from the submitting agency. Evidence submitted by the public defender in a criminal proceeding shall be given the same measure of confidentiality in the laboratory as evidence submitted by a police agency or prosecutor. The results shall only be released to the public defender or his investigator. The prosecutor can obtain the results only with the permission of the public defender, through a valid discovery, or a court order (I.C. 19-861). As agreed to in the contract, blood/urine alcohol and/or toxicology results may also be released to the Idaho Transportation Department. Reports may be released as hard documents, faxes, email attachments, and/or electronically through a secure web interface. The web interface requires a unique login, secure password, and a user agreement to be signed by each user.*

Calibration certificates for breath testing instruments submitted to ISPFS for calibration are accessible on the ISPFS public website. The certificate is available to any individual using the instrument serial number and includes information such as the submitting agency, test results and calibration status.

14.2.1.6 When giving laboratory results to telephone callers, extreme caution shall be exercised. If the caller is authorized to receive the results, then the following procedures shall be followed: If the voice of the caller is recognized, then the results may be given out. If a caller's voice is unfamiliar, the ISPFS employee will politely break the conversation and return the call using a phone number known to belong to the agency employing the individual.

14.2.1.7 In the case of transmission of test results by facsimile or other electronic means (i.e. email or secure web-based interface), the requirements of this International Standard shall be met. When sending reports of examination by fax or email attachment, reasonable precautions are taken to ensure that the report is being transmitted to an appropriate receiver. Access to the web interface is limited, controlled, and secure. All web interface users must be approved by the ISPFS Quality Manager.

14.2.1.7.1 Examination reports are faxed or emailed to parties authorized to receive them in accordance with 14.2.1.5) and to fax numbers or email addresses that have been verified as belonging to appropriate receivers. (This can be an informal process and the sender just needs to be reasonably certain that they are sending results to a party that is entitled to them by a fax number or email address that the sender reasonably believes to be appropriate.)

14.2.1.7.2 The fax of an examination report addresses a particular person and includes a confidentiality notice and the total number of pages being sent. ISP emails have a confidentiality notice in the body of the email. A record of a fax or email being sent shall be recorded in the case correspondence log of the case record in ILIMS. The actual email(s) may be attached as a document on the case info tab of ILIMS. This record indicates the phone number the fax was sent to or the email address(es) of the intended recipient.

14.2.1.7.3 The sender verifies that the fax of an examination report was successful by reviewing the fax transmission report for the number of pages sent and an indication that the transmission was successfully sent.

14.2.1.8 After a report is issued, the analyst may discuss the report and case specific information with any officer of the court that requests consultation. As a professional courtesy, the prosecuting attorney is notified of any case specific discussions with officers of the court at the earliest convenience of the laboratory. Analysts may have a conversation with officers of the court and answer general questions that are not related to a specific case without seeking permission from or notifying the opposing attorney.

14.2.1.9 The evidence tracking system forensic services uses (ILIMS) is password protected and is only accessible by forensic services employees. Each employee has a unique login name and password.

14.2.1.10 All case reports are generated and processed through the secure ILIMS. Analysts generate their own reports in the ILIMS. After technical and administrative reviews are complete, a secure digital signature of the analyst and an issue date is affixed to the report by ILIMS.

14.2.1.11 Compiled case information, with confidential case information removed, may be provided for statistical or research purposes.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law be notified of the information provided.

4.2.3 Information about the customer obtained by sources other than the customer shall be confidential between the customer and the laboratory. The provider of this information shall be confidential to the laboratory and shall not be shared with the customer unless agreed by the source.

4.2.4 Personnel including any contractors, personnel of external bodies, or individuals acting on the laboratories behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

4.3 Ethics

4.3.1 Management and staff adhere to the ISPFS ethics policy (see Appendix A). ISP and ISPFS management will investigate and take appropriate quality system or personnel actions as appropriate to address ethical issues or complaints. Top management provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

5 Structural Requirements

5.1 Forensic Services is authorized by Idaho Code 67-2901(6) and is the forensic laboratory unit of the Idaho State Police (ISP), a department of the Idaho State Government. There are laboratories in Coeur d'Alene, Meridian, and Pocatello and its headquarters is in the Meridian ISP complex.

5.2 The laboratory shall identify management that has overall responsibility in the laboratory.

15.2.1 ISP Forensic Services Top Management is defined as the Laboratory System Director, Quality Manager, Deputy Quality Manager, Lab Managers, and Management Assistant (see sections 15.5b.2). ISP Forensic Services Key Management is defined as the Major/Manager, Laboratory System Director, Quality Manager, Lab Managers, Discipline Leads/Technical Leads, ILIMS Administrator, and State CODIS Administrator (see section 15.5b.2)

5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

Coeur d'Alene Lab	**Meridian Lab**	**Pocatello Lab**
Drug Analyses, Quantitative Analyses of Meth, Cannabis Typification	Drug Analyses, Cannabis Typification	Drug Analyses, Cannabis Typification
Blood and Urine Toxicology		Blood and Urine Toxicology
Alcohol and Volatile Analysis, Breath Alcohol Calibration	Alcohol and Volatile Analysis, Breath Alcohol Calibration	Alcohol and Volatile Analysis, Breath Alcohol Calibration
Firearms/Toolmarks		
	DNA Casework, Body Fluid Identification, DNA Database Analyses	
Ignitable Liquids		
	Latent Print Processing and Comparisons	

5.4 The laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at customer's facilities.

15.4.1 *Forensic Services creates, implements, and maintains a management system appropriate to the services provided. The quality policies, procedures, analytical methods, work instructions, and forms are documented to the extent necessary to assure the quality of examination results. In order to achieve compliance of the staff with the management system, it is communicated to, understood by, available to, and implemented by the appropriate personnel. The policies, procedures, analytical methods, and work instructions of the management system are in force regardless of the work site.*

15.4.2 *The management system is documented as follows: quality policies are contained in this quality manual and numbered the same as the related ISO/IEC 17025:2017 clause. Procedures provide instruction regarding the implementation of quality policies. They are numbered the same as the related quality policy plus 10 and directly follow the related policy in the quality manual. For example, the quality procedure that corresponds to section 4.1.4 of this Quality Manual is numbered 14.1.4 and directly follows policy 4.1.4 in the manual, is italicized, and in blue when viewed electronically. A procedure may encompass more than one section of this quality manual. Each discipline has analytical methods and training plans and may have work instructions and/or forms. In addition, Forensic Biology has additional policies for conforming to national standards for DNA analysis and the convicted offender databases. These policies are maintained with the analytical methods and work instructions for forensic biology. All the internally approved documents of the management system are maintained in the electronic document management system and can be accessed by all Forensic Services staff.*

5.5 The laboratory shall:

5.5a) Define the organization and management structure of the laboratory, its place in any parent organization and relationships between management, technical operations and support services, through the aid of an organizational chart.

15.5a *The relationship between Forensic Services and the Idaho State Police, its parent organization, is on-line in the agency intranet in the Employee Handbook, section 1.03.*

5.5b) Specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities.

15.5b.1 The relationships between the various levels of management, the quality management, technical operations, and support services of Forensic Services is defined in the organizational chart for Forensic Services. This chart is located in the quality section in Qualtrax.

15.5b.2 The points below describe the responsibilities, authority, and interrelations of personnel that manage, perform or verify work affecting the results of laboratory activities.

ILIMS Administrator

- *Oversee programming of approved changes to ILIMS.*
- *Maintain software documentation regarding ILIMS changes.*
- *Maintain the ILIMS manual and submit changes to the Quality Manager.*
- *Coordinate with disciplines working on process improvements.*
- *Work with vendors servicing ILIMS.*
- *Oversee ILIMS change request process.*
- *Work with external agencies interfacing with ILIMS.*
- *Coordinate the development of a paperless casework environment.*
- *Coordinate with ISP IT staff to resolve computer and network problems and to interface laboratory instruments with ILIMS.*

***ILIMS Team** [System Director, Quality Manager, Management Assistant, designated Lab Manager(s), and designated Analyst(s)]*

- *Assist the ILIMS Administrator with his/her responsibilities and perform these responsibilities in the absence of the ILIMS Administrator.*

Forensic Evidence Specialist

- *Manage, maintain and handle forensic evidence.*
- *Manage administrative systems and related support functions for the laboratory office.*
- *Provide direct and technical/analytical support services to forensic scientists and external customers.*
- *Assist in specialized and routine standardized chemical and biological laboratory procedures.*

- *Assist with laboratory administrative quality related duties.*
- *Customer service in coordinating the needs of the user agencies.*
- *Develop and maintain electronic and paper scientific records.*
- *Provide training to local law enforcement agency staff and new specialists in operating the ILIMS data entry and tracking systems as well as evidence procedures.*

Forensic Evidence Specialist Coordinator

- *Coordinate resolution to laboratory evidence issues.*
- *May perform administrative review of casework.*
- *Report deficiencies to supervisor.*
- *Review and create instruction manuals in the discipline.*
- *Develop and maintain training plans in the discipline.*
- *Approve training plan in conjunction with Quality Manager.*
- *Provide a report for the annual management system review*
- *Respond to deficiencies when assigned by the Quality Manager.*
- *Participate in evidence audits as assigned.*

Management Assistant

- *Compile statistical reports for Forensic Services.*
- *Participate in the management system review annually.*
- *Administer Forensic Services purchasing process*
- *Oversee Forensic Services restitution deposits*
- *Participate in evidence audits as assigned.*
- *Coordinate resolution to laboratory evidence issues.*

Headquarters Administrative Assistant

- *Provide administrative support to System Director and Quality Manager*
- *Coordinate Idaho sexual assault kit tracking program*

Forensics IT Operations & Support Analyst

- *Monitors problem/change activities*
- *Coordinates interactions between technical staff and end-users to respond to requests*
- *Provides training to users on hardware and software applications*
- *Performs testing activities*
- *Installs and maintains hardware and software products*
- *Configures user and network equipment according to department standards*
- *Installs, configures, and tests application software packages*

- *Assists in defining system standards and procedures*
- *Installs network infrastructure equipment hardware*
- *Identifies, evaluates, and corrects hardware, software, or operations problems*
- *Makes recommendations for future hardware and software additions or enhancements*

Forensic Scientist 1 (entry level analyst)

- *Follow analytical methods and the quality and safety procedures.*
- *Document quality controls and work.*
- *Check that the report issued for analysis they perform is accurate.*
- *Report results of all analysis performed through written/electronic reports.*
- *Perform analysis in only examinations they are approved to perform.*
- *Technical review of casework.*
- *Administrative review of casework.*
- *Report deficiencies to supervisor.*
- *May testify on results of analysis.*

Forensic Scientist 2 (journey level analyst)

- *Follow analytical methods and the quality and safety procedures.*
- *Document quality controls and work.*
- *Check that the report issued for analysis they perform is accurate.*
- *Report results of all analysis performed through written/electronic reports.*
- *Testify in legal settings regarding the analysis performed as expert witnesses.*
- *Perform analysis in only examinations they are approved to perform.*
- *Technical review of casework.*
- *Administrative review of casework.*
- *Report deficiencies to supervisor.*
- *Perform technical audits.*
- *Demonstrate technical competence by obtaining approved certification for the primary discipline to which they are assigned (examples of approved certification - ABC certification, ABFT, or IAI latent fingerprint certification.) This certification shall be obtained within the first three years after being selected/promoted for the position of Forensic Scientist 2.*

Forensic Scientist 2/Crime Scene Coordinator (journey level analyst)

- *FS 2 duties as listed above.*
- *Train police officers and medical personnel in collection of evidence and crime scene processing and documentation.*
- *Coordinate introductory and continuing crime scene training for ISPFS employees.*
- *Coordinate ISPFS responses to crime scenes state-wide.*
- *Coordinate crime scene response gear, PPE, supplies, and equipment state-wide.*
- *Coordinate development and maintenance of crime scene methods and manuals.*
- *Provide assistance at complex crime scenes.*
- *Demonstrate technical competence by obtaining IAI latent fingerprint certification within the first three years after being selected/promoted to an FS2 level position, and by obtaining IAI crime scene certification (minimum of Investigator certification). Crime scene certification shall be obtained within the first three years after being selected/promoted for the position of FS2/Crime Scene Coordinator.*

Forensic Scientist 3 (discipline lead, journey level analyst)

- *Follow analytical methods and the quality and safety procedures.*
- *Document quality controls and work.*
- *Check that the report issued for analysis they perform is accurate.*
- *Report results of all analysis performed through written/electronic reports.*
- *Testify in legal settings regarding the analysis performed as expert witnesses.*
- *Perform analysis in only examinations they are approved to perform.*
- *Technical review of casework.*
- *Administrative review of casework.*
- *Report deficiencies to supervisor.*
- *Perform technical Audits*
- *Demonstrate technical competence by obtaining approved discipline specific certification within one year of being appointed to their current position.*
- *Approval of new trainees*
- *Review and create analytical methods in their discipline.*
- *Evaluate what proficiency tests are needed in their discipline and approve the proficiency testing program.*
- *Determine requirements for supplies and services used in their discipline.*

- *Approve use of methods that are not part of the management system in conjunction with quality manager.*
- *Approve deviations from analytical methods.*
- *Review or creates validation plans.*
- *Maintain validation records.*
- *Participate annually in the management system review including reports of activities within disciplines.*
- *Develop and maintain training plans for their discipline.*
- *Approve training plan in conjunction with Quality Manager.*
- *Approve analytical methods in conjunction with Quality Manager.*
- *Respond to deficiencies.*
- *Evaluate contractors for potential conflict of interests and approve them for the specified activity*
- *Removal of a scientist from casework and/or technical review as necessary due to quality or personnel issues*

Forensic Scientist 3 (supervisor, journey level analyst)

- *Follow analytical methods and the quality and safety procedures.*
- *Document quality controls and work.*
- *Check that the report issued for analysis they perform is accurate.*
- *Report results of all analysis performed through written/electronic reports.*
- *Testify in legal settings regarding the analysis performed as expert witnesses.*
- *Perform analysis in only examinations they are approved to perform.*
- *Technical review of casework.*
- *Administrative review of casework.*
- *Report deficiencies to supervisor.*
- *Perform technical Audits*
- *Demonstrate technical competence by obtaining approved discipline specific certification within three years of being appointed to their current position.*
- *Participate annually in the management system review including reports of activities within disciplines.*
- *Approve training plan in conjunction with Quality Manager and discipline lead.*
- *Approve training requests.*
- *Explain and ensure adherence to Idaho State Police Forensic Services policies and procedures.*

- *Evaluate and document performance of subordinates, and oversee development and implementation of employee development plans, annual goals and objectives, and work performance plans.*
- *Removal of a scientist from casework and/or technical review as necessary due to quality or personnel issues*

Forensic Scientist 4 (discipline lead, supervisor, journey level analyst)

- *Follow analytical methods and the quality and safety procedures.*
- *Documentation of quality controls and work.*
- *Check that the report issued for analysis they perform is accurate.*
- *Report results of all analysis performed through written/electronic reports.*
- *Testify in legal settings regarding the analysis performed as expert witnesses.*
- *Perform analysis in only examinations they are approved to perform.*
- *Technical review of casework.*
- *Administrative review of casework.*
- *Perform technical audits.*
- *Demonstrate technical competence by obtaining approved discipline specific certification within one year of being appointed to their current position.*
- *Approval of new trainees.*
- *Review and create analytical methods in their discipline.*
- *Evaluate what proficiency tests are needed in their discipline and approve the proficiency testing program.*
- *Determine requirements for supplies and services used in their discipline.*
- *Approve use of methods that are not part of ISP system along with quality manager.*
- *Approve deviations from analytical methods.*
- *Review or create validation plans.*
- *Maintain validation records.*
- *Participate in the management system review annually.*
- *Develop and maintain training plans in their discipline.*
- *Approve training plan in conjunction with Quality Manager.*
- *Approve analytical methods in conjunction with Quality Manager.*
- *Respond to deficiencies.*
- *Approve training requests.*
- *Explain and ensure adherence to Idaho State Police Forensic Services policies and procedures.*

- *Evaluate and document performance of subordinates, and oversee development and implementation of employee development plans, annual goals and objectives, and work performance plans.*
- *Evaluate contractors for potential conflict of interests and approve them for the specified activity*

Quality Manager/Laboratory Improvement Manager

- *Follow analytical methods and the quality and safety procedures.*
- *Technical review of casework.*
- *Administrative review of casework.*
- *Documentation of quality controls and work.*
- *Maintain training documentation.*
- *Approval of trainees to perform independent examination.*
- *Approval of trainee in conjunction with discipline lead.*
- *Review deviations from analytical methods to ensure they are compliant with quality system.*
- *Review of requests to use a non-ISP method to ensure compliance with quality system.*
- *May approve deviations from administrative procedures.*
- *Maintain records for administrative procedure deviations.*
- *Organize and provide proficiency tests.*
- *Send responses to proficiency test providers.*
- *Send proficiency test results to the accrediting body or sign release of results for submission by the proficiency test provider.*
- *Send relevant corrective action responses resulting from proficiency tests to the accrediting body.*
- *Evaluate nonconforming work; issue corrective and preventive actions.*
- *Retain documentation of preventive and corrective action requests.*
- *Retain documentation for external technical reviewers.*
- *Archive quality documents.*
- *Maintain approval for health and safety, quality and procedure manuals.*
- *Monitor laboratory practices to verify continuing compliance with policies and procedures related to quality.*
- *Issue quality audit report to lab manager and Laboratory System Director.*
- *Review of new analytical methods.*
- *Approve new analytical methods in conjunction with the discipline lead.*
- *Notify staff when new analytical methods are implemented.*
- *Schedule and coordinate management system audits.*

- *Organize, participate in and prepare a report for the annual Management System Review.*
- *Oversee accreditation application, assessment, and surveillance.*
- *Maintain a register of approved subcontractors and verification documentation for the competence of subcontractors.*
- *If qualified in the discipline, may perform FS2 responsibilities.*
- *If performing casework analysis, demonstrate technical competence by obtaining ABC certification. This certification shall be obtained within 3 years of being appointed to this position, when the individual is performing casework analysis.*
- *Review and approve recommendations from conflict resolution before any administrative report is issued.*
- *Removal of a scientist from casework and/or technical review as necessary due to quality or personnel issues*

Deputy Quality Manager

- *Assist the Quality Manager with his/her responsibilities and perform these responsibilities in the absence of the Quality Manager.*

Lab Manager

- *Follow analytical methods and quality and safety procedures.*
- *Documentation of quality controls and work.*
- *Check that the report issued for analysis they perform is accurate.*
- *Report results of all analysis performed through written/electronic reports.*
- *Testify in legal settings regarding the analysis performed as expert witnesses.*
- *Perform analysis in only examinations they are approved to perform.*
- *Technical review of casework.*
- *Administrative review of casework.*
- *Approve training requests.*
- *Ensure that proficiency tests are submitted to the Quality Manager before the due date or a deviation has been requested.*
- *Respond to deficiencies.*
- *Review requests for external examination along with the discipline lead and an analyst.*
- *Custodian of keys and security codes for lab.*
- *Designate non-Forensic Service employees who are allowed unrestricted access to Forensic Services laboratories.*
- *Schedule and prioritize workload.*

- *Evaluate and document performance of subordinates, and oversee development and implementation of employee development plans, annual goals and objectives, and work performance plans.*
- *Explain and ensure adherence to Idaho State Police Forensic Services policies and procedures.*
- *Represent organization to clients, and public.*
- *Approve deviations from administrative procedures.*
- *Participate in annual Management System Review, which includes continual improvement of the management system.*
- *Respond to customer service surveys and compile annual survey report.*
- *If performing casework analysis, demonstrate technical competence by obtaining ABC certification. This certification shall be obtained within 3 years of being appointed to this position, when the individual is performing casework analysis.*
- *Certify that the laboratory has performed two evidence audits during the calendar year.*
- *Removal of a scientist from casework and/or technical review as necessary due to quality or personnel issues*

Laboratory System Director

- *Approve technical reviewers from labs that are not ISO/IEC 17025 accredited.*
- *Approve deviations from casework acceptance policy.*
- *Approve exceptions for ABC, IAI and discipline specific testing requirements.*
- *Represent organization to clients, and public.*
- *Approve employee cross-training requests.*
- *Approve training requests.*
- *Approve corrective and preventative actions.*
- *Participate in annual Management System Review.*
- *Removal of a scientist from casework and/or technical review as necessary due to quality or personnel issues*

15.5.b3 Each laboratory has a safety officer with defined responsibilities (Section 2.2 Health and Safety Manual) and authority (Section 2.1.1 Health and Safety Manual) to ensure that the health and safety program is implemented and followed. The Laboratory Manager (in consultation with the Quality Manager) shall appoint the safety officer and communicate the appointment to laboratory staff. Written documentation of the appointment shall be retained.

5.5c) Document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of results.

15.5c Each analytical method and related work instructions and forms used for examinations are contained in the approved documents of the management system. The control and archival of these documents is described in procedure 8.3, and 8.4 regarding document control and the required contents are described in procedure 17.2.1.8, which deals with analytical methods and their validation. The documentation requirements for examinations, which are performed as exceptions to this procedure, are described in procedure 17.2.1.7.3.

5.6 The laboratory shall have personnel who irrespective of other responsibilities have the authority and resources needed to carry out their duties, including:

5.6a) implementation, maintenance and improvement of the management system;

5.6b) identification of deviations from the management system or from procedures for performing laboratory activities.

5.6c) initiation of actions to prevent or minimize such deviations.

5.6d) reporting to the laboratory management on the performance of the management system and any need for improvement.

5.6e) ensuring the effectiveness of laboratory activities.

5.7 Laboratory management shall ensure that:

5.7a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and others requirements.

15.7a.1 Communication processes:

15.7a.1.1 Statewide management meetings are held on a periodic basis to discuss and resolve issues and receive directives from top management.

15.7a.1.2 Each laboratory of Forensic Services has laboratory wide staff meetings on a periodic basis. Important issues from statewide or laboratory wide management meetings and directives from the Laboratory System Director are disseminated at those meetings.

15.7a.1.3 Discipline leads communicate with the individuals in their discipline as appropriate. Face-to-face meetings of members of disciplines (either in person or via video) are held at least twice per calendar year. Additionally, discipline leads perform on-site visits to the other laboratories where work is performed in their discipline at least once per calendar year unless exempted by the Quality Manager.

15.7a.1.4 The Quality Manager holds face-to-face meetings (in person or via video) with the discipline leads at least twice per calendar year. Discipline leads whose discipline is located in a single laboratory performs on-site visits to the other laboratories on a periodic basis.

15.7a.1.5 As needed, the Laboratory System Director has written or verbal communication with staff.

15.7a.1.6 The summary of the annual management review is provided to all staff.

15.7a.1.7 Proposed changes to the management system are announced to all individuals that potentially would be affected by the change and invited to comment. When the management system is changed, the changes are announced to all the affected individuals and the documented changes are available.

15.7a.1.8 The current documents of the management system are available to all staff.

15.7 a.1.9 Management resolves all formal complaints by the staff about the management system that includes the recording of complaints, along with their investigation, and remediation as appropriate. Staff is given feedback about the resolution of formal complaints.

5.7b) The integrity of the management system is maintained when changes to the management system are planned and implemented.

6 Resource Requirements

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

6.2 **Personnel**

6.2.1 All personnel of the laboratory, either internal or external that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including

requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3 The laboratory shall ensure that personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations (see procedures 16.2.5 a-f)

6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities (see procedures 16.2.5 a-f)

6.2.5 The laboratory shall have procedures and retain records for:

6.2.5a determining the competence requirements

16.2.5a.1 All analysts, regardless of their qualifications or past work experience, must satisfactorily complete a competency test prior to assuming casework responsibility. Satisfactory completion of competency testing means achieving the intended results. Failure to achieve the intended results requires review and/or retraining until such time as satisfactory performance is achieved. Competency testing includes written and/or oral evaluation on background knowledge of scientific literature and/or identification of known and unknown materials and/or the calibration of instrumentation.

16.2.5a.2 Competency tests will be provided by the discipline lead or designee. The Quality Manager will designate the provider if the discipline lead is being tested. Competency tests shall test the individual on relevant topics and/or samples covered during training, mimic actual casework, and may undergo suitability review, prior to their use. It is incumbent upon the discipline lead to review and discuss with the examinee, in a timely manner, any deficiencies noted during the testing and to formulate retraining as needed. The QA Manager will maintain results of competency testing and provide required notification that a forensic scientist is allowed to analyze work in a given discipline/subdiscipline.

16.2.5a.3 All internally prepared competency and proficiency tests will be logged into ILIMS in the lab in which it is created and handled like casework. When competency or proficiency tests containing controlled substances are shipped to another lab, they are required to have a signature confirmation (just like casework).

16.2.5a.4 Any controlled substances competency or proficiency tests prepared "internally" after 09-01-2011 will have preparation documentation that will be kept in the lab in which the test was prepared. The record will document the name, lot number, the amount of controlled substance placed in each sample, the case number (once it is assigned), the name of the person who prepared the test, and the delivery confirmation sheet (if the sample is sent to another lab). When the controlled substance competency or proficiency test is complete, the sample(s) will be returned to the evidence vault and disposed of using the regularly scheduled drug burn procedure.

16.2.5a.5 For any ISPFS personnel writing laboratory reports, a competency test shall include:

- *Examination of sufficient unknown samples/instruments to cover the anticipated spectrum of assigned duties and evaluate the individual's ability to perform proper testing methods.*
- *A written report to demonstrate the individual's ability to properly convey results and/or conclusions and the significance of those results/conclusions.*
- *A written or oral examination to assess the individual's knowledge of the discipline, category of testing or task being performed.*

16.2.5a.6 Technical support personnel must satisfactorily complete competency testing prior to assuming independent responsibility for any task that could reasonably be expected to affect the outcome of any examination.

16.2.5a.7 Analysts working in any subdiscipline of forensic science must satisfactorily complete competency testing in each subdiscipline prior to assuming casework responsibility in that subdiscipline. Analysts transferring to a lab where analysis has been temporarily halted must successfully complete a competency test before resuming casework.

6.2.5b Selection of personnel

16.2.5b.1 The laboratory follows the hiring procedures of the Idaho State Police, these procedures are located on-line in the agency intranet in the Employee Handbook, section 03.04. Current job descriptions for managerial, scientific, and technical support personnel involved in examination are updated and maintained by ISP Human Resources and are available on the Idaho Department of Human Resources website. Minimum contents of job descriptions include where applicable:

- *Responsibilities with respect to performing examinations;*
- *Planning of examinations and evaluation of results;*
- *Responsibilities for reporting opinions and interpretations;*
- *Responsibilities with respect to analytical method development and validation;*
- *Expertise and experience required;*
- *Qualifications and training programs;*
- *Managerial duties.*

Job Descriptions (position titles begin with ISP except Laboratory Improvement Manager, [e.g., ISP Forensic Scientist 2]) are available for all positions at the Department of Human Resources web site.

- *ISP Forensic Evidence Specialist*
- *ISP ILIMS Programmer/Administrator*
- *ISP Forensic Scientist 1*
- *ISP Forensic Scientist 2*
- *ISP Forensic Scientist 3*
- *ISP Forensic Scientist 4*
- *ISP Forensic Laboratory Manager*
- *Laboratory Improvement Manager/ Quality Manager*
- *ISP Laboratory System Director/Laboratory Bureau Chief*

16.2.5b.2 Scientific/Technical Support Personnel Qualifications

Education

16.2.5b.2.1 ISPFS analysts and management must hold a baccalaureate, masters, or doctoral degree in a physical or biological science from an accredited U.S. or Canadian institution. Degrees for Biology/DNA must be in a biology or chemistry related science. Acceptable institutions are those accredited by or those which have pertinent educational programs accredited by commissions or agencies recognized by the U.S. Office of Education.

16.2.5b.2.2 Applicants with education obtained at a foreign institution must, at their expense, have credentials evaluated by Educational Credential Evaluators, Inc., Milwaukee, WI; International Education Research Foundation, Inc., Los Angeles, CA; or World Education Services, Inc., New York, NY. Reports must be sent directly to ISP Human Resources by the evaluating organization. These degrees may be accepted on a case-by-case basis, in lieu of a US or Canadian degree, upon review of the evaluation report

16.2.5b.2.3 The education of each employee shall be verified prior to being hired by Forensic Services. A copy of the college transcript (including specific required coursework) and proof of graduation for all personnel with education requirements shall be retained by the Quality Manager.

16.2.5b.2.4 The minimum degree and course requirements listed in this section only apply to staff hired after this policy was revised December 30, 2015. Successful completion of a course means a college or university defined passing grade.

16.2.5b.2.4.1 Analysts working in Chemistry (controlled substances/fire evidence) must have successfully completed a minimum of seventeen (17) semester (or 26 quarter) units of college level chemistry course work. Chemistry coursework must include laboratory and cover general chemistry, organic chemistry and quantitative/instrumental analysis.

16.2.5b.2.4.2 Analysts working in the Toxicology and Alcohol disciplines must have successfully completed a minimum of seventeen (17) semester (or 26 quarter) units of college level chemistry course work. Chemistry coursework must include laboratory and cover general chemistry, organic chemistry and quantitative/instrumental analysis.

16.2.5b.2.4.3 Analysts working in the Forensic Biology discipline must have successfully completed a minimum of seventeen (17) semester (or 26 quarter) units of chemistry or biology related college level coursework. Coursework must include at least one course each in biochemistry, genetics, and molecular biology totaling 9 semesters (or 14 quarter) units. Additionally, coursework in statistics or population genetics is required. When performing DNA analysis and where applicable, analysts shall meet the educational requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories.

16.2.5b.2.4.4 DNA Technical Leads must have successfully completed a minimum of seventeen (17) semester (or 26 quarter) units of chemistry or biology related college level coursework. Coursework must be a combination of undergraduate and graduate courses and include at least one course each in biochemistry, genetics, molecular biology, and statistics (or population genetics) totaling 12 semesters (or 18 quarter) units. At least 3 of the 12 semester units must be at the graduate level. DNA technical leads where applicable shall meet the educational requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories.

16.2.5b.2.4.5 Analysts working in the Firearms/Toolmarks discipline must have successfully completed a minimum of seventeen (17) semester (or 26 quarter) units of college level chemistry course work. Chemistry coursework must include laboratory and cover general chemistry, organic chemistry and quantitative/instrumental analysis.

16.2.5b.2.4.6 Analysts working in the Latent Prints/Impression Evidence discipline must have successfully completed a minimum of twelve (12) semester (or 18 quarter) units of college level studies in a relevant physical or biological science which may include biology, chemistry, biochemistry, and/or physics. A statistics course may be applied to meeting the minimum coursework hours.

16.2.5b.2.4.7 Lab Managers, Quality Managers, and Laboratory System Directors must have successfully completed a minimum of nineteen (19) semester (or 29 quarter hours) of college level studies in a relevant physical or biological science which may include biology, chemistry, biochemistry, pharmacology, physics, and/or toxicology, a minimum of twelve (12) semester (or 18 quarter hours) of these courses must be in chemistry. A statistics course may be applied to meeting the minimum science coursework hours.

16.2.5b.2.4.8 Technical support personnel (laboratory technicians/assistants) must meet the educational requirement(s) specified in their job description. However, most jobs will require completion of at least a full year each of general and organic chemistry prior to beginning work. Additionally Forensic Evidence Specialists may be trained and assigned laboratory assistant/technician duties. The duties and associated experience or education required is documented in the FES Roles Lab Assistant/Technician form.

6.2.5c Training of personnel:

16.2.5c Forensic Services management ensures the competency of forensic scientists and technical support performing examinations, writing examination reports, testifying, operating equipment, and performing technical and administrative review. Appropriate supervision is provided for employees undergoing training. Forensic scientists are approved to perform independent examinations only after demonstrating appropriate education, training, experience, skills, and successful completion of competency testing.

Analysts have education, training, and experience commensurate with their duties for positions in which specific requirements have been established by regulatory or governing bodies (e.g. DNA technical lead and DNA analyst).

Forensic Services has a documented and comprehensive training program to ensure that individuals have the knowledge, skills, and abilities needed to perform examinations in each discipline or subdiscipline for which services are provided.

All employees participate in employee development as described in 16.2.5f.3 in order to maintain a high level of competency.

Typically, the need for retraining is identified through the discovery of nonconforming work and is handled in accordance with the nonconforming work/corrective action process described in section 7.10 and 8.7 of this manual.

16.2.5c.1 Discipline/sub discipline training plans: a training plan shall be developed and updated as required by the discipline lead. The training plan shall be based on relevant analytical methods. All knowledge, skills, and abilities necessary to perform casework analysis shall be included in the training plan.

16.2.5c.1.1 Training plan format and contents:

16.2.5c.1.2 The training plan shall include a sign-off mechanism which describes the assignment/activity the trainee has completed and documents who approved the assignment as being complete, as well as the date of approval/completion. This may be accomplished through the electronic quality compliance system.

16.2.5c.1.3 History page: shall provide a list of revisions with the revision dates, including the current revision.

16.2.5c.1.4 Introduction: each training plan shall have an introduction.

16.2.5c.1.5 Roles and Responsibilities of each individual involved in the training process.

16.2.5c.1.6 References, if appropriate, shall be included somewhere in the training plan.

16.2.5c.1.7 The numbering system: Section 1 shall be 1; Topic 1 shall be 1.1; and Item 1 shall be 1.1.1, etc.;

16.2.5c.1.8 Each page of a training plan shall have the date issued and the revision number (rev. #) in the bottom right hand corner.

16.2.5c.2 The following elements shall be included in the training plan:

16.2.5c.2.1 Acceptance criteria will be defined for any tests, examination or technique specific training included in the plan.

16.2.5c.2..2 General policies and procedures regarding note taking and writing reports.

16.2.5c.2.3 Review of specific health and safety hazards associated with performing the applicable analytical method(s).

16.2.5c.2.4 Background and scientific theory on which the examination(s) is based as appropriate;

16.2.5c.2.5 Theory, operation, maintenance, and troubleshooting of instrument(s) used.

16.2.5c.2.6 Training in the use and understanding of analytical methods shall include the analysis of training samples. The trainee may, under the direct observation of a competent analyst, handle case samples, but the trainer will make all conclusions and must be present and observe all aspects of the work (the trainee works as the hands of the trainer). All evidence in the "hands of the trainer" process will be checked out by the trainer and the chain of custody shall be maintained in the name of the trainer/trained analyst. Probative samples may be independently handled by the trainee if the evidence can be analyzed without changing it (e.g. comparison of latent prints or bullets). Examination reports shall be based solely on examinations performed by or directly observed by approved analysts. The report will be issued by the trainer/trained analyst. The analytical notes will clearly indicate the samples handled by the trainee. In the case of controlled substances, if an additional training sample is taken it will be stored in a secure locked location (either a drug locker or the controlled substance cabinet).

The additional sample amount retained will be comparable to the amount taken in the course of analysis for the method which the trainee will perform on that sample. The samples will be labeled with the case and item number from which they were obtained. The samples will be logged into a "Controlled Substances Training Samples" log book. The log will include the date the sample was retained, the analyst retaining the samples initials, the case and item number, a description, location, the date destroyed or used in analysis, and initials from an analyst verifying it was consumed/destroyed. The "Controlled Substance Training Samples" log book and any samples currently retained at the time of the audit will be audited annually.

16.2.5c.2.7 Competency test: shall test the ability of the analyst to perform examinations using the equipment and analytical methods for which the analyst is training. The results and supporting data shall not be technically reviewed, administratively reviewed, or verified prior to submission to the trainer. (See section 16.2.5a.5 for additional information regarding competency testing.)

16.2.5c.2.8 The training plan shall include a unit on the presentation of evidence in court and applicable criminal and civil law procedures. This training may be provided by several ways such as verbal instruction, either internal/external or reading of appropriate printed articles followed by discussion and review with the trainer. Successful completion of this unit is demonstrated by a satisfactory evaluation for the mock court. General court procedure training is also covered in the ISPFS Core Training.

16.2.5c.2.9 Mock court regarding the type of casework for which the analyst is being trained. A Laboratory Manager, the section Supervisor, the Quality Manager, or the Laboratory System Director shall evaluate the testimony with input from the discipline lead. Feedback from any staff attendees should also be provided to the supervisor and discipline lead to be reviewed with the trainee. This requirement shall be met when the trainee receives a documented satisfactory evaluation.

16.2.5c.2.10 Supervised cases: the number and type of cases shall be specified in the plan. Supervised case analysis is defined as the performance of the analytical methods on actual case material under close supervision. The supervising analyst is responsible for regularly observing the trainee and ensuring they properly perform casework activities including casework documentation, evidence handling, following the analytical method, performing and interpreting test methods and data, and reporting results as set forth in the quality system. The supervising analyst(s) shall be documented in the case record. Disciplines may have their own additional requirements for supervised cases. The Quality Manager must grant approval prior to the trainee starting supervised cases. The Quality Manager will ensure that all of the essential components of the training plan for the method(s) or skill the analyst is being signed off on have been completed (this includes, but is not limited to, competency testing, mock court, court room training, and general forensic knowledge).

16.2.5c.2.11 Training in the performance of technical review. This may occur at a point in time following the approval to perform independent analysis.

16.2.5c.2.12 The ISPFS Core training will cover the following areas: general knowledge of forensic science and Forensic Services practices and procedures such as maintaining chain of custody and evidence receiving; training for new analysts in other forensic disciplines; study and review of the Idaho State Police policies and the Forensic Services Quality Manual; appropriate safety training to include review of the Forensic Services Health and Safety Manual.

16.2.5c.2.13 New employees will complete the currently approved ethics course as part of their core training program. A change to the currently approved ethics course must be approved by the Laboratory System Director. All forensic services employees shall complete the Annual ISP Ethics Training and any other ethics training that may be designated by the Laboratory System Director.

16.2.5c.3 Steps in training an individual:

16.2.5c.3.1 Obtain the written approval of the Laboratory System Director prior to commencing training in a new discipline. Approval to train a newly hired employee is implied and does not require the approval of the Laboratory System Director.

16.2.5c.3.2 Contact the appropriate discipline lead. The discipline lead is responsible for assessing any applicable training previously completed by the trainee, reviewing the current training plan, assigning the appropriate modules, and organizing the training. The discipline lead may designate an on-site trainer.

16.2.5c.3.3 Training shall take place in accordance with the appropriate approved training plan. Before training is initiated, the trainee shall have a copy of their training plan with an anticipated timeline for completion of each module to be completed, this plan will be forwarded to the quality manager and other involved parties as appropriate. The trainee will be provided with any supplemental training activities added to their training program. It is anticipated that the timeline may change throughout the course of training; however, significant delays and/or supplemental activities in a training program shall be communicated with the Laboratory Manager, Quality Manager, and System Director.

16.2.5c.3.4 All steps in training an individual shall be documented as they are completed. Training does not have to proceed in a specified order. However, supervised case analysis shall only occur after the Quality Manager grants approval. The Quality Manager will ensure that all of the essential components of the training plan for the method(s) or skill the analyst is being signed off on have been completed (this includes, but is not limited to competency testing, mock court, court room training, and general forensic knowledge).

16.2.5c.3.5 Specific aspects of training shall be covered only to the extent necessary with a particular analyst to ensure that they know and understand the material. An individual may fulfill training requirements through prior training and/or experience. Training requirements that are fulfilled through prior training and/or experience shall be documented and submitted to the Quality Manager along with the rest of the training documentation.

16.2.5c.3.6 Review of documentation: once all the training is completed except for performing supervised cases, the discipline lead shall review all documentation regarding the training to determine if the trainee performed all required training and is competent to perform the analysis. The discipline lead (Laboratory Manager if the discipline lead is being approved) shall forward the following documentation to the Quality Manager: Note: it is important for the discipline lead to maintain communication with the trainer throughout the process in order to ensure milestones are being met with satisfactory results, and in order to identify any potential concerns at the earliest opportunity.

16.2.5c.3.7 Completed training checklist from the training plan (if not done electronically in the quality compliance system) and other documentation as necessary;

16.2.5c.3.8 Competency test with an evaluation and answer sheet/correct answer.

16.2.5c.3.9 Written recommendation by the discipline lead based on the evaluation of the reviewed training documents.

16.2.5c.3.10 The Quality Manager shall ensure that all quality standards for training have been met. When the Quality Manager receives documentation and is satisfied that the training elements have been successfully completed, written approval shall be granted to perform analysis and testify as an expert regarding the examinations for which the analyst was trained.

16.2.5c.4 The Quality Manager shall be the training officer for Forensic Services. As such, the Quality Manager shall maintain documentation regarding the training of each employee.

16.2.5c.5 Each staff member is responsible for updating his/her training record in Qualtrax.

16.2.5c.6 It is the responsibility of each employee to ensure that his/her affidavit of qualification and/or curriculum vitae accurately reflect successfully completed training.

16.2.5c.7 Technical support staff that perform some aspect of casework analysis shall have documented training, competency testing, and proficiency test regarding the casework analysis performed.

16.2.5c.8 Training programs for analysts shall include training in the presentation of evidence in court and a mock court regarding the discipline/subdiscipline for which the training is being given. (Procedures 16.2.5c.2.9 and 16.2.5c.2.8) The training does not have to be repeated if the analyst is trained in additional discipline/subdisciplines, but a discipline/subdiscipline specific mock court does have to be held.

16.2.5c.9 Training programs for analysts shall include training in the application of ethical practices in forensic sciences, a general knowledge of forensic science, and the applicable criminal and civil law procedures. (Procedures 16.2.5c.2.13 and 16.2.5c.2.8) The training does not have to be repeated if the analyst is trained in additional disciplines/subdisciplines.

16.2.5c.10 The Forensic Services management formulates goals with respect to the education, training, and skills of the laboratory personnel. Specific educational requirements for staff, by discipline, are documented in 16.2.5b.2.4 and the general education requirements by class are stated in the job descriptions. The training and skills required for each position are defined in 15.5b.2 and the class job descriptions. The management also identifies training needs, provides such as needed for staff, and outlines various opportunities for employee development and participation and has quality procedures for the implementation of this policy. Approved training plans are appropriate for the examinations performed and, the effectiveness of training is evaluated prior to the trainee being approved to perform independent casework.

16.2.5c.11 Journals and References related to Forensic Science: Each laboratory of Forensic Services provides access to resources such as books, journals and other relevant publications or electronic media dealing with each subdiscipline for which service is provided in that laboratory. Each employee also has direct access to the educational resources of the Internet.

6.2.5d Supervision of personnel;

6.2.5e Authorization of personnel; (see 16.2.5c.3 steps in training an individual) Management approves individuals to perform specific examinations and to testify on associated results. The approval to perform analysis encompasses related sampling, issuing examination reports, operating the instruments necessary to carry out the examination, and offering opinions. Additionally, approval to perform analysis serves as the authorization for the analyst to participate in validation activities within the discipline. Records of relevant educational and professional qualifications, training, experience, and competency testing for all technical and contracted personnel (including approval date to perform given examinations) are maintained by the Quality Manager

6.2.5f Monitoring competence of personnel

16.2.5f.1 Each analyst engaged in testing activities shall successfully complete at least one proficiency test per calendar year in each discipline and at least one proficiency test per accreditation cycle in each subdiscipline in which the forensic scientist or technician performs examinations.

16.2.5f.1.1 DNA analysts and technical support personnel performing DNA analysis comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories. DNA Proficiency tests shall be tracked by the assigned due date.

16.2.5f.1.2 The laboratory shall have a documented schedule for proficiency testing which is being followed by each analyst and technical support person; refer to procedure 17.7.2.9 for this schedule.

16.2.5f.2 Each Forensic Services laboratory participates in at least one external proficiency test annually, in every discipline of forensic science in which it provides services. ISO/IEC 17043 Accredited test providers are used for external proficiency tests. Refer to section 7.7.2 for additional proficiency testing requirements.

16.2.5f.3 Certification and Employee Development

16.2.5f.3.1 In an effort to continually improve the skills of its scientists, Forensic Services requires that all analysts obtain approved certification, in at least the primary discipline in which they are approved to perform testing, no later than three years after becoming a Forensic Scientist 2. The primary discipline will be designated by the laboratory manager for individuals who perform testing in more than one section. Approved certifications: ABC (molecular biology, fire debris, drug analysis), IAI (latent print), ABFT (alcohol and toxicology), AFTE (firearm, toolmark), additional certification bodies may be evaluated and approved by the quality manager. Exceptions require prior authorization by the Laboratory System Director.

16.2.5f.3.2 A Forensic Scientist 3 or 4, who assumes discipline lead responsibilities, must already hold approved certification in the discipline in which he/she supervises work, or such status must be achieved within one year of assuming discipline lead responsibilities. Approved certifications: ABC (molecular biology, fire debris, drug analysis), IAI (latent print), ABFT (alcohol and toxicology), AFTE (firearm, toolmark), additional certification bodies may be evaluated and approved by the quality manager. The Laboratory System Director must authorize exceptions.

16.2.5f.3.3 *Analysts that do not obtain their primary discipline certification within 3 years of becoming an FS2 analyst in that discipline are subject to termination. Documentation of successful passage must be provided to ISP on or before the three year anniversary of becoming an FS2 analyst in that discipline. If the assigned primary discipline changes, the analyst will have 3 years from the date the new primary discipline was designated by management to obtain the approved certification in that discipline. Failure to provide documentation of passage in the new discipline on or before the 3 year anniversary of the new discipline being designated will be subject to termination.*

Note: Individuals who possess an approved certification in an area other than their primary discipline as of June 29, 2017 (the date of issuance of revision 1 of this manual) will have three years from that date to obtain certification in the primary discipline in which they are approved. Certification in general criminalistics will fulfill the primary discipline requirement for members of management performing casework.

16.2.5f.3.4 *Forensic Services shall pay all costs associated with taking general and discipline appropriate certification tests approved by management, the annual fees for maintaining certification, and for all costs associated with proficiency testing to remain certified within a given specialty.*

16.2.5f.3.5 *Forensic Services will make every effort to ensure that adequate opportunities to maintain required certification are afforded to all scientists; however, it is incumbent upon the individual to monitor and maintain certification once such has been acquired. As such, Forensic Services shall also pay for approved attendance at seminars, professional meetings, etc., necessary to maintain the required certification. Analysts that lose their primary discipline certification will be terminated 1 year after the loss date if reinstatement or new certification paperwork is not provided to ISP on or before the one year anniversary of losing certification in that discipline. Certified analysts that lose certification due to leave longer than two months will have 1 year from being restored to casework to provide ISP with documentation of certification or employment will be terminated.*

16.2.5f.3.6 *Forensic Services encourages staff members to develop their potential by identifying training needs and taking advantage of opportunities for professional development.*

16.2.5f.3.7 *An employee development plan shall be written annually for each employee and reviewed by the employee and their supervisor. The employee is responsible for developing the plan and is encouraged to seek input from the supervisor. This plan shall be compatible with the mission of the laboratory, Forensic Services, and the Department. The plan shall be based on mutually accepted objectives and shall include provisions independently addressed by the employee, as well as provisions requiring agency support. A new plan may build on or enhance the plan from the previous year.*

16.2.5f.3.8 *Career advancement/career enhancement is available from a wide variety of sources. The following list contains some suggested sources for training.*

- *Professional societal meetings such as the NWAFS or AAFS.*
- *Seminars.*
- *Short courses such as those provided by instrument companies.*
- *Training provided by the DEA, FBI, CCI, or other governmental entities.*
- *Private vendors offering courses in computer software use, career enhancement, etc.*
- *Department and the Division of Human Resources training.*
- *College courses.*
- *Annual discipline meetings.*
- *On-the-job training.*
- *On-line or computer based training.*

16.2.5f.4 The process for application and follow-up to employee development opportunities is as follows:

- *Staff members interested in attending training (in-state or out-of-state) shall apply for training using currently approved form or electronic process equivalent and should make the request at least 30 days in advance.*
- *If possible, the immediate supervisor and the laboratory manager shall approve all training requests. Discipline leads should also approve any discipline specific training requests.*
- *The training request shall be submitted to the Headquarters office for approval.*
- *The request shall be approved or denied by the Laboratory System Director (or appointed authority) for in-state requests and by the Major, Lt. Colonel, and Colonel (or appointed authorities) for out-of- state requests based on considerations such as need, budget (current funding situation), caseload demand, and input from the appropriate Discipline Lead, the Lab Manager, and the Quality Manager.*
- *When follow-up reports, etc. for prior training attendance, are more than 60-days delinquent, requests for new training may not be approved until such reporting is made current.*
- *Applicant shall be informed whether his/her request for training was approved or denied.*
- *Application for college classes shall follow ISP procedure.*
- *Follow-up to training shall include providing the following:*

A certificate of completion (or the agenda, if a certificate is not available).

- *Names and qualifications of instructors/presenters (or reason why the information is not available),*
- *A brief description of the teaching points.*

- *A brief evaluation of the training. It is expected that individuals returning from training will present pertinent information to their discipline or lab. The information may be disseminated as part of a discipline/lab meeting or in a briefing email distributed to discipline/lab members. Providing a copy of the email or meeting minute notes will fulfill this requirement (the training evaluation is not necessary for required annual trainings, training in which all pertinent staff have attended, ISP supervisor related training, or other non-career development seminars/classes).*

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to the following.

6.2.6 a development, modification, verification and validation of methods, this is covered in 7.2.2 validation of methods and 6.2.5e authorization of personnel.

6.2.6 b analysis of results, including statements of conformity or opinions and interpretations, this is covered in section 7.8 reporting of results and 16.2.5c.3 steps in training an individual.

6.2.6 c report, review and authorization of results, this is covered in 16.2.5c.3 steps in training an individual. Lists of authorized analysts and technical reviewers is maintained by the quality manager and are accessible to all staff electronically in the document management system.

6.3 Facilities and environmental conditions

6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results. These conditions may include but are not limited to, security, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activity shall be documented.

16.3.2 *An evaluation is performed when drafting analytical methods to determine if any accommodation and/or environmental conditions need to be controlled in order for a proposed analytical method to give accurate results. The approved analytical method shall specify the acceptable range for accommodation or environmental conditions that need to be controlled as determined through the evaluation. The examination process is stopped when accommodations or environmental conditions are outside the specified range and/or jeopardize the results of examinations being performed.*

6.3.3 The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures.

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but are not limited to:

6.3.4a Access to the operational area of each laboratory is controllable and limited. Visitor access to the operational areas of a laboratory is restricted.

16.3.4a.1 Access to the laboratory:

16.3.4a.1.1 Only personnel staffed to the laboratory as part of their routine function (e.g., forensic scientists, forensic evidence specialists, laboratory technicians and assistants, lab managers, the Quality Manager, the Laboratory System Director, the Police Services Major, and administrative support) or those individuals designated by either the laboratory manager, system director, or quality manager shall have unrestricted access to any forensic laboratory during normal duty hours, after-duty hours, and the opening and closing of the laboratory.

16.3.4a.1.2 A written record is kept of each emergency access to a laboratory.

16.3.4a.2 Laboratory visitors:

16.3.4a.2.1 Anyone entering the operational areas of the laboratory who is not an ISP Forensic Services employee shall be required to sign a log book prior to entering any such portion of the laboratory. Operational areas of the laboratory are defined as anywhere within the ISP designated ISPFS laboratory space that evidence is open or being analyzed, and any evidence storage area.

16.3.4a.2.2 This logbook shall contain pertinent information to identify the individual, the time period of the visit, and the reason for the visit.

16.3.4a.2.3 Laboratory personnel shall normally accompany any visitor accessing operational portions of the laboratory. However, visitors, such as instrument repair technicians, may be left alone in an area of a laboratory, while repairing an instrument provided that the following requirements are met: a monitor is assigned to ensure that these security requirements are followed; all evidence in the area is securely locked up; the visitor remains in the work area except to leave or locate the monitor; and the visitor is checked regularly.

16.3.4a.2.4 Visitors shall don appropriate safety attire.

16.3.4a.3 All exterior entrance/exit points have adequate security control.

16.3.4a.3.1 Entry and Exit points to the laboratory shall have operable locks. The entries shall be locked at all times when not under the direct supervision of staff. The laboratory is alarmed after working hours when the laboratory is not occupied.

16.3.4a.4 Internal areas requiring limited/controlled access have a lock system.

16.3.4a.4.1 Laboratory rooms with restricted access are kept locked unless occupied by designated staff. Keys, door security codes, or keycards to restricted areas are only issued to designated staff. A room may have restricted access on a periodic basis. The laboratory manager must designate who has access to restricted rooms.

16.3.4a.5 Accountability for all keys, magnetic cards, etc., is documented and their distribution limited to those individuals designated by the laboratory manager to have access.

16.3.4a.5.1 The laboratory manager or designee is the custodian of the record for all keys, pass cards, security codes, etc. allowing access to the laboratory and to restricted rooms. A record of the individuals having possession of all such devices allowing access to the laboratory and restricted rooms shall be maintained either in hard copy or electronically.

16.3.4a.5.2 All security codes, keys, etc. shall be surrendered upon termination of employment. Security codes shall be removed in a timely fashion from any electronic access device whenever an individual leaves employment, loses or compromises any such device. Locks shall be rekeyed, replaced, or taken out of service whenever a key associated with that lock is lost or compromised.

16.3.4a.6 Evidence storage areas are secured to prevent theft or tampering and there is limited, controlled access. The storage conditions are such as to prevent loss, deterioration and contamination and to maintain the integrity and identity of the evidence. This applies before, during, and after examinations have been performed. (Procedures 17.4)

16.3.4a.7 A fire detection system is maintained at each laboratory.

6.3.4b prevention of contamination, interference or adverse influences on laboratory services

16.3.4b.1 Effective separation between neighboring areas is made when activities are incompatible. Care must be taken with the performance of incompatible activities to ensure the accuracy of results.

16.3.4b.2 Analytical balances shall not be used when vibrations caused by laboratory or non-laboratory equipment would impair the accuracy of weighing. (If vibration is an on-going problem, the balance could be protected by a special anti-vibration platform.)

16.3.4b.3 Visitors may be restricted from operational areas where they could contaminate or disrupt work. Reasonable viewing accommodations (e.g. closed circuit video) will be made available when ISPFS is court ordered to provide evidence analysis viewing.

16.3.4b.4 Measures are taken to prevent cross-contamination as appropriate through separation by space, time, or physical barriers. These measures may include having only one exhibit open at a time and/or analyzing questioned and known samples at a different time or place.

16.3.4b.5 Measures are taken to ensure good housekeeping. Each laboratory shall typically be cleaned on a weekly basis and the cleaning may include sweeping floors, emptying trash, etc. Other janitorial services shall be provided periodically as needed. Each laboratory shall be maintained in a generally presentable condition and all essential cleaning will be performed that is required to protect evidence from contamination and the staff from unnecessary health and safety risks. Special measures are taken on a situation by situation basis as necessary.

16.3.4b.6 Laboratories are to be cleaned by contract cleaning staff only if the door to the individual laboratory is open and staff is present in the facility.

16.3.4b.7 Laboratory counters, hoods, and equipment shall be cleaned as needed by the staff

16.3.4b.8 Tools, equipment, and materials are stored in their proper location at the end of each workday unless continuous or extended analysis requires use of the equipment.

6.3.4c effective separation between areas with incompatible laboratory activities. See 16.3.4b.1

6.3.5 Appropriate care is taken to ensure that environmental conditions do not invalidate the results or adversely affect the required quality of any examination. Particular care is taken if sampling and/or examinations, which can be affected by environmental conditions, are performed outside the permanent laboratory facility.

6.4 Equipment

6.4.1 The laboratories of Forensic Services have all the equipment necessary for the performance of approved analytical methods. This includes apparatus needed for sampling, preparation, and analysis.

6.4.2 When equipment is used that is outside the permanent control of Forensic Services, staff ensures that all the requirements of the management system are met prior to use of the equipment.

6.4.3 Forensic Services creates and implements quality procedures for the safe handling, storage, use and planned maintenance of equipment to ensure proper functioning and in order to prevent contamination or deterioration. If specified in the analytical method that equipment may be used offsite the method will have procedures for transportation of the equipment.

16.4.3 Maintenance plans for equipment are described in corresponding analytical methods, if appropriate. All equipment will be stored in the laboratory and is handled and used by approved analysts or trainees under supervision of approved analysts.

6.4.4 Forensics services verifies the equipment conforms to specified requirements before being placed into service.

16.4.4 Prior to being placed into service and when equipment goes outside the direct control of Forensic Services for a period of time, Forensic Services ensures that the performance and/or calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

6.4.5 Equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

16.4.5 The accuracy required and the specifications relevant to the examinations performed for equipment used for measurement are included or referenced in the analytical methods.

6.4.6 Equipment shall be calibrated when, the measurement accuracy or measurement uncertainty affects the validity of the reported results, and or calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7 The forensic laboratory has an established calibration program, for equipment that requires calibration. This program is reviewed and

adjusted as necessary in order to maintain confidence in that status of calibration.

16.4.7.1 Each piece of equipment/instrument used in casework analysis that requires calibration or performance verifications shall have a documented program. This analytical program shall reflect the current requirements based on the use of the instrument/equipment. The program shall be included in or referenced in the analytical methods, for which the instrument/equipment is used, may be an in-house program included with the calibration record, maintenance record (for performance verification) or may be a manufacturer-supplied program for calibration or performance verification.

16.4.7.2 New instruments/equipment shall not be used for casework analysis until the discipline lead has approved the calibration program and documentation form, if required, the performance verification and documentation, if required, the maintenance program and documentation form, and confirmed that the appropriate performance verification, calibration, and maintenance has been performed.

6.4.8 All equipment that requires calibration is labeled to indicate the status of its calibration whenever practical. The label includes the date last calibrated and 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, is taken out of service, and clearly marked until it has been repaired and demonstrated to perform correctly. The effect of the defect or departure from specified limits on previous tests examinations is evaluated and the laboratory initiates the control of nonconforming work policy and procedure if it is determined that the equipment defect or departure could have adversely effected the results of analysis.

6.4.10 When intermediate checks and/or performance verifications are needed to maintain confidence in the status of equipment these checks are carried out in accordance with the related quality procedure and the appropriate analytical method.

16.4.10.1 Calibration, intermediate checks, and/or performance verifications of equipment that has a significant impact on the results of an examination are performed after any activity that might significantly affect the equipment such as maintenance or repair.

16.4.10.2 Intermediate check intervals and performance verification intervals established by the manufacturer are complied with unless the user has documentation demonstrating that the equipment is stable for some longer time interval.

16.4.10.3 Discipline leads will determine if any equipment needs to have an intermediate check and/or performance verifications after shutdowns, whether deliberate or unplanned.

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

16.4.11 Correction factors and reference values are addressed as appropriate in the analytical methods using calibration and reference materials.

6.4.12 Equipment used for examinations, including hardware and software, are safeguarded from adjustments that invalidate test results/status.

16.4.12 To safeguard equipment from adjustments that would invalidate the test results, all equipment used for examinations are located in secure areas within the laboratory. This equipment is only used by trained personnel or by individuals working under the direct supervision of trained personnel.

6.4.13 Records are maintained for equipment which can influence laboratory activities. Each piece of equipment/instrument will have its own record in the lab near the instrument, or in a location denoted in the analytical method (the laboratory may also maintain an equipment list.) The records shall include the following, where applicable:

a) Identity of the equipment and its software and firmware version;
b) Manufacturer's name, type identification, and serial number or other unique identification;
c) Evidence of verification that equipment conforms with specified requirements;
d) Current location,
e) Calibration dates, results of calibration, adjustments, acceptance criteria, and the due date of the next calibration or calibration interval, and performance verifications, where applicable;

16.4.13 e) A calibration record shall be maintained for all pieces of equipment that require intermediate checks or calibration. This record shall contain the following documentation, at a minimum:

- *Type of instrument and its unique identification;*
- *Calibration procedure and/or intermediate check procedure;*
- *Acceptance criteria for calibration and/or intermediate checks;*
- *Appropriate interval of calibration and/or/ intermediate checks;*
- *Date performed,*
- *Results, reference standard, and initials of individual performing calibration.*

f) Documentation of reference materials, results, acceptance criteria, relevant dates and period of validity.

g) Maintenance plan, where appropriate, schedule of performance verifications, where applicable, and the maintenance and performance verifications carried out;

16.4.13g) A maintenance record shall be kept for all pieces of equipment that require maintenance, repair, or performance verification. The record shall contain the following documentation at a minimum:

- *Type of instrument and unique identifier;*
- *Maintenance procedure(s);*
- *Schedule for maintenance;*
- *Acceptance criteria if applicable;*
- *Maintenance performed, date the maintenance was performed, and initials of individual performing maintenance;*
- *Repairs performed: date; initials of individual performing repair if employed by ISP Forensic Services; name and company, if the person performing the repair is not employed with ISP Forensic Services.*
- *Performance verification, if required, and the acceptance criteria.*

h) A description of damage, malfunctions, modifications or repair to the equipment; This will be documented in the maintenance record of the instrument along with the disposition of the instrument after maintenance has been performed.

6.4.14 Personnel are trained and authorized operate Forensic Services equipment. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer) are readily available for the equipment users.

16.4.14.1 Forensic Service personnel who have successfully completed their approved training plan or employees and contract technical reviewers working under the direct supervision of trained personnel are authorized to use the corresponding equipment/software. Trained interns are also permitted to use equipment/software (see 9.1.2). Individuals not employed by ISP Forensic Services or under contract to provide repair, service, or technical review will not be permitted to use laboratory instrumentation, equipment, or software.

16.4.14.2 Maintenance shall be performed in accordance with up-to-date instructions in the documented procedure on or near the schedule required by the maintenance procedure. Some instruments are used by multiple disciplines, which may differ in their calibration and maintenance procedures. Only one procedure needs to be used if it meets the requirements of all users.

6.5 **Metrological traceability**

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing the measurement uncertainty, linking them to an appropriate reference.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory (ISO/IEC 17025 lab that is accredited to provide that service) or

16.5.2a The following measuring equipment may require calibration traceable to a SI primary standard:

- *Balances*
- *Thermometers or other temperature measuring devices*
- *Pipettes excluding volumetric class A glassware*
- *Volumetric glassware excluding class A glassware*
- *Rulers and other distance measuring devices*
- *Syringes used for quantitative analysis*

16.5.2a.1 Each discipline shall designate in the analytical methods the measuring equipment that requires calibration and whether calibration shall be performed by a vendor or by laboratory staff.

b) certified values of certified reference material provided by a competent producer with stated metrological traceability or to the SI (labs accredited to 17034) or

c) 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 traceability to an appropriate reference e.g.:

a) certified values of certified reference materials provided by a competent producer

b) results of reference measurements procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

16.5.3.1 Authenticating and using reference material and controls:

16.5.3.1.1 Reference material and controls shall be authenticated prior to being used for casework examinations unless they are obviously authentic such as a human blood control drawn from a Forensic Services employee. A certificate of analysis received from the manufacturer may serve as authentication for standard material and controls.

16.5.3.1.2 There shall be a clear demarcation between reference materials and controls that have been authenticated and those that have not been authenticated.

16.5.3.1.3 The procedure used to authenticate reference material and controls shall be documented in an analytical method. Alternatively, the analytical method can designate the controlled document used to authenticate standards and controls.

16.5.3.1.4 The reference materials and controls used in an analytical method shall be described in an appropriate analytical method.

16.5.3.1.5 Records shall be maintained of the results obtained for reference materials and controls for casework analysis. These results may be centrally stored or located in the case record. If these results are centrally stored, then either the case file or the analytical method shall designate that they are centrally stored and describe the file where these results are stored.

16.5.3.1.5 Reference materials and controls shall not be used past their expiration date unless the stability or integrity is first checked and the discipline lead gives documented approval. The discipline lead must notify the lab manager(s) of these variances. Circumstances may arise where the expiration date is not applicable, and the purpose of the standard material or control has been altered, (e.g. Cerilliant drug reference materials have expiration dates that are applicable for quantitative analysis but do not apply for qualitative analysis).

16.5.3.2 Authenticating and using controlled substances reference material:

16.5.3.2.1 All controlled substances that are retained by a laboratory of Forensic Services shall be entered into the appropriate controlled substances inventory except controlled substance standards that can be purchased without a DEA license.

16.5.3.2.2 ***Primary standards:*** *These are the bulk amounts of controlled substance reference material obtained from manufacturers and stored in high security in the Meridian laboratory. Small amounts (see bench standards below) are dispensed as bench standards and used in analysis. The Coeur d' Alene laboratory is authorized to maintain primary standards of methamphetamine for quantitative analysis. The same security measures listed below for the primary standards located in Meridian will be followed in Coeur d' Alene for these standards. When a primary standard (or a sample being treated as a primary standard) is being used the analyst using the standard is responsible for securely storing the standard during that time. The standard should be checked out just prior to using it and returned to the primary storage cabinet shortly after the analysis or transfer is complete.*

16.5.3.2.2.1 Access to the primary standards cabinet (located only in Meridian) shall be limited to personnel designated by the laboratory manager. The laboratory manager shall maintain a list of the personnel having access to this drug cabinet.

16.5.3.2.2.2 The primary standards cabinet shall remain locked at all times except when being accessed by designated personnel.

16.5.3.2.2.3 The primary standards cabinet shall be structured in such a way that two designated personnel shall be required to open this cabinet at any given time.

16.5.3.2.2.4 A logbook shall be maintained for the primary standards cabinet that shall list the date and signature or initials of personnel accessing the primary drug cabinet.

16.5..3.2.2.5 Inventories shall be kept of the primary standards listing drug, source (if known), initial gross weight, audit record, and authentication.

16.5.3.2.2.6 The gross weight of the primary standard and the container shall be entered into the inventory form prior to removing any reference material from its container. After a portion of the standard has been removed from the container, the gross weight of the primary standard including the weight of the container, the date, and the initials of the user shall be entered into the inventory form.

16.5.3.2.2.7 After use, the primary standard container shall be returned to the double locking cabinet. Both parties involved in obtaining the primary standard shall initial the log sheet.

16.5.3.2.2.8 The total weight of the primary standard and container shall be audited annually.

16.5.3.2.3 ***Bench standards*** *(A limited quantity of an authenticated and traceable drug standard that is used in the examination of drug evidence. The security measures for bench standards are less stringent than those for primary standards.):*

16.5.3.2.3.1 Allowable amounts of bench standards: marijuana, psilocybin mushrooms, and GHB - 50 grams; Schedule I and II controlled substances, 300 milligrams; and Schedule III, IV, and V controlled substances, one gram or five tablets.

16.5.3.2.3.2 The bench standards shall be maintained in a secured part of the laboratory.

16.5.3.2.3.3 An inventory sheet shall be created when any drug is added to the bench standards of a laboratory. This sheet shall reflect the name of the drug, source, date added, the initial net/gross weight, and how authenticated.

16.5.3.2.3.4 A gross weight shall be recorded in the inventory sheet each time a bench standard is removed from its container along with the name of the user and the date.

16.5.3.2.3.5 The combined weight of the bench standard and container shall be audited annually.

16.5.3.2.3.6 Quantities of controlled substances in excess of the amounts allowed for bench standards may be held and used by individuals performing research and development. However, the Laboratory System Director shall grant prior approval in writing for each request. In some cases the Laboratory System Director may require the substance to be handled like a primary standard.

16.5.3.2.4 ***Secondary standard****: (this is a laboratory produced or casework sample that has been authenticated by comparing it or the significant component(s) to authenticated controlled standards by either GC/MS or FTIR). The resulting record of this comparison shall be maintained. Secondary standards shall be treated like primary standards/bench standards, as applicable, in regards to appropriate amounts, storage, inventory, documentation, and traceability. If a secondary standard is retained from casework and the amount exceeds the amount allowed to be retained for training (about the same amount as needed to perform testing and must not consume more than half of the original sample), the investigating officer (the law enforcement agency's appointed authority or prosecuting attorney's appointed authority are also acceptable) must grant written permission prior to retaining the sample. The written permission will be placed in the case file. The case number from which the sample was obtained will be incorporated into the inventory sheet either as the lot number or noted on the sheet for reference.*

16.5.4 Reference collection: Groups of common items intended to assist in determining the class or individual characteristics of evidence.

- *Fully documented: description of pertinent characteristics, such as make and model of a firearm or chemical name of a drug standard. Documentation may be made on the reference material itself, on it proximal packaging, or as part of database record.*
- *Uniquely identified: Each item or group of similar items will have a unique name as described in the written policy regarding the reference collection. Examples of ways that individual data or items in a reference collection may be uniquely identified include a laboratory generated alphanumeric code, database generated alphanumeric code, or the name of the item if unique.*
- *Properly controlled: Limiting access to the reference collection.*

16.5.4.1 Current reference collections:

- *Firearm reference collection*
- *Controlled substance reference collection*
- *FTIR laboratory developed reference database*
- *GC/MS laboratory developed reference database*
- *Fire debris reference collection*
- *Toxicology parent drug and metabolites*

6.5.5 Intermediate checks: checks needed to maintain confidence in the calibration of reference standards and reference materials are carried out according to the appropriate analytical methods on the schedules defined in the methods.

6.5.6 Transport and storage: Each discipline that utilizes reference standards or reference materials shall have an established program for handling, transporting, storing, and using reference standards/reference materials to the extent necessary to prevent contamination or deterioration and to protect the integrity of the reference standard/reference material. These programs are described in the discipline- related analytical methods.

6.6 **Externally provided products and services (purchasing)**

6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used when such products and services:

a) are intended for incorporation into the laboratory's own activities

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider.

c) are used to support the operation of the laboratory.

6.6.2 The laboratory shall have a procedure and records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services.

16.6.2a Evaluation of products and services:

16.6.2a.1 Each discipline lead will evaluate the supplies used in the analytical methods for their discipline. The discipline lead will identify supplies for which more than one technical specification of a supply is available and the technical specification could affect the quality of examinations performed. The evaluation of the supplies will be based on how the supply is intended to work for the examination performed.

16.6.2a.2 Discipline leads will specify, in appropriate documents, the quality levels for all supplies that are subject to this procedure/policy and compile a list of these supplies and the required quality levels. Discipline leads will need to review this list whenever analytical methods are added or changed.

16.6.2a.3 Critical products and services: The discipline lead for each discipline will identify any products and services that are critical to the quality of analysis. The discipline lead will provide the required specifications for critical supplies and services, these will be added to the list and designated as critical. This list will be reviewed by the discipline lead annually and whenever analytical methods are added or changed.

16.6.2a.4 This list will be maintained as a quality record. It must be available to staff who orders supplies. When a list is revised, the appropriate staff will be notified.

b) defining the criteria for evaluation selection, monitoring of performance and re-evaluations of the external providers

16.6.2b Evaluation of suppliers of products and services: An evaluation of the provider for these products and services will be performed and documented. The criteria for evaluation may include but is not limited to references, accreditation, formal recognition, or past performance. Documentation will be forwarded to the Quality Manager. The Quality Manager will store the records and a list of approved providers will be published in the laboratory electronic document management system. Staff will order critical products and services from the approved providers only. The discipline leads will re-evaluate the suppliers annually. Suppliers will be monitored through the review of ordering documentation, at least quarterly.

c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer.

16.6.2c.1 *Each laboratory manager will designate who is responsible for the ordering of products that have specific technical specifications and services that affect the quality of examinations.*

16.6.2c.2 *When making an order regarding supplies which have technical specifications, the designated purchaser will check the supply/service list and ensure that the technical specifications comply with the list. The designated purchaser shall initial and date the ordering document to verify that the technical specifications agree with the listed requirements.*

16.6.2c.3 *The ordering document containing the documented verification will be stored as appropriate so that it can be retrieved and compared to the supplies that are received.*

16.6.2c.4 *When the request for service or supply order is made verbally, written documentation must be maintained.*

16.6.2c.5 *Refer to the Idaho State Police Employee Handbook for purchasing procedures.*

16.6.2c.6 *When supplies that have defined technical specifications are received, the supplies will be checked against the ordering document to verify that the quality level of the received supplies are acceptable.*

16.6.2c.7 *If the supplies comply with the ordering document, the staff receiving the supply will initial and date the supply if feasible. If it is not feasible to initial and date the supply, then the review will be documented on either the ordering document or packing slip.*

16.6.2c.8 *If supplies purchased have technical specifications, verification will be performed to document that the supplies meet requirements set forth by the discipline lead.*

16.6.2c.9 *If a supply is stored in the laboratory prior to verification, measures must be taken to ensure that the supply is verified before use. Such measures include either marking the supply as unverified or storing it in a location intended for unverified supplies*

16.6.2c.10 *Documentation of service must include the date of service, description of service performed, results of service and the name of the service provider, when applicable.*

d) taking actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

16.6.2d 1 *Whenever a supply does not meet the required specification(s), the vendor will be notified of the failure to provide the specified supply; the supply will be returned to the vendor if possible; the discipline lead, lab manager, and the quality manager, shall be notified of the discrepancy; and the quality manager shall record the discrepancy.*

16.2.2d.2 Single instances or minor discrepancies from what was ordered compared to what was received shall be handled according to the paragraph above with no further action. The discrepancy will be documented and be available for monitoring review.

16.2.2d.3 Where the ability of the vendor to supply the required quality of a supply becomes questionable as demonstrated by multiple delivery discrepancies or a few very serious discrepancies, the use of the vendor shall be suspended.

16.2.2d.4 A suspended vendor shall not be used until demonstrating adequate corrective action to ensure that the discrepancy will not recur except as follows: If Forensic Services uses a vendor whose ability to deliver supplies that meet specifications is questionable or if the required specification cannot be determined without on-site analysis, then each lot shall be tested by an approved analytical procedure with the results recorded and the supply cleared for use prior to being used for evidence or quality control.

6.6.3 The laboratory shall communicate its requirements to external providers for:

a) the products and services to be provided: (would be included in purchase document)

b) the acceptance criteria; (would be included in purchase documents or correspondence.)

c) competence, including any required qualification of personnel; (would be included in purchase documents)

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises (this does not currently apply to ISPFS)

6.6.4 Subcontracting

16.6.4 If a Forensic Services laboratory subcontracts the analysis of evidence; the work is placed with a competent subcontractor. Competent subcontracting forensic laboratories include laboratories that are accredited to ISO/IEC 17025 or other laboratories that have been assessed for competency and have been approved for use by the discipline lead and Quality Manager.

Since the three laboratories of Forensic Services operate under the same management system and overall administration, evidence transfers between these three laboratories for purposes of analysis is not subcontracting.

16.6.4.1 Each subcontractor laboratory employed by Forensic Services to provide the analysis of evidence must establish competency to perform such subcontracted work. The discipline lead is responsible for insuring that a subcontractor laboratory has met requirements for evidence analysis within a given forensic discipline. All documentation of analytical competency must be obtained prior to Forensic Services submitting samples for analysis and a subcontractor's documentation of competency will reside with the Forensic Services Quality Manager.

16.6.4.2 Customers are advised of work (or any portion thereof) that is being subcontracted in writing, when appropriate, and their approval is obtained (preferably in writing).

16.6.4.3 Forensic Services is responsible to the customer for the work performed by a subcontractor.

16.6.4.4 In circumstances where the customer or a regulatory authority specifies the laboratory to be used, Forensic Services is not responsible for the results and no contractual relationship exists between Forensic Services and any such laboratory.

16.6.4.5 If the customer chooses to submit evidence items to a contract laboratory for DNA analysis, any additional/subsequent items for the same case should also be submitted to the contracting laboratory for testing. ISPFS is under no obligation to accept items of evidence for DNA testing, once the customer has outsourced a portion of the case, due to national standards regarding data acceptance and sample consumption issues.

16.6.4.6 Results and/or data produced by subcontractors shall undergo technical review and approval prior to release to customers.

7 Process Requirements

Forensic Services requires that customers agree to the terms and conditions of Forensic Services for analyzing their evidence prior to examinations. These conditions are as follows: the staff of Forensic Services determines the examinations to be performed, the scope of analysis, the items of evidence to analyze, the laboratory of Forensic Services that provides the examination, the sampling plan that will be followed, the structure, and content of the examination report. The act of submitting the evidence to Forensic Services and completing the electronic ILIMS submission process or a paper submittal form indicates that the submitting agency agrees to the terms and conditions of Forensic Services for analyzing their evidence. These terms and conditions are available on the Forensic Services web site and posted in the receiving area of each laboratory.

7.1 **Review of requests, tenders and contracts**

7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

a) The needs of the customer regarding the evidence or calibration items including the examination(s) or calibration(s) desired are adequately defined, documented, and understood given the nature of the evidence, circumstances, and legal charges.

b) Forensic Services has the capability and resources to provide appropriate service in regards to the request.

c) Where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer approval

d) The appropriate analytical methods are selected to meet the needs of the customer.

17.1.1.1 The ISPFS customer agreement contract states that Forensic Services staff will select the appropriate analytical method to be utilized in analyzing evidence or calibrating breath instruments according to laboratory guidelines in accordance with ISO/IEC 17025 or accreditation standards. Prior to the examination or calibration of evidence/items, laboratory personnel (a FES or employee assigned FES duties) will evaluate the request to ensure that the needs of the submitting party are understood and that Forensic Services has the capability and resources to perform the services that are being requested Any communications between the laboratory and the submitting agency to clarify or resolve differences shall be recorded in the activity log or case info tab "case correspondence section" of ILIMS. Items received in the laboratory requesting digital forensic analysis (Cyber) will be accepted for evidence storage and transfer only. ISPFS does not currently provide this analysis and the acceptance of this evidence does not imply a contract for ISPFS to perform this examination.

- *If a case has multiple service requests, and the laboratory accepts the case but does not complete all of the service requests, the customer will be notified either through case correspondence or by a statement in the case report. For example:*
- *A blood sample with a request for both toxicology and alcohol, and the alcohol result is greater than a 0.10. A statement is placed on the alcohol report indicating that toxicology testing was requested, but was not performed, due to the alcohol level.*
- *A blood sample with a request for both toxicology and alcohol. The submission indicated there was a valid breath test of a 0.04. The lab staff could contact the agency letting them know alcohol testing would not be completed because there was a valid breath test.*

17.1.1.2 At the time this section of the quality manual was last revised, Forensic Services had approved analytical methods and can provide examinations in the following areas:

- *Forensic biology screening and DNA analysis*
- *Controlled substance analysis and cannabis typification*
- *Firearms, toolmark examinations, and serial number restorations*
- *Impression evidence: latent print processing and comparisons*
- *Toxicology analysis: qualitative and/or quantitative analysis of urine and blood for drugs of abuse and other impairing substances; quantitative or qualitative analysis of blood and vitreous humor for ethyl alcohol and other commonly abused volatiles; and ethyl alcohol and other commonly encountered volatiles contained in beverages or liquids*
- *Fire debris/arson evidence analysis/ignitable liquids*
- *Breath alcohol calibration*

17.1.1.3 The implied contract gives the analyst the discretion of selecting the appropriate examinations to be performed to provide the most useful information to the customer

7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered inappropriate or out of date.

7.1.3 Statements of conformity to a specification or standard for the test or calibration, the specification or standard and the decision rules are inherent in the requested specification or standard.

7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer: Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of results.

7.1.5 The customer shall be informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.7 The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

7.1.8 Records of review, regarding the examinations or calibrations to be performed, including any significant changes, are maintained. A log of conversations with the submitting party or other individuals regarding evidence acceptance/rejection, case analysis, conclusions and opinions, and consultation will be maintained in the case record.

17.1.8.1 Each request will be reviewed when the evidence is received. The person that receives and accepts the evidence will document this review by accepting the evidence in ILIMS. The review will cover any work that is subcontracted.

17.1.8.2 All pertinent discussions with the submitting party or others regarding case acceptance and analysis will be documented. The documentation will include the date, the name of the forensic services employee involved in the discussion, the name and agency with whom the discussion took place with and the essence of the conversation. Documentation of the conversation will be maintained in the associated case record in ILIMS.

17.1.8.3 The ISPFS customer agreement contract states that Forensic Services staff will select the appropriate analytical method to be utilized in analyzing evidence according to laboratory guidelines in accordance with ISO/IEC 17025 or accreditation standards and that a customer will be informed if an examination decided upon by ISPFS significantly deviates from the customer's request. Any communications between the laboratory and the submitting agency to explain deviations shall be recorded in the case record.

7.2 Selection, verification and validation of methods.

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement of uncertainty as well as statistical techniques for analysis of data.

17.2.1.1.1 Analytical methods: A written document that specifies the steps, equipment, and materials necessary to perform a task properly. Analytical methods are written to provide instruction and standardization for activities affecting quality. In forensic services, they are used primarily to describe the accepted manner of performing casework analysis. It is acceptable for the analytical methods to contain more information than is required by this manual as long as information does not contradict the requirements for analytical methods as stated within this manual.

17.2.1.1.2 Infrequently performed tests or analyses: Infrequently performed tests or analyses are those which are contained within an approved analytical method but are not used on a routine basis for casework. Tests/analyses that have not been used for casework within the given laboratory within a six month period will have competence verified through reverification before the test/analysis is performed on casework samples. This may be accomplished by running the appropriate controls for the method.

7.2.1.2 All analytical methods, procedures, and supporting documentation, such as work instructions, standards, manuals and reference data relevant to the laboratory activities shall be kept up to date and shall be made readily available to personnel (see 8.3)

7.2.1.3 The laboratory shall ensure that when it specifies and uses a standard analytical method that it uses the latest valid version of that method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

7.2.1.4 The contract specifies that the laboratory will select an appropriate method. Methods may be developed from methods published in international, regional or national standards, or by reputable technical organizations, or in scientific texts or journals, or as specified by the manufacturer of the equipment, Laboratory –developed or modified methods can also be used.

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds periodic review shall be carried out to confirm the needs of the customer are still being fulfilled. Any modification to the development plan shall be approved and authorized.

7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, and authorized. The customer accepts potential deviations in the contract.

17.2.1.7.1 There may be situations that require deviation from quality policies. Permission, preferably in writing, from the Laboratory System Director, Quality Manager, or a Laboratory Manager, shall be obtained prior to the deviation. The deviation, necessity for the deviation, and prior permission shall all be documented in a record maintained by the Quality Manager. If the permission to deviate from a policy was verbal, the permission shall be documented after the fact and included with the record.

17.2.1.7.2 Deviation from an analytical method: It is expected that the staff of forensic services will follow approved analytical methods. However, the nature of the work in forensic science sometimes presents non-typical situations where an approved analytical method does not fit. This policy describes the steps that an analyst shall take when deviating from approved analytical method(s). Deviations should be requested prior to the deviation as much as possible; however, there may be occasions when the deviation is not realized until after it has occurred. These instances will be evaluated on a case by case basis to determine whether a deviation is appropriate and will only be granted prior to reporting the result/conclusion.

*17.2.1.7.2.1 **Practices:** when an analyst realizes that for some reason he/she would like to deviate from an approved analytical method, the analyst shall contact the discipline lead to initiate a deviation. The discipline lead and the analyst shall review the deviation. If the discipline lead needs to initiate a deviation from the analytical method, the discipline lead shall contact their immediate supervisor. If the supervisor does not have the technical expertise to determine the scope of the deviation he or she should consult an analyst that does. The deviation is submitted to the Quality manager after technical approval.*

*17.2.1.7.2.2 **Deviation documentation** – the approved deviation will be placed into the electronic document management system; the case record for a deviation shall contain or reference the documentation noting the following:*

- *Description of the deviation.*
- *Justification for the deviation and evaluation of deviation effects.*
- *Concurrence by the discipline lead, or supervisor (if discipline lead is requesting deviation) to the deviation.*
- *Quality approval. The Quality Manager or designee will review the deviation to ensure it meets the requirements of the quality system.*

17.2.1.7.3 Methods may be developed for special or unique situations. They must be validated and approved by the discipline lead and the Quality Manager, but they do not have to be designated as an approved analytical method for Forensic Services. Appropriate documentation shall be kept in the case file.

7.2.1.8 Laboratory-developed analytical methods

The introduction of analytical methods developed by the staff of Forensic Services is a planned activity carried out by qualified staff equipped with adequate resources. A documented plan for the development of analytical methods shall be prepared prior to writing analytical methods. The discipline lead shall forward a copy of the plan to the Quality Manager, prior to its implementation and supervise the development of the analytical method. Plans are updated as necessary to incorporate new information as development proceeds and there is effective communication between all participants developing the analytical method. Customers agree prior to the analysis of evidence to accept non-standard analytical methods in use by Forensic Services. Non-standard analytical methods are validated and approved prior to being used on evidence. New analytical methods are developed according to and contain the information outlined in the related quality procedure.

17.2.1.8 Contents of analytical methods:

17.2.1.8.1 The numbering system: Section 1 shall be 1; Topic 1 shall be 1.1; and Item 1 shall be 1.1.1, etc.

*17.2.1.8.2. **History page:** This shall provide a list of revisions, the revision date, and the date accepted.*

*17.2.1.8.3 **Background/References:** This section may refer to the manufacturer's protocol or some other source from which this method was derived. It may in practice contain a variety of openings by way of providing the background information about the analytical method that is to follow. This section may be brief. Often an analytical method will be based on some literature reference. Other suggested references include relevant technical documents, published/accepted methods, in-house manuals, and equipment manuals. These will also be listed in this section*

*17.2.1.8.4 **Scope:** Specify the applicability of the analytical method and/or the range of samples for which it is suitable.*

17.2.1.8.5 ***Equipment/Reagents:*** *This shall be a list of the equipment needed to perform this analytical method. It is recommended that the list of equipment be as generic as possible. However, if the procedure requires specific equipment, that equipment shall be designated in the analytical methods. Equipment shall have calibration/intermediate checks and maintenance procedures and accompanying calibration/intermediate checks and maintenance logs as appropriate. This section will also list the reagents necessary to perform this analytical method. In some analytical methods, the preparation of the reagent will be described in this section while in other analytical methods preparation is elsewhere.*

17.2.1.8.6 ***The step-by-step procedure:*** *This section will vary depending on the analytical methods and the discipline. The writer needs to strive for the right level of detail. Too much detail makes an analytical method too cumbersome while too little detail leaves out important steps needed to perform the procedure properly.*

17.2.1.8.7 ***Detection and Identification Criteria****: Depending on the method, the detection and identification criteria may be part of the step-by-step procedure, a separate section of the analytical methods or in some cases, a totally separate analytical method. The identification criteria shall be included in one of these locations.*

17.2.1.8.8 ***Limitations to the method:*** *Does not need to be a separate section. However, limitations to a method shall be listed somewhere in the analytical methods, if applicable.*

17.2.1.8.9 ***Accommodation or environmental factors****: If there are applicable accommodation or environmental factors, which must be taken into account when performing the analytical method, they must be included in the method.*

17.2.1.8.10 ***Safety Concerns:*** *Specific or unique safety hazards shall be listed as part of the analytical methods if there are specific or unique safety concerns.*

17.2.1.8.11 ***Work Instructions:*** *Work instructions will be listed as a section of the applicable method if used by the discipline. Work instructions are a step-by-step process that is used to supplement the analytical method. Work instructions are not intended to replace the analytical method and the purpose of the work instructions is to provide a step-by-step guide for designated processes in the laboratory. The analyst is still responsible for knowing, understanding, and following the analytical method that the work instruction is based on (e.g. a list of steps to follow in the extraction of benzodiazepines from urine.) The discipline lead will ensure the work instructions comply with the analytical method and that the level of detail is appropriate. Work instructions must have a reference to the analytical method(s) they supplement. When an analytical method is updated it is the responsibility of the discipline lead to review corresponding work instructions and ensure compliance with the updated analytical method.*

17.2.1.8.12 The location of instrumental batch files, standards, and controls that apply to multiple cases shall either be indicated in the case file or in the analytical methods. If indicated in the analytical methods, the analytical methods shall indicate that the file is stored centrally in the laboratory.

17.2.1.8.13 As appropriate, analytical methods shall contain a discussion of precautions, sample preparation, and possible sources of error.

17.2.1.8.14 Include quality criteria as applicable:

- *If an equipment calibration is in a separate document, specify in the appropriate analytical method, the calibration procedure to use.*
- *Blanks, duplicates, standards, and positive and negative controls.*
- *Independent positive controls if the analytical methods generate quantitative results*
- *Acceptance criteria in regards to quality measures if applicable.*
- *The uncertainty of measurement will be addressed in analytical methods in which a quantitative result is reported.*

17.2.1.8.15 Each analytical method shall be uniquely identified, each page of an analytical method shall be numbered, designate the total number of pages, and the revision number (rev. #) and issue date in the bottom right hand corner.

7.2.2 Validation of methods

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as necessary to meet the needs of the given application or field of application. Analytical methods and equipment in place before April 1, 2001, do not need validation studies as they have been validated through proficiency testing and usage over an extended period of time. Nor do they require validation if they are rewritten to conform to an updated format. Methods and equipment validated between April 1, 2001 and issue date of this procedure must have documentation of validation and meet the procedural requirements that were in effect during that time. Only method and equipment validation begun after January 10, 2007 needs to meet the listed requirements. Validation may include one or a combination of the following.

a) Calibration or evaluation of bias and precision using reference standards or reference materials.
b) Systematic assessment of the factors influencing results
c) Testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) Comparison of results achieved with other validated methods;
e) Interlaboratory comparisons;
f) Evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

17.2.2.1.1 Validation is the confirmation by examination using objective evidence that the requirements for the intended use for a specific analytical method are fulfilled. The process of validation assesses risk; limitations of the method will be included in the analytical methods as appropriate.

17.2.2.1.2 Validated Analytical methods must be comprised of validated techniques or methods that are appropriate for the examination.

17.2.2.1.2.1 Methods need to be validated or revalidated:

- *Before their introduction into routine use.*
- *Whenever conditions change for which the method has been validated that may potentially have an effect on the outcome of casework analysis.*

- *Whenever the method is changed or reconfigured, in a way that may potentially have an effect on the outcome of casework analysis.*

17.2.2.1.2.2 General guidelines:

- *The person or team performing the validation shall have a complete understanding of the theoretical basis for the method. Individuals not approved for independent analysis in the discipline, must be authorized by the discipline lead to participate in the validation prior to beginning.*
- *If a method parallels or supersedes an existing method, the proposed method and the current method shall be compared using split samples if possible.*
- *It is recommended that the known samples be designed to resemble actual evidence materials as closely as possible so that the effects of such factors as the matrix of the sample, sample age, degradative environment, and sample homogeneity are taken into account. This is particularly important when attempting to apply a methodology to forensic materials originally developed for routine chemical or clinical samples.*

17.2.2.1.3 The extent and depth of validation studies shall be consistent with the novelty of the proposed analytical method.

- ***Standard methods** (published/validated standard methods) require a performance check to demonstrate the method works in the ISPFS lab environment in which it will be used.*
- ***Non-standard methods** (methods and techniques that are widely accepted in the science community that are being adopted by Forensic Services) require demonstration that the method or technique is accurate and reliable when performed by trained ISP Forensic Services personnel.*
- ***Laboratory-developed methods** (novel methods developed independently by Forensic Services) would require extensive validation.*

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new validation shall be performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for intended use, shall be relevant to customer's needs and consistent with specified requirements. (The DNA section will also follow the current Quality Assurance Standards)

17.2.2.3 Performance characteristics can include but are not limited to:

- *Measurement range*
- *Accuracy*

- *Selectivity/Specificity*
- *Limit of detection*
- *Limit of quantitation*
- *Measurement uncertainty of results*
- *Linearity*
- *Reputability/reproducibility*
- *Robustness against external influences*
- *Cross sensitivity against interference with matrix*
- *Bias*
- *Stability*

7.2.2.4 The laboratory shall retain the following records of validations:

a) The validation procedure used;
b) Specifications of the requirements;
c) Determination of the performance characteristics of the method;
d) Results obtained;
e) A statement on the validity of the method, detailing its fitness for the intended use.

17.2.2.4.1 The validation study must include:

- ***Validation plan-*** *the validation plan is a plan that includes the following elements. This plan must be approved before the validation study can be initiated.*
- ***Validation scope*** *- A list of minimum requirements, which are essentially acceptance specifications for the method.*
- ***Materials-*** *materials needed for the method.*
- ***Safety-*** *the safety procedures that apply to the method will be reviewed prior to beginning validation testing; this would include storage and disposal of chemicals.*
- ***Procedure-*** *this is a step-by-step description of the validation activities. This would include the performance characteristics that will be evaluated for the method.*
- ***Executive Summary****-brief events summary including major conclusions.*
- ***Results****-descriptive observations of test results, hard data from testing.*
- ***Conclusion*** *-this is a complete evaluation of the validation.*
- ***Reference****- list the sources for procedure or supporting procedure.*
- ***Names*** *- individuals who conducted validation, their title, and date of validation.*

- ***Competency*** *– documentation of competency testing of individuals who will be using the method at the conclusion of the validation. The participation in the validation may serve as the competency of those individuals to the extent they were involved but must be stated if so.*
- ***Approval****- The study will be evaluated and a fit for use memo will be drafted. The original memo will be kept with the quality manager and a copy will be stored with the validation study.*

17.2.2.4.2 The Quality Manager will approve validation plans before the validation study is initiated. At the discretion of the Quality Manager, the approval process can be performed with the assistance of a scientific review committee. The scientific review committee will be comprised of up to three individuals appointed by the Quality Manager. Documentation of this review and approval will be kept with the validation study and may be recorded by signing the validation plan or sending an e-mail stating the validation plan was reviewed and accepted.

17.2.2.4.3 Validation must be documented and the documentation will be kept with the validation study. Documentation must be sufficient to ensure that any qualified individual could evaluate what was done, by whom, when and replicate the validation process. Documentation will be available for review and will be maintained and stored by the discipline lead.

17.2.2.4.4 The quality manager reviews the documentation and determines if the documentation is adequate and if the validation study meets the specifications of the validation plan or may appoint a scientific review committee consisting of up to three individuals to review and approve the validation data. Validation data are evaluated against the stated performance criteria and conclusions about the validation study are made.

17.2.2.4.5 A fit for use memo is approved by the quality manager. The method or technique may then be incorporated into analytical methods.

7.3 Sampling

7.3.1 Sampling methods are included in the analytical methods. The methods address factors to be controlled to ensure the validity of subsequent testing and or calibration results. Sampling methods shall be, whenever reasonable based on statistical methods.

7.3.2 **Definition of sampling/sampling plan from Section three**: Sampling is a process whereby examining a portion of a substance allows the analyst to make inferences about the properties of the whole. A sampling plan is documented in an analytical method and describes how the representative

sample is collected, and the inferences that can be made by the analyst about the properties of the whole.

Sample selection – the process used to choose the evidence or portions of the evidence that will be examined. Conclusions are only made about the portion of evidence analyzed when the process of sample selection is employed. Sample selection involves such considerations as amount of evidence available, significance of the evidence, number of specimens available for analysis, etc. Sample selection is not sampling, which is a process of inferring properties of substances based on a representative sample.

17.3.2 As applicable, each discipline shall document in their analytical methods a sampling plan and/or sample selection for substances to be tested. Sampling plans shall, whenever practical, be based on appropriate statistical methods and shall address the factors to be controlled to ensure the validity of the test results.

7.3.3 The laboratory will retain records when a sampling plan is used. These records will include, where relevant:

a) the sampling plan used, if more than one is available;
b) the date of sampling;
c) data to identify and describe the sample;
d) the person performing the sampling;
e) relevant equipment used;
f) relevant environmental or transport factors;
g) diagrams or other equivalent means to identify the sampling location, when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.4 Handling of test or calibration items

7.4.1 Forensic Services maintains and follows quality procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of evidence and includes provisions necessary to protect the integrity of evidence, calibration items, and the interests of Forensic Services and its customers. In the rare instance that a customer provides handling instructions with the item, the lab will follow that request or contact the customer to resolve any concerns. Calibration items submitted to the lab are not considered evidence and as such, are not required to comply with the laboratory's packaging, sealing and storage requirements.

The calibration items are barcoded and scanned for tracking purposes in the laboratory.

17.4.1 Casework acceptance:

17.4.1.1 It is the responsibility of Forensic Services to provide support to law enforcement agencies, prosecutors, and public defenders. In order to provide the timely service, it is important to limit the services to situations that will resolve criminal cases or will support administrative license suspension (ALS). Deviation from these criteria shall have the approval of the Laboratory System Director.

17.4.1.2 Forensic Services shall accept evidence from law enforcement agencies (city, county, state, or federal), other governmental investigative units, prosecuting attorneys, public defenders, or other entities by court order. No work shall be done for private defense attorneys or the private sector in general.

17.4.1.3 Idaho School Districts shall be allowed to submit non-random juvenile drug tests (NJDT) samples only, in compliance with District policy as prescribed by Idaho Code 33-210. Idaho School Districts submitting NJDT samples shall do so through one individual per district or building in accordance with Forensic Services procedures for evidence handling and submission.

17.4.1.4 Evidence shall be accepted for analysis only if it shall assist in the identification of suspects, resolution of criminal charges against an individual, or establish whether a crime took place. Curiosity cases shall not be accepted.

17.4.1.5 Generally, a forensic evidence specialist should receive evidence. Evidence may be submitted via the ILIMS pre-log feature. The laboratory has provisions for the transfer of digital evidence. These files will be transferred by the submitting agency to the secured "Server File Manager". Upon notification from the submitting agency that the files have been transferred, the forensic evidence specialist will accept the case and the chain will reflect that the digital item is in the "Server File Manager" location in ILIMS (note: forensic evidence specialists do not have physical custody of, or access to, digital evidence stored in the Server File Manager). Evidence submissions will only be documented on a paper submission form with an extenuating circumstance, and the reason will be documented in ILIMS. "Accident victim samples" (AV) are not required to be pre-logged or have a paper submission form. AV samples have a form in the kit that accompanies the sample. The description of each item provided by the agency is populated into ILIMS along with the date of submission.

17.4.1.6 Customers are requested to make their own changes/corrections in the pre-log system before submission. ISPFS staff members are encouraged to request that customers correct information in pre-log before the evidence is accepted into the laboratory. ISPFS staff members may make changes to the case information after submission on the laboratory side of ILIMS, although these corrections will not alter the information in pre-log. The ISPFS staff member receiving the change request from the customer is responsible to update the information in ILIMS and document the reason for the change. Customer requested changes to ILIMS should be mirrored in the pre-log database by the ISPFS staff member emailing the change request to ISPFS headquarters staff. When an exact crime date is not known by the submitting agency, the date will be left blank in ILIMS.

17.4.1.7 A customer dropping off evidence shall be offered an ILIMS receipt for the evidence submission. Toxicology forms are not required for Toxicology evidence, provided the evidence has an appropriate chain of custody on the external packaging material. If the Toxicology kit does not have a chain of custody on it, then the Toxicology submission form must be signed by the FES (or designee), the lab case number noted on the form, and the submission form scanned into the case info tab of ILIMS. The original Toxicology submission form (when present) is retained through analysis and returned to the agency with the evidence.

17.4.1.8 Evidence containers should be appropriate to the evidence and the analysis requested. If evidence is received in a manner that will lead to deleterious change, immediate steps shall be taken to prioritize analysis, repackage evidence, reject evidence or return evidence without analysis. Documentation of the situation and action taken shall be included in the case record. If an item is simply rejected, the only documentation retained is located in the ILIMS activity log as an "unlogged evidence" record.

17.4.1.9 Sharp or pointed objects or items with sharp edges (e.g. knives, razors, glass) shall be confined within packaging that renders these objects safe to handle.

17.4.1.10 Requirements for syringes:

17.4.1.10.1 The syringe shall be packaged in an appropriate biohazard safety tube. The evidence envelope must be clearly labeled as containing a syringe upon submission to the laboratory. The FES will verify the package labeling at the time of submission. Improperly packaged syringes will be returned without analysis (lab staff has the discretion to return the individual item containing the syringe or the entire case without analysis.). If a syringe is being shipped without a needle, alternate shipping packaging may be used in the event the biohazard safety tube is not adequate to contain the item. The needle-less syringe should be secured within the package and the package label should indicate that the item is a syringe but does not have a needle.

17.4.1.10.2 Syringes will be analyzed according to the controlled substances analytical method regarding sample selection.

17.4.1.11 Transportation and Handling of Evidence Outside the Laboratory:

Evidence (other than controlled substances) may be transported by an ISPFS employee for the purpose of evidence examination, database entry, and/or technical review/technical verification. Specific examples would include firearm/toolmark technical verification and peer review, firearm/toolmark test firing (high powered rifles), and creating witness panels for distance determinations. Care shall be taken to secure the evidence while in transport. Evidence shall not be left in an unattended (locked or unlocked) vehicle for an extended period of time. The vehicle and second laboratory facility will be considered an extension of the ISP laboratory for chain of custody purposes. The evidence must remain in the possession of the ISPFS employee or in a short-term secured evidence storage area assigned to the ISPFS employee for temporary use. For additional evidence transport information see section 17.4.4.13 for Crime Scenes and section 17.4.4.9.7 for Court.

17.4.1.12 Return of evidence without analysis: There are a variety of circumstances that may result in the evidence being returned without analysis even though it has been logged into ILIMS. With guidance from the analytical methods, the analyst has the discretion to determine which items of evidence will be analyzed in a case.

- *If an item of evidence is checked out and opened, a report will be issued describing what was done; all items that are checked out at that time by that analyst associated with that assignment will be listed on that report. If the analyst opening the evidence discovers they are not approved to perform the type of analysis that is necessary for that item, the seals, packaging and evidence description will be documented in the case file. The item will be assigned to a qualified analyst and the second analyst will issue the report.*
- *If no items in an analyst's possession associated with an assignment are opened, or if the evidence is not checked out, it will be noted in the case record.*
- *Evidence submitted for persons suspected of driving under the influence of alcohol or other intoxicating substances, and qualifying sexual assault kits will not be returned to a submitting agency without examination if the criminal case is resolved and the evidence meets ISPFS policy and analytical methods for examination. The analysis for ALS (unless the subject is dead) will be run before the evidence is returned (per IDAPA 39.02.72), qualifying sexual assault kit mandated for analysis by Idaho code will also be run.*

17.4.1.13 Disposal of evidence:

- *Accident Victim (AV) kits submitted for Alcohol processing and statistical purposes (see 17.4.4.9.4).*

17.4.1.14 Retained evidence: Examples of evidence that may be retained by ISPFS.

- *Latent and Impression evidence digital images.*

7.4.2 Evidence is systematically and uniquely identified upon submission to a Forensic Services laboratory. This identification follows Forensic Services quality procedures and is used throughout the time the evidence is in a laboratory. This unique identification ensures that evidence cannot be confused physically or when referred to in Forensic Services records. The system accommodates sub-division of groups of items, creation of items, and the transfer of items of evidence within or from a laboratory.

17.4.2 System for identifying test items:

17.4.2.1 Original receipt of an item

When evidence is received it will be assigned a unique laboratory case number. Each evidence package in a case will be assigned a unique item number. A barcode will be generated for each evidence item; the case number and item number appears on the barcode label. The corresponding barcode label shall be placed on the item.

17.4.2.2 Transferring items

When an item is transferred from one ISPFS lab to another ISPFS lab, the item will use the same unique identifier and barcode originally assigned to it. The chain of custody for each item will reflect the transfer.

17.4.2.3 Resubmissions

If an item of evidence is returned to the submitting agency and then resubmitted to the lab for additional analysis, the item will use the same unique identifier and barcode originally assigned to it. The item is logged in ILIMS under a new submission and the ILIMS checkbox for the resubmitted item(s) is marked and the requested service is checked. Resubmittal of items analyzed and returned to the agency prior to October 15, 2013 require a new ILIMS barcode.

17.4.2.4 Evidence that is split, combined or created in the lab

When evidence is split or created in the lab it will be uniquely identified and tracked.
There are two methods that may be used for this process:

- *The first method may be used for creating or splitting evidence. The analyst will create the new item in ILIMS by going to the items tab for the case or under analysis and selecting the item of evidence that was split or created from, and then clicking the sample button. The new item will have the same item number as its originator with a .1 added to it. If multiple items are split or created from one item the designator will progress sequentially. If the new item is further split, it would have the same number as the one it was split from with a .1 added to the end of it (e.g. test fires from a firearm that comes into the lab as C2014-1300-1 would be designated C2014-1300-1.1). If additional test fires were created, they would be C2014-1300-1.2, and if later it turned out one of the test fires needed to be split from C2014-1300-1.2, the new item would become C2014-1300-1.2.1.*

When a new item is created in ILIMS, the internal chain of custody is automatically started with the item in the possession of the creator. The creator will place the unique barcode on the new item. Chain of custody on these items will be handled the same as any evidence, and further transfers will be handled the same as other evidence. The analyst must enter in ILIMS a clear description of what the new item is and where it originated. Additionally, the case report shall describe the evidence and its disposition. The ILIMS container feature may be used to store and transport these items.

- *The second method may be used to create one item that contains multiple splits, sub-items, or combined evidence. When using this method, the analyst would go to the items tab for the selected case in ILIMS. The analyst will create a new evidence item. When creating the new item, the analyst must clearly describe in the ILIMS item description what is contained in the new item, and where it originated. Additionally, the case report will describe the evidence and its disposition. When a new item is created in ILIMS, the internal chain of custody is automatically started with the item in the possession of the creator. The analyst will place the unique barcode on the new items, and further transfers will be handled the same as other evidence.*
- *Items that are created to return a work product, such as DNA extracts, may be created in ILIMS at any point during the analysis, but are not considered evidence until analysis is complete and they are scanned to an outgoing evidence location for a laboratory, vault evidence locker, or FES.*

17.4.2.5 Each item (or sub-item) added to digital workplace (e.g. latent/impression images and/or enhancements) will have a unique identifier assigned in digital workplace. The chain of custody will then be tracked in digital workplace. The laboratory report will reflect that digital images were retained by the laboratory.

7.4.3 Received evidence that does not meet Forensic Services specifications in regards to condition, packaging, or seals shall be recorded. The method used to correct seals (per section 17.4.4.8.1 of this manual) shall be recorded. Forensic Services will contact the submitting party regarding the condition of the evidence before the analysis if there is doubt as to the suitability of the evidence for examination or if the evidence does not significantly conform to the description. Questions, uncertainty, or discrepancies require documentation and may result in the evidence being returned to the customer. All communication regarding such incidents shall be recorded.

17.4.3.1 If evidence is submitted to the laboratory, it may be rejected for the following reasons: it is unsuitable for analysis, it is being submitted for a service the lab system does not perform, it is not sealed properly, it is not packaged appropriately, it presents an unsafe or hazardous condition, and any condition that the Forensic Evidence Specialist (FES) deems problematic for the integrity of the evidence.

17.4.3.2 If evidence comes into the lab by common carrier (UPS, U.S. Mail, Fed-Ex, etc.) and is rejected (sent back to the agency before being logged into ILIMS), the evidence will be returned with documentation of why it was returned. The external chain of custody will be filled out for the evidence items. The ILIMS activity log is used for the unlogged evidence entry. The log will include documentation of the items being returned. Rejected evidence can be stored temporarily in the laboratory. Forensic Services has appropriate facilities and quality procedures to avoid deterioration, loss, or damage of evidence until the earliest time the evidence can be shipped back to the submitting agency. The "unlogged evidence entry" shall reflect the short-term storage.

17.4.3.3 If evidence is brought into the lab in person by a customer, the FES will not take control of the evidence until the requirements for acceptance are met.

17.4.3.4 If all items from an entire case or discipline are returned without analysis, the assignment will be closed in ILIMS and a reason documented in the case record; however, a report of examination is not required.

7.4.4 Forensic Services has appropriate facilities and quality procedures for avoiding deterioration, loss or damage of evidence during storage, handling, and preparation for analysis. Submitted evidence shall, as soon as feasible, be stored in the evidence vault or dedicated cold storage (collectively referred to as vault) until checked out for analysis unless special handling or storage requirements dictate storage elsewhere. Handling instructions for particular items of evidence will be followed. When items have to be stored or conditioned in a specified environment, these conditions are maintained, monitored, and recorded. Forensic Services implements quality procedures for storage and security of evidence that protect the integrity of evidence in its control.

17.4.4.1 All evidence in long-term storage shall be sealed in accordance with Forensic Services protocol.

17.4.4.2 All evidence shall be properly logged into the evidence inventory system (i.e. ILIMS or digital workplace).

17.4.4.3 The evidence storage areas shall be kept clean and well organized.

17.4.4.4 The evidence vault shall be kept locked except when authorized personnel are in the vault.

17.4.4.5 The only individuals who are authorized to enter the vault unsupervised are the custodians of the vault who are directly responsible for the evidence stored in the vault. An evidence vault entry log shall be kept and any access to the vault by a non-FES shall be documented.

17.4.4.6 When a custodian of the vault ceases to have custody over the vault or its contents, all evidence in the vault or any area accessible to the custodian shall be audited. The vault and all evidence in the laboratory shall be audited at least twice annually. One audit will be in conjunction with the internal audit and the other will be an audit directed by the Lab Manager. The Lab Manager will receive a copy of the final audit report of any evidence audit and shall address any discrepancies. The vault will be audited upon the change of a Laboratory Manager, and the final audit report will be provided to the Laboratory System Director. The inventory portion of the audit shall consist of accounting for all evidence the laboratory should have and identifying any evidence the laboratory should not currently have in custody. In addition to an evidence inventory, each audit shall include a check of evidence seals and chain of custody signatures on the items.

17.4.4.7 Evidence that requires specific storage conditions will have those conditions monitored. Refrigerators and freezers requiring monitoring will have a thermometer equipped with an alert system set to go off if the temperature goes out of range. If an alert is activated, a description of what happened will be documented. If it is indicated that the refrigerator is broken, it will be marked out of service and evidence will be transferred to an operational refrigerator. The thermometer will have a calibration check performed at minimum, once every two years.

Evidence requiring special storage conditions are listed below:

- *Cyber:*
  - *Cellular Devices (Devices capable of receiving a wireless (cellular) network signal) are to be stored in a Ramsey box or wrapped in a minimum of three layers of tinfoil.*

- *Latents/Impression:*
  - *Routine latent/impression evidence is stored at room temperature unless there are special circumstances.*
- *Forensic Biology:*
  - *Liquid reference blood samples and sexual assault evidence collection kits containing liquid bloods are to be refrigerated.*
  - *Human remains (includes fetal tissue, bones, teeth, and other tissue samples) are frozen.*
  - *Dried reference bloodstains are frozen.*
  - *DNA extracts and DNA packets containing extracts are frozen.*
- *Blood collection kits:*
  - *Refrigerated storage until preparation for analysis.*
  - *Refrigerated storage post analysis until return to agency.*
- *Urine collection kits:*
  - *Frozen or refrigerated storage until preparation for analysis.*
  - *Refrigerated or frozen storage while in the custody of the analyst.*
  - *Frozen storage post analysis until return to agency.*
- *Blood and urine collection kits:*
  - *Refrigerated storage until preparation for analysis.*
  - *Refrigerated storage post analysis until return to agency.*
  - *The urine sample(s) from the kit may be separated and stored frozen while in the analyst's possession.*
- *Controlled Substances (Items indicated to be khat, or perishable food/drink products):*
  - *Refrigerated while in main laboratory vault.*
- *Fire Debris:*
  - *Soil samples stored frozen until analysis*
  - *Other samples refrigerated while in main laboratory vault.*

17.4.4.8 Any evidence not in the process of examination shall be maintained in a secured, limited access storage area and stored under proper seal. Forensic Evidence Specialists have the authority to reject evidence if it is not properly sealed.

17.4.4.8.1 Evidence sealing requirements

17.4.4.8.2 Proper seals shall include heat seal, tamper indicating seal, tape seal or lock seal. A container is "properly sealed" (the term intact on toxicology submittal forms means properly sealed) only if its contents cannot readily escape and only if entering the container results in obvious damage/alteration to the container or its seal.

17.4.4.8.3 If tape is used to seal evidence, then standard evidence tape shall be initialed (or otherwise identified) to document the person sealing the evidence (scotch tape is not acceptable). Heat sealed and tamper indicating sealed packages shall have initials or other identification across the heat or tamper indicating seal to be properly sealed. Lock seals shall be initialed or otherwise marked to document the person sealing the evidence. Staples do not provide seals. Manufactured seams do not need to be taped and initialed.

17.4.4.8.4 Packaged evidence received by a laboratory, which does not bear the initials or identification of the person sealing the evidence container, is not properly sealed.

17.4.4.8.5 All evidence that requires seals shall be properly sealed by the submitting agency, however exceptions may be made as required. ISP Forensics may provide a proper seal by: (1) placing a piece of evidence tape perpendicularly across the seal with the initials of the person receiving the evidence if the seal is lacking initials. If the seal is not adequate, clear packing tape may be placed over the first seal (this makes it possible to see how the evidence was received), and then evidence tape is placed perpendicularly across the packing tape and initialed to provide the seal or (2) resealing the complete package in a heat sealed envelope or other container with proper initials. Documentation of actions performed to correct the seal shall be noted in the remarks section for the evidence submission. Forensic Services shall ensure that accepted evidence stored in ISP vaults is properly sealed. The items shall be documented as "not sealed" and a description of how a proper seal was provided shall be entered in the "remarks" section of the Quick Create screen of ILIMS and is viewable in the submissions tab.

17.4.4.8.6 Original, non-reproducible comparison samples (e.g. inked fingerprint cards or tire impressions) shall be properly packaged and sealed as evidence for submission to ISP Forensic Services.

17.4.4.9 Procedures to prevent loss, damage, or deterioration of evidence and to secure unattended evidence while being examined.

17.4.4.9.1 Evidence shall be maintained under the control of the party currently responsible for it according to the chain of custody. Evidence vaults, individual evidence lockers, and jointly controlled evidence storage facilities are provided so that staff, as appropriate, can maintain control of evidence in their custody. However, during the process of examining evidence, if an examiner needs to leave for a short time, such as to use the restroom, and will be returning immediately, it is not necessary to return the open evidence to a secured storage location if it is in a secure area, unless leaving the evidence unsecured may pose a contamination or safety concern.. This is also true for large or cumbersome items or evidence requiring extended processing time (see 17.4.4.10). Refer to procedure (16.3.4a.2 visitor procedure) for instructions on evidence handling when there are visitors in the lab.

17.4.4.9.2 Diligence shall be exercised to ensure that evidence is protected from loss, contamination, deleterious change, and/or cross-transfer that would diminish the value of the evidence or its analysis.

17.4.4.9.3 Prior to the forensic scientist returning evidence to a FES, the forensic scientist shall seal the evidence with evidence tape and date and initial (or sign) the evidence tape unless for some reason it is not practical to seal the evidence.

17.4.4.9.4 Evidence shall be returned only to a party having legal responsibility. Generally, this is a representative of the submitting agency. Accident victim samples will be retained by the laboratory and destroyed after 90 days from the date of report unless a written request is made to return the sample. Digital Forensics (Cyber) evidence that is submitted to ISPFS for storing and transfer can be released to and accepted back from a representative of the ISP Cyber Unit.

17.4.4.9.5 A customer picking up evidence shall be offered the final ILIMS custody transaction receipt. A shipping box shall leave with a completed packing list. Toxicology cases will leave the laboratory with the original toxicology submission form (with chain of custody information completed for the lab). The Toxicology submittal form will not be scanned into ILIMS at the end of the process as the ILIMS chain of custody is the laboratory transaction of the return to the agency.

17.4.4.9.6 All returned evidence handled by a common carrier, (the U.S. Postal Service or United Parcel Service, etc.) shall have an adequate receipt acknowledging delivery. All such receipts are to be placed in the case record.

17.4.4.9.7 Unless extenuating circumstances exist, Forensic Services personnel shall not transport evidence to court. When circumstances justify evidence, other than controlled substances, to be transported to court, an exception may be granted by the Laboratory Manager. Controlled substances shall never be transported or carried by forensic services personnel, without written permission from the Laboratory System Director.

17.4.4.10 In-process-of-examination evidence is based on a reasonable period of activity in a case and a justifiable expectation of frequent examination. Items in which the examination or analysis is considered to be actively "in process" can be stored temporarily, up to 6 months, in an unsealed condition, only if they are in a secure location such as a personal evidence locker. In-process evidence stored in a jointly controlled evidence storage location must be stored in a tamper evident manner. If it is not feasible to store items in this manner (such as large items temporarily stored in a locked examination room), access should be restricted as much as possible, and a notation of all staff having access to the area will be noted in the case record. The samples must remain free of contamination or cross-transfer at all times.

17.4.4.11 Each article of evidence that has been analyzed including articles of evidence generated by the analyst shall be uniquely marked for identification with the laboratory number and individualizing designators if necessary and the signature or initials of the analyst. If the article itself cannot be marked (e.g. too small or marking the evidence would destroy evidence), then the outer packaging, repackaged item or identifying tag must be marked with the appropriate information. In some cases, the evidence may require additional packaging to achieve compliance with this policy. For example, if one heroin balloon out of an evidence envelope that contained three balloons is analyzed, the article that was analyzed may need to be placed in additional packaging so that it can be labeled to distinguish it from the two that were not analyzed. The serial number of a firearm meets the labeling requirements if recorded in the case documentation.

17.4.4.12 When evidence, such as latent prints and impressions, can only be recorded or collected by photography and the impression itself is not recoverable, the photograph, digital image, or negative of the image is treated as evidence. If an impression discipline comparison or verification is performed using a record obtained from a secured database (such as BCI or FBI), the hard copy exemplar is not required to be maintained as evidence (see 17.4.4.14.1). If the exemplar is produced from an item of evidence and is reproducible, the hard copy exemplar is not required to be maintained as evidence (such as footwear exemplars). If the exemplar is an original, and not from an item of evidence (such as fingerprint exemplars from an autopsy), then the exemplar shall be treated as evidence.

17.4.4.13 Evidence collected from a crime scene by laboratory personnel is protected from loss, cross transfer, contamination and/or deleterious change, whether in a sealed or unsealed container, during transportation to an evidence facility. Where appropriate, further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. Forensic Services staff members are authorized to transport the items listed below from the field. The Lab Manager may authorize transportation of additional items on a case-by-case basis. The Lab Manager may also delegate the authority to make this exception in their laboratory.

- *Authorized items to transport:*
  - *Latent lifts taken from in the field where a representative of the responsible agency is unavailable or unable to take control of the lifts,*
  - *post mortem fingerprint cards,*
  - *tire test impressions,*
  - *plant samples for ISP District 3 Investigations taken from suspected marijuana plants in the vehicle bay,*
  - *memory cards with digital images (see 17.4.4.12),*
  - *toxicology/biology samples taken at autopsies.*

Evidence collected from a crime scene shall be appropriately identified, packaged and entered into the evidence control system as soon as practical. Evidence will not be analyzed until after it has been logged into ILIMS or Digital Workplace.

General photography for scene documentation is considered part of the note taking process and need not be treated as evidence, except as described in 17.4.4.12.

17.4.4.14 Forensic Services creates and implements policies and procedures for the operation of individual characteristic databases (ICD). DNA database/CODIS is the only ICD currently maintained by Forensic Services. The NIBIN database is maintain by another agency, and the ABIS database in Idaho is maintained by another state department. When ICD samples are treated as evidence, the policies and procedures for handling evidence contained in section 7.4/17.4 are followed. Procedures for handling ICD samples when they are treated as reference samples are included in appropriate analytical methods.

17.4.4.14.1 Forensic Services has established which individual characteristic database (ICD) samples are treated as evidence and which are treated as reference materials. ICD samples can be treated as evidence or reference materials within the same ICD collection provided that this is clearly documented, there is an identifiable difference between these categories, individuals who work with the ICD understand which categories of ICD samples are evidence verses reference materials, and each category of ICD samples are treated appropriately as described in this policy/procedure.

17.4.4.14.1.1 Individual characteristic database samples treated as evidence, shall meet the chain-of-custody, evidence sealing and protection, evidence storage and evidence marking requirements of the Forensic Services Management System.

- *Each CODIS ICD sample obtained from casework shall be treated as evidence.*
- *Each NIBIN/IBIS ICD sample obtained from casework shall be treated as evidence.*

17.4.4.14.1.2 Individual characteristic database samples treated as reference samples, shall meet 17.4.4.14.1.3 through 17.4.4.14.1.6

- *Each CODIS ICD sample obtained from a convicted offender in conjunction with Idaho Code 19-5506 shall be treated as reference material.*
- *Each NIBIN/IBIS ICD sample submitted as an exemplar will be treated as reference samples.*

17.4.4.14.1.3 Each individual characteristic database sample under the control of Forensic Services shall be uniquely identified according to the written policies controlling the operation of the database.

17.4.4.14.1.4 Individual characteristic database samples under the control of Forensic Services shall be protected from loss, cross transfer, contamination, and/or deleterious change. They must be maintained so as to be useable for the comparison purposes for which they were obtained. Samples submitted for the DNA database will be retained by the lab indefinitely.

17.4.4.14.1.5 Access to the individual characteristic database samples under the control of the laboratory shall be restricted to persons authorized by the laboratory manager.

17.4.4.14.1.6 Access to these samples shall be limited to those individuals having a legitimate purpose with regards to the ICD. The Laboratory Manager shall maintain a list (written or electronic) of those individuals authorized to access ICD samples and establish a security system to ensure that only those authorized individuals can access reference ICD samples.

7.4.5 Forensic Services is able to demonstrate that the evidence examined and reported on was that submitted to the laboratory. The chain-of-custody record for evidence is maintained from the time of receipt and reflects all internal transfers. The chain-of-custody record lists each person taking possession of an item of evidence, or the location of that item. At a minimum this record includes:

a) A signature/initials or electronic equivalent to a signature of the person/location receiving evidence;
b) The date of receipt or transfer;
c) Unique identifier of the evidence.

17.4.5 Evidence transferred between individuals shall be documented. The official laboratory chain of custody includes: the electronic chain kept in ILIMS for evidence received after 10/15/2013, the submission form(s), the written internal chain of custody form(s), the unlogged evidence form/log, the ILIMS unlogged evidence activity log for evidence received after 10/15/2013, and digital workplace data (printed or electronically stored). Not all of these chain records will exist in each case. The appropriate forms are used in each case.

- *All cases accepted by the laboratory will have a case record in ILIMS.*
- *Digital images that are considered evidence will have digital workplace chain of custody records.*
- *Cases where evidence was not properly submitted initially may have unlogged evidence log or activity log documentation.*
- *Internal chain of custody transfers before October 15, 2013 will usually be recorded on the "written internal chain," but may also be on the submission form. Chain of custody transfers on or after October 15, 2013 are performed electronically in ILIMS or Digital Workplace.*

17.4.5.1 Once evidence is submitted in the laboratory, all sub-items shall be tracked through a documented chain of custody to the same extent in which the original items are tracked.

17.4.5.2 Evidence that is accepted and stored in the laboratory shall be properly sealed (see procedure 17.4.4.8.1).

7.5 Technical Records

7.5.1 Forensic services ensures that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

17.5.1 Technical and administrative records that are maintained for each case:

17.5.1.1 A laboratory case file consists of both administrative documentation and technical records, which may be received or generated by the laboratory. Examples of administrative documentation include records of requests, tenders or contracts, chain of custody, case-related conversations, receipts, description of evidence packaging and seals. Administrative documentation that is generated by the laboratory shall be stored in the laboratory case file or centrally stored. ILIMS, for example contains administrative documentation that is centrally stored. All administrative records, received or generated for a specific case, are identified by the unique laboratory number or submitting agency case number. Multi-paged administrative records that are bound together or are electronically one document may be at a minimum identified by the unique laboratory number on the first page of the record only. Administrative records in the ILIMS will be electronically associated with a case. Each page of hard copy administrative Chain of Custody records must be labeled with a laboratory number.

17.5.1.2 Technical records include such things as references to procedures followed, tests conducted, standards and controls used, diagrams, instrumental printouts, photographs, observations, and results of examinations. The laboratory case file shall include all technical records generated in the laboratory, unless the documentation is centrally stored. The location of the centrally stored instrumental batch files, standards, and controls that apply to multiple cases shall either be indicated in the case file or in the analytical method. If indicated in the analytical method, the method shall indicate that the file is stored centrally in the laboratory.

17.5.1.2.1 Observations, data, and calculations are recorded at the time they are made and are identifiable to a specific examination. If original observations are handwritten, it is acceptable to transcribe the handwritten observations to an electronic form, but the original handwritten observations must also be maintained as part of the examination records. Handwritten observations in paper copy may be destroyed once an electronic representation/scan has been attached to the appropriate ILIMS electronic case.

17.5.1.2.2 The records required to support conclusions shall contain sufficient information to enable another competent analyst, to evaluate what had been performed and interpret the data. When a test result or observation is rejected the analyst shall document the reason for rejection in the case record.

17.5.1.2.3 Where instrumental analyses are conducted, operating parameters shall be recorded or have traceability through the records.

17.5.1.2.4 Examination documentation shall contain an adequate description of the evidence container, the evidence, the condition of the seals, and the date the evidence was opened.

17.5.1.2.5 The unique laboratory number and the handwritten initials of the analyst or secure electronic equivalent of initials or signature are required on each page of the technical records in the case file. When technical records are prepared by an individual(s) other than the analyst who interprets the findings, prepares the report, and/or testifies concerning the record, the initials of that individual(s) are on the page(s) of technical records representing his/her work. It is clear from the case record who performed all stages of the examination and when each stage of examination was performed. Laboratory personnel who write reports and/or testify based on examination documentation generated by another person(s) shall document a review of all relevant pages of examination documentation in the case record.

17.5.1.2.6 Technical records, such as photocopies of thin layer chromatograms or instrumental printouts, which bear the appropriate identifiers (lab number plus the individual identifiers as necessary and the examiner's initials) on an original document, may be copied or made electronic for filing in multiple cases without the necessity of placing original identifiers on each copy.

17.5.1.2.7 The notes packet that is maintained in the electronic case record will be page numbered, and the total number of pages (or number of pages in the assignment for cases with multiple assignments) is, at a minimum, indicated on the first page. When technical documentation is recorded on both sides of a page each side shall be treated as a separate page.

17.5.1.2.8 Technical documentation shall be of a permanent nature whenever possible. Handwritten notes and observations shall be in ink. Pencil (including color) may be appropriate for diagrams or making tracings. Once converted to an electronic format, all documentation is considered of a permanent nature, no matter the original medium.

17.5.1.2.9 When data from multiple cases is recorded on a single printout or worksheet, the unique laboratory number of each case, for which data was generated, shall be appropriately recorded on the document. The printout may then be kept in a central file if it is referenced in all case files for which data was generated, or referenced in the analytical method. However, examination documentation that is centrally stored that applies to multiple cases such as instrumental data, only needs to be marked with the initials of the examiner, the run date, and sufficient information to relate the centrally stored data to the appropriate cases. (The run date may be sufficient to relate centrally stored data regarding standards, controls, or calibration to the appropriate cases. Whereas, the unique laboratory number would be necessary to identify data that applies only to a specific case in the batch.)

17.5.1.2.10 Where abbreviations or symbols specific to the laboratory are used in the examination records, the meaning of the abbreviations or symbols are clearly documented. Abbreviations and symbols that are widely accepted by the scientific community do not require documentation of meanings. For example, g may be used as an abbreviation for gram without further explanation or GC/MS may be used as an abbreviation for gas chromatograph mass spectrometer without further explanation. Abbreviation lists used by individuals, sections, disciplines, or laboratories are available in the laboratory electronic document management system.

17.5.1.2.11 When an independent check of analytical findings ("technical verification") is performed, the record of the review shows that the examination data has been checked and approved, the date performed, and the identity of the reviewer. The individual performing the review will possess expertise in the examination being reviewed.

17.5.1.2.12 The initials and/or signature of the person(s) checking the results (typically the admin/tech reviewer) will be documented in the case record. Secure electronic approval of technical review in ILIMS is acceptable to document technical, administrative, or combined technical/administrative review.

7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

17.5.2.1 Changes to handwritten technical records are not erased, made illegible or deleted, instead are crossed out and the correction alteration is entered alongside. All alterations to technical records are identifiable to the person making the change and are dated. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data. Electronic data relied upon for conclusions is either printed for the case record, or stored in an electronic database accessed by software with an audit trail. Placing handwritten annotations, and notes on forms or computer printouts is not considered an alteration or insertion, it is part of note keeping.

17.5.2.2 Any change made to completed hard copy examination records generated and/or maintained in an electronic form shall be tracked (sufficient to show what was changed, when it was changed and who changed it). Examination records generated and/or maintained in an electronic form shall be considered complete post analysis but prior to final technical verification, technical review, or administrative review of the records. In the case of instrument printouts (or other supplemental documentation), if an additional printout is created or a correction is made to information that relates to that case, the original pages submitted for review must remain in the case record (notations may be made to clarify the purpose of the supplemental documents). If an instrument printout (or other supplemental documentation) was inadvertently placed in the case file and is not part of that case, it may be removed without notation since it was not actually an observation associated with that case.

7.6 **Evaluation of measurement of uncertainty**

7.6.1 The forensic lab shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 Calibrations performed by the lab, including of its own equipment, shall have the uncertainty of measurement evaluated for all calibrations.

7.6.3 The forensic laboratory will estimate uncertainties for testing methods providing quantitative analysis results. When the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

17.6.3.1 Reporting Uncertainty of Measurement: At a minimum, uncertainty will be reported for quantitative values that are determined to have statutory significance. The uncertainty at these levels will be reported on the examination report. Specific reporting criteria and procedures are covered in the applicable discipline analytical methods (i.e. the disciplines of controlled substances, alcohol, firearms).

17.6.3.2 The uncertainty estimate must be part of the validation plan. One possible approach to calculating uncertainty is deriving a standard deviation from measurement data. It will need to be determined in the validation plan the number of replicate data needed. From the replicate data the population standard deviation would be calculated. The confidence interval of 95.5% will be used so the estimation of uncertainty is +/- 2 population standard deviations from the mean. The estimate of uncertainty would be stated. You are 95.5% confident that the true value is within the range stated +/- 2 std dev. If a discipline chooses to use a 99.7% confidence interval for reporting, the discipline analytical method will reflect the requirement.

17.6.3.3 If an analytical method is found to have bias, this must also be factored into the estimation of uncertainty.

17.6.3.4 The uncertainty level may be updated as more data becomes available from using the procedures. The updates will be centrally stored in the laboratory.

17.6.3.5 Each analytical method from which quantitative results are reported shall contain or make reference to instructions for reporting the uncertainty of measurement.

7.7 Ensuring the validity of results

7.7.1 Forensic Services creates and implements quality procedures that are utilized to monitor the reliability of testing results. The resulting data is recorded and maintained so that trends are detectable over time. Where practical, statistical techniques are used in reviewing results. Analytical testing is monitored using quality controls appropriate to the examinations. The range of quality control activities employed by Forensic Services includes, but is not necessarily limited to the following:

a) Use of reference materials or quality control materials;
b) Use of alternative instrumentation that has been calibrated to provide traceable results;
c) Function check(s) of measuring and testing equipment
d) Use of check or working standards with control charts, where applicable;
e) Intermediate checks on measuring equipment;
f) Replicate tests or calibrations using the same or different methods
g) Retesting or recalibration of retained items
h) Correlation of results for different characteristics of an item;
i) Review of reported results (technical review and verification)
j) Intralaboratory comparisons
k) Testing of blind sample(s)

Note: Not all of the quality control activities listed above are used in every discipline.

17.7.1.1 Quality control activities will be specified in the analytical methods, the use of controls and standards will be recorded in the case record.

17.7.1.2 Reliability documentation and preparation of reagents.

17.7.1.2.1 Reagents shall be routinely tested to determine if they are providing the appropriate chemical or biological response. The schedule for this testing will be established in the appropriate analytical method(s).

17.7.1.2.2 Some reagents are prepared in a batch and used for extended periods of time without being tested with a standard or control each time they are used. These reagents shall be tested before initial use and may be tested on a periodic basis as required by the analytical method or used for a specific period of time. The test results shall be documented. Other reagents are tested with a control each time they are used, such as phenolphthalein. Therefore, these reagents do not require other testing. These results shall be documented.

17.7.1.2.3 The records regarding reagents used for a single analysis and then disposed of shall be maintained in the casework notes.

Reagents of questionable reliability and expired reagents shall be discarded. However, an expired reagent may continue to be used if tested with a positive and negative control each time it is used, and the appropriate discipline lead has approved the use of the expired reagent in writing before the release of results.

17.7.1.2.4 *Reagents shall be prepared according to formulas located in controlled documents. These reagents are labeled with, at a minimum, identity of the reagent, concentration (as appropriate), date of preparation and/or lot number, identity of the preparer, storage conditions (where relevant), and hazard warning (where necessary). If the storage conditions and/or hazard warnings, where relevant and necessary, are included in the analytical method or reagent recipe, they do not need to be included on the label. Records are maintained for the results of testing and an evaluation of the test results. The reliability testing shall occur before use or if appropriate, concurrent with testing.*

17.7.1.2.5 *Storage of Supplies: Supplies that affect the quality of examinations shall be stored in accordance with the manufacturer's instructions unless otherwise documented. Chemicals maintained in storage areas external to the laboratory are not required to comply with the manufacturer's recommendations for storage temperature.*

17.7.1.3 ***Monitoring testimony****: Forensic Services monitors the testimony of all testifying personnel on an annual basis.*

17.7.1.3.1 *Courtroom testimony provides a means for the forensic scientist to communicate results and conclusions stated in a laboratory report or general scientific knowledge. The goal of the forensic scientist is to accurately present conclusions, explain analytical techniques, offer expert opinions, and make clear to the court any questions regarding a laboratory report in a particular case. The analyst shall ensure that the testimony given is scientifically consistent with the documentation in the case file.*

17.7.1.3.2 *Each testifying staff member shall be evaluated at least once per calendar year. An evaluation by the supervisor is encouraged biennially. If adequate evaluations of courtroom testimony cannot be obtained (as determined by the lab manager and quality manager or system director) to meet the requirements in 17.7.1.3.3, testifying staff may be evaluated using section 17.7.1.3.7*

17.7.1.3.3 *Evaluation shall be by direct observation, questionnaire, review of court transcripts, or telephonic solicitation by laboratory staff to one or more officers of the court for responses to the controlled evaluation form.*

17.7.1.3.4 *A testifying staff member who is inexperienced in courtroom testimony or a forensic scientist new to Forensic Services shall be reviewed in person by Forensic Services staff when he/she first testifies, if possible; as the individual gains experience, direct review by staff can be alternated with review by other means.*

17.7.1.3.5 *A reviewer from Forensic Services shall fill out the controlled court testimony evaluation form and critique the forensic scientist as soon as possible after the peer review process. The Forensic Services reviewer should be an individual experienced in courtroom testimony. The testifying staff member shall be given feedback on the positive aspects of the testimony as well as areas that may need improvement. The evaluation will include, at minimum, appearance, performance, and effectiveness of presentation.*

17.7.1.3.6 *Corrective action shall be initiated in accordance with section 8.7, of this quality manual if the courtroom evaluation indicates any issues in the testimony that require remediation. If the issues were of a minor nature, remediation would consist of feedback during the peer review process.*

17.7.1.3.7 *Proficiency tested personnel who do not testify during a calendar year will be evaluated by the Laboratory Manager or their designee. At minimum, an evaluation of the analyst's responses to typical/commonly encountered testimony related questions in one of their areas of expertise will be conducted. Documentation of the evaluation will be retained by the Laboratory Manager*

17.7.1.3.8 *Testimony monitoring records will be retained as a quality record (18.4.2.2.4), but not less than one full accreditation cycle*

7.7.2 The laboratory shall monitor its performance by comparison with results or other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following.

a) participation in proficiency testing;
b) participation in interlaboratory comparisons other than proficiency testing

17.7.2 Proficiency testing is an integral part of a quality program. To obtain the maximum benefits from proficiency testing, Forensic Services shall emphasize the educational aspects of the program rather than punitive aspects when taking any corrective action.

17.7.2.1 Proficiency testing objectives:

- *Verify that analytical methods are valid.*
- *Ensure that quality work is being performed.*
- *Identify areas where additional training would be beneficial.*
- *Demonstrate the competence of the analytical system, (i.e. examiner and technical reviewer).*

17.7.2.2 Accuracy of results:

17.7.2.2.1 Quantitative Proficiency Test Evaluation

- *The below evaluation criteria are general criteria for quantitative proficiency tests. Individual disciplines may have specific evaluation and acceptance criteria for proficiency tests that take precedence over these general instructions.*
- *Quantitative proficiency tests will be evaluated by comparisons of the analyst/laboratory result to the measured value given by the provider, not the listed value.*
- *The provider measured mean and standard deviation will determine the acceptance criteria. The measured mean of the analyst/laboratory must fall within the acceptance criteria.*
- *Acceptance Criteria:*
- *Passing Score (≤2 SD or it falls in the uncertainty range): An analyst/laboratory result that is within 2 standard deviations or less of the provider result or the result falls within the lab's expanded uncertainty from the mean result for that method (whichever is greater) will be scored as passing.*
- *Warning Score: (>2 to ≤3 SD): An analyst/laboratory result that is greater than 2 standard deviations but 3 or less standard deviations of the provider result will be flagged as a "Warning" result. A warning result is NOT immediately considered nonconforming work. Items that receive this flag should be investigated and documented in a QAR. A corrective action may or may not be necessary pending the investigation.*

- *Failing Score: (>3 SD): An analyst/laboratory result that is greater than 3 standard deviations of the provider result will be considered as failing, and thus nonconforming work. A QAR and corrective action will be initiated.*
- *If the score is passing or a warning and the analyst/discipline lead/lab manager determines there is a discrepancy in the standard deviation of the laboratory/analyst result, an investigation may be initiated and documented in a QAR; however a corrective action may or may not be necessary pending the investigation.*

17.7.2.2.2 Qualitative Proficiency Test Evaluation

- *Results are correct if they meet any of the following criteria:*
- *Results agree with the target values and/or intended responses.*
- *The answer is correct within the limits of qualifying statements in the conclusion.*
- *The results are consistent with a consensus of the participants. (The results from accredited labs shall provide the basis for achieving a consensus if those results are readily available. A consensus of participants is defined as at least 75 per cent of participants obtaining the same answer(s) on the proficiency test.)*
- *If there is not a consensus of the participants, then results may or may not be evaluated by the Quality Manager for nonconformities depending on the circumstances.*
- *Following an analytical method correctly which would not provide specific answers shall not be considered as incorrect.*

17.7.2.3 Responsibilities of the quality manager:

- *Prepare a four year proficiency testing plan to be evaluated annually.*
- *Obtain discipline lead input and approval of the yearly proficiency testing program.*
- *Provide appropriate and timely proficiency tests.*
- *Distribute and track tests.*
- *Coordinate responses to the test provider.*
- *Correspond with and provide relevant corrective action responses to the accrediting body for tests in which the results reported were outside of consensus results.*
- *Maintain the proficiency test reports for all analysts as well as the documents from the test providers that are not maintained in an accessible form by the test provider.*

- *Evaluate the results of proficiency tests and issue an evaluation report that can be accessed by the analyst, the analyst's supervisor, lab manager and discipline lead. FES staff will access the proficiency test evaluation report, if the status is satisfactory the PT evidence associated with that evaluation may be properly destroyed or otherwise dispositioned as "non-evidence."*
- *Discipline leads or other experts may be consulted prior to issuing reports when the interpretation of proficiency test results requires a subject matter expert. Consultation with the DNA technical lead is always required when evaluating an inconclusive DNA proficiency test result.*

17.7.2.4 Responsibilities of the discipline lead:

- *Deciding what proficiency tests are required for the discipline and for specific individuals.*
- *Approve the annual proficiency testing program.*
- *Consult with analysts on technical questions as appropriate.*
- *Consult with the quality manager when the interpretation of proficiency test results requires a subject matter expert.*

17.7.2.5 Responsibilities of the laboratory manager:

- *Create and maintain a file for the storage of pre-ILIMS proficiency tests within that laboratory, until they have met the records destruction timeline.*
- *Ensuring that proficiency tests are done in a timely manner and forwarded to the quality manager for submission to the external provider.*

17.7.2.6 Responsibilities of the analyst:

- *All analysts shall participate in at least one proficiency test per calendar year in each discipline (controlled substances, firearms, forensic biology, etc.) and in at least one proficiency test per accreditation cycle in each subdiscipline (toolmarks, serial number restoration, etc) in which he/she performs casework analysis. The practical portion of the competency test may serve as the proficiency test during the first calendar year of analysis in a given discipline/subdiscipline. DNA analysts shall participate in proficiency tests in accordance with the current national DNA guidelines.*
- *Except for justifiable circumstances, proficiency tests shall be submitted to the provider by the stated due date. When such cannot be met, an analyst shall notify his supervisor and the quality manager before the due date and get an extension for completing a proficiency test, if necessary.*

17.7.2.7 Proficiency tests are analyzed by approved analytical methods. The overall performance of Forensic Services personnel on proficiency tests is reviewed as part of the annual management review and preventive action is taken as necessary. Proficiency tests are not subject to policies adopted for efficiency or expediency of casework.

17.7.2.7.1 A proficiency test shall be treated like a routine case as much as possible. This includes logging it in as a case, storing it as a case, providing normal chain of custody, performing the routine administrative and technical review, and issuing a report in ILIMS. Proficiency test provider data sheets as well as the ILIMS report for the proficiency test case shall be technically and administratively reviewed. (See section 16.2.5a.3 for additional information)

- *All parts of a proficiency test shall be examined as completely as approved analytical methods allow, to the same extent as casework.*
- *Quantitation of controlled substances proficiency tests shall not be performed unless the provider will be providing an evaluation of the quantitative results.*
- *Multiple analysts may perform different parts of the examination of a proficiency test if that is how casework is examined.*
- *Analysts participating in the same round of proficiency testing will not share or compare their results prior to reporting (i.e. submitting report and results/data sheets for technical review). If two analysts do the same proficiency test, ideally a different analyst will perform the review; in cases where this is not feasible the technical and administrative reviews will not be done until each analyst has completed the case and submitted it for technical review, except where the testing is performed as a team (if that is how casework is performed).*
- *Submission Process:*
- *Note: The analyst will complete the case notes and report in ILIMS and submit for technical review.**
- *Collaborative Testing Services (CTS) Test:*
- *The analyst shall complete the CTS data sheets through the CTS portal at www.cts-portal.com.*
- *Once the data sheets have been completed, the analyst shall forward the test to the Idaho State Police Forensic Services Analysts Group for technical and administrative review.*
- *Technical and Administrative Review:*
  - *The analyst performing the review shall perform and document the technical and administrative review in ILIMS.**
  - *The technical reviewer will also complete a review of the CTS data sheets on the CTS portal. On the CTS portal the reviewer will claim the test, complete a technical and administrative review of the data sheets, and record comments as appropriate. If corrections are necessary, the test shall be returned to the ISPFS Analysts Group for the analyst to claim. Once corrections are made to the data sheets, the test shall be returned to the ISPFS Analysts Group for technical/administrative review.*

- *After completion of the reviews, the technical reviewer shall forward the CTS portal documentation to the ISPFS Quality Manager Group for submission to CTS (Biology Screening and DNA tests will be forwarded to the ISPFS DNA Technical Lead Group at the completion of the administrative/technical review for the TL to review and forward to the QM Group). The Quality Manager (or designee) submits proficiency tests to CTS after verifying submission by a reviewer and completing the accreditation and release of results information for the test submission. This allows CTS to submit results directly to the laboratory's accrediting body.*
- *Once submitted to CTS, an automatic email is generated by the CTS portal to the analyst and Quality Manager. The Quality Manager attaches the PDF file of the submission (with associated comments and history) to the case in ILIMS.*
- *A copy of the submission is retained by the Quality Manager in the proficiency test records.*
- **DNA Database CTS tests do not have data or reports in ILIMS. DNA Database technical and administrative review will be performed and documented outside ILIMS. Cases will be administratively closed.*
- ***CTS tests with only one person submitting for the discipline will follow all the appropriate steps, but none of the CTS online submission applies to the tests not being submitted to CTS. The CTS forms on the non-submitted tests will be provided to the Quality Manager after technical review for upload to the ILIMS case file.*
- *Other Proficiency Test Providers:*
- *Providers using electronic/online submission: The analyst will complete the data sheets through the provider's online submission portal and will save the results (the analyst will not submit the results). The data sheets will be printed and provided to the technical reviewer to complete a technical and administrative review. Once the review and any necessary corrections have been completed, the reviewer will date/initial the approved test data sheets and attach them in ILIMS. The reviewer will then notify the Quality Manager that the test has been completed and reviewed in the portal.*
- *The Quality Manager (or designee) submits proficiency tests to the provider, through the portal, after verifying the review and completing the accreditation and release of results information for the test submission. This allows the provider to submit results directly to the laboratory's accrediting body.*

- *Providers without electronic/online submission: Proficiency test data sheets will be uploaded to ILIMS by the analyst prior to technical review. After technical review is complete, the Quality Manager (or designee) will download the submission sheets from ILIMS and submit them to the provider via fax and after filling out the accreditation and release of results information (this allows the provider to submit the results directly to the laboratory's accrediting body). A paper copy of the submission is retained by the Quality Manager in the proficiency test records.*
- *Internally Prepared Proficiency Test:*
- *Internal proficiency test data sheets (where applicable) will be uploaded to ILIMS by the analyst prior to technical review. After technical review is complete, the Quality Manager (or designee) will download the data sheets from ILIMS and retain a paper copy in the proficiency test records.*

17.7.2.7.2 Proficiency test samples may be used as training samples or for competency testing as determined by the discipline lead.

17.7.2.7.3 Scientific Research Tests are not treated as proficiency tests.

17.7.2.8 The Forensic Services proficiency testing program complies with accreditation proficiency testing requirements.

17.7.2.9 Each analyst engaged in testing activities shall successfully complete at least one proficiency test per calendar year in each discipline and at least one proficiency test per accreditation cycle in each subdiscipline in which the forensic scientist or technician performs examinations.

17.7.2.9.1 DNA analysts and technical support personnel performing DNA analysis comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories. DNA Proficiency tests shall be tracked by the assigned due date.

17.7.2.9.2 The laboratory shall have a documented schedule for proficiency testing which is being followed by each analyst and technical support person; refer to procedure 17.7.2.6 for this schedule.

17.7.2.10 Each Forensic Services laboratory participates in at least one external proficiency test annually, in every discipline of forensic science in which it provides services. ISO/IEC 17043 Accredited test providers are used for external proficiency tests.

17.7.2.11 Records of proficiency testing are maintained and the records contain at a minimum, the following:

a) The test set identifier;
b) How samples were obtained or created;
c) Identity of the person taking the test;
d) Dates of analysis and completion; (may be the start/finish date)
e) Originals or copies of all data and notes supporting the conclusions; (full details of the analyses/examinations undertaken and the results and conclusions obtained)

f) The proficiency test results;

g) All discrepancies noted;

h) An indication that performance has been reviewed by criteria established by Forensic Services and feedback provided to the analyst;

i) Details of the corrective actions taken (when necessary).

17.7.2.12 Proficiency testing records are controlled as quality records (section 18.4.2.2) and must be retained in the laboratory for at least ten years. See section 18.4.2.2.4 for retention information.

7.7.3 Data from monitoring activities is evaluated, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of the monitoring activities are found to be outside pre-defined criteria, planned action is taken to correct the problem and prevent incorrect results for being reported.

7.8 Reporting of results

7.8.1 General

7.8.1.1 The results shall be reviewed and authorized prior to release.

17.8.1.1.1 Technical verification is a process of independently performing a comparison or analyzing evidence to determine if the reviewer comes to the same conclusion regarding the analysis as the analyst. Analytical methods define if and when technical verification is needed.

17.8.1.1.2 Technical review is a review of the examination documentation and the conclusion (s) expressed in the report of analysis. The reviewer must ensure that:

- *The conclusions are reasonable, within the range of conclusions for the analytical method (s) followed*
- *Conformance with proper analytical methods and applicable laboratory policies and procedures.*
- *Accuracy of test reports and the data supports the results and/or conclusions in the test report.*
- *Associations are properly qualified in the test report; and*
- *The test report contains all the required information.*
- *Technical reviews shall be conducted by personnel that were not involved in the testing performed for the component(s) being reviewed.*
- *The reviewer must ensure that the analytical methods used were appropriately followed, the examination was within the scope of the method, and that applicable laboratory policies and procedures were followed.*

- *The reviewer must also ensure that the details of all the tests and observations are described in the notes and that all centrally stored examination documentation is appropriate and properly filed. The review shall include a check of calculations and testing data transfers unless the calculation and/or data transfer is performed in an automated manner that has been validated.*
- *The reviewer must ensure associations are properly qualified in the report, and that the test report contains all required information.*
- *Technical review must be performed in every case for which a report is issued including negative and inconclusive results. The review must be performed before results of analysis are released. Discrepancies found during technical review or differences of opinion regarding the acceptability of the examinations and/or the content of the report must be resolved before results of analysis can be released. If differences of opinion between the technical reviewer and the analyst cannot be resolved during the technical review, then the policy regarding conflict resolution must be used to resolve the difference of opinion (17.8.1.1.2.2) before the results are released.*
- *Technical review is documented by the initials of the technical reviewer and the date of the review for DNA database. For all other disciplines, the technical review of the report is documented by the name of the reviewer and the date of the review completion in ILIMS. Technical review of batch/component data will be documented with the batch/component data and will include the reviewer's name and the date the review was completed. When technical review is conducted by an approved external reviewer, documentation of the review will be attached in the case record and the administrative reviewers name and review date will be reflected in ILIMS.*

17.8.1.1.2.1 Technical reviews are conducted by individuals that have expertise gained through training and experience in the discipline being reviewed and are approved for such. An individual conducting technical review need not be a forensic scientist being proficiency tested in the sub-discipline. The three kinds of casework review are technical review, administrative review and technical verification.

17.8.1.1.2.1.1 Analysts approved to perform casework in a discipline/subdiscipline may perform technical review in that discipline/subdiscipline if they are placed on the technical review list for that discipline/subdiscipline by the Quality Manager, with input from the discipline lead. This list is maintained electronically by the Quality Manager and is available to all staff.

Technical reviews by staff who are not approved to perform casework in a discipline/subdiscipline requires documented approval maintained by the Quality Manager prior to performing technical reviews by the appropriate discipline lead or appropriate lab manager if the approval is for the discipline lead.

- *Individuals that performed an examination in the past may continue to provide technical review providing the proposed technical reviewer understands and is familiar with the current analytical methods, understands the operation of analytical instruments, and can determine whether the conclusion(s) are supported by the examination documentation.*
- *Analysts that perform similar or parallel casework analysis may perform technical review provided that they understand and are familiar with the current analytical method, understand the operation of analytical instruments, and can determine whether the conclusion(s) are supported by the examination documentation.*

17.8.1.1.2.1.2 External technical review requires:

- *The qualifications of the reviewer be documented and on file with the Quality Manager. The Laboratory System Director shall approve external reviewers who are not from an ISO/IEC 17025 accredited laboratory.*
- *The technical reviewer shall be supplied with the pertinent analytical methods.*
- *A checklist with sign-off shall be supplied to the reviewer with each case.*
- *The checklist shall contain sufficient detail to establish that the conclusion is justified by the examination documentation and that the appropriate Forensic Services analytical methods were followed. The checklist shall be approved prior to any external technical reviews by the discipline lead or lab manager, whichever is appropriate.*

17.8.1.1.2.2 Conflict resolution: If differences in interpretation between the casework analyst and the technical reviewer or verifier cannot be resolved during technical review/verification of casework analysis, the discipline specific plan should be followed. In the absence of a discipline specific conflict resolution procedure, the following general process shall be followed:

- *Conflict resolution shall not compel an individual to sign a case report containing opinions and/or conclusions with which the analyst disagrees.*

A third party analyst, qualified in the discipline, will be provided a copy of the original data and notes, excluding conclusion. After the third party has documented their conclusion, a mediation meeting will be held with the discipline lead (if the discipline lead is one of the parties then their supervisor will fill this role or appoint a party to fill the role) and all analysts involved. If during mediation an agreement cannot be reached on a conclusion in which the original analyst is comfortable reporting, an administrative report, containing the most conservative opinion, can be issued by the discipline lead. If the group decides that an administrative report is warranted, the ISPFS Quality Manager shall be consulted.

The case record will contain documentation of the conflict and resolution.

17.8.1.1.3 Administrative Review is a review performed to ensure that the laboratory reports issued by the staff of Forensic Services are editorially correct and to ensure that the laboratory reports and their examination records are consistent with Forensic Services policies. Administrative review is documented by the initials of the administrative reviewer and date of review for DNA database. For all other disciplines, the administrative review is documented by the name of the reviewer and the date of the review completion in ILIMS.

17.8.1.1.3.1 Though different employees may be involved in the final compilation of a case report, the individual who signs it as the analyst is ultimately responsible for the contents of the report and the accuracy of the information presented in the report.

17.8.1.1.3.2 Someone other than the analyst who wrote the examination report must administratively review each examination report or crime scene report and this administrative review must be documented. Typically, the administrative review is performed during the technical review, and may be documented as a single signature and date. The individual who performs administrative review shall be familiar with Forensic Services note taking and documentation requirements. Additional administrative reviews may be performed as desired, but must be documented if performed.

17.8.1.1.3.3 The report and documentation shall be reviewed for conformance to casework documentation guidelines and quality policies and procedures.

17.8.1.1.3.4 The report shall be reviewed for consistency with accepted conventions for spelling, grammar and word usage.

17.8.1.1.3.5 The information from ILIMS in the report shall be reviewed to ensure that the report accurately transferred the information.

17.8.1.1.3.6 The case records shall be reviewed to ensure conformance with quality policies 17.5.1.2.5-7.5.2.2 (these policies deal with initials, page numbering and case identification numbers).

17.8.1.1.3.7 The test report shall be reviewed to ensure all key information is included.

17.8.1.1.3.8 The accuracy of the evidence description in ILIMS and the electronic chain of custody (to that point in time) are checked, and this is documented on the review checklist.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

17.8.1.2.1 Results of examinations are reported in a Forensic Services examination report. Reports include all information necessary to interpret results along with other information that may be required by Forensic Services quality procedures. Examination reports are issued electronically via a secure website.

17.8.1.2.2 A test report will be created and released to the submitting party for all examinations that are completed, (with the exception of those performed to provide information for use in investigative databases).

17.8.1.2.3 If an examination is started but not yet completed and the laboratory receives a request to cancel examination from the customer, or notification that the case has been adjudicated, the request will be documented and placed in the case record. Analysis will be halted and a report will be issued documenting what analysis was done. The exceptions to this procedure are DUI cases with non-deceased subjects and qualifying sexual assault kits mandated for analysis by Idaho code; these types of samples will be analyzed regardless of the request to cancel or case status

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

17.8.1.3 Customers implicitly agree to the Forensic Services report format and content when they submit evidence for examination. Simplified reporting includes some of the information required in 7.8.2 to 7.8.7, while other information is available in the case record and is readily available.

7.8.2 Common requirements for reports

7.8.2.1 The examination report contains the following information unless notation specifies that the information is part of the case record:

a) A title;
b) Name and address of laboratory,
c) The location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
d) The laboratory case number on each page such that the page is recognized as a part of the report; and the end of the report is identified by the analyst's signature;
e) Submitting agency name; the address of the submitting agency is in the case record (the address of the submitting agency is in the DEPTNAME table of ILIMS);
f) Tests performed are contained in the case record;
g) A description of, the condition of, and unambiguous identification of the item(s) received by the analyst. This may be a description of the packaging, labeling, and/or unique identifiers for items not opened. A description of "not opened" by itself is not sufficient. A more detailed description may be in the notes. The condition of the item will be in the case record unless the condition of the evidence is material to the interpretation of the examination report.);
h) Date of evidence acceptance; is located on the report, sampling date when applicable is in the examination documentation.
i) The date(s) of analysis is found in the examination documentation;
j) The date of issue of the report;
k) Reference to sampling plan where this is relevant to the validity or application of results;
l) Where relevant, a statement to the effect that the results relate only to the items that were examined;
m) Examination result and, where appropriate, units of measurement;
n) Additions to, deviations, or exclusions from the method are located in the examination documentation.
o) The name(s), function(s) and signature(s) of the examiner. When a competency tested analyst trainee performs supervised case analysis, the trainee will sign the report;
p) Clear identification when results are from external providers;
q) A statement referencing the disposition of the evidence received by the analyst.

7.8.2.2 Forensic Services is responsible for all information provided in the report, except when information is provided by the customer: Data provided by the customer shall be clearly identified. In addition, a disclaimer shall be put on the report when information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage, it shall state in the report that the results apply to the sample as received.

7.8.3 Specific requirements for test reports

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

a) information on specific test conditions, such as environmental conditions;
b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6)
c) where applicable the measurement uncertainty presented in the same unit as the measurand or in a term relative to the measurand (e.g. percent) when:
- it is relevant to the validity or application of the test results
- a customer requests it
- the measurement uncertainty affects conformity to a specification limit.

d) deviations from or additions to the analytical method and information on specified test conditions;

7.8.3.2 Where the laboratory is responsible for sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4 Specific requirements for calibration certificates

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

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent)
b) the conditions under which the calibrations were made that have influence on the measurement results;

c) a statement identifying how the measurements are metrologically traceable (see ISO/IEC 17025: 2017 (E) Annex A)
d) the results before and after any adjustment or repair if available;
e) where relevant , a statement of conformity with requirements or specifications (see 7.8.6);
f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer

7.8.5 Reporting sampling – specific requirements

Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2 reports shall contain the following where necessary for the interpretation of results

a) the date of sampling
b) unique identification of the evidence or item (including name of manufacturer, model and serial numbers as appropriate)
c) the location of sampling including any diagrams sketches or photographs;
d) a reference to the sampling plan and sampling method;
e) details of any environmental conditions during sampling that affect the interpretation of the results;
f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk associated with the decision rule employed, and apply the decision rule.

7.8.6.2 The laboratory shall report the statement of conformity such that the statement clearly identifies:

a) to which results the statement of conformity applies
b) which specifications, standards or parts thereof are met or not met;
c) the decision rule applied (unless it is inherent in the requested specification or standard.

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

17.8.7.1 Forensic Services personnel who issue findings, including writing reports and providing testimony, based on examination documentation generated by another person(s) shall complete and document the review of all relevant pages of examination documentation in the case record.

17.8.7.2 When associations are made, the significance of the association shall be communicated clearly and qualified properly in the report.

17.8.7.3 When comparative examinations result in the elimination of an individual or object, the report shall clearly communicate the elimination.

17.8.7.4 When no definitive conclusions can be reached, the test report shall clearly communicate the reason.

The author(s) of a test report shall have conducted, participated in, observed, supervised, or technically reviewed the examination or testing.

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

17.8.7.2 All reports contain a "conclusions and interpretations" section

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with customer; a record of the dialogue shall be retained.

7.8.8 **Amendments to reports**

7.8.8.1 When an issued report needs to be changed or amended or re-issued, any change or information shall be clearly identified and, where appropriate the reason for the change included in the report. See procedure 17.8.8.3

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document or data transfer; which includes the statement amended report, such amendments shall meet the requirements of this document. See procedure 17.8.8.3

7.8.8.3 When it is necessary to issue a completely new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

17.8.8.3 When errors or omissions in casework are noted, the forensic scientist has the obligation to ensure that an incorrect report does not leave the laboratory. However, if it is necessary to make material amendments to a report, an amended report shall be issued. The amended report shall be the same document as the original report modified electronically with any corrections or amendments. The heading for the amended report shall contain the words "Amended." At the beginning of the amended report, a statement shall be inserted that describes the changes made in the amended report. The original report shall be left in the case record. ILIMS will "reset" the original report and retain a copy. The original report contains a watermark disclaimer about the report being amended. Information entered incorrectly by an agency representative in ILIMS prelog will be reflected on the laboratory report. ISPFS will make corrections requested by a customer at any point before the laboratory report is issued. The laboratory will not issue amended reports (will not make changes after a report has been issued) for ILIMS prelog entry errors or omissions made by customers.

7.9 **Complaints**

7.9.1 Forensic Services considers complaints (see definition Section 3) by customers or other parties as opportunities for improvement of the management system and customer service. Forensic Services creates and implements a quality procedure regarding complaints that includes the recording of complaints along with their investigation and remediation.

7.9.2 A description of the handling process for complaints is available to any interested party in this manual, a copy is published on the internet. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

17.9.2 Complaints that do not involve quality management issues will be addressed by following the Idaho State Police 03.02 "Complaints" procedure, 03.01 "Incident Review and Administrative Investigations" procedure, 03.10 "Problem Solving" and 03.13 "Progressive Discipline and Disciplinary Due Process" procedures, or other ISP procedures as appropriate. These types of complaints are not considered as relating to laboratory activities. Complaint procedures in the subsequent sections address complaints related to laboratory activities.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

17.9.3 Complaints Procedure:

17.9.3.1 Complaints regarding laboratory personnel, policies or procedures, or quality management may come from internal or external sources. Personnel that become aware of a complaint have the responsibility to communicate the complaint to their management staff or up through the chain of command as may be appropriate. Management has the responsibility to ensure that complaints are investigated and appropriately addressed in accordance with the guidelines listed below:

17.9.3.1.1 Complaints that arise out of quality management issues that do not conform to quality policies and/or procedures shall be directed to the Quality Manager and investigated in accordance with Forensic Services Quality Manual Section 7.10 "Control of Nonconforming Work". Quality Manual sections 8.7 "Corrective Action" and/or 18.6.1 "Preventive Action" will be considered where appropriate.

17.9.3.1.2 If an employee determines that the complaint originated due to a misunderstanding of ISP or Forensic Services policy/procedure, the employee may respond directly to the complainant and attempt to resolve the issue by discussing existing policies/procedures and resolve the complaint.

17.9.3.1.3 All complaints and resulting documentation of investigation, findings, and resolution will be kept on file in accordance with ISP procedure 02.07 (Records Management) and 03.01 (Administrative Review and Investigation) retention schedules. All complaint investigation files shall be exempted from disclosure to the public pursuant to Idaho Code 9 – 335

17.9.3.1.4 Each Lab Manager will maintain a Complaint Log. The log will contain a brief synopsis of each complaint received in that laboratory. The purpose of this log is to track types and causes of complaints in order to allow management to improve customer service and identify possible policy failures. The synopsis recorded in the complaint log will contain the following information:

a) Name of the organization that filed the complaint
b) Date of complaint
c) Reason for complaint
d) Findings
e) Approval
f) Resolution/Remediation (including formal notice of complaint handling to complainant.
g) Evaluation if there is risk to impartiality and risk/opportunity.

Complaint Logs will be filed by calendar year and will be kept on file for a minimum of two years.

7.9.4 The laboratory the complaint pertains to shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

17.9.6 If the outcome is delivered by an individual involved with the activity, it will be reviewed by an individual not involved in the complaint. This review and approval will be documented in the complaint log.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10 **Nonconforming Work**

7.10.1 Forensic Services takes appropriate action when any aspect of its work activity does not conform to the management system. Forensic Services policy and quality procedures ensure that:

17.10.1.1 Nonconforming work and noncompliance with the management system can be discovered as a result of external or internal audits, management reviews, proficiency testing, customer feedback, instrument malfunction (operational difficulties, maintenance problems, or calibration problems), quality control, technical review, etc.

17.10.1.2 Deviations from desired analytical outcomes that are discovered through the quality measures employed during analysis/review and designated by the management system are not usually considered to be nonconformities for purposes of this procedure. They must be satisfactorily resolved before completing analysis and issuing an examination report. These deviations may be treated as non-conformances, if appropriate.

a) The responsibilities and authorities for the management of nonconforming work are defined.

17.10.1a Any employee of Forensic Services who identifies nonconforming work shall immediately inform his/her supervisor, the discipline lead, or any other member of top management, of the nonconforming work. It is encouraged, but not required, for the reporting individual to disclose their identity. The "Quality Action Report" (QAR) workflow is initiated to report and initially investigate nonconforming work. The workflow is available to all ISP Forensic Services employees in the laboratory electronic quality compliance system. The reporting individual, informed supervisor, the discipline lead, or top management team member will complete step one of the QAR workflow and submit to the Quality Manager.

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

17.10.1b.1 When nonconforming work is identified that affects the results of analysis and has a systemic effect or could affect work in progress or future work. The supervisor, discipline lead, Laboratory Manager, Quality Manager, or Laboratory System Director shall halt all nonconforming work; and hold examination reports as necessary; and ensure that the appropriate supervisor, discipline lead and other top management members are made aware of the nonconforming work. For example, the DNA discipline lead has authority to halt or terminate forensic biology analysis due to technical problems within the section and the CODIS manager has authority to terminate laboratory participation in CODIS in the event of a problem until the reliability of the CODIS computer data can be assured. Halting work may include the removal of a scientist from casework and/or technical review until the issue has been satisfactorily resolved.

17.10.1b.2 An evaluation of all nonconformities, whether related to analysis or deviations from the management system, is made by the Quality Manager and the discipline lead if appropriate. However, neither shall evaluate nonconformities for which they may be responsible. QAR's that are determined to be nonconformities will be classified as class 1, 2, or not significant according the associated level of risk.

17.10.1b.3 Class 1 nonconformity: The nature and cause of the nonconformity raises immediate concern regarding the validity of results. An example of a Class 1 analytical nonconformity is a false identification or a false positive.

17.10.1b.4 Class 2 nonconformity: The nonconformity is due to a problem which may affect the validity of results, but is not persistent or serious enough to cause immediate concern for the overall validity of results. An example of a Class 2 analytical nonconformity is a false negative.

17.10.1b.5 Not significant nonconformity: The nonconformity is determined to have only minimal effect or significance, is unlikely to recur, is not systemic, and does not significantly affect the fundamental validity of results. Typically, this type of nonconformity is the product of a transcription error that results in a report being released that contains a result that is inconsistent with the examination documentation.

c) an evaluation is made to the significance of nonconforming work, including an impact analysis on previous casework.

17.10.1c The impact on analysis and past casework will be evaluated and documented in the corrective action development plan by the individual that develops the corrective action plan.

d) a decision is taken on the acceptability of non-conforming work.

17.10.1d The Quality Manager will complete the classification step within the workflow and make any pertinent comments regarding the significance and/or initial investigation. A corrective action will automatically be initiated for all class 1 and 2 nonconformities (see section 17.10.1). Any immediate action taken will be listed either by the reporting party or the Quality Manager, as applicable.

e) where necessary, the customer(s) is notified and examination reports are "reset," as necessary.

17.10.1e When examination reports based on nonconforming work that could have an effect on the results are released, the customers are notified. Documentation of the notification shall be retained in ILIMS as part of the case record. Examination reports with unsubstantiated or incorrect conclusions will be "reset" in ILIMS, and the original report will no longer be visible to customers. The original "reset" report shall be retained in the ILIMS. A reset report may be replaced by an amended report (see Section 7.8.8).

f) the responsibility for authorizing the resumption of work is defined.

17.10.1f When analytical methods have been halted or an analyst removed from casework, the work shall be reinstituted and examination reports issued only after the Discipline Lead and the Quality Manager have approved the resumption of work and the release of related examination reports in writing.

7.10.2 The laboratory shall retain records for nonconforming work and actions as specified in 7.10.1 bullets b) to f).

7.10.3 The corrective action mandated by the management system is promptly followed where the evaluation indicates that the nonconforming work is a Class 1 or Class 2 nonconformity (as defined in the procedure). No corrective action will be issued for nonconformities that are not significant.

7.11 Control of data and information management

7.11.1 The laboratory shall have access to the data and information needed to perform laboratory activities.

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage, or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation. (Commercial off the shelf software in general use within its designed application range can be considered to be sufficiently validated).

17.11.2 Custom software and custom software updates will be tested for functionality prior to being put into use. If the software is discipline specific the discipline lead will test or assign a tester; quality related and general system software will be tested or assigned for testing by the quality manager; ILIMS will be tested or assigned for testing by the ILIMS administrator. Documentation that the software was tested and approved will be stored with the appropriate discipline lead, quality manager, or the ILIMS administrator.

7.11.3 The laboratory information management system(s) shall:

a) be protected from unauthorized access;

17.11.3a *Electronic records shall be stored so that they can only be viewed or amended with controlled access. Servers shall be stored in controlled and limited access areas. The ILIMS and document management system has both user restrictions and password protection. The database for CODIS is password protected. Electronic records posted on the department public website are digitally secured to prevent changes. All records are securely contained in case files or case records, in laboratory central storage, in the limited access ISP warehouse, in the limited access ILIMS or Digital Workplace system, or in other limited access storage at ISP headquarters. Records that contain confidential or sensitive information shall be burned or shredded when they need to be destroyed. It is acceptable for ISPFS staff members to access ILIMS remotely through a secure Virtual Private Network (VPN) session on a department issued computer. Appropriate actions will be taken by staff members while outside of the laboratory to secure their terminal and prevent unauthorized access.*

b) be safeguarded against tampering or loss

17.11.3b *Electronic records will be protected and backed up to prevent loss of these records. ISP's Criminal Justice Information Services (CJIS) is in charge of backing up Forensic Services computer systems, to include; the network drives (including electronic quality files), ILIMS, Qualtrax, DNA Submission Tracker, Digital Workplace, and CODIS databases. Electronic records are backed up nightly by CJIS. Stand-alone databases that Forensic Services maintain are also protected and backed up. Instrumental parameters stored electronically on instruments or computers not connected to network drives need to be printed or electronically backed up.*

c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recoding and transcription.

17.11.3c.1 The integrity of the test data from computers and automated equipment is demonstrated by the use and monitoring of controls. Required controls to ensure proper environmental and operating conditions are specified in analytical methods. Analytical methods shall address any special environmental or operating conditions required for a piece of equipment.

17.11.3c.2 All computers and automated equipment in the laboratory operate under controlled and standard environmental conditions (i.e. moderate room temperature, appropriate ventilation). Computers, instruments, and equipment shall be on uninterrupted power (wherever possible) when samples cannot be rerun. ISPFS analyst and general computers are on a regular replacement schedule and computer service issues are addressed by ISP CJIS Technicians. Instrument computers are repaired and replaced as necessary, but are not on a regular replacement schedule due to instrument/computer compatibility concerns.

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

17.11.3e failures of the information management systems that could affect integrity of data will be considered non-conforming work and follow the associated procedures.

7.11.4 When the laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

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

7.11.6 Calculations and data transfers shall be checked in an appropriate systematic manner.

8 Management System requirements

8.1.1 General

The laboratory shall establish, document, implement, and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements, ISP Forensic services will implement a management system in accordance with ISO/IEC 17025:2017(E) option A.

8.1.2 Option A

As a minimum, the management system of the laboratory shall address the following:

- management system documentation (8.2)
- control of the management system documents (8.3)
- control of records (8.4)
- actions to address risks and opportunities (8.5)
- improvement (8.6)
- corrective actions (8.7)
- internal audits (8.8)
- management reviews (8.9)

8.2 **Management system documentation**

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfillment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

18.2.1 All the documents of the management system are available to each employee in their approved form and it is expected that employees will implement these management documents as written. As part of their training, each employee is required to read all documents of the management system, relevant to their position, and be tested on their knowledge and understanding. Evaluation of the examinations will be performed by the Quality Manager or Supervisor. The supervisor, or designee, will cover correction or feedback as necessary, with the employee. The successful completion of the

examination(s) are documented in the employee's training record. Changes in approved documents and new documents are communicated to the appropriate individuals. Each employee of Forensic Services is required to annually read and affirm that they have read and understand the management documents relevant to their position. This review may be performed at any point during the calendar year, but shall be performed and documented before the end of the calendar year. Objective proof of the annual review will be maintained by the Laboratory Manager or in the electronic document management system. This includes, but is not limited to, the Policy/Procedure manual and related documents that by extension are included in the Policy/Procedure Manual such as hyperlinked agency procedures; pertaining analytical methods, work instructions and form; and, the health and safety manual. The implementation of the management system is monitored and enforced through annual audits, management reviews, technical and administrative review of casework, and testimony review.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

8.2.3 The laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

18.2.3 The laboratory commitment to this policy is documented in the management review, internal audits, customer feedback, complaints resolutions procedures, and control of non-conforming work.

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, reference from or linked to the management system.

8.2.5 All personnel involved in the laboratory activities shall have access to the parts of management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents

8.3.1 Forensic Services creates and implements quality procedures to control all documents of the management system whether internally generated or from external sources

18.3.1.1 The Quality/Procedure manual and the Health and Safety manual are published by the authority of the Laboratory System Director of Forensic Services. All analytical methods, training manuals, work instructions and controlled forms are issued under the authority of the Quality Manager. Employees of Forensic Services are expected to follow them as written or seek an exception, if provided for.

18.3.1.2 The Quality Manager or designee shall maintain a recoverable hard copy or electronic copy of all versions/revisions of the quality documents. This may be done in the laboratory electronic document management system.

18.3.1.3 External documents are controlled as part of the management system when they contain instructions or policy that are adhered to as part of the management system. This includes, for example, standard analytical methods adopted by a discipline within Forensic Service and maintenance or calibration methods from an equipment manual, which are adopted by a discipline with Forensic Services. External documents that are adopted as part of the management system must be documented in the registry of management documents (see 18.3.2 f.1).

8.3.2 The laboratory shall ensure that:

a) documents are approved for adequacy prior to use by authorized personnel;

18.3.2a Review and approval of management documents: Before any controlled draft document of the management system, either new or revised, is approved, the following series of steps shall be completed:

18.3.2a.1 The revision or original draft of the document shall be accessible to potential users and their management. Typically, a comment period is allowed to permit reviewers to read, review, reflect, and comment on the draft document. Depending on the nature of the draft and the responses from the reviewers, the draft document may go through several cycles of reviewing and editing. If practical, draft revisions of documents should show the editing that is planned for the document. Each revision of a management system document shall have a history page and a documented approval. Forms do not require a history page.

18.3.2a.2 Finalized analytical methods are submitted to the Quality Manager for review and approval. The Quality Manager approves analytical methods, training plans, and discipline specific forms if the document contains the required elements and all mandatory reviews have been successfully completed. The Laboratory System Director approves quality policies, quality procedures, and health and safety policies after review by the Quality Manager.

18.3.2a.3 *After approval of any management system document, the document users are notified of the new revision.*

18.3.2a.4 *Approvals for all management system documents, which are currently approved for use in Forensic Services, are maintained in the electronic document management system.*

18.3.2a.5 *Registry of controlled management documents: A registry is maintained of all approved documents of the management system whether of internal or external origin including the quality policies/procedures, health and safety policies, analytical methods, and forms. This is available in the laboratory electronic document management system. For internally generated management documents, the registry consists of the electronic ISPFS document tree and contains the name, revision number, and issue date when expanded. Entries in the registry for externally generated documents must be unique and typically contain the name of the document and the issue or publication date and will be maintained on a spreadsheet within the document management system. Staff is expected to compare the revision number and issue date of any hard copy document they possess to registries if there is any doubt that their hard copy is current.*

b) documents are periodically reviewed, and updated as necessary;

18.3.2b *The Quality Manager reviews the quality policies/ procedures, and the health and safety policies annually to ensure that the policies reflect current laboratory practices, current normative references, and best practices as feasible. The appropriate discipline lead shall review the training plans, analytical methods, and analytical forms annually. This review may be performed at any point during the calendar year, but shall be performed and documented before the end of the calendar year. Management system documents shall be updated when the review indicates that it is needed. The reviews will be documented in the laboratory electronic document management system.*

c) changes and the current version status of documents are identified;

18.3.2c.1 *Where practical, drafts of revised documents identify new or altered text. ISPFS identifies new or altered text in document revisions using different color text, underlined text for additions, or stricken text for deletions. Software tools like "track changes" or similar editing or comment functions may be used, but are not required. When changes are approved, the history section of the document denotes which sections were changed. Some document history sections may also contain a brief explanation of the change.*

18.3.2c.2 *The document name, revision number and issue date are listed on the footer of internally created documents.*

18.3.2c.3 Updated management system documents are approved through the same quality procedure as new documents. The designated personnel shall have access to pertinent background information upon which to base their review and approval. Anyone considering making changes to the quality documents will need to know historical, legal or jurisdictional data behind such policies before making any changes

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

18.3.2d The approved documents of the management system are accessible to all staff electronically in the document management system. Only the Quality Manager and Deputy Quality Manager have permissions to add, delete, or edit the files stored in the quality folder of the document management system. The discipline leads have limited permissions to add and edit files within their specific section folders. Staff may print approved management system documents, but they are responsible for ensuring that they are working from currently approved documents. Work instructions are contained within an analytical method and are created with the intention of making a hard copy available near the equipment or the work area where they would be used. External documents controlled as part of the management system will be maintained in the electronic document control system where appropriate (e.g. DNA QAS document and accrediting body standards), with the Quality Manager (e.g. ISO/IEC 17025 standards), or in proximity to the instrument or laboratory work area in which it is used (e.g. instrument user manuals, and reference books).

e) documents are uniquely identified;

18.3.2e Documents of the management system are uniquely identified by naming each document, providing the date of issuance, revision number, page numbering, and the issuing authority. The pages of all documents of the management system are numbered 1 of X to X of X where X stands for the total number of pages in the document. Exceptions are allowed to this policy as appropriate. For example, a form that is clearly only one page long would not require numbering.

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

18.3.2f.1 A registry is maintained of all approved documents of the management system whether of internal or external origin including the quality policies/procedures, health and safety policies, analytical methods, and forms. This is available in the laboratory electronic document management system. For internally generated management documents, the registry consists of the electronic ISPFS document tree and contains the name, revision number, and issue date when expanded. Entries in the registry for externally generated documents must be unique and typically contain the name of the document and the issue or publication date and will be maintained on a spreadsheet within the document management system, if an electronic version cannot be added to the document management system. Staff is expected to compare the revision number and issue date of any hard copy document they possess to registries if there is any doubt that their hard copy is current.

18.3.2f.2 The document users are notified when a management system document is updated. It is the responsibility of individuals retaining hard copies of documents to destroy obsolete versions or mark the copy as "obsolete" and remove them from the working areas of the laboratory when they are informed of a revision.

8.4 Control of records

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfillment requirements in this document.

8.4.2 The laboratory shall implement the controls needed for identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available. See 7.11.3 for procedures on protection, and back-up of records. (Additional requirements for technical records in 7.5)

18.4.2.1 Case records will be identifiable by Forensic Services unique case number and will be indexed by this number. Case records (notes, etc.) will be contained and collected in an appropriate manner by the analyst and/or responsible personnel. Records will be accessible to authorized personnel and properly maintained by filing and storing them to prevent loss or damage. Electronic records will be disposed of when the retention time has been exceeded, but after any remaining evidence has been returned or destroyed. See 15.8.1.f for a description of retained evidence)

18.4.2.2 Record retention procedure:

18.4.2.2.1 At a minimum all current year and previous year case files shall be stored in a secure area maintained by Forensic Services. Closed case files that do not meet the current and previous year criteria may be transferred to a secondary storage location with limited access. The potential for damage to the files by fire, water, heat, and humidity shall be minimized as much as feasible. Original paper case files/records will not be taken out of the laboratory building with the exception of court order, transfer to long-term storage, and witness panels for technical verification and review. Technical and administrative records created outside of the laboratory (crime scenes, test fires, etc.) will be added to the case record in the laboratory as soon as practical.

18.4.2.2.2 Technical records such as case files and related technical records, calibrations and calibration logs, maintenance records, control and standard authentications, etc., are retained ten years then destroyed, with the exception that, case files for death investigation (homicide, suicide, and vehicular manslaughter), missing persons, sexual assault, and cases with a CODIS eligible profile, as well as DNA database batch records, and CODIS hit confirmation records are retained permanently. Homicide cases will be stored separately and not transferred to a secondary location for storage.

18.4.2.2.3 Electronic case records will be retained for 10 years before being destroyed/deleted, with the exception that, case files for death investigation (homicide, suicide, and vehicular manslaughter), missing persons, sexual assault, and cases with a CODIS eligible profile, as well as DNA database batch records, and CODIS hit confirmation records are retained permanently.

18.4.2.2.4 Records that document compliance with the management system (quality records) are retained ten years then destroyed. Quality records are archived by the Quality Manager as hard copies in limited access storage areas at ISP headquarters, electronically on protected network drives, or within the laboratory electronic document management system. Examples are proficiency testing records, corrective action records, audit records, and validation plan approval. Purchasing records that document compliance with purchasing policies are maintained by the Laboratory Managers (or their designees), headquarters, and/or ISP Financial Services.

18.4.2.2.5 Training records and continuing education records, held by the Quality Manager, are retained ten years after an individual leaves employment with Forensic Services then destroyed.

18.4.2.2.6 Card files and/or electronic databases used to reference case files shall also be retained according to the retention schedule above. Card files and/or electronic databases shall be stored in a manner and location most appropriate for the specific file to ensure continued accessibility.

18.4.2.2.7 Obsolete copies of each controlled document revision (i.e. analytical methods, controlled laboratory system manuals and forms, and controlled manufacturer documents) are archived by the Quality Manager as indexed hard copies in limited access storage areas at ISP headquarters, electronically on protected network drives, or within the laboratory electronic document management system. When controlled records maintained by individual disciplines are no longer used or referenced in discipline methods or manuals, the records shall be provided to the Quality Manager for archiving. The document retention on laboratory system controlled documents is indefinite.

8.5 Actions to address risks and opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results;
b) enhance opportunities to achieve the purpose and objectives of the laboratory;
c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
d) achieve improvement

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities

18.5.2a risk will be evaluated and addressed as part of the complaint, nonconforming work, and management review process. Opportunities will be evaluated and addressed in the management review.

b) how to:

- integrate and implement these actions into its management system;
- evaluate the effectiveness of these actions.

18.5.2b.1 The compliant log will document the evaluation of risk and risks to impartiality. If action is taken to address the risk, it will be documented in the resolution of the complaint. Complaints are reviewed during the management review. If it does not appear the actions taken to address the risk(s) were adequate, additional actions will be created and tracked in the management review process or it will be addressed as non-conforming work if appropriate.

18.5.2b.2 The non-conforming work process has a component to address risk, where risk is evaluated to require action; the actions to be taken will be documented in the non-conforming work process along with the completion and effectiveness.

18.5.2b.3 Risk to impartiality, risk and opportunities will be reviewed and evaluated during the management review. Actions to be taken will be added to the action plan with a timeframe for completion. Completion and effectiveness of these action will be completed in subsequent management meetings.

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

8.6 Improvement

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

18.6.1 Preventive action procedure

18.6.1.1 This procedure will be implemented when improvement opportunities or potential nonconformities are identified. Preventive actions may be identified from management reviews, audits, customer response form, etc.

18.6.1.2 A Preventive Action may be issued in response to a "Quality Action Report" (section 14.9.1.a). The Quality Manager or designee normally evaluates the QAR and designates the classification resulting in the initiation of a preventive action. However, if the actions or responsibilities of the Quality Manager are to be reviewed as part of QAR, then the Deputy Quality Manager will perform the evaluation and classification. The preventive action is issued to the staff member with the technical or supervisory responsibility to evaluate and resolve the potential nonconformity.

18.6.1.3 If the preventive action is not processed in the designated time frame, the next higher level of authority in the chain-of-command is notified of the delinquency. If the preventive actions performed are not consistent with the approved corrective action plan, the corrective action will be reissued for additional actions.

18.6.1.4 The person who initiated the preventive action will evaluate the results of the completed preventive action to determine if the preventive action was performed as proposed and if it was effective. A revised preventive action will be implemented or the preventive action may be reissued to the next level of authority if the preventive action is not effective.

8.6.2 The laboratory shall seek feedback, both positive and negative from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service.

18.6.2. Customer Feedback Procedure:

18.6.2.1 The System Director creates and makes available a customer services response survey with input and guidance from management staff.

18.6.2.2 Customer Directed Input: The survey is available on-line and/or in the evidence intake area for each laboratory.

Forensic Services Directed Input: Quarterly, a customer service survey is conducted. An attempt is made to contact a variety of agencies and investigators. The survey is not intended to be a random or statistically significant survey. The investigator or contact person for 10% of the cases (or a maximum of 10 cases, whichever is less) from each discipline in each laboratory per quarter is surveyed. No survey will be performed for DNA database samples. The survey will be provided with a copy of the case report in a sampling of cases. The survey is primarily emailed with an attached electronic copy of the laboratory report. When an email address cannot be obtained for the investigator, a hard copy of the report and survey will be mailed directly to the investigator. In addition, Forensic Services offers the customer service response survey to customers or stakeholders when receiving verbal feedback about the operation of Forensic Services or its staff as a means of collecting useful feedback for continual improvement of its operations.

18.6.2.3 All customer service response surveys received are retained electronically until after the related management review and, when needed, reviewed by the Laboratory System Director and Police Services Major.

18.6.2.4 On an on-going basis, each Laboratory Manager evaluates and resolves issues based upon customer survey responses. Annually, each Laboratory Manager summarizes customer service response surveys received in the preceding calendar year in a written report for the management review. These reports are reviewed during the annual management review and acted on as appropriate.

18.2.6.5 When the customer feedback can reasonably be interpreted as a complaint about Forensic Service, a copy of the Customer service response survey will be treated as a complaint and processed according to the Complaint Procedure, Section 4.8.

8.7 Corrective actions

8.7.1 When a nonconformity occurs, the laboratory shall:

a) react to the nonconformity and as applicable:

- take action to control it
- address the consequences

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere by:

- reviewing and analyzing the nonconformity;
- determining the causes of the nonconformity;
- determining if similar nonconformities exist or could potentially occur;

18.7.1b.1 A Corrective Action may be issued in response to a "Quality Action Report" (section 7.10). The Quality Manager or designee normally evaluates the QAR and designates the classification resulting in the initiation of a corrective action. However, if the actions or responsibilities of the Quality Manager are to be reviewed as part of the QAR, then the Deputy Quality Manager will perform the evaluation and classification, in consultation with the Laboratory System Director, as necessary. The investigation and corrective action development is issued to the lab manager with authority over the laboratory at which the nonconformity occurred, in conjunction with the relevant discipline lead, as applicable.

18.7.1b.2 ***Root Cause Analysis****: A corrective action performed by Forensic Services begins with an investigation to determine the root cause of the problem. Root cause analysis is the key and sometimes the most difficult part of the corrective action process. Often the root cause is not obvious and careful analysis of all potential causes of the problem is required. A careful evaluation of all potential root cause(s) needs to be completed to determine the most likely root cause(s). Possible root cause(s) include the nature of the sample, analytical methods, quality procedures, staff skills and training, consumables, or equipment and its calibration.*

c) implement any action needed

18.7.1c.1 Potential corrective actions are identified by the investigator, in conjunction with the discipline lead (as appropriate), to resolve the root cause(s), and the corrective action is chosen that is most likely to prevent recurrence of the nonconformity.

18.7.1c.2 The corrective action plan will be developed with completion dates for each step of the plan. For continuing actions, such as quarterly or monthly reviews milestone dates will be listed. The corrective action should be proportional to the seriousness of the nonconformity.

18.7.1c.3 The need for competency testing shall be evaluated as part of the corrective action plan for analyst based nonconformities and included as appropriate and necessary.

18.7.1c.4 The completed investigation and corrective action plan must be submitted by the response due date, unless an extension has been granted. The Quality Manager (or designee) and Discipline Lead (when appropriate) will review the corrective action plan. If necessary, revisions will be made in consultation with the investigator. When the Quality Manager and Discipline Lead (when appropriate) have accepted the plan, the corrective action plan will be assigned for implementation. The progress towards completion of a corrective action plan will be monitored as appropriate.

18.7.1c.5 As steps in the plan are completed, the assigned individual will record what was done, the date the step was completed, and will attach documentation demonstrating the completion.

d) review the effectiveness of any corrective action taken

18.7.1d.1 The person who initiated the corrective action (usually the Quality Manager) will evaluate the results of the completed corrective action to determine if the corrective action was performed as proposed and if it was effective. If the corrective action was not effective, a revised corrective action will be implemented or the corrective action may be reissued to the next level of authority.

18.7.1d.2 If the corrective action is not processed in the designated time frame the next higher level of authority in the chain-of-command is notified of the delinquency. If the corrective actions performed are not consistent with the approved corrective action plan, the corrective action will be determined to be not effective and reissued for additional actions.

18.7.1d.3 If it becomes apparent during the process of performing corrective action that the designated corrective action will not resolve the nonconformity, the Quality Manager (or designee) and Discipline Lead (when appropriate) will review and revise the corrective action plan.

18.7.1d.4 When the Quality Manager (or designee) has determined that the plan has been completed appropriately and the actions were effective, it will be submitted to the Laboratory System Director for review. Upon the Laboratory System Director's approval, the corrective action is completed and notification is sent to the appropriate individuals. The completed Quality Action Reports (including all corrective action measures) is maintained in the laboratory electronic quality compliance system.

e) updates risks and opportunities determined during planning, if necessary

18.7.1e If risks or opportunities are identified that should be considered for planning, they will be forwarded to the system director for inclusion of risk and opportunity assessment during the management review.

f) make changes to the management system as necessary

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory shall retain records as evidence of

a) the nature of the nonconformities, cause(s) and any subsequent action taken;
b) the results of any corrective action.

8.8 **Internal audits**

8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether then management system

a) conforms to:

- The laboratory's own requirements for its management system, including the laboratory activities;
- The requirements of ISO/IEC 17025:2017€

b) Is effectively implemented and maintained

18.8.1 Internal audits address all elements of the management system. The Quality Manager plans and organizes the audits as required by the schedule and requested by the management. Auditors are trained in the auditing process.

8.8.2 The laboratory shall

a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

18.8.2a Quality Audits Procedure: a variety of internal audits are performed. The purpose of these audits is to ensure compliance with the Management System and remediate nonconformities through corrective action either formal or informal. The following are the guidelines for performing internal quality or technical audits:

18.8.2a.1 All auditors shall be trained prior to performing audits. Training may be offered internally or provided through such programs as the A2LA or ANAB assessor training program.

18.8.2a.2 The Quality Manager schedules audits, as requested by management, with a lead-time for the on-site portion of two to six months when possible. Audits may be broken up into different activities which are conducted throughout the audit cycle. The Quality Manager or designee organizes and leads audits. Audit will be performed annually. The quality manager will determine which requirements of the management system and normative references will be audited each year, in the course of the audit cycle all requirements of the normative references and management system will be audited.

b) define the audit criteria and scope for each audit

18.8.2b *Audits shall be comprehensive and performed from audit checklists with the goal of auditing against requirements of the management system and the normative references consistent with the purpose of the audit. A substantial portion of quality audits and all technical audits include a review of case files and other technical records.*

18.8.2b.1 *Technical Audit Procedure: technical audits may be performed as part of the annual quality audits. Suggested tasks for technical audits include:*

Review significant number of cases for:

- *Appropriate use of approved analytical methods.*
- *Conclusions.*
- *Documentation.*
- *Controls and standards - appropriately used and authenticated.*
- *Review use of equipment.*

Check equipment to determine:

- *If it was validated according to approved methods/procedures.*
- *If calibrations were performed using designated methods and appropriately documented.*
- *If maintenance procedures were performed as required using designated methods.*

Other suggested tasks:

- *Discuss issues and problems with individual analysts and with groups.*
- *Review quality issues particular to the discipline.*

c) ensure that the results of the audit are reported to relevant management;

18.8.2c.1 *On-site audits are concluded with an exit conference. Conference participants consist of lab management, lead auditor, available audit team members, and other attendees as invited by the lab manager. The lead auditor or designee should summarize the audit at this conference.*

18.8.2c.2 *The final written report shall be completed in a timely manner and include a summary, findings, recommendations, and commendations. If the on-site audit concludes all of the audit activities, the report should be provided at the conclusion of the exit conference, if possible.*

d) implement appropriate correction and corrective actions without undue delay

18.8.2d.1 *A finding is a significant deviation from the Management System and may require that a corrective action be initiated. Findings must be objective and verifiable and the nonconformity must involve a deviation from the documented management system or normative references. While a finding will be noted, a corrective action may not be issued if the finding has been previously resolved or can be corrected while the audit team is performing the audit. However, this would only be applicable to simple findings where the accuracy of analysis is not impacted and root cause analysis is not necessary.*

18.8.2d.2 *Significant potential nonconformities discovered during the audit are remediated through a preventive action requests.*

18.8.2d.3 *Commendation: noteworthy action, process, or document that is observed during the course of an audit.*

18.8.2d.4 *Recommendation: these are not nonconformities from the quality standards or audit findings, but are opportunities for management to evaluate improvement ideas. The System Director will follow-up and discuss these with the Laboratory Manager.*

e) retain records as evidence of implementation of the audit program and the audit results

18.8.2e *Internal audits are recorded and the record is retained for a minimum of one accreditation cycle*

8.9 Management reviews

8.9.1 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) Changes in internal and external issues that are relevant to the laboratory;
b) Fulfilment of objectives;
c) Suitability of policies and procedures;
d) Status of actions from previous management reviews;
e) Outcome of recent internal audits;
f) Corrective actions;
g) Assessments by external bodies;
h) Changes in volume and type of the work or in the range of laboratory activities;
i) Customer and personnel feedback;
j) Complaints;
k) Effectiveness of any implemented improvements;
l) Adequacy of resources;
m) Results of risk identification (to include risks to impartiality);
n) Outcomes of the assurance of the validity of results; and
o) Other relevant factors, such as monitoring activities and training.

The management review includes consideration of related subjects at regular management meetings.

18.9.2 Management Review Procedure:

18.9.2.1 The purpose of this management review is as follows:

- *To ensure that the management system continues to be effective, suitable, and fulfill the current and future needs of Forensic Services and its clients.*
- *To ensure that action items from the last management review were completed and to assess their effectiveness.*
- *To create an action plan based on the current management review with assignments to individuals and timelines for completion.*
- *To create an action plan for performing internal audits for the following calendar year*
- *To begin the process for the annual update of the goals and objectives of Forensic Services.*
- *Consideration of previous management review minutes, focusing on the action items and assessing the effectiveness of actions that were taken.*

18.9.2.2 The Laboratory System Director shall establish the time, place, and agenda for a management system review. A management review is conducted at least once during each calendar year. Attendees shall include, but are not limited to, the Laboratory System Director, laboratory managers, the Quality Manager and/or their respective designees. The Laboratory System Director shall provide an agenda to the attendees in advance of the meeting. The agenda shall include, but is not limited to, the topics described in this procedure. Minutes shall be taken and disseminated as appropriate.

18.9.2.3 Proposed Management review agenda:

18.9.2.3.1 The Quality Manager shall present summaries of the following topics for which activities have occurred since the last management review:

- *Internal audits including findings, potential nonconformities, recommendations, and commendations.*
- *Assessments by external organizations.*
- *Corrective and preventive actions.*
- *Proficiency testing results.*
- *Reports of activities within disciplines.*
- *Continued suitability of policies, procedures, analytical methods, and work instructions.*
- *Personnel training.*
- *Recommendations for improvement, and effectiveness of implemented improvements.*
- *Other quality control activities as appropriate.*

18.9.2.3.2 The laboratory managers shall summarize and consider the following topics for their laboratory:

- *Customer feedback.*
- *Changes in the volume and type of work undertaken.*
- *Complaints and their resolution.*
- *Changes in requested service.*
- *Additional services/instruments/analytical methods.*

18.9.2.3.3 The Laboratory System Director will:

- *Review resources.*
- *Review and evaluate goals and objectives.*
- *Formulate action plans with a timeframe for completion.*
- *Evaluate risks to impartiality*
- *Evaluate risks and opportunities, define actions to be taken, review effectiveness of actions since the last management review for risks and opportunities.*

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a) The effectiveness of the management system and its processes;
b) Improvement of the laboratory activities related to the fulfillment of the requirements of this document;
c) Provision of required resources;
d) Any need for change.

18.9.3.1 Minutes and action items retained as a quality record. Quality records are retained for 10 years in accordance with 18.4.2.2.4 They are always retained for at least one cycle of accreditation.

18.9.3.2 Findings from management reviews and the actions that arise are recorded in the minutes of the management review meeting. Management shall ensure that the actions are completed within an appropriate and agreed upon timeline.

9 Administrative Policies

9.1 PERSONNEL POLICIES

9.1.1 Offices shall observe Official State of Idaho business hours, which are Monday through Friday from 8:00 A.M. until 5:00 P.M. The standard work schedule may be altered if authorized by the Laboratory System Director.

9.1.2 Guidelines for interns (Laboratory managers can make exceptions to these guidelines if appropriate.):

- Shall be non-funded positions.
- Chosen on a first-come, first-serve basis.
- Shall be college juniors and above interning for college credit toward a degree in Chemistry, Biology, Molecular Biology, or a closely related science or shall already possess a degree in one of the above areas.
- Have a recommendation from a professor, faculty advisor, or other professional.
- Pass background check and polygraph.
- Shall only be accepted if a forensic scientist or Laboratory Manager volunteers to supervise and mentor the individual. Upon approval from the Laboratory Manager, specific duties of interns shall be left to the discretion of their supervising forensic scientist.
- Shall have a Manager or forensic scientists assigned as a supervisor. Interns shall have an appropriate level of supervision for the tasks they are assigned.
- Shall become familiar with ISP Procedures governing conduct and confidentiality and Forensic Services health and safety policies.
- Shall not participate in crime scene investigations including clandestine drug laboratories unless accompanied by a forensic scientist. Access to very sensitive or hazardous areas shall not be permitted.
- May attend autopsies when accompanied by a forensic scientist.
- Shall not be allowed in any area of the laboratory after business hours unless accompanied by a forensic scientist.

- Shall not perform analysis on samples from casework upon which conclusions are based. The forensic scientist assigned to a case may take an additional sample from casework that the intern may analyze for experience or training purposes. The sample may only be taken if the reserve after removing the second sample is greater than ½. In the case of controlled substances, the additional sample taken will be stored in a secure locked location (either a drug locker or the controlled substance cabinet). The additional sample amount retained will be comparable to the amount taken in the course of analysis for the method which the trainee will perform on that sample. The samples will be labeled with the case and item number from which they were obtained. The samples will be logged into a "Controlled Substances Training Samples" log book. The log will include the date the sample was retained, the analyst retaining the samples initials, the case and item number, a description, location, the date destroyed or used in analysis, and initials from an analyst verifying it was consumed/destroyed. The "Controlled Substance Training Samples" log book and any samples currently retained at the time of the audit will be audited annually.
- Interns shall have an appropriate level of documented training to perform tasks in the laboratory. Interns may perform quality control or other tasks they have been trained to perform. Interns shall have training and be signed off on any analytical equipment they operate independently.

9.2 SUBPOENA POLICY AND WITNESS FEES

9.2.1 Subpoenas shall be prioritized in the chronological order in which they are received at the laboratory. In cases where multiple subpoenas are accepted for a given day, it shall be the duty of the forensic scientist to notify the attorneys of the conflict so that they are aware of the situation and can work out the scheduling conflict.

9.2.2 Idaho State Police Forensic Services personnel will provide testimony in Driving Under the Influence cases when an approved breath testing instrument was used under the following circumstances, if requested:

- As an expert for the prosecution when the defense has acquired its own expert;
- As an expert for the public defender when the prosecution has acquired its own (non-ISPFS) expert;
- An unusual circumstance has occurred surrounding the administration of a DUI breath test.

9.2.3 When summoned to State or Federal Court in criminal cases, or job related civil cases, employees shall report to the court as part of their normal work related duties. Subpoenas received from private attorneys should be addressed with the laboratory manager and handled on a case by case basis. If the court pays witness fees, they shall be remitted to Idaho State Police Financial Services.

9.3 CRIME SCENES AND CLANDESTINE LABORATORY CALL-OUT AND ASSISTANCE

9.3.1 The Idaho State Police Forensic Services shall provide support at crime/clan-lab scenes subject to the following guidelines.

9.3.2 The following are recommended guidelines for responding to crime scenes:

When assistance is requested, determine the nature of the crime, the agency and officer requesting laboratory assistance, and any other information that may help identify the needs of personnel at the scene. Notify the Crime Scene Coordinator, relaying the above information. The Crime Scene Coordinator will notify the relevant Lab Manager. The Lab Manager will notify the Laboratory System Director, who will make a courtesy notification to the Police Services Major. The Crime Scene Coordinator may also contact the district captain of ISP Investigations and communicate pertinent information and request for assistance.

If Forensic Services elects to respond, they shall notify additional forensic scientists who may be of assistance at the scene and proceed to the laboratory to collect any required supplies.

Forensic Services personnel shall identify themselves to law enforcement personnel who are present at a crime scene.

9.3.3 Law enforcement shall obtain a warrant for the specified crime scene prior to forensic services personnel entering and/or processing the scene. ISPFS personnel shall be allowed to review the warrant before entering the scene and will request a copy for their documentation. Deviations from this policy must be approved by the ISPFS Major.

9.3.4 Law enforcement personnel shall secure the scene prior to laboratory personnel becoming involved on-site. Forensic Services personnel shall not remain at a crime scene or clandestine lab if insufficient law enforcement officers are present to maintain security. When the security of a crime scene or clan lab becomes uncertain or safety conditions become compromised, Forensic Services personnel may immediately leave the premises. The forensic scientist shall notify the appropriate authorities as to the reason the departure was necessary.

9.3.5 Only trained clandestine laboratory personnel shall be allowed to enter a suspected clandestine laboratory site. Forensic scientists so trained shall

have completed the requisite course-work as outlined by Forensic Services and the Department. Prior to entry into such, Forensic Services personnel shall put on clothing and safety equipment commensurate to the circumstances. Prior to entering a potential laboratory, Forensic Services personnel shall ensure that fire and safety personnel have been notified or are present.

9.3.6 Only the minimum quantities of clandestine laboratory products, precursors, or equipment shall be collected by Forensic Services personnel assisting at these scenes. Samples collected at clandestine laboratories shall consist of only a few milliliters of liquids or a very few grams of solids.

9.3.7 Forensic Services shall not accept responsibility for, or transport of, chemicals, equipment, etc. collected at clandestine laboratory scenes. To maintain a safe work environment, Forensic Services will not accept large quantities of chemicals, solutions or equipment seized at clandestine laboratories. Forensic Services shall not accept responsibility for destruction or storage of any chemicals collected at such scenes.

9.3.8 ISPFS personnel shall write a report for each field services response. The field services report shall detail the names and duties of ISPFS personnel at the scene, observations made and activities performed at the scene, evidence collections made (and disposition of the evidence), and the results of any presumptive tests performed at the scene. A team report is acceptable provided the signatory of the report is responsible for the content of the report, meets the requirements in section 5.10.3.8 of this manual, and is technically qualified to offer any conclusions listed in the report.

9.4 DRESS CODE

9.4.1 Forensic laboratories contain many chemical and biological substances that are damaging to clothes and/or harmful to people.

9.4.2 Policies contained in the Health and Safety Manual regarding appropriate attire for working in the laboratory shall be adhered to.

9.4.3 The ISP dress code was modified to allow the following attire for forensic scientists who work in a laboratory on a daily basis, for personnel responding to crime scenes or clan laboratories, or for other work situations where casual dress is most appropriate:

- ISP issued scrubs are the official uniform of Forensic Services. ISP issued scrubs are the only allowable "casual dress" in ISP laboratories or ISP administrative buildings. Jeans are acceptable for field services response. Pants shall be in good condition with no holes and no stains.
- Polo shirts are acceptable for wear in the laboratory. They shall be in good condition with no holes or stains. T-shirts are not acceptable.
- Shoes (conservative in appearance) shall be protective of the feet, provide support and cushion when working or standing on hard surfaces, and provide a gripping surface on the floor.
- Forensic Services staff shall have a ready change of clothes for court or other duties requiring more formal attire when wearing the permissible casual attire to work.
- This dress code applies to Forensic Evidence Specialists (FES).
- Standard department policies apply when FS employees are performing duties where more formal attire is appropriate such as appearing as an expert in court, providing training, etc.
- Employees not meeting this dress code (as interpreted by the Laboratory Manager or Laboratory System Director) may be asked to change their clothes on their own time.

10 Appendix Section

Idaho State Police Forensic Services Code of Ethics

Adapted from the Department of Justice Code of Professional Responsibility for the Practice of Forensic Science

1. Accurately represent relevant education, training, experience, and areas of expertise.

2. Be honest and truthful in all professional affairs including not representing the work of others as one's own.

3. Foster and pursue professional competency through such activities as training, proficiency testing, certification, and presentation and publication of research findings.

4. Commit to continuous learning in relevant forensic disciplines and stay abreast of new findings, equipment, and techniques.

5. Conduct research and forensic casework using the scientific method or agency best practices. Where validation tools are not known to exist or cannot be obtained, conduct internal or inter-laboratory validation tests in accordance with the quality management system in place.

6. Handle evidentiary materials to prevent tampering, adulteration, loss, or nonessential consumption of evidentiary materials.

7. Avoid participation in any case in which there is a conflict of interest.

8. Conduct examinations that are fair, unbiased, and fit-for-purpose.

9. Make and retain contemporaneous, clear, complete, and accurate records of all examinations, tests, measurements, and conclusions, in sufficient detail to allow meaningful review and assessment by an independent professional proficient in the discipline.

10. Ensure interpretations, opinions, and conclusions are supported by sufficient data and minimize influences and biases for or against any party.

11. Render interpretations, opinions, or conclusions only when within the practitioner's proficiency or expertise.

12. Prepare reports and testify using clear and straightforward terminology, clearly distinguishing data from interpretations, opinions, and conclusions. Reports should disclose known limitations that are necessary to understand the significance of the findings.

13. Do not alter reports and other records or withhold information for strategic or tactical advantage.

14. Document and, if appropriate, inform management or quality assurance personnel of nonconformities[1] and breaches of law or professional standards.

15. Honestly communicate with all parties (the investigator, prosecutor, defense, and other expert witnesses) about all information relating to their analyses, when communications are permitted by law and agency practice.[2]

16. Inform the prosecutors involved through proper laboratory management channels of material nonconformities or breaches of law or professional standards that adversely affect a previously issued report or testimony.[3]

[1] Nonconformities are any aspect of laboratory work that does not conform to its established procedures. An evaluation of the nonconformity risk is appropriate to deciding whether or not reporting is necessary.
[2] Agency practice may vary depending on the status of the case or due to safety concerns.
[3] Prosecutors have independent reporting requirements based on codes of professional responsibility and ethics.