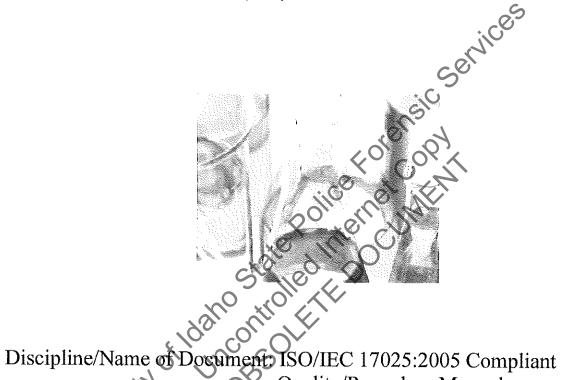
Idaho State Police Forensic Services

Approval for Quality System Controlled Documents



Quality/Procedure Manual

Revision Number: 10

Issue Date: 08/27/2010

APPROVED BY: Major/Manager

Checklist Submitted and Checked NA

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.

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. As Major for the Idaho State Police Forensic Services, I therefore affirm our commitment to this policy.

Major Kedrick Wille

8/27/10

Date

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Idaho State Police Forensic Services

ISO/IEC 17025:2005 COMPLIANT

Quality/Procedure Manual

Revision 10 Issued August 27, 2010

Idaho State Police Forensic Services ISO/IEC 17025:2005(E) Compliant Quality/Procedure Manual

Revision 8: Changes made to 14.1.5 c.10. This revision is effective February 8, 2010 and issued under the authority of the Major/Manager.

Revision 9: Changes made to Definitions, Org Chart, 14.1.4.4, 14.9.1 d, 14.13.1.2.1, 15.2.1.1.3.3, 15.8.1.4, 15.8.4.1.2, 15.8.4.1.3, 15.8.4.3.5, 15.9.3.1.1, 6.1.3.7, 6.1.3.13, 6.4.3.5. This revision is effective May 24, 2010 and issued under the authority of the Major/Manager.

Revision 10: Changes made to mission statement, quality objectives, 14.1.5 c. 15.2.1.1.2.10, 15.8.1.1.5, 15.8.2.4, 15.8.2.5, 15.8.2.6, 15.8.2.6.1, 15.8.2.6.2, 6.4.3.1, Appendix A. This revision is effective August 27, 2010 and issued under the authority of the Major/Manager.

Accepted changes for Revision 11: Changes made to (). These changes are effective when issued and are issued under the authority of the Major/Manager

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Issuing Authority: Major/Manager

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******	Training Records Retention Required Education Competency Testing see also 15.2.1.1.2.7 Journals and Scientific Reference Books mmodation and Environmental Conditions	
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***************************************	One-time Use Methods (not ISP methods)	
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Quality Objectives

- 1. To receive customer feedback, analyze, and consider and react 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 achieve a 90 % or better customer satisfaction rating based on customer service surveys.
- 4. To provide training to all staff in the requirements and responsibilities of the quality management system.
- 5. To maintain staff, facilities, and equipment capacity to satisfy turnaround requirements and effectively and efficiently meet demands.
- 6. To establish key initiatives (including quality objectives) for Forensic Services for the coming year after annual review.
- 7. 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.
- 8. To undergo periodic third-party evaluations for compliance with national and international standards and the international system.
- 9. 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.

2.0 NORMATIVE REFERENCES

ASCLD/LAB – International, Estimating Uncertainty of Measurement Policy, September 1, 2004, Rev. 0.1.

ASCLD/LAB – International, Measurement Traceability Policy, September 1, 2004, Rev. 0.1.

ASCLD/LAB - International, Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, January 24, 2006, Rev. 2.1.

International Organization of Standardization (ISO) / International Electrochemical Commission (IEC), ISO/IEC17025 - General requirements for the competence of testing and calibration laboratories, 2005. (ISO/IEC 17025:2005)

U.S. Department of Justice (DOJ), Federal Bureau of Investigations (FBI), Quality Assurance Standards for DNA Databasing Laboratories, 2009.

U.S. Department of Justice (DOJ), Federal Bureau of Investigations (FBI), Quality Assurance Standards for Forensic DNA Testing Laboratories, 2009.

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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 or verbal by both parties to the examination(s) that will be performed.

Corrective action – action that is reactive to eliminate the cause of a current nonconformity or other undesirable situation.

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.) Here are two examples of critical supplies: (1) drug standards that are verified by comparison of chemical/physical properties (mass spectra for example) to reliable literature references. (2) Methamphetamine drug quant control/external standard: accepted as accurate based on the reliability of the supplier.

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 laboratory managers, the quality manager and the Major/Manager of Forensic Services.

Forensic Services – 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.

Section 3 - Definitions Pg. 2 of 6 **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.

Recalled Report – a report that is obtained back from the submitting agency due to an unsubstantiated or incorrect conclusion. A report may also be recalled due to nonconforming work. A recalled report may be replaced by a corrected Replacement Report.

Record – a 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 (VIM 6.13) — Material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

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.

Replacement Report - a corrected report that may be issued to the submitting agency after the original report has been recalled.

Request – the analysis asked for by the submitting agency on evidence received in the laboratory

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Issuing Authority: Major/Manager

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 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 — a document detailing specific steps for performing a procedure or operating a piece of equipment/instrumentation.

Section 3 - Definitions Pg. 6 of 6

- **4.1.4.1** The responsibilities and authority of the laboratory manager are defined in section 4.1.5 (f) of this quality manual.
- **4.1.4.1.1** Each laboratory manager is provided sufficient authority to make and enforce management decisions regarding the operation of a laboratory.

4.1.5 Forensic Services management:

- 4.1.5 a) Ensures that the management and technical staff who, irrespective of other duties, possess adequate resources and authority to carry out their assigned duties in regard to implementation, maintenance and improvement of the management system, to identify departures from the management system or analytical methods, and to initiate actions to prevent or minimize departures from the management system.
- 4.1.5 b) Has arrangements to ensure that management and personnel are free from undue internal and external pressures that may adversely affect the quality of their work. The integrity of the services provided is the responsibility of all personnel Management ensures that employees are never instructed or required to after, slant, or falsify data or reports, whether written or spoken.
 - 14.1.5 b) 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:
 - 14.1.5 b.1) ISP Conduct Expectations (01.02 Conduct Expectation) which contain 18 specific directives, e.g. honesty, integrity, customer service, not accepting granuities, not using your position to favor any segment of the community, etc.
 - 14.1.5 b.2) SP Outside Employment procedure (03.06 Outside Employment), which prohibits secondary employment that constitutes a conflict of interest with their ISP position.
 - 14. 1.5 b.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.
 - 14.1.5 b.4) The Forensic Services procedure 14.8 (Complaints), ISP procedure (03.01 Administrative Review and Investigation), 03.02 (Complaints) and 03.10 (Problem Solving and Due Process) provide remedies for conflict resolution for employees, supervisors, managers, and customers.
 - 14.1.5 b.5) The Idaho State Legislature sets the annual budget for each state agency. A budget is appropriated to each division within ISP. The Major/Manager over

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- and return the call using a phone number known to belong to the agency employing the individual.
- 14.1.5 c.7) Faxed reports: See section 5.10.7 including the policy and procedure.
- 14.1.5.c.8) Reports regarding 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). Analysts may have a conversation with an attorney and answer general questions that are not related to a specific case without seeking permission from or notifying the opposing attorney.
- 14.1.5 c.9) The evidence tracking system forensic services uses is password protected and is only accessible by forensic services employees.
- 14.1.5 c.10)An analyst may either type their own reports or provide a written draft or form to administrative staff for typing and formatting. No typist initials (typed or handwritten) will appear on the report. The scientist/analyst will review the report and sign it if they approve. Quee technical and administrative review is complete and documented in the ease record, the FES will close the case in the electronic tracking software and initial and date the case record as closed. The Laboratory Manager (or Acting Daboratory Manager) may close cases in the absence of a FES.
- 4.1.5 d) Creates and implements procedures to ensure that staff avoids involvement in activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.
 - integrity.

 14.1.5 d.1) The Idaho State Police conduct expectations procedure is located at <u>01.02 Conduct Expectation</u>
 - 14.1.5.d.2) The Idaho State Police outside employment procedures are located at <u>03.06</u>
 Outside Employment
- **4.1.5** e) Defines the organization and management structure of Forensic Services, its place in the Idaho State Police, and the relationships between quality management, technical operations, and support services, through the aid of an organizational chart.
 - 14.1.5 e. 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.
- 14.1.5 e.2) 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 on the following page:

- **4.1.5 f)** Defines the responsibility, authority, and interrelationships for all personnel who manage, perform, or review work affecting the quality of tests:
 - 14.1.5 f) The points below describe the responsibilities, authority, and interrelations of personnel that manage, perform or verify work affecting the quality of tests. The roles and responsibilities of the personnel listed below include measures to ensure compliance with ISO/IEC 17025:2005.

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 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 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 ABC certification for Diplomate 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 3 (discipline leader, 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 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.

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- Review or create validation plans.
- Maintain validation records.
- Participate in the quality 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.

Quality 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.
- Announce approval of trainees to perform independent examination.
- Approval of trainee in conjunction with discipline leader.
- Review requests for major 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 ASCLD/LAB.
- Issue corrective and preventative action requests.
- Retain documentation of preventative and corrective action requests.
- Retain documentation for external technical reviewers.
- Maintain backup of all quality documents.
- Archive quality documents.
- Maintain approval for health and safety, quality and procedure manual.
- Issue quality audit report to lab manager and Major/Manager.
- Review of new analytical methods.
- Approve new analytical methods in conjunction with the discipline leader.
- Notify staff when new analytical methods are implemented.
- Organize, participate in and prepare a report for the annual Quality System Review.
- Compile the annual ASCLD/LAB report.
- Oversee ASCLD/LAB application, assessment, and surveillance.
- Maintain a register of approved subcontractors and verification documentation for the competence of subcontractors.

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- Approve employee cross-training requests.
- Approve training requests.
- Participate in annual Quality System Review.
- 4.1.5 f.1) Each employee is accountable to only one supervisor per job function, as demonstrated in the organizational chart following 4.1.5 e).
- **4.1.5** g) Provide adequate supervision in each laboratory for personnel that perform examinations, including trainees, by persons familiar with the analytical methods, their purpose, and the assessment of results.
- 4.1.5 h) Appoints a discipline leader for each discipline who has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of examinations performed in their discipline. These discipline leaders are designated in the organization chart following 4.1.5 e).
- 4.1.5 i) Appoints a quality manager for Forensic Services and provides direct access to the highest level of management at which decisions are made regarding Forensic Services policy and resources. The quality manager has the responsibility and authority to ensure that the management system is implemented and followed.
- 4.1.5 j) When a key employee is unavailable for work assignments and they have not appointed a temporary backup, persons responsible for performing the duties of the unavailable key employee are assigned as follows:

Position

Major/Manager

(1) Quality Manager

(2) Meridian laboratory manager

Quality Manager

Laboratory Manager Discipline Leader

Deputy Quality Manager The senior discipline leader in that laboratory

A senior member of that discipline appointed by the

Major/Manager

Laboratory Manager

- 4.1.5k) Personnel are made aware of the significance and importance of their activities and how they contribute to the objectives of the management system
- Top management ensures that appropriate communication processes are established and 4.1.6 that communication takes place regarding the effectiveness of the management system.
 - 14.1.6 Communication processes:
 - 14.1.6.1 Statewide management meetings are held on a periodic basis to discuss and resolve issues and receive directives from top management.
 - 14.1.6.2 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 Major/Manager are disseminated at those meetings.
 - 14.1.6.3 Discipline leaders communicate with the individuals in their discipline as appropriate. Management encourages face-to-face meetings of members of disciplines, as appropriate.

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4.2 MANAGEMENT SYSTEM

- 4.2.1 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.
 - 14.2.1.1 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 14.3 regarding document control and the required contents are described in procedure 15.4, 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 15.4.
 - 14.2.1.2 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. If correction or feedback is necessary, the examination will be returned to the supervisor for resolution with the employee. The Quality Manager will record successful completion of the examination(s) in the employee's personnel file. Changes in approved documents and new documents are communicated to the appropriate individuals. Each employee of Forensic Services annually is required to 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. 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.
 - 14.2.1.3 There may be situations that require deviation from quality policies.

 Permission, preferably in writing, from the Major, Quality Manager, or a

Section 4.2 – Management System Page 1 of 3

- 4.2.6 The roles and responsibilities of the discipline leaders and the quality manager including their responsibility for ensuring compliance with ISO/IEC 17025 are defined in section 4.1.5 f) of this Quality Manual under the headings of Quality Manager, Forensic Scientist 3 (discipline leaders for controlled substances, toxicology, and breath alcohol), and Forensic Scientist 4 (discipline leader/supervisor for forensic biology and latents/impression evidence).
- 4.2.7 Top management maintains the integrity of the management system when changes to the

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- the document contains the required elements and all mandatory reviews have been successfully completed. The Major/Manager approves quality policies, quality procedures, and health and safety policies after review by the Quality Manager. The checklist is not retained by the Quality Manager, but the approval form shall document that the checklist was submitted and checked.
- 14.3.2.1.3 The document becomes effective on the approval date listed in the approval form. Forms in use prior to the implementation of this policy, May 7, 2007, are approved for use and listed on the approved documents list.
- 14.3.2.1.4 After approval of any management system document, the Quality Manager notifies all users by email, adds the document to the electronic file of approved documents, archives the outdated document, removes the outdated electronic document from the "International Management System" folder, and updates the list of approved documents.
- 14.3.2.1.5 The Quality Manager shall maintain the approvals for all management system documents, which are currently approved for use in Forensic Services.
- 14.3.2.1.6 Registry of controlled management documents: The Quality Manager or designee maintains a registry of all approved documents of the management system whether of internal or external origin including the quality policies, quality procedures, health and safety policies, analytical methods, work instructions, and forms. This list is available electronically in the "International Management System" folder. For internally generated management documents, the registry contains the name, revision number, and issue date. 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. Staff is expected to compare the revision number and issue date of any hard copy document they possess to this list if there is any doubt that their hard copy is current.
- **4. 3.2.2** Forensic Services has quality procedures to ensure that the documents of the management system are:
- 4. 3.2.2 a) available to the staff in their authorized edition at all locations where operations essential to the effective functioning of a laboratory are performed.
 - 14.3.2.2 a) The approved documents of the management system are accessible to all staff electronically in the Forensic Services shared drive in the folder "International Management System". Only the Quality Manager, Deputy Quality Manager, Major/Manager, or Management Assistant can add, delete, or edit the files stored in this folder due to the property settings for this folder. Staff may print approved management system documents, but they are responsible for ensuring that they are working from currently approved documents. Work instructions are published with the intention of making a hard copy available near the equipment or the work area where they would be used.

Section 4.3 - Document Control Page 2 of 5 **4.3.2.3** 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.

4.3.3 Document changes

- 4.3.3.1 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. However, correction of spelling, punctuation, numbering, grammar, or other minor changes may be made to a document of the management system without reissuing the document providing that the change does not alter the meaning of the document.
- 4.3.3.2 Where practical, drafts of revised documents identify new or altered text.
- **4.3.3.3** Forensic Services does not temporarily issue management system documents using an abbreviated approval process.
 - When it becomes necessary to immediately update a portion of the ISP 14.3.3.3 Quality/Procedure Manual of Health and Safety Manual, a "change directive" may be issued. The proposed change wording goes through the formal approval process. Once approved by the Major/Manager, an implementation email is circulated from the Quality Manager to all users. The approval date for the change directive is the effective date for the change. A sequential tracking number is assigned to the change by the Quality Manager. The wording of the effected paragraph in the official electronic Oversion of the ISP Quality/Procedure Manual or Health and Safety Manual will remain unchanged. The text in the official manual will be changed to the color red and hyperlinked to the new/approved wording. Red hyperlinked text in either of these manuals alerts the user that an approved change has been made to the section. The new/approved wording will be maintained on the secure "International Management System" shared drive for comparison. Within six months of the issue of the first "change directive," the official manual shall be revised to reflect the approved "change directive" wording. The change directive approvals will be retained by the Quality Manager.
- **4.3.3.4** Forensic Services creates and implements a quality procedure for making and controlling changes in the computerized documents of the management system.

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4.4 REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

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 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.

- **4.4.1** Forensic Services creates and implements quality procedures for review of requests for analysis of submitted evidence. The policies and procedures for reviews leading to an implied contract for examination of evidence shall ensure that:
 - a) The needs of the customer regarding the evidence including the examination(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) The appropriate analytical methods are selected to meet the needs of the customer.
 - 14.4.1.1 Prior to the examination of evidence, laboratory personnel will evaluate the request as stated on the Evidence Submission Form (ESF) 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.
 - 14.4.1.2 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 fire evidence
 - Firearms, tool mark examinations, and serial number restorations
 - Impression evidence: latent print processing and comparisons, footwear, and tire track analysis
 - 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.
 - 14.4.1.3 The implied contract gives the analyst the discretion of selecting the

Section 4.4 - Review of Requests, Tenders, and Contracts Page 1 of 2

4.5 SUBCONTRACTING OF EXAMINATIONS

4.5.1 When 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 either to ISO/IEC 17025 or ASCLD/LAB — Legacy or other laboratories that have been assessed for competency and have been approved for use by the discipline leader 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.

- 14.5.1) Each contract laboratory employed by Forensic Services to provide the analysis of evidence must establish competency to perform such contracted work. The discipline leader 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.
- 4.5.2 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).
- **4.5.3** Forensic Services is responsible to the customer for the work performed by a subcontractor.

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.

- 14.5.3) 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. ISP 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.
- **4.5.4** Forensic Services maintains a registry of all subcontractors to whom evidence may be submitted for analysis and the evidence of compliance with ISO/IEC 17025, compliance with ASCLD/LAB Legacy, or an assessment by Forensic Services for the work in question.

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14.6.2.2 Verifying supplies

- 14.6.2.2.1 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.
- 14.6.2.2.2 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.
- 14.6.2.3 Supplies that do not meet specifications
- 14.6.2.3.1 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 leader, lab manager, and the quality manager, shall be notified of the discrepancy, and the quality manager shall record the discrepancy.
- 14.6.2.3.2 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.
- 14.6.2.3.3 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.
- 14.6.2.3.4 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.
- 4.6.3 Ordering documents for supplies and services affecting the quality of laboratory output contain descriptions of the services and supplies ordered. The ordering documents for supplies shall contain the technical specifications when these specifications could affect the quality of examinations. These ordering documents are reviewed and approved for technical content prior to release.

14.6.3 Purchase of supplies and services

- 14.6.3.1 Each laboratory manager will designate who is responsible for the ordering of supplies that have specific technical specifications and services that affect the quality of examinations.
- 14.6.3.2 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

4.7 SERVICE TO THE CUSTOMER

- **4.7.1** Forensic Services cooperates with customers to the extent possible with the aim of enhancing customer satisfaction. Cooperation is extended in several ways:
 - a) If necessary, review the case with the customer prior to performing analysis to clarify the request for service, determine which items will be examined, the examinations to be performed, and possible outcomes.
 - b) Interpret the results of the examination(s) for the customer as necessary.
- **4.7.2** Forensic Services seeks customer feedback, both positive and negative, regarding the services that it provides. The feedback is used and analyzed to improve the management system, analytical activities, and customer service.
 - 14.7.2 Customer Feedback Procedure:
 - 14.7.2.1 The Quality Manager creates and makes available a customer services response survey with input and guidance from management staff.
 - 14.7.2.2 <u>Customer Directed Input:</u> 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 NIBIN entry or DNA database cases. 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.

- 14.7.2.3 All customer service response surveys received are retained within each laboratory until after the related management review and, when needed, review by the Major/manager.
- 14.7.2.4 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 to the Quality Manager by the end of January. These reports are reviewed during the annual management

Section 4.7 - Service to the Customers Page 1 of 2

4.8 **COMPLAINTS:**

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.

- 14.8 Complaints Procedure:
- 14.8.1 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:
- 14.8.1.1 Complaints that do not involve quality management issues will be addressed by following the Idaho State Police 03.02 "Complaints" procedure, 03.01 "Administrative Review and Investigations" procedure, 03.10 "Problem Solving and Due Process" procedure, or other ISP procedures as appropriate.
- 14.8.1.2 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 4.9 "Control of Nonconforming Work". Quality Manual sections 4.11 "Corrective Action" and/or 4.12 "Preventive Action" will be considered where appropriate.
- 14.8.1.3 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.
- 14.8.1.4 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
- 14.8.1.5 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

4.9 CONTROL OF NONCONFORMING WORK

- **4.9.1** 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:
 - 14.9.1.1 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.
 - 14.9.1.2 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 nonconformances, if appropriate
 - a) The responsibilities and authorities for the management of nonconforming work are designated and actions (including halting work and withholding examination reports, as necessary) are defined and taken.
 - Any employee of Forersic Services who identifies nonconforming work shall 14.9.1 a) immediately inform his/her supervisor, the discipline leader, or any other executive management, of the nonconforming work. The "Nonconforming Work Report is utilized to report and initially investigate nonconforming work. The Nonconforming Work Report is available to all ISP Forensic Services employees on the shared drive. The reporting individual, informed supervisor, the discipline leader, or executive management team member will complete Section of the Nonconforming Work Report and forward the document to the Quality Manager. It is encouraged, but not required, for the reporting individual to disclose their identity. The supervisor, discipline leader, Laboratory Manager, Quality Manager, or Major/Manager shall halt all nonconforming work; and hold examination reports as necessary; and ensure that the appropriate supervisor, discipline leader and other executive management are made aware of the nonconforming work. For example, the DNA discipline leader 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 technical review until the issue has been satisfactorily resolved.

Section 4.9 - Control of Nonconforming Work Page 1 of 3 be recalled. Recalled reports will be requested back from the submitting agency. The original report shall be left in the case file. The analyst shall mark the original report by adding a statement noting that the report has been recalled and initial and date the statement. It is recommended that these be the only markings on the original report. Suggested wording for the notation is "This report has been recalled." The electronically stored report in the evidence tracking system shall have a line added at the beginning and end of the report marking it as "RECALLED" unless (or until) a replacement report is issued.

A recalled report may be replaced by a corrected "Replacement Report." A replacement report will be issued to the submitting agency. The heading for the replacement report shall contain the words "Replacement Report." At the beginning of the replacement report, a paragraph shall be inserted that describes the reason for the replacement report, document that it is replacing the original report, and provide the original report date. This paragraph needs to be highlighted in some manner that will draw the attention of the reader. In ETS, two of the options are to write the paragraph in capital letters or to put the paragraph in quotes. If a replacement report is issued, only the replacement report shall be stored electronically in the evidence tracking system.

- e) The authority for the resumption of testing is defined.
- 14.9.1 e) 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 Leader and the Quality Manager have approved the resumption of work and the release of related examination reports in writing.
- **4.9.2** 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 analytical nonconformity (as defined in the procedure), a significant Class 3 nonconformity with some likelihood of recurrence, or there is doubt about the compliance of Forensic Service's operations with its management system. No corrective action will be issued for Class 3 analytical and management system nonconformities that are not significant and/or are not recurring.

4.11 CORRECTIVE ACTION

- **4.11.1 General:** Forensic Services designates appropriate authorities for implementing corrective action when nonconforming work or departures from the management system occur and creates and implements a quality procedure for carrying out this policy.
 - 14.11.1.1 (CAR Section I): A "Corrective Action Report" (CAR) may be issued in response to a "Nonconforming Work Report" (section 14.9.1.a). The Quality Manager or designee normally issues the CAR. However, if the actions or responsibilities of the Quality Manager are to be reviewed as part of CAR, then the Major/Manager issues the CAR. The CAR investigation and corrective action development is issued to the supervisor or discipline leader with immediate authority over the staffing level at which the nonconformity occurred. Safety issues will likely be directed to the lab manager.
- **4.11.2** Cause analysis: A corrective action performed by Forensic Services begins with an investigation to determine the root cause of the problem. 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.
 - 14.11.2 (CAR Section II): 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 pattern of the sample, analytical methods, quality procedures, staff skills and training, consumables, or equipment and its calibration.
- **4.11.3 Selection and implementation of corrective actions:** Potential corrective actions are identified, where such are needed, and the corrective action is chosen that is most likely to correct the problem and prevent its recurrence.

The corrective action(s) taken is appropriate given the magnitude and risk of the problem. (i.e. the benefit of the corrective action should not outweigh the cost of resources to implement the corrective action). Required changes resulting from corrective actions are documented and implemented.

- 14.11.3.1 (CAR Section II continued): Potential corrective actions are identified by the investigator to resolve the root cause(s), and the corrective action is chosen that is most likely to prevent recurrence of the nonconformity.
- 14.11.3.2 If an extended corrective action plan is necessary, it will be developed with completion dates for each major step of the plan. For continuing actions, such as quarterly or monthly reviews, an action plan with milestone dates will

Section 4.11 – Corrective Action Page 1 of 3

record that policies have been updated, any action plans or additional audits have been satisfactorily completed, and that competency testing required for Class 1 and 2 Analytical Nonconformities was passed.

- 14.11.4.4 (CAR Section V): The Major/Manager (or designee) makes the final determination if the issue was appropriately resolved. Upon the Major's approval, the CAR is officially completed. The CAR is returned to the Quality Manager for distribution to the appropriate Laboratory Manager(s), Discipline Leader(s), and the affected individual(s). The Quality Manager will maintain the originals.
- 14.11.4.5 A summary of each CAR issued during the applicable time period will be reported to ASCLD/LAB in the ISP Annual Accreditation Report.
- 4.11.5 Additional audits: When the identification of a nonconformity creates doubt of compliance to the management system and the nonconformity presents a serious issue in regards to the accuracy of examinations provided (i.e. class one or class two analytical nonconformity) Section 14.9.1, the appropriate areas of activity are audited in a timely manner. This audit often would be performed after the implementation of corrective action to determine its effectiveness. These audits are performed in accordance with Internal Audit Policy/Procedure 4.14/14.14.

Issuing Authority: Major/Manager

4.13 CONTROL OF RECORDS

4.13.1 General

- **4.13.1.1** Forensic Services creates and implements quality procedures for identifying, collecting, indexing, accessing, filing, storing, maintaining, protecting, backing up, and disposing of quality and technical records. Quality records include reports from internal audits and management reviews, as well as, corrective and preventive action records.
 - 14.13.1.1 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. Records will be disposed of when the retention time has been exceeded. (See 14.13.1.2)
- **4.13.1.2** All records are legible and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage, deterioration, and loss. Retention times for records are established and followed.

14.13.1.2 Record retention procedure:

- 14.13.1.2.1 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 hundity shall be minimized as much as feasible.

 Original case files 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, NIBIN entry, etc.) will be added to the case record in the laboratory as soon as practical.
- 14.13.1.2.2 Fechnical 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, death investigation (homicide, suicide, and vehicular manslaughter), missing persons, and sexual assault case files are retained permanently. Homicide cases will be stored separately and not transferred to a secondary location for storage.
- 14.13.1.2.3 Electronic case records will be retained for 10 years before being destroyed.
- 14.13.1.2.4 Records that document compliance with the management system (quality records) are retained ten years then destroyed. Examples are proficiency testing records, corrective action records, audit records, and purchasing records that document compliance with purchasing policies.

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- 14.13.2.1 The initials and/or signature of the person(s) responsible for sampling and performing each examination will be on the relevant technical records. The initials and or signature of the person(s) checking the results will be documented in the case file.
- **4.13.2.2** Observations, data, and calculations are recorded at the time they are made and are identifiable to a specific examination.
- **4.13.2.2.1** Technical records reflect the date(s) of examination. Documenting the date analysis is started and the date the analysis is completed, is sufficient if allowed within a particular discipline.
- 4.13.2.3 Changes to technical records are made so as not to obscure or delete the previous data entry. Mistakes are not erased, made illegible, or deleted, but instead are crossed out and the correct value/verbiage entered alongside. All alterations and insertions to technical records are signed or initialed by the person making the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data.
- 4.13.2.3.1 Additions to technical records will be initialed by the person making the addition.
- **4.13.2.4** Forensic Services creates and implements a quality procedure that identifies the technical and administrative records that are maintained for each case.
 - 14.13.2.4 Technical and administrative records that are maintained for each case:
 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 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. ETS, for example contains administrative documentation that is centrally stored.

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.

Section 4.13 - Control of Records Page 3 of 5 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.)

- **4.13.2.10** When technical documentation is recorded on both sides of a page, each side shall be treated as a separate page.
- **4.13.2.11** 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.
- **4.13.2.12** 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.
- 4.13.2.13 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.

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- 14.14.1.7 Significant potential nonconformities discovered during the audit are remediated through preventive action requests (PAR).
- 14.14.1.8 Commendation: noteworthy action, process, or document that is observed during the course of an audit.
- 14.14.1.9 Recommendation: a deviation from best practice but not the quality system or a nonconformity to a quality standard, which is either not significant enough or is not pervasive enough to rise to the level of a finding. It is suggested that recommendations be corrected, but it is not required.
- 14.14.1.10 Audits are concluded with an exit conference. Conference participants consist of lab management, auditors, and other attendees as invited by the lab manager. Auditors should summarize the audit at this conference and leave a draft report, if possible.
- 14.14.1.11 The final written report shall be completed in a timely manner and include a summary, corrective and preventive actions, recommendations, and commendations.
- 14.14.1a Technical Audit Procedure: technical audits may be performed as part of the annual quality audits. Suggested tasks for technical review 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.
- **4.14.1.1** An internal quality audit and health and safety audit are conducted each calendar year in each laboratory.

The discipline leader, or another expert in the discipline, shall perform an annual technical review of their discipline in each laboratory that offers services in the specialty. Technical audits are optional for disciplines that are only offered at one laboratory.

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4.15 MANAGEMENT REVIEWS

- 4.15.1 The executive management of Forensic Services in accordance with a predetermined schedule and the quality procedure conducts a review of the management system and analytical activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. Results of the review are used to update goals, objectives and action plans for the coming year. The review takes into account:
 - a) Suitability of policies and quality procedures, analytical methods, work instructions, and forms;
 - b) Reports from managerial and supervisory personnel;
 - c) The outcome of recent internal audits;
 - d) Corrective and preventive actions;
 - e) Assessments by external organizations;
 - f) Results of inter-laboratory comparisons or proficiency tests;
 - g) Changes in the volume and type of work undertaken,
 - h) Customer feedback;
 - i) Complaints;
 - j) Recommendations for improvement;
 - k) Other relevant factors, such as quality control activities, resources, and personnel training.

The management review includes consideration of related subjects at regular management meetings.

- 14.15.1 Management Review Procedure:
- 14.15.1.1 The purpose of this management review is as follows:
- 14.15.1.1.1 To ensure that the management system continues to be effective, suitable, and fulfill the current and future needs of Forensic Services and its clients.
- 14.15.1.1.2 To ensure that action items from the last management review were completed and to assess their effectiveness.
- 14.15.1.93 To create an action plan based on the current management review with assignments to individuals and timelines for completion.
- 14.15.1.1.4 To begin the process for the annual update of the goals and objectives of Forensic Services.
- 14.15.1.1.5 Consideration of previous management review minutes, focusing on the action items and assessing the effectiveness of actions that were taken.
- 14.15.2 The Major/Manager shall establish the time, place, and agenda for a management system review. Attendees shall include, but are not limited to, the Major/Manager, laboratory managers, the Quality Manager and/or their respective designees. The Major/Manager shall provide an agenda to the attendees in advance of the meeting. The agenda shall include, but is not

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5.1 GENERAL TECHNICAL REQUIREMENTS

- **5.1.1** Many factors contribute to the accuracy and reliability of the examinations performed in the laboratories of Forensic Services. These factors include contributions from:
 - a) Human factors (section 5.2);
 - b) Accommodation and environmental conditions (section 5.3);
 - c) Analytical methods and method validation (section 5.4);
 - d) Equipment (section 5.5);
 - e) Measurement traceability (section 5.6);
 - f) Sampling (section 5.7);
 - g) Handling of evidence (section 5.8).
- **5.1.2** Forensic Services takes the factors listed in Section 5.1.1 above into consideration when developing analytical methods, work instructions, forms, personnel training, and in selecting and calibrating equipment.
- 5.1.3 Forensic Services creates and implements a quality procedure for routinely checking the reliability of its reagents.
 - 15.1.3.1 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).
 - 15.1.3.2 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.
 - 15.1.3.3 The records regarding reagents used for a single analysis and then disposed of shall be maintained in the casework notes.
 - 15.7.3.4 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 leader has approved the use of the expired reagent.
- 5.1.3.1 Reagents shall be prepared according to formulas located in controlled documents. These reagents are labeled with, at a minimum, identity of the reagent, date of preparation and/or lot number. Records identifying the employee preparing the reagent are maintained along with the results of testing and an evaluation of the test results. The reliability testing shall occur before use or if appropriate, concurrent with testing.

Section 5.1 - General Technical Requirements Page 1 of 1 15.2.1.1.2 The following elements shall be included in the training plan:

used.

- 15.2.1.1.2.1 General knowledge of forensic science and Forensic Services practices and procedures such as maintaining chain of custody, writing notes, and reports. Each discipline training manual shall provide training for new analysts in other forensic disciplines. This training may be accomplished by observation, reading materials, conversations, or formal training courses.
- 15.2.1.1.2.2 Study and review of the Idaho State Police policies and the Forensic Services Quality Manual.
- 15.2.1.1.2.3 Appropriate safety training to include review of the Forensic Services Health and Safety Manual and review of specific health and safety hazards associated with performing the analytical method(s).
- 15.2.1.1.2.4 Scientific theory on which the examination(s) is based as appropriate; 15.2.1.1.2.5 Theory, operation, maintenance, and troubleshooting of instrument(s)
- 15.2.1.1.2.6 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 trainee must initial the examination record for the work performed and the trainer/trained analyst must confirm observations and conclusions by initialing or signing each page of the examination records.
- 15.2.1.1.2.7 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 5.2.6.2 for additional information regarding competency testing.)
- 15.2.1.1.2.8 The training plan shall include a unit on the presentation of evidence in court. 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.
- 15.2.1.1.2.9 Mock court regarding the type of casework for which the analyst is being trained. A Laboratory Manager, the Quality Manager, or the Major/Manager shall evaluate the testimony with input from staff attendees.

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- 15.2.1.1.3.7 Completed training checklist from the training plan and other documentation as necessary;
- 15.2.1.1.3.8 Competency test with an evaluation and answer sheet/correct answer.
- **15.2.1.1.3.9** Written recommendation by the discipline leader based on the evaluation of the reviewed training documents.
- 15.2.1.1.3.10 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. If an analyst is required to testify in court while still in the training program, the discipline leader and Quality Manager must grant written approval before the analyst testifies.
- 15.2.1.1.3.11 The approval of an individual to perform analysis in a specific discipline or subdiscipline shall be announced to all staff of Forensic Services.
- 15.2.1.1.4 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 in a central training file.
- 15.2.1.1.5 Each staff member is responsible for updating his/her training record on file with the Quality Manager.
- 15.2.1.1.6 It is the responsibility of each employee to ensure that his/her affidavit of qualification and/or curriculum vitae accurately reflect successfully completed training.
- 15.2.1.1.7 Technical support staff that perform some aspect of casework analysis shall have documented training competency testing, and proficiency test regarding the casework analysis performed.
- 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 15.2.1.1.2.8 and 15.2.1.1.2.9) 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.
- 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 5.2.6.1 and the general education requirements by class are stated in the job descriptions. The training and skills required for each position are defined in 14.1.5 f) 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

Section 5.2 - Personnel Page 4 of 9 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.

- 15.2.2.7 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
- 15.2.2.8 Here is the process for application and follow-up to employee development opportunities:
 - 15.2.2.8.1 Staff members interested in attending in-state training shall apply for training using the ISP Training Request form or its current equivalent. Staff members interested in attending out-of-state training shall apply for training using the out-of-state travel request or its current equivalent and should make the request at least 30 days in advance.
 - 15.2.2.8.2 If possible, the immediate supervisor and the laboratory manager shall approve all training requests.
 - 15.2.2.8.3 Discipline leaders may initiate training requests for analysts in their discipline. The discipline leaders shall be consulted regarding training in their discipline provided that they are available for consultation in the time frame required for the approval of the training request.
 - 15.2.2.8.4 The training request shall be submitted to the Headquarters office for approval.
 - 15.2.2.8.5 The request shall be approved or denied by the command staff based on considerations such as need, budget (current funding situation), caseload demand, and input from the appropriate discipline leader.
 - 15.2.2.8.6 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 paperwork is made current and filed with the quality manager.
 - 15.2.2.8.7 Applicant shall be informed whether his/her request for training was approved or denied.

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Major/Manager

Management approves individuals to perform specific examinations and to testify on 5.2.5 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. 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. This information is available upon request. Services

5.2.6 Scientific/Technical Support Personnel Qualifications

5.2.6.1 Education

- 15.2.6.1.1 The education of each employee performing ease analysis shall be verified prior to being hired by Forensic Services. When required by the job description, a copy of the college transcript (including specific required coursework) and proof of graduation for all Forensic Scientists and technical support personnel shall be retained by the QA Manager.
- 15.2.6.1.2 The educational requirements for staff listed below only apply to staff hired after this policy was adopted January 10, 2007. Specific course requirements for Toxicology analysts are required for individuals hired after July 31, 2008.
- 5.2.6.1.1 Analysts working in Chemistry (controlled substances/fire evidence) must possess a baccalaureate or advanced degree in chemistry, biology, or forensic science/closely related field that is substantially equivalent. They must have taken general chemistry, organic chemistry, and quantitative analysis/analytical chemistry.
- 5.2.6.1.2 Analysts working in the Toxicology discipline must possess a baccalaureate or an advanced degree in a toxicology, chemistry, biology, or forensic science/closely related field that is substantially equivalent. They must have taken general chemistry, organic chemistry, and quantitative analysis/analytical chemistry.
- 5.2.6.1.3 Analysts working in the Forensic Biology discipline must possess a baccalaureate or an advanced degree in a biology, molecular biology, chemistry, biochemistry, or forensic science/closely related field that is substantially equivalent. When performing DNA analysis and where applicable, analysts and the discipline leader 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.
- **5.2.6.1.4** Analysts working in the Firearms/Tool marks or Latent Prints must possess a baccalaureate or advanced degree in chemistry, biology, or forensic science/closely

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5.3 ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

5.3.1 Laboratory accommodations and environmental conditions facilitate the correct performance of examinations. These conditions may include, but are not limited to, security, energy sources, lighting, heating, ventilation, water purification, air supply, and vacuum.

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.

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.

- 5.3.2 Accommodations and environmental conditions are monitored, controlled, and recorded as required by analytical methods, where they may influence the accuracy of the results. For example, biological sterility, dust, air quality, electromagnetic interference, humidity, electrical supply, and temperature are monitored as appropriate to the technical activities concerned. The examination process is stopped when accommodations or environmental conditions are outside the specified range and/or jeopardize the results of examinations being performed.
- 5.3.3 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. For example:
 - Analytical balances shall not be used when vibrations caused by laboratory or non-laboratory equipment would impair the accuracy of weighings. (If vibration is an on-going problem, the balance could be protected by a special anti-vibration platform.)
 - Visitors should be restricted from areas where they could contaminate work areas such as forensic biology.

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

5.3.4 Forensic Services controls access to its facilities as appropriate to protect evidence from

Section 5.3 - Accommodation and Environmental Conditions Page 1 of 4

- c) Internal areas requiring limited/controlled access have a lock system.
- 15.3.4.1 c) 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.
- d) Accountability for all keys, magnetic cards, etc., is documented and their distribution limited to those individuals designated by the laboratory manager to have access.
- 15.3.4.1 d.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.
- 15.3.4.1 d.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.
- e) Each laboratory is monitored during vacant hours by an intrusion alarm.
- f) Evidence storage areas are secured to prevent theft or interference 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 both before, during, and after examinations have been performed. (Procedure 15.8.4)
 g) A fire detection system is maintained at each laboratory.
- 5.3.5 Measures are taken to ensure good housekeeping in each laboratory as detailed in the accompanying quality procedure. Special measures are taken on a situation-by-situation basis as necessary.
 - 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.
 - 15.3.5.2 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.
 - 15.3.5.3 Laboratory counters, hoods, and equipment shall be cleaned as needed by the staff.
 - 15.3.5.4 Tools, equipment, and materials are stored in their proper location at the end

5.4 ANALYTICAL METHODS AND METHOD VALIDATION

5.4.1 General

Forensic Services uses appropriate analytical methods for the examinations performed, which include, where necessary, directions for sampling, handling, transport, storage, preparation of items to be analyzed, estimates of measurement uncertainty, and evaluation of test data by statistical techniques.

Work instructions for the use and operation of all relevant equipment and the handling and preparation of items for testing are available where lack of such work instructions could jeopardize the examination. The approved analytical methods, work instructions, and reference data relevant to the examinations performed are maintained as controlled documents of the management system and are readily available to staff.

Any deviation from an approved analytical method must be technically justified, authorized, documented in accordance with the appropriate quality procedure prior to use, and accepted by the customer if appropriate.

Standard analytical methods that contain sufficient and concise information for performing an examination and contain all elements required by Forensic Services need not be rewritten as an official Forensic Services analytical method. However, the analytical method must still be approved prior to being used.

- 15.4.1.1 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.
- 15.4.1.2 Methods not adopted by Forensic Services (One-time use analytical methods)

 This procedure describes the process for performing an examination with a method that has not been adopted by Forensic services. For example, checking a thermometer in a child abuse case using a Standard Method.

 An analytical method that has not been adopted by ISP Forensic Services: The variation in case samples requires that the forensic analyst have the flexibility to exercise discretion in selecting a method most appropriate to a problem at hand. The analyst needs to contact the appropriate discipline leader if the analyst proposes to use a method that has not been adopted by ISP Forensic Services. The discipline leader can approve the use of an analytical method if:

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- 15.4.2.1 Practices: when an analyst realizes that for some reason he/she would like to depart from an approved analytical method, the analyst shall contact the discipline leader. The discipline leader and the analyst shall review the modification and decide if the deviation is minor or major. If the discipline leader needs to depart from the analytical method the discipline leader 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.
- 15.4.2.2 Minor deviation the case record for a minor deviation shall contain documentation noting the following:
 - Description of the deviation.
 - Determination that the deviation was minor.
 - Concurrence by the discipline leader, or supervisor (if discipline leader is requesting deviation) to the deviation.
- 15.4.2.3 Major deviation the case record for a major deviation shall contain documentation noting the following:
 - Description of the deviation from the analytical method
 - Determination that the deviation was major.
 - Either a copy of the validation study or reference to the location of the validation study.
 - Concurrence by the discipline leader, or supervisor (if discipline leader is requesting deviation) to the deviation from the formal analytical method and approval of the validation study.
 - Acknowledgement of review by the quality manager for consistency with the quality system.
- 15.4.3 Methods may be developed for special or unique situations. They must be validated and approved by the discipline leader 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.
- **5.4.2.1** Prior to implementation of a validated analytical method new to Forensic Services, its reliability is demonstrated in-house, against the documented performance characteristics for that analytical method. Records of performance verification are maintained for future reference (refer to validation procedure (5.4.5) for details).

5.4.3 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 leader shall forward a copy of the plan to the Quality Manager, prior to its implementation and supervise the development of the

- **15.4.3.10** 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.
- 15.4.3.11 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.
- 15.4.3.12 Safety Concerns: Specific or unique safety hazards shall be listed as part of the analytical methods if there are specific or unique safety concerns.
- 15.4.3.13 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 and identify the file.
- 15.4.3.14 As appropriate, analytical methods shall contain a discussion of precautions, sample preparation, and possible sources of error.
- 15.4.3.15 Include quality criteria as applicable:
- 15.4.3.15.1 If an equipment calibration is in a separate document, specify in the appropriate analytical method, the calibration procedure to use.
- 15.4.3.15.2. Blanks, duplicates, standards, and positive and negative controls.
- 15.4.3.15.3 Independent positive controls if the analytical methods generate quantitative results
- 15.4.3.15.4 Acceptance criteria in regards to quality measures if applicable.
- 15.4.3.15.5 The uncertainty of measurement will be addressed in analytical methods in which a quantitative result is reported.
- 15.4.3.16 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. #) in the bottom right hand corner. It is considered a good practice to place the effective date on the document but not required.
- 15.4.3.17 Work Instructions: 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. (Some examples where work instructions might be used: a detailed set of instructions on how to start up, acquire and print results from the FTIR, a list of steps to follow in the extraction of benzodiazepines from urine.) The discipline leader 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 leader to review corresponding work instructions and ensure compliance with the updated analytical method.

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.

- 15.4.5.2.4 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 our lab environment.
 - 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 (povel methods developed independently by Forensic Services) would require extensive validation.
- 15.4.5.2.5 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.
 - o Materials-materials needed for the method.
 - Sufety- 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.
 - 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.

Section 5.4 - Analytical Methods and Method Validation Page 7 of 12 lower end of the working range. The upper end of the working range must be determined. The level of acceptable variation from the calibration curve at various concentrations must be determined. This is generally performed by preparing standard solutions at five concentrations; the standards should be prepared and analyzed a minimum of three times. Ideally the different concentrations should be prepared independently, and not from aliquots of the same master solution. In the final procedure a tighter range of three standards is generally used, and in some instances, a single standard concentration is used. A correlation coefficient of >. 995 is generally considered as evidence of acceptable fit of the data to the regression line.

- 15.4.5.3.4 Ruggedness: this is an intermediate precision study. The precision obtained when multiple analysts, using multiple instruments, on multiple days in the same laboratory, perform the method. Different sources of reagents or multiple lots of columns may be used in this study. This specification helps to isolate which of the above factors contribute to significant variability in results.
- 15.4.5.3.5 Accuracy: the accuracy of a method is the closeness of the measured value to the true value for the sample. Accuracy is often determined in one of three ways. Analyzing a sample at a known concentration and comparing the values can assess accuracy. When available the standard should be a certified reference standard. Another approach is to compare the test results from the new method to results from an existing alternate method that is known to be accurate. The most widely used approach is to spike blank matrices with the analyte of interest.
- 15.4.5.3.6 Precision: this is the amount of scatter in results obtained from multiple analyses of a homogeneous sample. To be meaningful, the precision study must be performed using the exact sample and standard preparation procedures that will be used in the final method.
- 15.4.5.3.7 Repeatability: the first precision study is the instrument or injection repeatability. Generally a minimum of 10 injections of one sample solution is made to test the performance of the instrument. The second repeatability study in precision assesses the method. This data is obtained by repeatedly analyzing, in one laboratory on one day, aliquots of a homogeneous sample, each of which has been independently prepared according to the method procedure.
- 15.4.5.3.8 Reproducibility: the precision of a method in multiple labs with multiple users. This is determined by testing homogeneous samples in multiple laboratories.
- 15.4.5.3.9 Robustness: the ability of a method to remain unaffected by small changes in parameters, for example injection volume or addition of base to the standards and samples.
- 15.4.5.3.10 Stability: it may be essential to determine if sample solutions are stable

Section 5.4 - Analytical Methods and Method Validation Page 9 of 12 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. The chances are 95.5 in 100 that the error is less than +/- 2 std dev.

15.4.6.2.2 If an analytical method is found to have bias, this must also be factored into the estimation of uncertainty. A publication that gives guidance on this can be referenced at

http://nvl.nist.gov/pub/nistpubs/jres/102/5/j25phi.pdf

- 15.4.6.2.3 The uncertainty level may be updated as more data becomes available from using the procedures. The updates will be centrally stored in the laboratory.
- 15.4.6.2.4 Each analytical method from which quantitative results are reported shall contain or make reference to instructions for reporting the uncertainty of measurement.
- **5.4.6.3** When estimating measurement uncertainty, all significant sources of uncertainty in the given situation are taken into account using accepted methods of analysis.

5.4.7 Control of Data

- **5.4.7.1** Calculations and data transfers are subject to appropriate checks in a systematic manner. (Section 5.9.4)
- **5.4.7.2** When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the Forensic Services ensures:
- a) computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use.

 Procedure 15.4.5.2 will be followed with the exception that the management assistant will serve the same role as a discipline leader in the validation of software used by the Forensic Evidence Specialists.
- quality procedures have been established and are followed for protecting data; the quality procedures include issues such as integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing. (Section 14.1.5 c, 4.13, and 5.3.4 including subsections and related procedures.)
- c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

Commercially developed software, in general use within its designed application range, such as word processing, database, or statistical programs may be considered sufficiently validated. In-house developed software or modifications made to off-the-shelf software

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5.5 EQUIPMENT

- 5.5.1 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. 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.
- 5.5.2 Equipment and software used for examinations and sampling are capable of achieving the accuracy required and comply with the specifications relevant to the examinations performed. Equipment has calibration, intermediate checks, and/or performance verification performed, as necessary, when the output of the equipment has a significant affect on the results of analysis. When received, equipment is checked to establish that it meets Forensic Services purchasing requirements, the relevant standard specifications, and has a calibration, intermediate check, and/or performance verification, as appropriate, before use.
 - 15.5.2.1 The accuracy required and the specifications relevant to the examinations performed for equipment and software are included or referenced in the analytical methods.
 - 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.
 - 15.5.2.3 All intermediate checks and performance verifications shall be performed in accordance with a documented program if the instrument is being used for casework analysis. (see 5.5.10)
 - New instruments/equipment shall not be used for casework analysis until the discipline leader 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.
- 5.5.3 Personnel who 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.

- **15.5.5.g)** 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.
- 5.5.6 Forensic Services creates and implements quality procedures for the safe handling, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. Forensic Services does not use measuring equipment from accredited services off-site and consequently does not have any procedures for transporting this equipment.
 - 15.5.6 Maintenance plans for measuring equipment are described in corresponding analytical methods, if appropriate. All measuring equipment will be stored in the laboratory and is handled and used by approved analysts or trainees under supervision of approved analysts.
- 5.5.7 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.
- 5.5.8 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.

5.6 MEASUREMENT TRACEABILITY

5,6.1 General

Traceability is the linkage of measuring equipment output to a recognized reference value (See definitions Section 3) and calibration is the set of operations that are performed to determine the relationship between the output of a piece of measuring equipment and a reference value (See definitions Section 3). For a balance, traceability is the linkage of weight as measured by the balance compared to an internationally accepted value for that weight.

All measuring equipment deemed by Forensic Services to have significant impact on the accuracy or validity of examination results is calibrated (providing that the measuring equipment requires calibration) prior to use in casework by the documented program for calibrating the measuring equipment. Section 15.5.2 of this manual regarding equipment provides guidance for the calibration of equipment.

- 5.6.1.1 (This supplemental standard is contained in the policies and related procedures 5.5.2 and 5.5.10.)
 5.6.2 Specific Requirements
 5.6.2.1 Calibration
- 5.6.2.1.1 Forensic Services is not a calibration laboratory. However, as applicable, the requirements of this standard have been incorporated into the quality policies and procedures in section 5.6.2.2.1.
- 5.6.2.1.2 Forensic Services is not a calibration laboratory. However, as applicable, the requirements of this standard have been incorporated into the quality policies and procedures in section 5.6.2.2
- 5.6.2.2 Testing
- 5.6.2.2.1 Forensic Services creates and implements a program of calibration to establish traceability to SI units of measurement for measuring equipment used in analysis as specified in the procedure that follows:

15.6.2.2.1.1:

Forensic Services calibrates measuring equipment that meets the following guidelines:

- Calibration is a significant factor in the accuracy of examinations.
- Output of the measuring equipment is in basic/derived SI units of measurement or U.S. customary system of units and traceable to SI units of measurement.

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- 4. Volumetric glassware excluding class A glassware
- 5. Rulers and other distance measuring devices
- 6. Syringes used for quantitative analysis
- 15.6.2.2.1.5 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.
- 5.6.2.2.2 Forensic Services currently only calibrates measuring equipment that is traceable to SI measurement standards and therefore has no policies for calibrating measuring equipment that is not traceable to SI measurement standards.
- 5.6.3 Reference Standards and Reference Materials
- **5.6.3.1 Reference standards:** Forensic Services creates and implements procedures for the calibration of reference standards. Whether performed internally or externally, calibration must provide traceability as described in procedure 15.6.2.2.1.1, where possible. The reference standards are to be used for their designated purpose only unless it has been demonstrated that some other use would not degrade their performance for calibration. If these reference standards are adjustable, they are calibrated before and after adjustment.

15.6.3.1.1 Reference standards:

- 15.6.3.1.1.1 For calibration of reference standards that is performed externally:
 - An analytical method shall designate that the calibration is performed externally and describe the frequency of calibration.
 - The contractor that provides the service is accredited to ISO/IEC 17025, if appropriate, to perform the calibration.
 - The calibration certificate shall be retained as a quality record in accordance with the policy regarding quality records.
- 15.6.3.1.1.2 For calibration of reference standards that is performed internally:
 - The calibration process and the frequency of calibration are described in an analytical method.
 - The record of calibration shall be maintained as a quality record.
- **5.6.3.2 Reference Material:** Where possible, reference material is traceable to SI units of measurement or to certified reference material. Internal developed reference material shall be verified by comparison to published data or other suitable technique.
 - 15.6.3.2.1 Authenticating and using reference material and controls:
 - 15.6.3.2.1(1) Reference material and controls shall be authenticated prior to being used for casework examinations unless they are obviously authentic such as a

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- 15.6.3.2.2.3 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.
- 15.6.3.2.2.2.4 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.
- 15.6.3.2.2.2.5 Inventories shall be kept of the primary standards listing drug, source (if known), initial gross weight, audit record, and authentication.
- 15.6.3.2.2.2.6 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.
- 15.6.3.2.2.7 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
- 15.6.3.2.2.2.8 The total weight of the primary standard and container shall be audited annually.
- 15.6.3.2.2.3 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.):
- 15.6.3.2.2.3.1 Allowable amounts of bench standards: martjuana, psilocybin mushrooms, and GHB - 50 grams; Schedule Land II controlled substances, 300 milligrams; and Schedule III, IV, and V controlled substances, one gram or five tablets.

 15.6.3.2.2.3.2 The bench standards shall be maintained in a secured part of the laboratory.
- 15.6.3.2.2.3.3 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.
- 15.6.3.2.2.3.4 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,
- 15.6.3.2.2.3.5The combined weight of the bench standard and container shall be audited omually.
- 15.6.3.2.23,6 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 Major/Manager shall grant prior approval in writing for each request.
- 15.6.3.2.2.4 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.
- 5.6.3.2.1 Reference collections of data or items/materials encountered in casework that are maintained for identification, comparison or interpretation purposes (e.g., mass spectra,

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5.7 SAMPLING

5.7.1 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.

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.

5.7.2 By submitting evidence to Forensic Services and using the standard submission forms, customers agree that submitted evidence is analyzed according to designated sampling plans and/or methods of sample selection.

When a customer requests a departure from a sampling plan the request is communicated to the analyst. The analyst must implement the quality procedure for departing from approved analytical methods 15.42 prior to making any sampling departure, and record the request and departure, if allowed, in the examination record. If the sampling departure significantly affects the results of the examination, it is noted in the examination report.

5.7.3 When sampling is performed; the sampling plan used, if more than one is available; the person performing the sampling; relevant environmental factors; and identification of the sampling location, if outside the typical laboratory setting, and the statistics the sampling method is based on, if appropriate, are documented.

- 15.8.1.1.6 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. This documentation will be located in the returned evidence log if the item is rejected, otherwise it will be kept in the case file.
- 15.8.1.1.7 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.
- 15.8.1.2 Requirements for syringes:
- 15.8.1.2.1 Forensic Services does not accept syringes with or without needles except in the carefully controlled manner described below. However, if the submitting agency chooses to submit an alcohol or water rinse from a syringe, then the sample may be submitted to Forensic Services as a routine case without going through the protective measures described below.
- 15.8.1.2.2 The agency shall contact the appropriate Forensic Services Forensic Evidence Specialist before the syringe and contents are submitted. That Forensic Evidence Specialist shall ascertain that all the guidelines below are being followed, and notify the Lab Manager. The entire case shall be returned without analysis, accompanied by a copy of this policy, if the Forensic Evidence Specialist is not contacted prior to the submission of the syringe.
- 15.8.1.2.3 The prosecutor associated with the case shall submit a letter requesting the examination. The letter shall state why it is necessary to the case for the contents of the syringe to be analyzed. This letter shall arrive at the laboratory attached to the evidence or faxed to the laboratory prior to submission, or the evidence shall be returned.
- 15.8.1.2.3 The syringe shall be packaged in an appropriate biohazard safety tube.
- 15.8.1.2.4 Generally, analysis of a syringe for controlled substances shall only be performed if the case is a death investigation or other exceptional/unusual case. Syringes shall not be accepted if other controlled substance evidence or any other evidence is available which provides the same proof that the examination of the syringe would provide.
- 15.8.1.2.5 Syringes shall be packaged separately if the syringe is part of a multi-exhibit case. If the syringe is not packaged separately, the entire case shall be returned.
- 15.8.1.3 Transportation and Handling of Evidence Outside the Laboratory:
- 15.8.1.3.1 Evidence (other than controlled substances) may be transported by an ISP FS employee for the purpose of evidence examination, database entry, and/or technical review. Specific examples would include firearm/toolmark technical verification and peer review, firearm/toolmark test firing (high powered rifles), creating witness panels for distance determinations, and firearm/toolmark NIBIN entry. Care shall be taken to secure the evidence while in transport. Evidence shall not be left in an unattended (locked or

Section 5.8 – Handling Items of Evidence Page 2 of 11 The system accommodates sub-division of groups of items, creation of items, and the transfer of items of evidence within or from a laboratory.

15.8.2 System for identifying test items:

15.8.2.1 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 below the barcode. The corresponding barcode will be placed on the item.

15.8.2.2 Transferring items

When an item is transferred from one lab to another the item will be logged in with the same unique case identifier but the item number will have that lab's letter added to the item number. For example if M20041789-1 was transferred to Pocatello the item would be logged in as M20041789-P1. A new barcode would be printed and placed on the item of evidence; a line will be drawn through the prior barcode. Prior barcodes shall not be removed or covered over.

15.8.2.3 Resubmissions

If an item of evidence is returned to the submitting agency and then resubmitted to the lab for additional analysis, the item will be togged in with the same case number and the item number will have an R added to the item number, the next time that item is submitted, it would be 2R and so on. For example, if M20041789-2 was resubmitted the new item number would be M20041789-2R, if it was returned and resubmitted again the new item number would be M20041789-2R2, and the next time it was resubmitted it would be M20041789-2R3. A new barcode would be printed and placed on the item; a line will be drawn through the prior barcode. Prior barcodes shall not be removed or covered over.

15.8.2.4 Splitting items

When evidence is split or divided into subsamples; the subsample will be packaged separately. (This method for logging in subsamples is for evidence that is not retained in the laboratory. The procedure for retained evidence is described in 15.8.2.5.) The new piece of evidence will be entered into ETS and the item number would be the same number as the original evidence with an A following it. If the evidence were to be subdivided more than once, the next item would be B and so on. The original barcode will be scanned to "DIVIDE", so that the electronic chain shows the item has been split. The new evidence package will need to have an external chain of custody placed on it and the analyst that split the evidence would be the first to sign that chain. The item description in ETS must state that it is a subsample from the original evidence's unique identifier. For example, the lab receives a court order to remove 0.3 grams of powder from C20051300-1 and send it to a private lab for analysis. The analyst would remove 0.3 grams from the original evidence; the 0.3 grams would be appropriately packaged and sealed

Section 5.8 – Handling Items of Evidence Page 4 of 11 The empty packaging would be placed back in the original evidence envelopes and sealed for return to the submitting agency. The new combined sample would be placed in a new evidence envelope. A new <u>submittal form</u> would be filled out. The new item would be logged in a new submittal and would be item M20091800-3.

- 5.8.3 Received evidence that does not meet Forensic Services specifications in regards to condition, packaging, or seals 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.
 - 15.8.3.1 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 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.
 - 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 ETS), 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 approved form will be used for the "unlogged evidence log." 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 log" shall reflect the short-term storage.

If evidence comes into one regional lab and is to be forwarded on to a different regional lab (with no testing in the original receiving lab) the "unlogged evidence log" will document the items being forwarded and, if necessary, short-term storage in the laboratory. The external chain of custody will be filled out for the evidence items. The submitting agency must grant permission for "forwarding" evidence (this requirement only applies to evidence that is not logged in or analyzed in the original receiving lab).

- 15.8.3.3 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.
- 15.8.3.4 If all items from an entire case or discipline are returned without analysis, it should be noted in the case file; however, a report of examination is not required.

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- Refrigerated storage during sampling phase of analysis.
- Frozen storage post analysis until destruction date.
- Freezer temperature and a refrigerator temperature will be monitored with a traceable thermometer equipped with a long sounding alarm.
- Urine toxicology samples in long-term storage shall be frozen.
- The thermometer will be at a minimum, calibrated triennially.
- Blood and urine toxicology collection kits:
- Refrigerated storage until preparation for analysis.
- Refrigerated storage during sampling phase of analysis.
- Post urine analysis, a secondary container is created for frozen storage until appropriate destruction date.
- Blood is stored under refrigeration until appropriate destruction date.
- **5.8.4.1** Any evidence not in the process of examination that must be placed in a container to protect it from loss, cross-transfer, or contamination is stored under proper seal. Forensic Evidence Specialists have the authority to reject evidence if it is not properly sealed.
 - 15.8.4.1 Evidence sealing requirements
 - 15.8.4.1.1 When it is necessary to place evidence in a container to protect it from loss, cross-transfer and/or contamination, the container must be properly sealed when it is not in the process of examination. For example, a rifle could be submitted to lab to be test-fired for NIBIN; this would not require that it be packaged, but a rifle that was submitted for latent prints must be packaged and properly sealed.
 - 15.8.4.1.2 Proper seals shall include heat seal, tamper indicating seal, tape seal or lock seal.

 A container is "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.
 - 15.8 4.9.3 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.
 - 15.8.4.1.4 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.
 - 15.8.4.1.5 All evidence that requires seals shall be properly sealed by the submitting agency,

Section 5.8 – Handling Items of Evidence Page 8 of 11 sample is returned to the submitting agency (or forwarded for additional testing), the original submittal form will be returned (or forwarded) with the sample. When the original submittal form is sent outside the laboratory, a copy will be made and placed in the case file. If the evidence sample is destroyed after the original submittal form leaves the laboratory, the destruction of the sample will be recorded on the copy in the case file. For those homicide, death investigation or rape case where a urine or a urine/blood combination toxicology kit has been submitted, a letter will be sent inquiring if the agency would like the sample destroyed or returned. The appropriate authority must sign and return the letter to Forensic Services. If an agency does not respond to the letter within 90-days the samples will be returned to the agency. The returned letters will be placed in the case files. Accident victim samples will be destroyed no sooner than 90 days after completion of analysis.

15.8.4.3.6 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 files.

- 15.8.4.3.7 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 substance evidence shall never be transported or carried by forensic services personnel, either from scenes or to court.
- **5.8.4.3.1** In-process-of-examination evidence is based on a reasonable period of activity in a case and a justifiable expectation of frequent examination.
- 5.8.4.4 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 packaging 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.
- **5.8.4.5** When evidence, such as latent prints and impressions, can only be recorded or collected by photography and the image itself is not recoverable, the photograph or negative of the image is treated as evidence.
- 5.8.4.6 Evidence collected from a crime scene by laboratory personnel is protected from loss,

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15.8.4.7.1.3 Each NIBIN ICD sample shall be treated as evidence.

- **5.8.4.7.1a** 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.
- **5.8.4.7.1b** Individual characteristic database samples treated as reference samples, shall meet 5.8.4.7.2 through 5.8.4.7.4.
- **5.8.4.7.2** 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.
- **5.8.4.7.3** 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.
- **5.8.4.7.4** Access to the individual characteristic database samples under the control of the laboratory shall be restricted to persons authorized by the laboratory manager.
 - 15.8.4.7.4 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.

- 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.

15.9.3.4 Responsibilities of the quality manager:

- Obtain discipline leader 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.
- Maintain the proficiency test reports for all analysts as well as the documents from the test provider.
- Evaluate the results of proficiency tests and issue a report to the analyst, the analyst's supervisor, and the discipline leader regarding the accuracy of the results obtained on a specific proficiency test.
- Issue notification to the YES staff that the PT evidence may be properly destroyed or otherwise dispositioned as "non-evidence."
- Discipline leaders 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 leader is always required when evaluating an inconclusive DNA proficiency test result.

15.9.3.5 Responsibilities of the discipline leader:

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

15.9.3.6 Responsibilities of the laboratory manager:

• Create and maintain a file for the storage of proficiency tests within

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Proficiency Review Program.

- **5.9.3.3** Each analyst shall take a proficiency test within the first year of being approved to perform casework analysis and at least one proficiency test per calendar year thereafter in each subdiscipline in which the forensic scientist or technician performs examinations.
- **5.9.3.3.1** Where applicable, 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.
- 5.9.3.4 Each Forensic Services laboratory participates in at least one external proficiency test annually, in every discipline of forensic science in which it provides services. ASCLD/LAB approved test providers are used when available. Other external proficiency tests will be obtained or prepared as decided by the discipline leader and Quality Manager.
- 5.9.3.5 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;
 - Details of the corrective actions taken (when necessary).
- **5.9.3.6** Proficiency testing records are controlled as quality records (section <u>4.13</u>) and must be retained in the laboratory for at least five years. See section <u>14.13.1.2.4</u> for retention information.
- **5.9.4 Technical Review:** Forensic Services creates and implements, a quality procedure for the technical review of all examination records and examination reports. The purpose of technical review is to ensure that the conclusions are supported by the examination documentation, are reasonable, and within the constraints of validated scientific knowledge.

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- participate in this review committee.
- Conflict resolution shall not compel an individual to sign a case report containing opinions and/or conclusions with which the analyst disagrees. The decision of the review committee may include reanalysis, issuance of an administrative report by the immediate supervisor of the analyst, or other suitable action based on an evaluation by the review committee. The decision of the review committee concerning the resolution of the conflict shall be reviewed and approved by the Major/Manager before it is implemented.
- **5.9.4.1** 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 subdiscipline. The three kinds of casework review are technical review, administrative review and technical verification.
 - 15.9.4.1.1 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 leader. 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 leader or appropriate lab manager if the approval is for the discipline leader.

- 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.

15.9.4.1.2 External technical review requires:

- The qualifications of the reviewer be documented and on file with the Quality Manager. The Major/Manager shall approve external reviewers who are not from an accredited laboratory either ISO/IEC 17025, or ASCLD/LAB Legacy.
- The technical reviewer shall be supplied with the pertaining analytical

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15.9.6 MONITORING COURT TESTIMONY:

- 15.9.6.1 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.
- 15.9.6.2 Each forensic scientist shall be evaluated at least once annually. An evaluation by the supervisor is encouraged biennially. If a forensic scientist did not testify during a calendar year, documentation must be entered in their employee record.
- 15.9.6.3 Evaluation shall be by direct observation, question daire, review of court transcripts, or telephonic solicitation by laboratory staff to one or more officers of the court for responses to the evaluation form.
- 15.9.6.4 A forensic scientist 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 forensic scientist gains experience, direct review by staff can be alternated with review by other means.
- 15.9.6.5 A reviewer from Forensic Services shall fill out the designated evaluation and critique the forensic scientist as soon as possible after the peer review process. The forensic scientist shall be given feedback on the positive aspects of the testimony as well as areas that need improvement.
- 15.9.6.6 Corrective action shall be initiated in accordance with section 4.9, of this quality manual if the controom 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.
- 5.9.7 Testimony monitoring records will be retained as a quality record (section 4.13), but no less than one full ASCLB/LAB *International* accreditation cycle.

k) Where relevant, a statement to the effect that the results relate only to the items that were examined.

5.10.3 Additional required information for examination reports:

- **5.10.3.1** Where necessary for the interpretation of results, examination reports include the following information:
 - a) Deviations from or additions to the analytical method and information on specific test conditions; (e.g. environmental conditions)
 - b) A statement explaining any non-compliance with the service requested;
 - c) The uncertainty associated with any quantitative result;
 - d) Opinions and interpretations; (Relates to 5.10.5)
 - e) Additional information required for specific examinations.
- **5.10.3.2** Where necessary for the interpretation of results, examination reports containing the results of sampling include the following:
 - a) Date of sampling;
 - b) Unambiguous identification of the evidence sampled;
 - c) Location of sampling, including any diagrams, sketches or photographs;
 - d) Reference to the sampling plan used;
 - e) Details of any environmental condition during sampling that may affect interpretation of the report;
 - f) Any specification of the sampling plan and deviations or additions to the sampling plan.
- **5.10.3.3** Forensic Services creates and implements quality procedures controlling the release of examination reports. (refer to 4.1.5c)
- **5.10.3.4** 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.
- **5.10.3.5** When associations are made, the significance of the association shall be communicated clearly and qualified properly in the report.
- **5.10.3.6** When no definitive conclusions can be reached, the reason(s) shall be documented in the case record.
- **5.10.3.7** The author(s) of a test report shall have conducted, participated in, observed, supervised, or technically reviewed the examination or testing.
- **5.10.4** Forensic Services does not issue calibration certificates and therefore does not have

Section 5.10 – Reporting the Results Page 2 of 4

- **5.10.9** When it is necessary to make material amendments to a report, the new report will be uniquely identified, clearly reference the report that is being amended, and will be titled an amended report. Amended reports must comply with the same quality policies and quality procedures as original reports. Forensic Services reports are not replaced with a new corrected report. If changes need to be made, an amended report is issued.
- 15.10.9 When errors or omissions in casework are noted, the forensic scientist has the

6.2 SUBPOENA POLICY AND WITNESS FEES

- 6.2.1 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.
- 6.2.2 Idaho State Police Forensic Services personnel shall accept subpoenas and testify in Driving Under the Influence cases when an approved breath testing instrument was used only in circumstances where:
- **6.2.2.1** The defense has acquired its own expert;
- 6.2.2.2 An unusual circumstance has occurred surrounding the administration of a DUI breath test that shall necessitate expert testimony on the part of Forensic Services.
- 6.2.3 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. If the court pays witness fees, they shall be remitted to Idaho State Police Financial Services.

6.2 – Subpoena Policy and Witness Fees Page 1 of 1

6.4 DRESS CODE

- **6.4.1** Forensic laboratories contain many chemical and biological substances that are damaging to clothes and/or harmful to people.
- **6.4.2** Polices contained in the Health and Safety Manual regarding appropriate attire for working in the laboratory shall be adhered to.
- 6.4.3 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:
- 6.4.3.1 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.
- 6.4.3.2 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 or hard surfaces, and provide a gripping surface on the floor.
- 6.4.3.4 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.
- 6.4.3.5 This dress code applies to Forensic Evidence Specialists (FES). If a FES is wearing casual attire, they shall wear a smock or a laboratory coat while interacting with the public. A FES shall not wear a smock or a laboratory coat at their desk.
- 6.4.3.6 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.
- 6.4.3.7 Employees not meeting this dress code (as interpreted by the Laboratory Manager or Major/Manager) may be asked to change their clothes on their own time.

Example #2: Submission form for composite from multiple lab items.

Idaho State Police, Forensic Services Evidence Submission/Receipt Form

				Lab Use Only	Lab	oratory Ca	se N	Vumber:	M180	01259			
				Date Received: 8/9/10 By: (Signature of receiv							iving FES)		
	IDA	HÒ		Received in person or via: (Analyst signature) Phone #:									
		and a		Forwarded to:		By:			Date:				
	Str.)	Received from:		By:			Date:				
				Lab Use Only When Returning Evidence									
				Idaho State Polic									
				Agency Represe		Date:							
	Boise Po	olice I		ot abbreviate) artment	se	se Agen			ry Case Number				
	County of O	ffense		Charge Trafficking					Court Date				
	Suspect Victim Subject		-	Juy, Bad				5/64	S, ,	4			
	Suspect		Nin	re Last, First	Dol	`O.	<u>~0</u>	State ID	# (fingerprints enly)				
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	Suspect Victim Subject			te Last, First	1001	20	1/1/	# (tingerprints only)					
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	(Mark one) Investigation		car	New	7.4	dditional ne number	M,	Email Ac		mittal [
	Detectiv	-							@whate	ver.com	ì		
	Agency Exhibit Number			Exhibit Description				Loca	ifion Foun	Type of Exam Requested (see below)			
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Type of exam: Biology (Bio), Controlled Substances (CS) or Fire Debris (FD), Firearms/Toolmarks (F/1), NIBIN Entry (NE), Fingerprints(FP), Serial Number Restoration (SNR), or Shoeprint/Tiretracks (S/T).

Toxicology and blood alcohol sample must use toxicology submittal form.

Agency representative: Submitting this form Indicates agreement to ISP Forensk: Services' terms and conditions, for analyzing this evidence as described at our web site: http://www.isp.idaho.gov/forensic/index.html

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Example #4: Submission form for subsample of composite from multiple lab items

Idaho State Police, Forensic Services Evidence Submission/Receipt Form

				Lab Use Only Laboratory Case					e Number: <u>M18001259</u>					
		-	,	Date Receiv	red:	8/9/	10	В	By: ((Signatur	e of recei	iving FES)		
	IDA	HO		Received in person 🖸 or via: (Analyst signature) Phone #:										
	2.3	STEE.		Forwarded	to:	Cda	lab	B	3y: <u>1</u>	Signature of	ending FES)	Date:	8/11/10	
	Carre Carre		,	Received fr	om:			B	Ву: _			Date:	_6	
				Lab Use Only When Returning Evidence									<u></u>	
				Idaho State Police:							Date:			
				Agency Representative:							Date:	~e)	· · · · · · · · · · · · · · · · · · ·	
	Submitting a Boise Po	Agency office 1	(Bon Den	not abbreviate) Date of Offenso				928	e Agency Case Number 5151					
	County of O		<u> </u>	Charge Trafficking				Court Date				,		
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	Suspect Victim								<u> </u>	Y				
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	Suspect Victim		_					711.		4/10	11			
	Subject Suspect		Nu	ue Last, Fürst				DOB	BOB State 1			D# (Boga prints enfy)		
	Victim Subject			ne Last First					DOB State II			O# (Ingerprints only)		
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	Detectiv	re San	nple		<u>0</u>		-1212	ds	amp	le@what	ever.com	1		
	Agency Exhibit Number		Exhibit Description					Lo	cation Foun	ıđ	Type of Exam Requested (see below)			
Lab Item 5a		sub-s	ampl	of composite of agency exhibit 52,55 and 56				M180	00125	9 - 5	cs			
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		0		, 0										
	No.	5												
	010													
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Type of exam: Biology (Bio), Controlled Substances (CS) or Fire Debris (FD), Firearms/Toolmarks (F/T), NIBIN Entry (NE), Fingerprints(FP), Serial Number Restoration (SNR), or Shoeprint/Tiretracks (S/T).

Toxicology and blood alcohol sample must use toxicology submittal form.

Agency representative: Submilling this form indicates agreement to ISP Forensic Services' terms and conditions, for analyzing this evidence as described at our web site: http://www.isp.idaho.gov/forensic/index.html

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