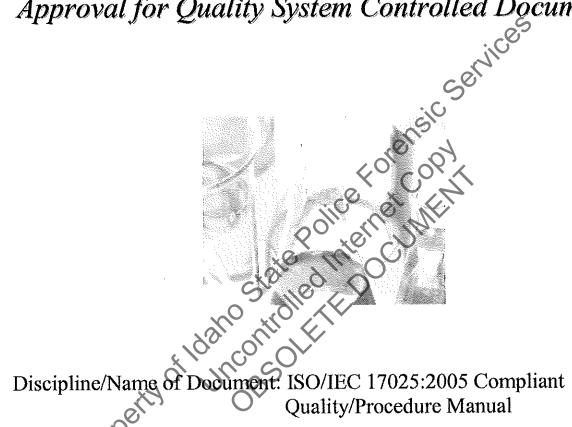
Idaho State Police Forensic Services

Approval for Quality System Controlled Documents



Quality/Procedure Manual

Revision Number: 2

Issue Date: 7/03/2007

Major/Manager



Idaho State Police Forensic Services

ISO/IEC 17025:2005 COMPLIANT

Quality/Procedure Manual

Revision 2 Issued July 03, 2007

HISTORY and APPROVAL

Revision 0 of the ISO/IEC compliant quality manual is effective January 10, 2007.

Revision 1: Update and changes to various sections. This revision is effective May 7, 2007 and issued under the authority of the Major/Manager.

Revision 2: Changes made to critical supply/service definition, 14.3.2.14, 15.2.1.1.2.6, Section 4.6, 5.4.6.2, 5.5.6, 15.8.3, and 15.8.4.3.5. This revision is effective only 3, 2007 and issued under the authority of the Major/Manager.

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MISSION STATEMENT

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.

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 Ralph Powell

7-3-07

Date

Section iii - Quality Policy Statement Pg. 1 of 2

Quality Objectives

- To receive customer feedback, analyze results, and consider and react to the results as part of the review of the management system.
- To provide an initial response to any customer complaint within 40 business hours.
- To provide annual training to all staff in the requirements and responsibilities of the quality management system.
- To establish key initiatives (including quality objectives) for Forensic Services for the coming year after annual review.
- To annually establish, review, and measure individual employee's objectives and their development plan to determine consistency in meeting Forensic Services and Idaho State Police strategic plans and governmental initiatives.
- To undergo periodic third-party evaluations for compliance with national and international standards and the internal management system.

1.0 SCOPE

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

This Quality Manual is applicable to the following examinations:

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

Coeur d'Alene Lab	Meridian Lab	Pocatello Lab
Controlled Substances	Controlled Substances	Controlled Substances
Toxicology (qualitative/quantitative)	ice et a	Toxicology (qualitative/quantitative)
Blood/Urine Alcohol	Blood/Urine Alcohol	Blood/Urine Alcohol
Firearms/Toolmarks	Biology (Screening and DNA)	
	6,000	Fire Evidence
	Impression Evidence	
. /	Latent Print (development,	
, 10	comparisons, and identification)	,

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

NORMATIVE REFERENCES 2.0

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

U.S. DOJ, FBI, Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories, 1999.

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

Administrative documentation (records) – documentation either received or generated by the laboratory. Administrative documentation includes records such as case related conversations, evidence receipts, description of evidence packaging and seals, investigative reports and other pertinent information.

Administrative review – a procedure performed to ensure that the examination reports issued by the staff of Forensic Services are editorially correct and to ensure that the examination reports and their documentation are compliant with Forensic Services policies and procedures.

Agency - ISP Forensic Services customers (submitting agency).

Analytical methods – written scientific methodologies approved for use by ISP Forensic Services staff for performing analyses. (Previously referred to as SOPs.)

Audit - a review conducted to compare the various aspects of the laboratory's performance with a standard for that performance. (ASCLD/LAB)

Bench standard – A limited quantity of a compound that is traceable back to a manufacturer and that is authenticated by comparing a spectrum from GC/MS or FTIR with literature or a previously authenticated standard.

Calibration —The process of determining the relationship between the readings obtained by a measuring instrument or system and the applicable units of some defined system of measurement.

Case record—all administrative records and technical records pertaining to a case that are received or generated by the laboratory. This may include, but is not limited to, the administrative and examination documentation maintained in the case file, electronic data, digital images, instrument maintenance and verification documentation, and reagent and standard quality control documentation.

Chain of custody - documented trail of possession or location of evidence.

Complaint – an expression of concern regarding some aspect of the management system, casework analysis or other work product, a report of analysis either written or presented in testimony, or the behavior of a staff member. While it is preferred to have a complaint received in written form; verbal complaints, anonymous complaints, or complaints from persons who

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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.

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Idaho State Police – a department within the Idaho State Government consisting of various units (one of which is Forensic Services) with the designated role of handling certain aspects of law enforcement and business regulations on a statewide basis.

Individual Characteristic Database -- A collection, in computerized, searchable form, of features associated with an object or person uniquely or with a high degree of probability.

Intermediate checks - checks needed to maintain confidence in calibration

Laboratory developed method – an analytical method that is developed within a Forensic Service laboratory.

Major deviation - A deviation of such scope that the applicability of the validation procedure is questionable or a deviation that has the potential to affect the accuracy of the analytical test.

Minor deviation - A deviation that would not affect the validation study for the analytical method or the accuracy of casework analysis performed using the analytical method. For example, substituting KOH for NaOH to adjust a pH would be a minor deviation.

Nonconforming work – work that does not meet one or more requirements of the quality system.

Non-standard analytical method – analytical methods developed by technical organizations, published in relevant scientific texts or journals, provided by instrument or reagent manufacturers, or analytical methods obtained from other laboratories.

Normative references – these are the external quality documents upon which the Forensic Services management system is based. Forensic Services complies with the quality standards in these documents

Performance verification – a set of operations to determine if a piece of equipment or instrumentation is working correctly within manufacturer's specifications or ISP specified parameters.

Preventive action - action that is proactive and identifies potential nonconformities

Primary standard – A compound that is traceable back to a manufacturer and that is authenticated by comparing with literature or a previously authenticated standard.

Proper seal - a seal that prevents loss, cross-transfer, or contamination while ensuring that

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attempted entry is detectable.

Quality – adhering to generally recognized standards of good laboratory practice and policies and procedures set forth in the management system.

Quality record - written or electronic text that is used to demonstrate compliance with the management system.

Reagent – a substance used because of its chemical or biological activity or because it takes part in or brings about a particular chemical or biological reaction.

Record – 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.

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

Root cause analysis – a process of fact finding used to evaluate all aspects of testing or the management system to identify the basis of the nonconformity.

Sample selection – the process used to choose the evidence or portions of the evidence that will be examined. Sample selection involves such considerations as amount of evidence available, significance of the evidence, number of specimens available for analysis, etc. Sample selection is not sampling, which is a statistical process of inferring properties of substances without performing analysis.

Sampling/Sampling plan —Sampling is a process whereby examining a portion of a substance allows the analyst to make inferences about the properties of the whole. A sampling plan is documented in an analytical method and describes how the representative sample is collected,

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and the inferences that can be made by the analyst about the properties of the whole.

Secondary standard – A laboratory produced or casework derived sample that has been compared to a primary or working standard by utilizing GC/MS or FTIR.

Standard analytical method – an officially recognized analytical method published in international, regional, or national standards. Examples of standard analytical methods are contained in Official Methods of Analysis of AOAC INTERNATIONAL.

Subcontract – to engage an outside laboratory to perform examinations, which Forensic Services, by an implied or explicit contract, previously agreed to perform. (This definition applies only when Forensic Services has an approved analytical method(s) and a qualified analyst to perform the examination but chooses to forward the sample to a laboratory, which is not a part of Forensic Services, for analysis.)

Technical records (examination documentation) - written or electronic text or data that result from carrying out examinations. It includes written examination notes, reference to analytical methods followed, standards and controls used, diagrams, printouts, photographs, observations, and results of examinations.

Technical review – a review of the case notes and the report to ensure that proper technical procedures were used and documented and that the analytical findings and documentation support the conclusions in the report.

Technical verification a process of independently performing a comparison or analyzing evidence to determine if the reviewer comes to the same conclusion regarding the analysis as the analyst.

Tender - an offer of denial or acceptance of a request to complete work.

Traceability – property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. (International Vocabulary of Basic and General Terms in Metrology, second edition 1993)

Uncertainty of measurement – an estimated value, within a specified confidence limit, that depicts a value of variability that can be attributed to the result or test.

Undue influence or pressure – any action or communication by an individual or individuals, either employed with Forensic Services or external to it, whose purpose or impact is to affect the technical judgment of Forensic Services staff, to adversely impact the compliance of Forensic

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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.

Work instructions — a document detailing specific steps for performing a procedure or operating a piece of equipment/instrumentation. Verification – confirmation, through supporting data, that the requirements for a specific

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ORGANIZATION 4.1

- Forensic Services is authorized by Idaho Code 67-2901(6) and is the forensic laboratory 4.1.1 unit of the Idaho State Police (ISP), a department of the Idaho State Government. There are laboratories in Coeur d'Alene, Meridian, and Pocatello and its headquarters is in the Meridian ISP complex.
- Forensic Services performs forensic examinations and related activities for the criminal 4.1.2 justice system within legislative mandates and subject to budgetary constraints and demands for service. In those disciplines/sub-disciplines that Forensic Services provides services, it meets or exceeds the standards of its normative references.
- The policies, procedures, analytical methods, and work instructions of the management 4.1.3 system are in force regardless of the work site.
- The responsibilities of ISP personnel that have an involvement or influence on the 4.1.4 services provided by Forensic Services are defined in order to identify potential conflicts of interest. The organizational structure of ISP is designed to prevent other units of the agency from adversely influencing the compliance of Forensic Services with its normative references. Forensic Services will not allow undue influence or pressure to be exerted on its staff by other employees or by outside individuals/entities.

Organization: 14.1.4

- The Director (Colonel) of the Idaho State Police is appointed by the 14.1.4.1 Governor. The Deputy Director (Lt. Colonel) is appointed by the Director. As appointed positions, these are "non-classified" and have no property interest (serve at the pleasure of the Governor) in their positions (Idaho Code 267-5303[b]).
- The Forensic Services Commander (Major/Manager) is not an appointed position and is required to go through the Department of Human Resources' competitive testing process. This position and all other employees in Forensic Services are "classified" positions and have a property interest (cannot be fired without due process) in their jobs (Idaho Code 67-5303).
- The Forensic Services Commander reports to the Deputy Director and has the 14.1.4.3 responsibility and authority to manage and direct the Forensic Services Division. The Forensic Services Commander supervises and directs the Forensic Services management team. The Forensic Services Management Team consists of the Quality Manager, three Laboratory Managers, and the Forensic Services Management Assistant.
- Key Idaho State Police (ISP) personnel that are not assigned to Forensic 14.1.4.4 Services (FS), but have influence on testing activities are:

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Major/Managers over the two remaining ISP Divisions:

Patrol Major

Investigations Major

These Managers have limited influence over some budget items and case priority.

Captains over the six Region Commands

Patrol Captains

Investigations Captains

These Captains have limited influence over case priority.

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 alter, 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 gratuities, not using your position to favor any segment of the community, etc.

14.1.5 b.2) ISP 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

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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 Forensic Services is responsible for the FS budget and issues dealing with the

FS budget.

14.1.5 b.6) Casework prioritization is the responsibility of the analyst with direction and authorization from their supervisor. Intersession from Lab Managers and/or the Major/Manager may be requested or imposed if undue pressure is exerted

upon any analyst to improperly adjust easework.

- 14.1.5 b.7) Rush Cases: While both are important, ISP Forensics values the quality of analysis more than the turn-around-time. An analyst who accepts a rush case is responsible for ensuring that the time frame given will not compromise established processes and procedures that safeguard quality analysis. Supervisors are also responsible to ensure that quality procedures are maintained and may adjust the time frame of a rush case if it becomes evident that technical requirements demand additional time in order to ensure a quality product. Analysis and supervisors are under no obligation to complete any rush cases by the defined deadlines if adequate time cannot be dedicated to the case in order to ensure quality standards are being met.
- 4.1.5 c) Creates and implements quality procedures to ensure that customer confidential information, including electronic storage and transmission of results, is protected from inappropriate release.
 - 14.1.5 c.1) Employees of forensic services are required to keep confidential all information obtained in their official capacities. Employees will not disseminate, access, or disclose any confidential information obtained in their official capacities except where legally authorized or per ISP and Forensic Services procedures and policies. Unauthorized distribution of confidential information is forbidden.

14.1.5 c.2) The Public Records Act, Idaho code 9-338 through 9-349 in conjunction with rules established by this agency governs the release of all department

documents and records to the general public.

14.1.5 c.3) The procedure for release of information through discovery in criminal cases is contained in the Idaho Criminal Rules, 16 (b)

14.1.5 c.4) The procedure for the release of information through a court order in criminal cases is contained in the Idaho Criminal Rules, 16 (b)(8)

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14.1.5 c.5) Results of examination shall only be released to the submitting agency or the prosecutor having jurisdiction over the case if the case was submitted by a police agency. The results shall be released to the defense attorney or other entity through a discovery, court order, or the permission of the prosecutor or a representative

from the submitting agency.

14.1.5 c.6) When giving laboratory results to telephone callers, extreme caution shall be exercised. If the caller is authorized to receive the results, then the following procedures shall be followed: If the voice of the caller is recognized, then the results may be given out. If a caller's voice is unfamiliar, politely break the conversation 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.

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.

14.1.5 d.1) The Idaho State Police conduct expectations procedure is located at 01.02 Conduct

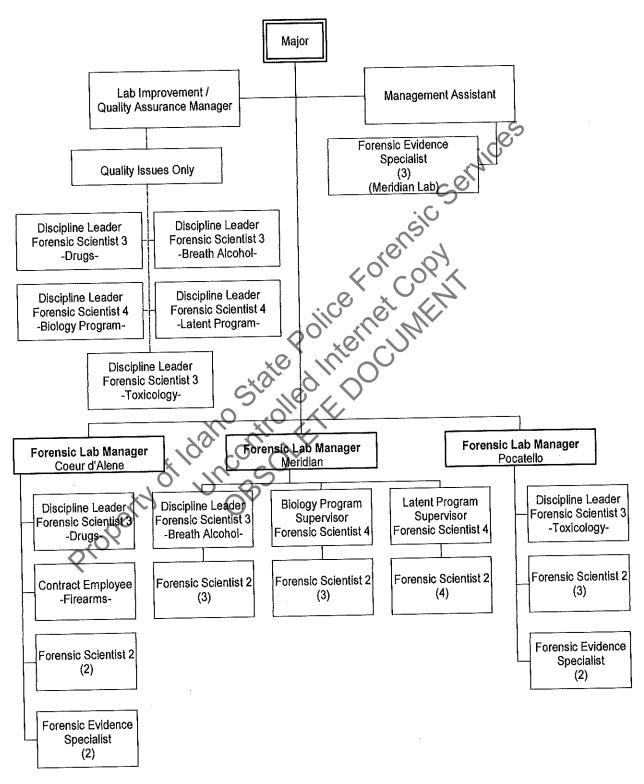
Expectation

- 14.1.5.4.2) 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.1) 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. http://intranet/ISP Employee
Handbook/documents/01-03 Organizational Chart.pdf

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:

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- 4.1.5 f) Defines the responsibility, authority, and interrelationships for all personnel who manage, perform, or review work affecting the quality of tests:
 - The points below describe the responsibilities, authority, and interrelations of 14.1.5 f) 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 or by July 1, 2007, whichever time frame is longer.

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.

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- 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 discipline specific certification within the first three years of being appointed to their current position in addition to ABC Diplomate or equivalent certification by July 1, 2007, whichever time frame is longer.
- Approval of new trainees
- Review and create analytical methods in their discipline.
- Evaluate what proficiency tests are needed in their discipline.
- Determine requirements for supplies and services used in their discipline.
- Approve use of methods that are not part of the management system in conjunction with quality monager.
- Approve deviations from analytical methods.
- Review or creates validation plans
- Maintain validation records.
- Participate annually in the quality system review including reports of activities within disciplines.
- Develop and maintain training plans for their discipline.
- Approve training plan in conjunction with Quality Manager.
- Approve analytical methods in conjunction with Quality Manager.
- Respond to deficiencies.

orensic Scientist 4 (discipline leader, supervisor, journey level analyst)

- Follow analytical methods and the quality and safety procedures.
- Documentation of quality controls and work.
- Check that the report issued for analysis they perform is accurate.
- Report results of all analysis performed through written reports.
- Testify in legal settings regarding the analysis performed as expert witnesses.
- Perform analysis in only examinations they are approved to perform.
- Technical review of casework.
- Administrative review of casework.
- Perform technical audits.
- Demonstrate technical competence by obtaining discipline specific certification within the first three years of being appointed to their current position in addition to ABC Diplomate or equivalent certification by July 1, 2007, whichever time frame is longer.
- Approval of new trainees.

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Review and create analytical methods in their discipline.

Evaluate what proficiency tests are needed in their discipline.

- Determine requirements for supplies and services used in their discipline.
- Approve use of methods that are not part of ISP system along with quality manager.

Approve deviations from analytical methods.

Review or create validation plans.

Maintain validation records.

- Participate in the 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.

Explain and ensure adherence to Idaho State Police Forensic Services policies and procedures.

Quality Manager

ger 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

- 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.

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Issued 07/03/2007

Issuing Authority: Major/Manager

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.
- Maintain a register of approved subcontractors and verification documentation for the competence of subcontractors.

Lab Manager

Follow analytical methods and quality and safety procedures.

Documentation of quality controls and work.

• Check that the report issued for analysis they perform is accurate.

Report results of all analysis performed through written reports.

Testify in legal settings regarding the analysis performed as expert witnesses.

Perform analysis in only examinations they are approved to perform.

Technical review of casework.

Administrative review of casework.

Approve training requests

Store proficiency test files for lab.

Respond to deficiencies.

Review requests for external examination along with the discipline leader and an analyst.

Custodian of keys and security codes for lab.

 Designate non-Forensic Service employees who are allowed unrestricted access to Forensic Services laboratories.

Schedule and prioritize workload.

Explain and ensure adherence to Idaho State Police Forensic Services policies
 and procedures.

Represent organization to clients, and public.

Approve deviations from administrative procedures.

 Participate in annual Quality System Review, which includes continual improvement of the management system.

Major/Manager

- Approve technical reviewers from labs that are not ASCLD/LAB accredited
- Review and approve recommendations from conflict resolution committee before decision is implemented.

Approve deviations from casework acceptance policy.

Approve exceptions for ABC, IAI and discipline specific testing requirements.

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).

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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) Assigns backups for key employees when they are unavailable for work assignments, persons responsible for performing the duties of the unavailable key employee are assigned as follows:

Position

Major/Manager

Quality Manager Laboratory Manager Discipline Leader

Backup (

(1) Quality Manager

(2) Meridian laboratory manager

Deputy quality manager

Senior discipline leader in that laboratory

Senior member of that discipline appointed by the

major/manager

Safety Officer

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.

Communication processes:

- Statewide management meetings are held on a periodic basis to discuss and resolve issues and receive directives from top management.
- Each laboratory of Forensic Services has laboratory wide staff meetings on a 14.1.6.2 periodic basis. Important issues from statewide or laboratory wide management meetings and directives from the Major/Manager are disseminated at those meetings.
- Discipline leaders communicate with the individuals in their discipline as 14.1.6.3 appropriate. Management encourages face-to-face meetings of members of disciplines, as appropriate.
- As needed, the Major/Manager has written or verbal communication with 14.1.6.4 staff.
- All staff, annually, is invited to provide input into the management review 14.1.6.5 process through their manager or supervisor. The summary of the annual

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management review is provided to all staff.

- 14.1.6.6 Proposed changes to the management system are announced to all individuals that potentially would be affected by the change and invited to comment. When the management system is changed, the changes are announced to all the affected individuals and the documented changes are available.
- 14.1.6.7 The current documents of the management system are available to all staff.
- 14.1.6.8 Management resolves all formal complaints by the staff about the management system that includes the recording of complaints, along with their investigation, and remediation as appropriate. Staff is given feedback about the resolution of formal complaints.
- 4.1.7 Each laboratory has a safety officer with defined responsibilities (Section 2.2 Health and Safety Manual) and authority (Section 2.1.1 Health and Safety Manual) to ensure that the health and safety program is implemented and followed.

4.2 MANAGEMENT SYSTEM

- 4.2.1 Forensic Services creates and implements 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 accuracy of examination results. In order to achieve compliance of the staff with the management system, it is communicated to, comprehended 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.
 - All the documents of the management system are available to each employee in 14.2.1.2 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. 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 includes but is not limited to the Policy/Procedure manual and related documents that by extension are meluded 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 Laboratory Manager, shall be obtained prior to the deviation. The deviation, necessity for the deviation, and prior permission shall all be documented in a record maintained by the Quality Manager. If the permission to deviate from a policy was verbal, the permission shall be documented after the fact and included with the record.

4.2.2 The overall objectives of the management system have been established and are reviewed during the annual management review. The quality policy statement (located at the Introduction to this quality manual along with the overall objectives) is issued under the authority of top management and contains, minimally, the following provisions:

a) Management's commitment to good professional practice while providing quality examinations.

b) Management's statement of Forensic Services standard of service.

c) The purpose of the management system related to quality.

- d) The requirement that all staff familiarize themselves with and follow the management system and that staff carry out all examinations in accordance with the written analytical methods, work instructions, and the policies of the management system.
- e) Management's commitment to comply with the normative references and to continually improve the effectiveness of the management system.
- **4.2.3** Top management provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.
- 4.2.4 Top management communicates the importance of meeting regulatory requirements and customer requirements, as appropriate.
- The management system is documented as follows: quality policies are contained in this 4.2.5 quality manual and numbered the same as the related ISO/IEC 17025:2005(E) clause and/or ASCLD/LAB International Supplemental requirements. Procedures provide instruction regarding the implementation of quality policies. They are numbered the same as the related quality policy plus 10 and directly follow the related policy in the quality manual. For example, the quality procedure that corresponds to section 4.1.4 of this Quality Manual is numbered 14.1.4 and directly follows policy 4.1.4 in the manual, is italieized, and in blue when viewed electronically. A procedure may encompass more than one section of this quality manual. Each discipline has analytical methods and training plans and may have work instructions and/or forms. In addition, Forensic Biology has additional policies for conforming to national standards for DNA analysis and the convicted offender databases. These policies are maintained with the analytical methods and work instructions for forensic biology. All the approved documents of the management system are maintained on a network drive and can be accessed by all Forensic Services staff.
- 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).

Top management maintains the integrity of the management system when changes to the 4.2.7 management system are planned and implemented.

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4.3 DOCUMENT CONTROL

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

The Quality/Procedure manual and the Health and Safety manual are published by 14.3.1.1 the authority of the Major/Manager of Forensic Services. All analytical methods, work instructions and forms are issued under the authority of the Quality Manager. Employees of Forensic Services are expected to follow them as written or seek an exception if provided for.

The Quality Manager or designee shall maintain an independent electronic backup 14.3.1.2 of the management system documents and update this electronic backup file at least

every three months.

External documents are controlled as part of the management system when they 14.3.1.3 contain instructions or policy that are adhered to as part of the management system. This includes, for example, standard analytical methods adopted by a discipline within Forensic Service and maintenance or calibration methods from an equipment manual, which are adopted by a discipline with Forensic Services. External documents that are adopted as part of the management system must be documented in the registry of management documents. See 14.3.2.2.

Document approval and issue 4.3.2

4.3.2.1 All documents of the management system are reviewed and approved by authorized personnel prior to being used by staff. A comprehensive list of approved management system documents, along with the current revision number and issue date, is maintained and available to all staff.

14.3.2.1 Review and approval of management documents: Before any controlled draft document of the management system, either new or revised, is approved, the

following series of steps shall be completed:

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

14.3.2.1.2 Finalized analytical methods are submitted to the Quality Manager along with a completed content checklist showing where or explaining how the particular

checklist item was achieved, as appropriate. The Quality Manager approves analytical methods, work instructions, training plans, and discipline specific forms if 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.

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

Issuing Authority: Major/Manager

used.

- 4. 3.2.2 b) periodically reviewed and revised as necessary to ensure suitability for use and compliance with applicable requirements.
 - 14.3.2.2 b) The Quality Manager reviews the quality policies, the quality procedures, and the health and safety policies annually to ensure that the policies reflect current laboratory practices, current normative references, and best practices as feasible. The appropriate discipline leader shall review the training plans, analytical methods, work instructions, and analytical forms annually. Management system documents shall be updated when the review indicates that it is needed. If no changes are made to the document after review, the review shall be documented by a brief signed memo or email from the discipline leader to the Quality Manager. If changes are needed, the revised document is sufficient to show the review was performed.
- 4. 3.2.2 c) promptly removed when invalid or obsolete from all point of issue or use or otherwise assured against unintended use:

14.3.2.2 c) The following controls have been instituted to ensure that only current approved

management system documents are utilized by staff:

14.3.2.2 c.1) The Quality Manager or designee maintains a list of all approved documents of the management system 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 and contains the name, revision number, and issue date for all currently approved management system documents. 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.

14.3.2.2 c.2) The Quality Manager will notify, typically by email, all users when a management system document is updated. It is the responsibility of individuals retaining hard copies of documents to destroy obsolete versions or mark the copy as "obsolete"

when they are informed of a revision.

14.3.2.2 c.3) A sampling of hard copies of management documents retained in a laboratory will be reviewed during the annual quality audit to ensure appropriate retention for controlled documents.

4.3.2.2 d) Retained documents are suitably marked as being obsolete when retained for archival purposes.

14.3.2.2 d) Quality policies/procedures, analytical methods, training plans, work instructions, forms, and normative references are archived permanently by the

Quality Manager or designee.

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.
- 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.
 - 14.3.3.4) The properties of the electronic folder "International Management System" are set to "Read Only" by the Information System for all staff except the Quality Manager, Deputy Quality Manager, the Major/Manager, and the Management Assistant. Therefore, only these four individuals can edit or delete the contents of this folder. This is the folder that contains all the electronic versions of the documents of the Management System available to staff.

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 tracks
 - 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.

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

- 14.4.1.3 The implied contract gives the analyst the discretion of selecting the appropriate examinations to be performed to provide the most useful information to the customer
- 4.4.2 Records of review, regarding the examinations to be performed, including any significant changes, are maintained. A log of conversations with the submitting party or other individuals regarding case analysis, conclusions and opinions, and consultation will be maintained in the case file.
 - 14.4.2.1 Each request will be reviewed when the case is received. The person that receives and accepts the evidence will document this review by signing the "received by" or "evidence technician/region" line on the Evidence Submission Form.
 - All pertinent discussions with the submitting party or others regarding case analysis will be documented. The documentation will include the date, the name of the forensic services employee involved in the discussion, the name and agency with whom the discussion took place with and the essence of the conversation. Documentation of the conversation will be maintained in the associated case file as an administrative document.
- 4.4.3 The review will cover any work that is subcontracted.
- 4.4.4/4.4.5

The contract with the customer gives Forensic Services flexibility for a given case before and after examination of the evidence has commenced. The submitting party may be notified if the service provided is significantly different from that anticipated.

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 unalytical 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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PURCHASING SERVICES AND SUPPLIES 4.6

Forensic Services purchases services and supplies that work as intended when performing 4.6.1 examinations according to approved analytical methods. Quality procedures exist for the purchase, reception and storage of reagents and consumables relevant to the examinations performed. Forensic Services purchases services that affect the quality of analysis only from vendors whose performance is satisfactory.

14.6.1.1 Evaluation of supplies:

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

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

14.6.1.1.3 This list will be maintained/controlled as a quality record. It must be available to staff who orders supplies. When a list is revised, it is the responsibility of the Quality Manager to notify the appropriate staff.

- Storage of Supplies: Supplies that affect the quality of examinations shall be stored 14.6.1.2 in accordance with the manufacturer's instructions unless otherwise documented. Chemicals maintained in storage areas external to the laboratory are not required to comply with the manufacturer's recommendations for storage temperature.
- Forensic Services checks purchased supplies, reagents and consumable materials that affect the quality of tests prior to use and only uses those supplies if they conform to the specified requirements of the analytical method. Records of actions taken to check compliance with this policy are maintained.

Documentation of Supply Verification 14.6.2.1

- 14.6.2.1.1 If supplies purchased have technical specifications, verification will be performed to document that the supplies meet requirements set forth by the discipline leader.
- 14.6.2.1.2 If a supply is stored in the laboratory prior to verification, measures must be taken to ensure that the supply is verified before use. Such measures include either marking the supply as unverified or storing it in a location intended for unverified supplies
- 14.6.2.1.3 Documentation of service must include the date of service, description of service performed, results of service and the name of the service provider,

when applicable.

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 quest(onable 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 purchaser shall initial and date the ordering document to verify that the technical specifications agree with the listed requirements.

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

14.6.3.4 When the request for service or supply order is made verbally, written documentation must be maintained.

- 14.6.3.5 The following link is for the Idaho State Police procedures for purchasing. \\\dilmon\\global\Directors Office\Procedures\effective\04.Financial \\\Transactions\04-07 purchasingr2.doc
- 4.6.4 Each discipline leader of Forensic Services shall determine any consumables, supplies and services that are critical to the quality of analysis. Suppliers of critical consumables, supplies or services are evaluated and approved before use. The current evaluations of the suppliers for such consumables, supplies, services, etc., and the list of approved vendors are maintained.

The criteria for evaluation may include, but is not limited to references, accreditation, formal recognition, or past performance.

- 14.6.4.1 Consumables and Supplies: The discipline leader for each discipline will identify any consumables and supplies that are critical to the quality of analysis. An evaluation of the suppliers for these consumables and supplies will be performed and documented. If supplies are verified in the laboratory, this verification will negate the need for evaluation of the supplier. Documentation will be forwarded to the Quality Manager. The Quality Manager will store the records and a list of approved providers will be published on the common drive. Staff will order critical consumables and supplies from the approved providers only.
- 14.6.4.2 Services: The discipline leader for each discipline will identify any services that are critical to the quality of analysis. An evaluation of the service provider for critical services will be performed and documented. Documentation will be forwarded to the Quality Manager and will be stored and a list of approved service providers will be published on the common drive.

SERVICE TO THE CUSTOMER 4.7

- Forensic Services cooperates with customers to the extent possible with the aim of 4.7.1 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.

- Forensic Services seeks customer feedback, both positive and negative, regarding the 4.7.2 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:
The Quality Manager creates and makes available a customer services 14.7.2.1 response form with input and guidance from management staff.

The form is available on-line and or in the evidence intake area for each 14.7.2.2 laboratory and included with approximately every tenth case (for example all case numbers ending in 0) when it is returned to the submitting customer. In addition, Forensic Services offers the customer service response form 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.

The customer service response forms received are retained within each 14.7.2.3 laboratory until after the related management review and review by the Major/manager.

- Annually, each laboratory manager evaluates and summarizes customer 14.7.2.4 service response forms received in the preceding calendar year in a written report to the Quality Manager as part of the annual management review. These reports are reviewed during the annual management review and acted on as appropriate.
- When the customer feedback can reasonably be interpreted as a complaint about 14.7.2.5 Forensic Service, a copy of the Customer service response form will be treated as a complaint and processed according to the Complaint Procedure, Section 4.8.

COMPLAINTS: 4.8

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:

Complaints regarding laboratory personnel, policies or procedures, or quality 14.8.1 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:

Complaints that do not involve quality management issues will be addressed 14.8.1.1 by following the Idaho State Police 63.02 "Complaints" procedure, 03.01 "Administrative Review and Investigations" procedure, 03,10 "Problem Solving and Due Process" procedure, or other ISP procedures as

appropriate.

Complaints that arise out of quality management issues that do not conform to 14.8.1.2 quality policies and/or procedures shall be directed to the Quality Manager and investigated in accordance with Forensic Services Quality Manual Section 49 "Control of Nonconforming Work". Quality Manual sections 4.11 "Corrective Action Cand/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.

- All complaints and resulting documentation of investigation, findings, and 14.8.1.4 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
- Each Lab Manager will maintain a Complaint Log. The log will contain a 14.8.1.5 brief synopsis of each complaint received in that laboratory with all personal information redacted. The purpose of this log is to track types and causes of complaints in order to allow management to improve customer service and

Section 4.8 - Complaints Page 1 of 2

identify possible policy failures. The synopsis recorded in the complaint log will contain the following information:

- a) Name of the organization that filed the complaint
- b) Date of complaint
- c) Reason for complaint
- d) Findings
- e) Resolution/Remediation

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

Forensic Services resolves complaints by employees regarding the through the same process used for customer complaints. 4.8.1 Forensic Services resolves complaints by employees regarding the management system

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 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.
 - 14.9.1 a) Any employee of Forensic Services who identifies nonconforming work shall immediately inform his/her supervisor, the discipline leader, or any other executive management, of the nonconforming work. 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.
 - b) An evaluation is made of the significance of nonconforming work:
 - 14.9.1 b) An evaluation of all nonconformities, whether related to analysis or deviations from the management system, is made by the Quality Manager and the discipline leader if appropriate. However, neither shall evaluate nonconformities for which they may be responsible. For nonconforming

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analysis of evidence, the evaluation shall determine whether the nonconformity is class 1, 2, or 3 analytical nonconformity. If the nonconformity is a class 3, nonconformity, the evaluation shall assess the significance and likelihood of recurrence.

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

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

a Class 2 analytical nonconformity is a false negative.

14.9.1 b.3) Class 3 analytical nonconformity: The nonconformity is determined to have only minimal effect or significance, is unlikely to recur, is not systemic, and does not significantly affect the fundamental validity of results. Typically, a Class 3 analytical nonconformity is the product of a transcription error that results in a report being released that contains a result that is inconsistent with the examination documentation.

14.9.1 b.4) For deviations related to noncompliance with the management system, the evaluation shall determine if the noncompliance is significant regarding both

the nature of the noncompliance and the frequency of occurrence.

c) Correction is taken immediately if possible, along with a decision regarding the acceptability of nonconforming examinations.

d) The customer(s) is notified and examination reports are recalled, as necessary.

- 14.9.1 d) When examination reports based on nonconforming work are released, the customers are notified and the examination reports are recalled if necessary.
- 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 Quality Manager has 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.

4.10 IMPROVEMENT

Forensic Services continually improves the effectiveness of its management system via the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

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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 The currently approved corrective action request form (CAR) will be used to

document all formal corrective actions.

14.11.1.2 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 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.

14.11.1.3 Potential corrective actions are identified to resolve the root cause(s) and the corrective action is chosen that is most likely to prevent recurrence of the nonconformity. A corrective action plan will be developed with completion dates for each major step of the plan if the corrective action chosen to remediate the nonconformity will require an extended period of time. The corrective action should be proportional to the seriousness of the nonconformity.

nonconjormuy.

14.11.1.3.1 Competency testing shall be included with each corrective action involving a Class 1 or Class 2 analytical nonconformity. If a deviation is found to be analysi based and the analyst permanently discontinues performing the analysis, the competency test may be waived.

14.11.1.3.2 Competency testing is not required to resolve a Class 3 analytical nonconformity.

- **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 The first step(s) and the key to performing effective corrective action is to determine the underlying cause(s) of the nonconformity. If the underlying cause(s) for the nonconformity is resolved through the corrective action there is a much better chance of preventing recurrence than if superficial and secondary causes for the nonconformity are corrected. Therefore, a careful evaluation of all potential root cause(s) needs to be completed to determine the most likely root cause(s). Possible root cause(s) include the nature of the sample, analytical methods, quality procedures, staff skills and training,

Section 4.11 – Corrective Action Page 1 of 2

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.

4.11.4 Monitoring of corrective actions: To ensure its effectiveness, corrective action is monitored

14.11.4.1 The completed corrective action with documentation or a corrective action plan must be submitted by the response due dute, unless an extension has been granted. The progress towards completion of a corrective action plan will be monitored as appropriate.

monitorea as appropriate.

14.11.4.2 If the corrective action is not processed in the designated time frame or if the corrective actions performed are not consistent with the approved corrective action plan; the CAR can be reissued to the next higher level of authority in the chain-of-command.

14.11.4.3 If it becomes apparent during the process of performing corrective action that the designated corrective action will not resolve the nonconformity, the party responsible for implementing the corrective action will inform the person who issued the CAR and revise the corrective action.

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

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.

PREVENTIVE ACTION 4.12

- 4.12.1 Opportunities for improvement and potential sources of nonconformities are identified. Preventive actions are developed, implemented, and monitored, to reduce the likelihood of the occurrence of the potential nonconformances and to take advantage of the improvement opportunity.
- 4.12.2 Forensic Services has a quality procedure for performing preventive actions that includes the initiation of preventive actions and application of controls to ensure that they are effective.

14.12.2 Preventative action procedure

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

14.12.2.2 The approved preventive action form (PAR) will be used to document all formal preventive actions.

14.12.2.3 The Quality Manager or Deputy Quality Manager normally issues the PAR. However, if the actions or responsibilities of the Quality Manager are to be reviewed as part of the PAR, then the Major/Manager issues the PAR. The PAR is issued to the staff member with the technical or supervisory responsibility to resolve the potential nonconformity.

Root cause analysis will be performed, as appropriate, and suitable preventive action will be selected and implemented. A preventive action plan will be written with completion dates for each major step of the plan if the preventive action will require an extended time period. Preventive action should be proportional to the seriousness of the potential nonconformity.

14.12.2.5 The PAR can be reissued to the next higher level of authority in the chain-ofcommand if it is not processed in the designated time frame or if the preventive actions performed are not consistent with the approved preventive action plan.

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

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 humidity shall be minimized as much as feasible.

14.13.1.2.2 Technical records such as case files and related technical records, calibrations and ealibration 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.

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

14.13.1.2.6 Card files and/or electronic databases used to reference case files shall also be retained according to the retention schedule above. Card files and/or

electronic databases shall be stored in a manner and location most appropriate for the specific file to ensure continued accessibility.

- 4.13.1.3 All records are held securely and in confidence. (procedure on confidentiality 14.1.5c)
 - 14.13.1.3 All records are securely contained in case files or in central storage. Records that contain confidential or sensitive information shall be burned or shredded when they need to be destroyed. (procedure on confidentiality 14.1.5c)
- **4.13.1.4** Forensic Services creates and implements quality procedures for electronic records to protect and back them up and prevent unauthorized access or amendment.
 - 14.13.1.4 Electronic records will be protected and backed up to prevent loss of these records. ISP's Criminal Justice Information Services (CJIS) is in charge of backing up Forensic Services computer systems, to include; the network drives, Evidence Tracking System (ETS), DNA Submission Tracker, and CODIS databases. Electronic records are backed up nightly by CJIS. Standalone databases that Forensic Services maintain are also protected and backed up. An electronic tape backup of the NIBIN system is performed weekly. Instrumental parameters stored electronically on instruments or computers not connected to network drives need to be printed or electronically backed up.

Electronic records shall be stored so that they can only be viewed or amended in Forensic Services laboratory facilities with controlled access. The Evidence Tracking System (ETS) has both user restrictions and password protection. The databases for CODIS and IBIS are password protected.

4.13.2 Technical Records

- 4.13.2.1 Forensic Services retains original records of observations, calculations, derived data, information to establish an audit trail, and the original or copy of each examination report for the period of time established by Idaho State Police archival policies. If possible, the records for each examination contain sufficient information to facilitate identification of factors affecting the uncertainty and to enable examinations to be repeated under conditions as close as possible to the original. These records include identification of personnel responsible for sampling, performing each examination, and checking results.
 - 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.

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- **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 with a single line 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 and identify the file.

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

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- **4.13.2.5** Records to support conclusions are such that in the absence of the analyst a competent analyst can evaluate what work was done in a case and interpret the data.
- **4.13.2.5.1** Documentation to support conclusions in the latent print discipline shall meet all applicable requirements in Appendix A ASCLD/LAB Latent Print Examination Documentation.
- **4.13.2.6** The unique laboratory number and the handwritten initials of the analyst or secure electronic equivalent of initials or signature are required on each page of the technical records in the case file.
- 4.13.2.7 When technical records are prepared by an individual(s) other than the analyst who interprets the findings, prepares the report, and/or testifies concerning the record; the initials of that individual(s) are on the page(s) of technical records representing his/her work. It is clear from the case record who performed all stages of the examination. Laboratory personnel who write reports and/or testify based on examination documentation generated by another person(s) shall document a review of all relevant pages of examination documentation in the case record.
- 4.13.2.7.1 Technical records, such as photocopies of thin layer chromatograms or instrumental printouts, which bear the appropriate identifiers (lab number plus the individual identifiers as necessary and the examiner's initials) on an original document, may be copied for filing in multiple cases without the necessity of placing original identifiers on each copy.
- **4.13.2.7.2** Examination data that is contained in the case file will be page numbered and the total number of pages is indicated on the first page of the technical record.
- 4.13.2.8 All administrative records, received or generated for a specific case, are identified by the unique laboratory number. Multi-paged administrative records that are bound together may be at a minimum identified by the unique laboratory number on the first page of the record only.
- 4.13.2.9 When data from multiple cases is recorded on a single printout or worksheet, the unique laboratory number of each case, for which data was generated, shall be appropriately recorded on the document. The printout may then be kept in a central file if it is referenced in all case files for which data was generated. However, examination documentation that is centrally stored that applies to multiple cases such as instrumental data, only needs to be marked with the initials of the examiner, the run date, and sufficient information to relate the centrally stored data to the appropriate cases. (The run

date may be sufficient to relate centrally stored data regarding standards, controls, or calibration to the appropriate cases. Whereas, the unique laboratory number would be necessary to identify data that applies only to a specific case in the batch.)

- **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 for 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.

INTERNAL AUDITS 4.14

- 4.14.1 Internal audits, of the three laboratories of Forensic Services, are performed on predetermined schedules and follow the quality procedure, which follows, to ensure compliance with the normative references and management system. Internal audits address all elements of the management system. The Quality Manager plans and organizes the audits as required by the schedule and requested by the management. Auditors are trained, qualified, and preferably independent of the workgroup(s) to be audited.
 - 14.14.1 Quality Audits Procedure: a variety of internal andits are performed. The purpose of these audits is to ensure compliance with the Management System and remediate nonconformities through corrective action either formal or informal. The following are the guidelines for performing internal quality or technical audits:

All auditors shall be trained prior to performing audits. Training may be 14.14.1.1 offered internally or provided through such programs as the ASCLD/LAB (Legacy or International) auditor training programs.

14.14.1.2 Audits shall be comprehensive and performed from audit checklists with the goal of auditing against all requirements of the management system and the normative references consistent with the purpose of the audit. A substantial portion of quality audits and all technical audits include a review of case files and other technical records

A sampling of hard copies of controlled management documents retained in 14.14.1.3 the laboratory is reviewed to ensure that they are either currently approved

for use or marked to indicate that they are obsolete.

14.14.1.4 The Quality Manager schedules audits, as requested by management, with a Vlead-time of two to six months when possible. The Quality Manager or designee organizes and leads audits.

14.14.1.4 Auditors are encouraged to audit within their own technical specialties provided they are from another laboratory and independent of the management of the laboratory they are auditing.

14.14.1.5 Ideally, teams of three or more individuals shall perform audits.

A finding is a significant deviation from the Management System and 14.14.1.6 typically requires that a corrective action request (CAR) be issued. Findings must be objective and verifiable and the nonconformity must involve a deviation from the documented management system or normative references. A CAR may not be issued if the finding can be corrected while the audit team is performing the audit. However, this would only be applicable to simple findings where the accuracy of analysis is not impacted and root cause

analysis is not necessary.

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.

Audits specific to forensic DNA laboratories shall be performed in compliance with current national quality standards.

- **4.14.1.2** Internal audits are recorded and the record is retained for a minimum of one ASCLD/LAB International accreditation cycle.
- 4.14.2 Information acquired during internal audits that casts doubt on the effectiveness of the operations is reviewed during the annual management review. Nonconformities to the management system or nonconforming analyses, which are identified during internal audits, result in appropriate action depending on the nature of the nonconformity. Potential nonconformities are handled as designated by the policy/procedure for preventive actions. Nonconformities to the management system or nonconforming analyses are processed in a timely manner as designated by the policy/procedure for control of nonconforming work, section 4.9. This includes notifying customers in writing regarding inaccurate work.
- 4.14.3 Records are made of the areas of activity being audited, the audit findings, corrective actions, and preventive actions.
- 4.14.4 Follow-up activity to the audit verifies and records the implementation and effectiveness of any corrective action.
- **4.14.5** Each laboratory submits an Annual Accreditation Report to ASCLD/LAB International yearly by the anniversary date on which the laboratory was officially accredited.

MANAGEMENT REVIEWS 4.15

- 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:
- 14.15.1.14 To ensure that the management system continues to be effective, suitable, and Ifulfill 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.
- 14.15.1.1.3 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.
- The Major/Manager shall establish the time, place, and agenda for a 14.15.2 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 limited to, the topics described in this procedure. Minutes shall be taken and disseminated as appropriate.

14.15.3 Proposed management review agenda:

- 14.15.3.1 The Quality Manager shall present summaries of the following topics for which activities have occurred since the last management review:
 - Internal audits including findings, potential nonconformities, recommendations, and commendations.
 - Assessments by external organizations.
 - Corrective and preventive actions.
 - Proficiency testing results.
 - Reports of activities within disciplines.
 - Continued suitability of policies, procedures, analytical methods, and work instructions.
 - Personnel training.
 - Recommendations for improvement.
 - Other quality control activities as appropriate.

 On the control activities as appropriate.
- 14.15.3.2 The laboratory managers shall summarize and consider the following topics for their laboratory:
 - Customer feedback?
 - Changes in the volume and type of work undertaken.
 - Complaints and their resolution.
 - Changes in requested service.
 - Additional services/instruments/analytical methods.

14.15.3.3 The Major Manager will:

- Review resources.
- Review and evaluate goals and objectives.
 - Formulate action plans with a timeframe for completion.
- 4.15.1.1 A management review is conducted at least once during each calendar year.
- **4.15.1.2** Each management review is recorded and the record is retained as a quality record. Quality records are retained for 10 years in accordance with 14.13.1.2. They are always retained for at least one ASCLD/LAB International cycle of accreditation.
- 4.15.2 Findings from management reviews and the actions that arise are recorded in the minutes of the management review meeting. Management shall ensure that the actions are completed within an appropriate and agreed timeline.

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GENERAL TECHNICAL REQUIREMENTS 5.1

Many factors contribute to the accuracy and reliability of the examinations performed in 5.1.1 the laboratories of Forensic Services. These factors include contributions from:

a) Human factors (section 5.2);

- isic services 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).
- Forensic Services takes the factors listed in Section \$1.1 above into consideration when 5.1.2 developing analytical methods, work instructions, forms, personnel training, and in selecting and calibrating equipment.
- Forensic Services creates and implements a quality procedure for routinely checking the reliability of its reagents. 5.1.3
 - Reagents shall be routinely tested to determine if they are providing the *15.1.3.1* appropriate chemical or biological response. The schedule for this testing will be established in the appropriate analytical method(s).
 - Some reagents are prepared in a batch and used for extended periods of time 15.1.3.2 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.
 - The records regarding reagents used for a single analysis and then disposed 15.1.3.3 of shall be maintained in the casework notes.
 - Reagents of questionable reliability and expired reagents shall be discarded. 15.1.3.4 However, an expired reagent may continue to be used if tested with a positive and negative control each time it is used, the appropriate discipline leader has approved the use of the expired reagent, and the discipline leader has notified the managers in the laboratories where the reagent is used.
- 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

Section 5.1 - General Technical Requirements Page 1 of 2

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.

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PERSONNEL 5.2

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

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

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

All employees participate in employee development as described in 5.2.2 and 15.2.2 in order to maintain a high level of competency

Typically, the need for retraining is identified through the discovery of nonconforming work and is handled in accordance with the nonconforming work/corrective action process described in section 4.9 and 4.11 of this manual.

15.2.1.1 Discipline sub discipline training plans: a training plan shall be developed and updated as required by the discipline leader. The training plan shall be based on relevant analytical methods. All knowledge, skills, and abilities necessary o perform casework analysis shall be included in the training plan.

15.2.1,10 Training plan format and contents:

- 15.2.1.1.1 The training plan shall contain a checklist with a list of appropriate topics and information about each topic that can be signed or initialed upon completion. If the sign-off is for a section of an analytical method rather than a task, the analytical method section shall be listed.
 - 15.2.1.1.1.2 History page: shall provide a list of revisions with the revision dates, including the current revision.
 - 15.2.1.1.1.3 Introduction: each training plan shall have an introduction.
 - 15.2.1.1.1.4 References, if appropriate, shall be included somewhere in the training
 - 15.2.1.1.1.5 The numbering system: Section 1 shall be 1; Topic 1 shall be 1.1; and Item 1 shall be 1.1.1, etc.;
 - 15.2.1.1.1.6 Each page of a training plan shall have the date issued and the revision

number (rev. #) in the bottom right hand corner.

15.2.1.1.2 The following elements shall be included in the training plan:

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;

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)

used:

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). 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 trainee must initial the examination record for the work performed by the trainee — initialing the notes is preferable.

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 and in accordance with the current testimony evaluation form. This requirement shall be met when the trainee receives a documented satisfactory

evaluation of a mock court using the current evaluation form.

15.2.1.1.2.10 Co-signed cases (After approval by the Quality Manager):

Performance of the analytical methods on actual case material under close supervision.

15.2.1.1.3 Steps in training an individual:

15.2.1.1.3.1 Obtain the written approval of the Major/Manager prior to commencing training.

15.2.1.1.3.2 Contact the appropriate discipline leader. The discipline leader is responsible for organizing the training. The discipline leader may designate an on-site trainer.

15.2.1.1.3.3 Training shall take place in accordance with the appropriate approved training plan.

15.2.1.1.3.4 All steps in training an individual shall be documented as they are completed. Training does not have to proceed in a specified order. However, co-signed case analysis shall only occur last after the Quality Manager has approved the rest of the training.

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

15.2.1.1.3.6 Review of documentation: once all the training is completed except for performing co-signed cases, the discipline leader shall review all documentation regarding the training to determine if the trainee performed all required training and is competent to perform the analysis. The discipline leader (Laboratory Manager if the discipline leader is being approved) shall forward the following documentation to the Quality Manager:

15.21.1.3.7 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. The Quality Manager shall then approve the trainee to perform co-signed analysis under supervision if feasible. (In certain situations, it would not be feasible to perform co-signed cases. For example, when an analyst is being trained to perform an examination new to Forensic Services.) When the Quality Manager receives documentation that the required number of co-signed examinations have been successfully performed, written approval shall be granted to perform analysis and testify as an expert

regarding the examinations for which the analyst was trained.

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.

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 procedures for the implementation of this policy. Approved training plans are appropriate for the examinations performed and, the effectiveness of training is evaluated prior to the trainee being approved to perform independent casework.

15.2.2 Certification and Employee Development

15.2.2.1 In an effort to continually improve the skills of its scientists, Forensic Services requires that all personnel obtain certification no later than three years after becoming a Forensic Scientist 2 (or by July 1, 2007, whichever time frame is longer). Forensic Scientists 2 performing analysis and proficiency testing in a

single discipline, may elect to sit for an ABC specialty (e.g., drug analysis, fire debris, molecular biology, etc.) or other recognized certification examination (e.g., ABFT, FTCB, IAI, etc.), for the discipline in which they work. Forensic Scientists 2, performing work in more than one discipline, may elect to sit for either the ABC criminalistics or a specialty examination in which they are doing work. Exceptions require prior authorization by the Major/Manager.

15.2.2.2 Prior to July 1, 2007, each Forensic Scientist 3 or 4 who possesses technical leader responsibilities shall obtain discipline-specific certification (F-ABC, ABFT, FTCB, IAI, etc.) within the first three years of being appointed to his/her current position or by July 1 2007 whichever time frame is longer. A Forensic Scientist 3 or 4, who assume technical leader responsibilities after July 1, 2007, must already hold ABC-Fellow, or equivalent status (e.g., ABFT, FTCB, IAI, etc.) in the discipline in which he/she supervises work, or such status must be achieved within one year of assuming discipline leader responsibilities. The Major/Manager must authorize exceptions.

15.2.2.3 Forensic Services shall pay all costs associated with taking general and discipline appropriate certification tests approved by management, the annual fees for maintaining certification, and for all costs associated with proficiency

testing to remain certified within a given specialty.

15.2.2.4 Forensic Services will make every effort to ensure that adequate opportunities to maintain certification are afforded to all scientists; however, it is incumbent upon the individual to monitor and maintain certification once such has been acquired. As such, Forensic Services shall also pay for approved attendance at seminars, professional meetings, etc., necessary to maintain certification.

15.2.2.5 Forensic Services encourages staff members to develop their potential by identifying training needs and taking advantage of opportunities for

professional development.

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

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- 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.
 - 15.2.2.8.8 Application for college classes shall follow ISP procedure.
 - 15.2.2.8.9 Follow-up to training shall include providing the following to the Quality Assurance Manager:
 - 15.2.2.8.9.1 A completed department Record of Training form,
 - 15.2.2.8.9.2 A description of the training or courses attended. (preferably the

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agenda, if available)
15.2.2.8.9.3 A brief evaluation of the training.

- 5.2.3 Forensic Services uses personnel who are employed by or under contract to Forensic Services. All personnel, whether under contract to Forensic Services or employed by Forensic Services, are properly supervised, competent, and work in accordance with the management system.
- 5.2.4 Current job descriptions for managerial, scientific, and technical support personnel involved in examination are updated every five years and maintained on the Human Resources website. Minimum contents of job descriptions include where applicable:
 - a) Responsibilities with respect to performing examinations;
 - b) Planning of examinations and evaluation of results:
 - c) Responsibilities for reporting opinions and interpretations,
 - d) Responsibilities with respect to analytical method development and validation;
 - e) Expertise and experience required;
 - f) Qualifications and training programs;
 - g) Managerial duties.
 - 15.2.4 Job Descriptions (position titles begin with ISP except Laboratory Improvement Manager, [e.g., ISP Forensic Scientist 2]) are available for all positions at the Department of Human Resources web site.
 - ISP Forensic Evidence Specialist
 - ISP Forensic Scientist T
 - ISP Forensic Scientist 2
 - ISP Forensic Scientist 3
 - ISP Forensic Scientist 3-DNA
 - ISP Forensic Scientist 4
 - ISP Forensic Scientist 4-DNA
 - ISP Forensic Laboratory Manager
 - Laboratory Improvement Manager
 - Major/Manager
- 5.2.5 Management approves individuals to perform specific examinations and to testify on associated results. The approval to perform analysis encompasses related sampling, issuing examination reports, operating the instruments necessary to carry out the examination, and offering opinions. 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.

5.2.6 Scientific/Technical Support Personnel Qualifications

5.2.6.1 Education

15.2.6.1.1 The education of each employee performing case 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.

- 5.2.6.1.1 Analysts working in Chemistry (controlled substances/fire evidence) and Trace Evidence must possess a baccalaureate or advanced degree in chemistry, biology, or forensic science/closely related field that is substantially equivalent. Chemistry analysts must have taken general chemistry, organic chemistry, and quantitative analysis.
- **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.
- 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 related field that is substantially equivalent.
- **5.2.6.1.5** Technical support personnel (laboratory technicians/assistants) must meet the educational requirement(s) specified in their job description. However, most jobs will require completion of at least a full year each of general and organic chemistry prior to beginning work.

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- 5.2.6.2 Competency Testing: All analysts, regardless of their qualifications or past work experience, must satisfactorily complete a competency test prior to assuming casework responsibility. Satisfactory completion of competency testing means achieving the intended results. Failure to achieve the intended results requires review and/or retraining until such time as satisfactory performance is achieved. Competency testing includes written and/or oral evaluation on background knowledge of scientific literature and identification of known and unknown materials.
 - 15.2.6.2 Competency tests will be provided by the discipline leader, designee, or by the Quality Manager if the discipline leader is being tested. Competency tests shall test the individual on relevant topics and/or samples covered during training, mimic actual casework, and may undergo suitability review, prior to their use. It is incumbent upon the discipline leader to review and discuss with the examinee, in a timely manner, any deficiencies noted during the testing and to formulate retraining as needed. The QA Manager will maintain results of competency testing and provide required notification that a forensic scientists is allowed to analyze work in a given discipline/subdiscipline.
- **5.2.6.2.3** Technical support personnel must satisfactorily complete competency testing prior to assuming independent responsibility for any task that could reasonably be expected to affect the outcome of any examination.
- **5.2.6.2.4** Analysts working in any subdiscipline of forensic science must satisfactorily complete competency testing in each subdiscipline prior to assuming casework responsibility in that subdiscipline.
- 5.2.7 Journals and References related to Forensic Science: Each laboratory of Forensic Services maintains a library and provides access to resources such as books, journals and other relevant publications or electronic media dealing with each subdiscipline for which service is provided in that laboratory. Each employee also has direct access to the educational resources of the Internet.

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 loss, tampering, and contamination.
- **5.3.4.1** Forensic Services creates and implements quality procedures that address laboratory security to ensure that:

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

15,3,4,1 a.1) Access to the laboratory:

- 15.3.4.1 a.1.1) Only personnel staffed to the laboratory as part of their routine function (e.g., forensic scientists, forensic evidence specialists, laboratory technicians and assistants, the quality manager, the Major/Manager and administrative support) or those individuals designated by the laboratory manager shall have unrestricted access to any forensic laboratory during normal duty hours, after-duty hours, and the opening and closing of the laboratory. Only the laboratory manager may add to or remove from the list of personnel having this access to the laboratory.
- 15.3.4.1 a.1.2) A written record is kept of each emergency access to a laboratory.

15.3.4.1.a.2) Laboratory visitors:

15.3.4.1.a.2.1) Anyone entering the restricted/operational areas of the laboratory who is not employed by ISP or does not work within the laboratory system shall be required to sign a log book prior to entering any such portion of the laboratory. Restricted/operational areas of the laboratory are defined as anywhere that evidence may be open or analyzed, and any evidence storage area.

15.3.4.1.a.2.2) This logbook shalf contain pertinent information to identify the individual, the time period of the visit, the staff member accompanying the visitor, and the reason for the visit.

- 15.3.4.1.4.2.3) Laboratory personnel shall normally accompany any visitor accessing restricted/operational portions of the laboratory. However, visitors, such as instrument repair technicians, may be left alone in an area of a laboratory, while repairing an instrument provided that the following requirements are met: a monitor is assigned to ensure that these security requirements are followed; all evidence in the area is securely locked up; the visitor remains in the work area except to leave or locate the monitor; and the visitor is checked regularly.
- 15.3.4.1.a.2.4) Visitors shall don appropriate safety attire, if such is a requirement of laboratory personnel within a given laboratory location.
- b) All exterior entrance/exit points have adequate security control.
- 15.3.4.1 b) Entry and Exit points to the laboratory shall have operable locks. The entries

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shall be locked at all times when not under the direct supervision of staff. The laboratory is alarmed after working hours when the laboratory is not occupied.

- 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 and they are only accessible 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 director 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.
 - 15.3.5.1 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.

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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 of each workday unless continuous or extended analysis requires use of the equipment.

Forensic Services documents its health and safety program in the Health and Safety 5.3.6 Manual. Continuing use of the program is demonstrated by one or more of the following: annual health and safety audits for each laboratory, health and safety training records, Inities c inplaints ex, in plaints e corrective or preventive actions related to nonconformities or potential nonconformities in regards to the Health and Safety Manual, or complaints expressed by staff regarding health and safety policies.

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

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Services. The discipline leader can approve the use of an analytical method if:

15.4.1.2.1 The analyst can demonstrate that the method is generally accepted by the scientific community and meets acceptable scientific standards.

15.4.1.2.2 Includes the use of appropriate positive and negative controls plus standards and reagents of satisfactory quality.

15.4.1.2.3 The quality manager has reviewed the analytical method to ensure consistency with the quality system.

15.4.1.2.4 The analyst and the discipline leader have decided whether validation is necessary and the validation study if performed, established the efficacy and reliability of the analytical method.

- 15.4.1.2.5 The analytical method, the approval of the use of the method by the discipline leader, acknowledgement of review by the quality manager, the validation study if performed or available from another source or the citation, the results of the controls, and the results of the case sample(s) shall all be documented in the case file.
- 5.4.1.1 All analytical methods are documented and available to laboratory personnel. The staff of Forensic Services can exercise discretion in selecting the analytical method most appropriate to the evidence being examined.
- 5.4.1.2 Appropriate controls and standards are specified in analytical methods and their use is recorded.
 5.4.2 Selection of analytical methods

Forensic Services chooses analytical methods including sampling that meet the needs of the customer and are appropriate for the evidence to be tested. Non-standard analytical methods and laboratory developed analytical methods are used only if adequately validated. Standard analytical methods (see definitions) are preferably used if available and appropriate. If a standard analytical method is used, the discipline leader ensures that the latest edition of the analytical method is used unless it is not appropriate or possible to do so. If modifications of standard analytical methods are made, the analytical method must be validated prior to use.

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.

15.4.2 Departure from an analytical method: It is expected that the staff of forensic services will follow approved analytical methods. However, the nature of the work in forensic science sometimes presents non-typical situations where an

> Section 5.4 - Analytical Methods and Method Validation Page 2 of 12

approved analytical method does not fit. This policy describes the steps that an analyst shall take before deviating from approved analytical method(s).

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.

- 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 analytical method. Plans are updated as necessary to incorporate new information as development proceeds and there is effective communication between all participants developing the analytical method.

15.4.3.1 Contents of analytical methods:

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

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

date accepted.

15.4.3.3 Background: This section may refer to the manufacturer's protocol or some other source from which this method was derived. It may in practice contain a variety of openings by way of providing the background information about the analytical method that is to follow. This section may be brief.

15.4.3.4 Scope: Specify the applicability of the analytical method and/or the range of

samples for which it is suitable.

15.4.3.5 Equipment: This shall be a list of the equipment needed to perform this analytical method. It is recommended that the list of equipment be as generic as possible. However, if the procedure requires specific equipment, that equipment shall be designated in the analytical methods. Equipment shall have calibration/intermediate checks and maintenance procedures and accompanying calibration/intermediate checks and maintenance logs as appropriate.

15.4.3.6 Reagents: The next section would be a list of reagents necessary to perform this analytical method. In some analytical methods, the preparation of the reagent will be described in this section while in other analytical methods preparation is elsewhere. Note: The reagents and equipment section can be

combined if both sections are short.

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

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

15.4.3.9 References: Often an analytical method will be based on some literature

reference. If it is not listed in the introduction, then it shall be listed here. The references can be listed in the background section if they are few in number. Other suggested references include relevant technical documents, published/accepted methods, in-house manuals, and equipment manuals.

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.

- 5.4.4 Non-standard analytical methods
 Customers agree prior to the analysis of evidence to accept non-standard analytical
 methods in use by Forensic Services. Non-standard analytical methods are validated and
 approved prior to being used on evidence. New analytical methods are developed
 according to and contain the information outlined in the related quality procedure.
- 5.4.5 Validation of analytical methods: Analytical methods in place before April 1, 2001, do not need validation studies as they have been validated through proficiency testing and usage over an extended period of time. Nor do they require validation if they are rewritten to conform to an updated format. Methods validated between April 1, 2001 and issue date of this procedure must have documentation of validation and meet the procedural requirements that were in effect during that time. Only method validation begun after January 10, 2007 of these procedures need to meet the listed requirements.
- **5.4.5.1** Validation is the confirmation by examination using objective evidence that the requirements for the intended use for a specific analytical method are fulfilled.
- 5.4.5.2 Forensic Services validates non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs of the given application. The forensic scientist performing the validation records the results obtained, the process used for the validation, and provides a written evaluation as to whether the method is fit for the intended use.
 - 15.4.5.2 Validation Analytical methods must be comprised of validated techniques or methods that are appropriate for the examination.
 - 15.4.5.2.1 Methods need to be validated or revalidated:
 - Before their introduction into routine use.
 - Whenever conditions change for which the method has been validated that may potentially have an effect on the outcome of casework analysis.
 - Whenever the method is changed or reconfigured, in a way that may potentially have an effect on the outcome of casework analysis.
 - 15.4.5.2.3 General guidelines:
 - The person or team performing the validation shall have a complete

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understanding of the theoretical basis for the method.

 If a method parallels or supercedes an existing method, the proposed method and the current method shall be compared using split samples if possible.

• It is recommended that the known samples be designed to resemble actual evidence materials as closely as possible so that the effects of such factors as the matrix of the sample, sample age degradative environment, and sample homogeneity are taken into account. This is particularly important when attempting to apply a methodology to forensic materials originally developed for routine chemical or clinical samples.

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 (novel methods developed independently by Førensic Services) would require extensive yalidation

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.

Materials- materials needed for the method.

 Safety- the safety procedures that apply to the method will be reviewed prior to beginning validation testing; this would include storage and disposal of chemicals.

• **Procedure**- this is a step-by-step description of the validation activities. This would include the performance characteristics that will be evaluated for the method.

- Results-descriptive observations of test results, hard data from testing.
- Conclusion -this is an evaluation of the validation.
- Reference- list the sources for procedure or supporting procedure.

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

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

15.4.5.2.8 The quality manager reviews the documentation and determines if the documentation is adequate and if the validation study meets the specifications of the validation plan or may appoint a scientific review committee consisting of up to three individuals to review and approve the validation data.

Validation data are evaluated against the stated performance criteria and conclusions about the validation study are made.

15.4.5.2.9 A fit for use memo is drafted by the discipline leader and approved by the quality manager. The method or technique may then be incorporated into analytical methods.

- 5.4.5.3 The range and accuracy of the values obtainable from validated analytical methods is relevant to the customer needs. Factors to consider may include: repeatability, linearity (quantitation), specificity, limits of detection, interference from the matrices, and reproducibility.
- 15.4.5.3 The performance characteristics of a validation plan includes, as applicable: (since forensic science covers a wide span of testing there may be other types of performance characteristics that are not listed below that may be evaluated. Some of the performance characteristics listed below also include suggestions on how that characteristic may be evaluated, this is only a guide and the analyst proposing the validation plan may use other scientifically acceptable means to evaluate performance characteristics.) (The DNA section

will also follow the DAB guidelines)

15.4.5.3.1 Selectivity: a study of interferences from the matrix and environmental affects.

15.4.5.3.2 Sensitivity: limit of detection (LOD)- lowest amount of analyte that will be detected and can be identified. Limit of quantitation (LOQ) - lowest concentration that has an acceptable level of uncertainty.

15.4.5.3.3 Linearity: the mathematical relationship that exists between concentration and response over a selected range of concentrations. The LOQ forms the 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 lighter 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,

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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 enough to allow for delays such as instrument breakdowns or overnight analysis using auto-samplers. For example, solutions may need to demonstrate stability over a 48-hour period. Standards and samples should be tested over at least a 48-hour period, and the quantitation of components should be determined by comparison to freshly prepared standards. An example of stability criteria: Acceptable stability of samples stored in solution for 48 hours is 2% change in standard or sample response, relative to freshly prepared samples.

15.4.5.3.11 Recovery: the amount of analyte that is actually recovered from an extraction.

15.4.5.3.12 Accommodations or environmental conditions: consideration of accommodations or environmental conditions that may affect the validation.

5.4.6 Estimation of uncertainty of measurement:

- **5.4.6.1** Forensic Services does not calibrate equipment and therefore does not need procedures for estimating the uncertainty of the calibrations of its measuring equipment.
- 5.4.6.2 Forensic Services creates and implements a quality procedure to estimate uncertainties of measurement for quantitative analysis included in the examination report except when the analytical method precludes such rigorous calculations. In certain cases, a valid estimation of uncertainty of measurement is not possible. In these cases, Forensic Services attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the analytical method and on the measurement scope and makes use of previous experience and validation data. At the time of issuance of this manual, Forensic Services is in the process of calculating uncertainties of measurement for quantitative analysis. These determinations will be complete and uncertainties reported, as necessary, by June 1, 2008.
 - 15.4.6.2 Uncertainty of Measurement: An uncertainty of measurement will be provided for quantitative results contained in examination reports or the quantitative

result will be reported only to the number of significant digits that are known to be accurate.

15.4.6.2.1 An example of a situation where significant digits does need to be reported: quantitative values are reported to less significant figures than the instrument or apparatus is calibrated (e.g. the weight of a drug is reported out in 100ths of a gram and the balance is calibrated to 1000ths of a gram). Documentation demonstrating that the calibration exceeds the accuracy of the reported value must be available.

15.4.6.2.2 A guide for measurement uncertainty is located at Quantifying Uncertainty in Analytical Measurement.

15.4.6.2.3 The uncertainty estimate must be part of the validation plan. One possible approach to calculating uncertainty is deriving a standard deviation from measurement data. It will need to be determined in the validation plan the number of replicate data needed. From the replicate data the population standard deviation would be calculated. The confidence interval of 95.5% will be used so the estimation of uncertainty is +/- 2 population standard deviations from the mean. The estimate of uncertainty would be stated. The chances are 95.5 in 100 that the error is less than +/- 2 std dev.

15.4.6.2.4 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

15.4.6.2.5 The uncertainty level may be recalculated and updated as more data becomes available from using the procedures. If the uncertainty level is recalculated it would be submitted as an amendment to the validation study.

15.4.6.2.6 Each analytical method from which quantitative results are reported shall contain 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 15.9.4.1.2)
- **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 must be validated in accordance with the 5.4.7.2 a)

5.4.7.2.1 Forensic Services does not perform the examination of digital evidence and therefore this supplemental clause in not applicable.

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.
 - 15.5.2.2 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.
 - 15.5.2.4 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.

- 15.5.3.1 Forensic Service personnel who have successfully completed their approved training plan or individuals working under the direct supervision of trained personnel will be authorized to use the corresponding equipment/software.
- 15.5.3.2 The successful completion of training will be documented in the employee's training file, which is maintained by the Quality Manager.
- 15.5.3.3 Maintenance shall be performed in accordance with up-to-date instructions in the documented procedure on or near the schedule required by the maintenance procedure. Some instruments are used by multiple disciplines, which may differ in their calibration and maintenance procedures. Only one procedure needs to be used if it meets the requirements of all users.
- 5.5.4 Analytical equipment and related software that has a significant impact on the results of examinations is uniquely identified, either with the serial number or other designation, when practical.
- 5.5.5 Records are maintained for equipment and software significant to the results of the examinations. Each piece of equipment/instrument will have its own record that contains, at a minimum:
 - a) Identity of the equipment and its software,
 - b) Manufacturer's name, model, type of equipment, and serial number or other unique identification;
 - c) Checks that the equipment complies with the specifications, bid specs, and/or analytical methods as appropriate;
 - d) Current location, as appropriate;
 - e) Manufacturer's instructions, if available, or reference to their location;
 - 1) Dates, copies of reports and certificates for all calibrations, performance verifications, adjustments, acceptance criteria, and the due date of next calibration, where applicable;
 - 15.55) A calibration record shall be maintained for all pieces of equipment that require intermediate checks or calibration. This record shall contain the following documentation, at a minimum:
 - Type of instrument and its unique identification;
 - Calibration procedure and/or intermediate check procedure;
 - Acceptance criteria for calibration and/or intermediate checks;
 - Appropriate interval of calibration and/or/intermediate checks;
 - Date performed,
 - Results, reference standard, and initials of individual performing calibration.

- g) Maintenance plan, where appropriate, schedule of performance verifications, where applicable, and the maintenance and performance verifications carried out;
- 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 Mantenance 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.
- 5.5.9 When equipment goes outside the direct control of Forensic Services for a period of time, Forensic Services ensures that the performance and/or calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service. The results of the check must be acceptable or the equipment will not be returned to service. Equipment being returned to Forensic Services after calibration from an approved vendor is excluded from this policy.
- **5.5.10** When intermediate checks and/or performance verifications are needed to maintain confidence in the status of equipment these checks are carried out in accordance with the related quality procedure and the appropriate analytical method.
 - 15.5.10.1 Calibration, intermediate checks, and/or performance verifications of equipment that has a significant impact on the results of an examination are performed after any activity that might significantly effect the equipment such as maintenance or repair.
 - 15.5.10.2 Intermediate check intervals and performance verification intervals established by the manufacturer are complied with unless the user has documentation demonstrating that the equipment is stable for some longer time interval.
 - 15.5.10.3 Discipline leaders will determine if any equipment needs to have an intermediate check and/or performance verifications after shutdowns, whether deliberate or unplanned
- 5.5.11 Forensic Services would create and implement a quality procedure to ensure that when calibrations give rise to a set of correction factors, copies of this data (e.g., in computer software) are updated if this practice was allowed. However, this practice is not currently allowed in Forensic Services and no quality procedure is necessary at this time.
- **5.5.12** Equipment used for examinations, including hardware and software, are safeguarded from adjustments that invalidate test results/status.
 - 15.5.12 To safeguard equipment from adjustments that would invalidate the test results, all equipment used for examinations are located in secure areas within the laboratory. This equipment is only used by trained personnel or by individuals working under the direct supervision of trained personnel.

MEASUREMENT TRACEABILITY 5.6

General 5.6.1

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 faboratory. However, as applicable, the requirements of this standard have been incorporated into the quality policies and

- 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 5.6.2.2.2.

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

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U.S. customary system of units and traceable to SI units of measurement.

When calibrations are performed, they must be traceable to relevant international SI measurement standards by an unbroken chain of comparisons or calibrations.

Examples of SI base units

LengthmeterMasskilogramTimesecondElectric CurrentampereTemperatureKelvin

Examples of SI derived units

Area square meter
Volume cubic meters
Temperature Celsius

Source: http://physics.nist.gov/cun/Units/units.html

Examples of U.S. customary system of units

Length: One inch international measure equals

exactly 25.4 millimeters

Mass: One pound avoirdupois equals exactly

453,59237 grams

15.6.2.2.1.2 Traceability for measuring equipment calibrated to SI units includes several essential elements (ILAC-G2: 1994)

- An unbroken chain of comparisons going back to a primary standard
- Known measurement uncertainty for each comparison
- Documented procedures for performing each comparison
- Established competence for each comparison performed in the chain
- Reference to appropriate primary standards
- Calibration repeated at appropriate intervals
- 15.6.2.2.1.3 External calibration services that are ISO/IEC 17025 accredited to calibrate the designated measuring equipment meet the requirement for traceability.
- 15.6.2.2.1.4 The following measuring equipment may require calibration traceable to a SI primary standard:

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- 1. Balances
- 2. Thermometers or other temperature measuring devices
- 3. Pipettes excluding volumetric class A glassware
- 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 human blood control drawn from a Forensic Services employee. A certificate of analysis received from the manufacturer may serve as authentication for standard material and controls.

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

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

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

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

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

15.6.3.20 Authenticating and using controlled substances reference material:

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

15.6.3.2.2.2 Primary standards: These are the bulk amounts of controlled substance reference material obtained from manufacturers and stored in high security in the Meridian laboratory. Small amounts (see bench standards below) are dispensed as bench standards and used in analysis.

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

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

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.

15.6.3.2.2.5 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: marijuana, 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.

15.6.3,223.5The combined weight of the bench standard and container shall be audited annually.

15.6.3.2.2.3.6 Quantities of controlled substances in excess of the amounts allowed for bench standards may be held and used by individuals performing research and development. However, the 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, motor vehicle paints or headlamp lenses, drug standards, typewriter print styles, wood fragments, bullets, cartridges, DNA profiles, frequency databases) are (if applicable) fully documented, uniquely identified, and properly controlled.

15.6.3.2.1.1 Definitions:

- Reference collection: Groups of common items intended to assist in determining the class or individual characteristics of evidence.
- Fully documented: documentation as to the description and source of the material. Documentation may be made on the reference material itself, on it proximal packaging, or as part of database record.
- Uniquely identified: Each item or group of similar items will have a unique name as described in the written policy regarding the reference collection. Examples of ways that individual data or items in a reference collection may be uniquely identified include a laboratory generated alphanumeric code, database generated alphanumeric code, or the name of the item if unique.
- Properly controlled: Limiting access to the reference collection.

15.6.3.2.1.2 Current reference collections:

- Firearm reference collection
- Controlled substance reference collection
- FTIR laboratory developed reference database
- GC/MS laboratory developed reference database
- Fire debris reference collection
 - Standard ammunition file
- Toxicology parent drug and metabolites
- 5.6.3.3 Intermediate checks: checks needed to maintain confidence in the calibration of reference standards and reference materials are carried out according to the appropriate analytical methods on the schedules defined in the methods. (Forensic Services currently has no reference standards or reference materials that have or require intermediate checks.)
- 5.6.3.4 Transport and storage: Each discipline that utilizes reference standards or reference materials shall have an established program for handling, transporting, storing, and using reference standards/reference materials to the extent necessary to prevent contamination or deterioration and to protect the integrity of the reference standard/reference material. These programs are described in the discipline- related analytical methods.

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 15.4.2 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.

5.8 HANDLING ITEMS OF EVIDENCE

5.8.1 Forensic Services maintains and follows quality procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of evidence and includes provisions necessary to protect the integrity of evidence and the interests of Forensic Services and its customers.

15.8.1.1 Casework acceptance:

15.8.1.1.1 It is the responsibility of Forensic Services to provide support to law enforcement agencies, prosecutors, and public defenders. In order to provide the timely service, it is important to limit the services to situations that will resolve criminal cases. Deviation from these criteria shall have the approval of the Major/Manager.

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

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

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

15.8.1.1.5 Generally, a forensic evidence specialist should receive evidence. Evidence shall not be accepted unless a properly completed ISP Forensic Services evidence submission form accompanies it. Submission forms are not required for proficiency tests, competency tests or from coroners/morticians when submitting fatality "accident victim samples" (However the form in the AV collection kit shall accompany the sample.). The submission form shall be used as an evidence receipt except for accident victim samples.

15.8.1.1.5.1 Information shall be transferred as provided by the submitting agency from the submittal form to the database. Significant amendments to the information provided on the submission form shall be documented, generally on the submission form.

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 syringer 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 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.

- 15.8.1.4 Return of evidence without analysis: There are a variety of circumstances that may result in the evidence being returned without analysis even though it has been logged into the evidence tracking system. With guidance from the analytical methods the analyst has the discretion to determine which items of evidence will be analyzed in a case. If an item of evidence is not analyzed, it will be noted in the case record.
- 5.8.1.1 Forensic Services is able to demonstrate that the evidence examined and reported on was that submitted to the laboratory. The chain-of-custody record for evidence is maintained from the time of receipt and reflects all internal transfers. The chain-of-custody record lists each person taking possession of an item of evidence, or the location of that item. At a minimum this record includes:
 - a) A signature/initials or electronic equivalent to a signature of the person/location

receiving evidence;

- b) The date of receipt or transfer;
- c) Unique identifier of the evidence.
- 15.8.1.1.1Evidence transferred between individuals shall be documented on the written chain of custody form, which is the official chain-of-custody. Transfer of evidence within a laboratory shall be documented on the written internal chain of custody. The original written internal chain of custody form will be maintained in the case file.

15.8.1.1.2The case file also contains a "chain-of-custody report" whose purpose is to assist in the tracking of evidence and is not an official chain-of-custody.

- **5.8.1.1.1** Once evidence is submitted in the laboratory, all sub-items shall be tracked through a documented chain of custody to the same extent that original items are tracked.
- 5.8.2 Evidence is systematically and uniquely identified upon submission to a Forensic Services laboratory. This identification follows Forensic Services quality procedures and is used throughout the time the evidence is in a laboratory. This unique identification ensures that evidence cannot be confused physically or when referred to in Forensic Services records. The system accommodates sub-division of groups of items, creation of items, and the transfer of items of evidence within or from a laboratory.

15.8.2 System for identifying test items:

Original reacipt 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

15.8.2.1

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 logged 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

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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 nore 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 O3 grams would be appropriately packaged and sealed. The new package would be logged into ETS and assigned the lab number and unique tem number C20051300-1A. The item would be described in ETS as subsample from C20051300-1. An internal chain would then be started; the analyst that created the subsample would be the first entry.

15.8.2.5 Creation of new evidence

15.8.2.5.1 Evidence that is generated by Forensic Services (usually a by-product of an existing piece of evidence), which will be retained by the lab indefinitely, is entered into ETS with the lab number and the item number as follows.

- DNA
- LE (lift cards for fingerprints and photos)
- IBIS (Integrated Ballistics Identification System)
- 15.8.2.5.2 If more than one package is created for one case the additional packages will be numbered consecutively. For example, in biology case M20050689 two packages of retained evidence would be numbered M20050689-DNA and M20050689-DNA-2. In ETS the item will be described as "RETAINED EVIDENCE", Description ("DNA PACKET", "LIFT CARDS", "PHOTOS", or "IBIS").
- 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

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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.
- 15.8.3.2 If evidence comes into the lab by common carrier 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. A log will be kept for rejected evidence, this log will be called "rejected evidence log" it will include documentation of the items being returned.
- 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.
- 5.8.4 Forensic Services has appropriate facilities and quality procedures for avoiding deterioration, loss or damage of evidence during storage, handling, and preparation for analysis. Submitted evidence shall be stored in the evidence vault until checked out for analysis unless special handling or storage requirements dictate storage elsewhere. Handling instructions for particular items of evidence will be followed. When items have to be stored or conditioned in a specified environment, these conditions are maintained, monitored, and recorded. Forensic Services implements quality procedures for storage and security of evidence that protect the integrity of evidence in its control.
 - 15.8.4.1 All evidence in long-term storage shall be sealed in accordance with Forensic Services protocol.
 - 15.8.4.2 All evidence shall be properly logged into the evidence inventory system.
 - 15.8.4.3 The evidence storage areas shall be kept clean and well organized.
 - 15.8.4.4 The evidence vault shall be kept locked except when authorized personnel are in the vault.
 - 15.8.4.5 The only individuals who are authorized to enter the vault unsupervised are the custodians of the vault who are directly responsible for the evidence stored in the vault. An evidence vault entry log shall be kept and any access

to the vault by a non-FES shall be documented.

- When a custodian of the vault ceases to have custody over the vault or it 15.8.4.6 contents, all the evidence shall be audited. The vault and all evidence shall be inventoried at least once annually.
- Evidence that requires specific storage conditions will have those conditions 15.8.4.7 monitored. Evidence requiring special storage conditions are listed below.
 - Latents/Impression:
 - Routine latent/impression evidence is stored at room temperature unless there are special circumstances.
 - Forensic Biology:
 - Liquid reference blood samples and sexual assault evidence collection kits containing liquid bloods are to be refrigerated.
 - Human remains (includes fetal tissue, bones, teeth, and other tissue samples) are frozen.
 - Dried reference bloodstains are frozen.
 - DNA packets are frozen.
 - Blood toxicology collection kits:
 - Refrigerated storage until preparation for analysis.
 - Refrigerated storage post analysis until return to agency.
 - The thermometer will be calibrated-triennially.
 - Urine toxicology collection kits:
 - Frozen storage until preparation for analysis.
 - 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.
 - Property of Idal. 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.

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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, 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.

15.8.4.1.3 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 packages shall have initials or other identification across the heat 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, however exceptions may be made as required. ISP Forensics may provide a proper seal by: (1) placing a piece of evidence tape perpendicularly across the seal with the initials of the person receiving the evidence if the seal is lacking initials. If the seal is not adequate, clear packing tape may be placed over the first seal (this makes it possible to see how the evidence was received), and then evidence tape is placed perpendicularly across the packing tape and initialed to provide the seal or (2) resealing the complete package in a heat sealed envelope or other container with proper initials. Forensic Services shall ensure that evidence stored in ISP vaults is properly sealed.

15.8.4.1.6 If toxicology collection kits are received with the Evidence Submission form sealed inside the box with the evidence, the seal may be broken to retrieve the form and the

item resealed before storage in the vault.

- **5.8.4.2** Evidence not in the process of examination is maintained in a secure and limited-access storage area.
- **5.8.4.3** Forensic Services creates and implements quality procedures to prevent loss, damage, or deterioration of evidence and to secure unattended evidence while being examined.

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15.8.4.3.1 Evidence shall be maintained under the control of the party currently responsible for it according to the chain of custody. Evidence vaults, individual evidence lockers, and jointly controlled evidence storage facilities are provided so that staff, as appropriate, can maintain control of evidence in their custody. However, during the process of examining evidence, if an examiner needs to leave for a short time such as for lunch, it is not necessary to return the open evidence to a secured storage location if it is in a secure area. This is also true for large or cumbersome items or evidence requiring extended processing time. In process evidence does not have to be sealed. Refer to procedure (15.3.4.1.2 visitor procedure) for instructions on evidence handling when there are visitors in the lab.

15.8.4.3.2 Diligence shall be exercised to ensure that evidence is protected from loss, contamination, deleterious change, and/or cross transfer and thereby diminish the

value of the evidence or its analysis.

15.8.4.3.3 Prior to the forensic scientist returning evidence to an FES, the forensic scientist shall seal the evidence with evidence tape and date and initial the evidence tape unless for some reason it is not practical to seal the evidence.

15.8.4.3.4 Evidence shall be returned only to a party having legal responsibility. Generally,

this is a representative of the submitting agency.

15.8.4.3.5 Unless a written request is made to return a urine sample, Forensic Services will dispose of such after 90 days from the date of report. 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 Controlled substance evidence shall not 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 you analyze one heroin balloon out of an evidence envelope that contained three balloons, you may need to put the article that was analyzed 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, cross transfer, contamination and/or deleterious change, whether in a sealed or unsealed container, during transportation to an evidence facility. Where appropriate, further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. Forensic Services does not generally transport evidence; however, on rare occasion it may be necessary for forensic laboratory staff to transport evidence. These exceptions need to be authorized by the Lab Manager. The Lab Manager may also delegate the authority to make this exception in their laboratory. Evidence collected from a crime scene shall be appropriately identified, packaged and entered into the evidence control system as soon as practical.
- 5.8.4.7 Forensic Services creates and implements policies and procedures for the operation of individual characteristic databases (ICD). When ICD samples are treated as evidence, the policies and procedures for handling evidence contained in section 5.8/15.8 are followed. Procedures for handling ICD samples when they are treated as reference samples are included in appropriate analytical methods.
- 5.8.4.7.1 Forensic Services has established which individual characteristic database (ICD) samples are treated as evidence and which are treated as reference materials. Some ICD samples can be treated as evidence and other ICD samples as reference materials within the same ICD collection provided that this is clearly documented, there is an identifiable difference between the these categories, individuals who work with the ICD understand which categories of ICD samples are evidence verses reference materials, and each category of ICD samples are treated appropriately as described in this policy/procedure.
 - 15.8.4.7.1.1 Each CODIS ICD sample obtained from a convicted offender in conjunction with Idaho Code 19-5506 shall be treated as reference material.
 - 15.8.4.7.1.2 Each CODIS ICD sample obtained from casework shall be treated as evidence.
 - 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 director.
 - 15.8.4.7.4Access 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.

ASSURING THE QUALITY OF EXAMINATION RESULTS 5.9

Forensic Services creates and implements quality procedures that are utilized to monitor 5.9.1 the reliability of testing results. The resulting data is recorded and maintained so that trends are detectable over time. Where practical, statistical techniques are used in reviewing results. Analytical testing is monitored using quality controls appropriate to the examinations. The range of quality control activities employed by Forensic Services may include, but is not necessarily limited to the following:

a) Reference collections;

b) Regular use of certified reference materials and/or internal quality control using secondary reference materials;

c) Statistical tables;

d) Positive and negative controls;

g) Participation in proficiency-testing programs,
h) Replicate examinations using the same
i) Retesting of eviden h) Replicate examinations using the same or different analytical methods;

j) Correlation of results for different characteristics of an item;

- k) Independent checks by other authorized personnel (technical review and verification).
- Ouality control data is evaluated and where data is found to be outside pre-defined 5.9.2 criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported.
- Forensic Services creates and implements a documented program of proficiency testing. 5.9.3

15.9.3 PROFICIENCY TESTING

- 15.9.3.10 Proficiency testing is an integral part of a quality program. To obtain the maximum benefits from proficiency testing, Forensic Services shall emphasize the educational aspects of the program rather than punitive aspects when taking any corrective action.
- Proficiency testing objectives: 15.9.3.2
 - Verify that analytical methods are valid.
 - Ensure that quality work is being performed.
 - Identify areas where additional training would be beneficial.
 - Demonstrate the competence of the analytical system, i.e. examiner and technical reviewer.

Accuracy of results: 15.9.3.3

Results are correct if they meet any of the following criteria:

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

15.9.3.4 Responsibilities of the quality manager.

- 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.
- 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 is always required when evaluating DNA proficiency tests.

15.9.33 Responsibilities of the discipline leader:

- Deciding what proficiency tests are required for the discipline and for specific individuals.
- 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 that laboratory
- Ensuring that proficiency tests are done in a timely manner and forwarded to the quality manager for submission to the external provider.

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15.9.3.7 Responsibilities of the analyst:

• All analysts shall participate in at least one proficiency test per year in each subdiscipline (controlled substances, firearms, forensic biology, etc.) in which he/she performs casework analysis. DNA analysts shall participate in proficiency tests in accordance with the current national DNA guidelines.

• Except for justifiable circumstances, proficiency tests shall be submitted to the provider by the stated due date. When such cannot be met, an analyst shall notify his supervisor and the quality manager before the due date and get an extension for completing a proficiency test, if necessary.

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

15.9.3.1.1 A proficiency test shall be treated like a routine case as much as possible.

This includes logging it in as a case, storing it as a case, providing normal chain of custody, and performing the routine administrative and technical review.

Examiners shall bring to bear whatever procedures and protocols they
possess to derive correct answers to the questions posed by the
proficiency test. All parts of a proficiency test shall be examined as
completely as approved analytical methods allow.

Quantitation of controlled substances proficiency tests shall not be performed unless the provider will be providing an evaluation of the quantitative results.

• Multiple analysts may perform different parts of the examination of a proficiency test if that is how casework is examined.

15.9.3.1.2 Proficiency test samples may be used as training samples or for competency testing.

15.9.3.1.3 Scientific Research Tests are not treated as proficiency tests.

5.9.3.2 The Forensic Services proficiency testing program complies with the ASCLD/LAB 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

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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.
- 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 Ouality 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;
- i) Details of the corrective actions taken (when necessary).
- 5.9.3.6 Proficiency testing records are controlled as quality records (section 4.13) and must be retained at least one full ASCLD/LAB-International accreditation cycle.
- Technical Review: Forensic Services creates and implements, a quality procedure for the 5.9.4 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.

Technical verification is a process of independently performing a comparison or 15.9.4.1 analyzing evidence to determine if the reviewer comes to the same conclusion regarding the analysis as the analyst.

Technical review is a review of the examination documentation and the 15.9.4.2 conclusion (s) expressed in the report of analysis. The reviewer must ensure that the

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conclusions are reasonable, within the range of conclusions for the analytical method (s) followed, and supported by the examination documentation

The reviewer must ensure that the analytical methods used were appropriately followed and the examination was within the scope of the method.

The reviewer must also ensure that the details of all the tests and observations are described in the notes and that all centrally stored examination documentation is appropriate and properly filed. The review shall include a cheek of calculations and testing data transfers unless the calculation and/or data transfer is performed in an automated manner that has been validated.

Technical review must be performed in every case for which a report is issued including negative and inconclusive results. The review must be performed before the report of analysis is released. Discrepancies found during technical review or differences of opinion regarding the acceptability of the examinations and/or the content of the report must be resolved before a report can be released. If differences of opinion between the technical reviewer and the analyst cannot be resolved during the technical review, then the policy regarding conflict resolution must be used to resolve the difference of opinion (15.9.4.3) before the report is released.

Technical review is documented by the initials of the technical reviewer and the date of the review and is maintained with the case file.

15.9.4.3 Conflict resolution: If differences in interpretation between the casework analyst and either the technical reviewer or discipline leader cannot be resolved during a review of casework analysis, the following process shall be followed:

 Mediation by a mutually agreed upon individual who is experienced and performs technical review in that casework analysis.

• Formation of a review committee: If the parties involved in the mediation cannot resolve their differences in interpretation, they shall notify their immediate supervisor and laboratory manager. The laboratory manager shall contact the quality manager to arrange the formation of a review committee within ten (10) days. The majority of the review committee shall be individuals who are experienced in the particular casework analysis in dispute. The quality manager may 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

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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 reviewers 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 inderstands 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 methods.
- A checklist with sign-off shall be supplied to the reviewer with each case.

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- The checklist shall contain sufficient detail to establish that the conclusion is justified by the examination documentation and that the appropriate Forensic Services analytical methods were followed. The checklist shall be approved prior to any external technical reviews by the discipline leader or lab manager, whichever is appropriate.
- 5.9.5 Administrative Review: Forensic Services creates and implements a quality procedure that requires administrative review of all case files prior to the release of analytical reports.
 - 15.9.5 Administrative Review is a review performed to ensure that the laboratory reports issued by the staff of Forensic Services are editorially correct and to ensure that the laboratory reports and their examination records are consistent with Forensic Services policies. Administrative review is documented by the initials of the administrative reviewer and date of review and is maintained with the case file.
 - 15.9.5.1 Though different employees may be involved in the final compilation of a case report, the individual who signs it as the author (i.e. affidavit/attestation), is ultimately responsible for the contents of the report, and the accuracy of the information presented in the report.
 - 15.9.5.2 Someone other than the analyst who performed the analysis and wrote the examination report must administratively review each examination report or crime scene report and this administrative review must be documented. Typically, the administrative review is performed during the technical review. The individual who performs administrative review shall be familiar with Forensic Services note taking and documentation requirements. Additional administrative reviews may be performed as desired.
 - 15.9.5.3 The report and documentation shall be reviewed for conformance to casework documentation guidelines and quality policies and procedures.
 - The report shall be reviewed for consistency with accepted conventions for spelling, grammar and word usage.
 - 15.9.5.5 The information from ETS in the report shall be reviewed to ensure that the report accurately reflects information provided by the agency on the submission form.
 - 15.9.5.6 The accuracy of the evidence description in ETS and the electronic chain of custody are checked by a FES and this is documented by initialing or signing the electronic chain.
- **5.9.6** Forensic Services creates and implements a quality procedure whereby the testimony of all testifying personnel, who offer expert opinions in court, is monitored on an annual basis

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, questionnaire, 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 courtroom evaluation indicates any issues in the testimony that require remediation. If the issues were of a minor nature, remediation would consist of feedback during the peer review process.

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.

5.10 REPORTING THE RESULTS

5.10.1 Each examination is reported clearly, accurately, objectively, and unambiguously as is possible within the constraints of scientific knowledge/opinion and in accordance with any specific instructions in the analytical method. All examinations are reported except those performed to provide information for use in investigative databases (e.g. CODIS or NIBIN).

Results of examinations are reported in a Forensic Services examination report. Reports include all information necessary to interpret results along with other information that may be required by Forensic Services quality procedures. (Examination reports are issued as hard copy; however, electronic copies may be available.)

Customers implicitly agree to the Forensic Services report format and content when they submit evidence for examination and complete the submission form (See section 4.4.). Forensic Services chooses to include some information required by ISO/IEC 17025:2005(E) in the report, while other information is available in the case file or at the laboratory.

- **5.10.2** The examination report contains the following information unless notation specifies that the information is in the case file or retained at the laboratory:
 - a) A title:
 - b) Name and address of laboratory, and location where examination(s) were carried out if different from the address of the laboratory;
 - c) The laboratory case number on each page such that the page is recognized as a part of the report; and the end of the report is identified by the analyst's signature;
 - d) Name of the submitting agency; the address of the submitting agency is on file;
 - e) Tests performed are contained in the case file;
 - f) A description of, the condition of, and unambiguous identification of the item(s) tested; (A more detailed description may be in the notes. The condition of the item will be in the case file unless the condition of the evidence is material to the interpretation of the examination report.)
 - g) Date of receipt of evidence is in the examination report; the date(s) of analysis is found in the examination documentation;
 - h) Reference to sampling plan where this is relevant to the validity or application of results;
 - i) Examination result and, where appropriate, units of measurement;
 - j) The name(s), function(s) and signature(s) of the examiner. When an analyst trainee performs analysis, both the trainee and the supervising forensic scientist must sign the written report;

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.

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- **5.10.4** Forensic Services does not issue calibration certificates and therefore does not have quality policies pertaining to the issuance of calibration certificates.
- **5.10.5** Opinions and interpretations are clearly marked as such in an examination report and the basis for the opinions and interpretations is documented in examination record. When opinions and interpretations contained in examination reports are expressed verbally to the customer, the essence of the conversation is recorded.
 - 15.10.5 All reports containing opinions and interpretations will contain a disclaimer stating, "This report does or may contain opinions and interpretations of the undersigned analyst based on scientific data." If opinions or interpretations are expressed verbally to a customer, the essence of the conversation will be recorded. These records will be maintained as an administrative record in the case file.
- 5.10.6 It is clearly noted in the examination report from Forensic Services when results from a subcontractor or any other independent laboratory are included or referenced in an examination report issued by Forensic Services. Subcontractors issue reports of examination either in writing or electronically.
- 5.10.7 When sending reports of examination by fax, accurate reproducibility is verified and reasonable precautions are taken to ensure that the report is being transmitted to an appropriate receiver. (See section 14.1.5 c.5 14.1.5 c.9 and 5.4.7.2)
 - 15.10.7.1 Examination reports are faxed to parties authorized to receive them in accordance with 4.1.5 c) and to fax numbers that have been verified as belonging to appropriate receivers. (This can be an informal process and the sender just needs to be reasonably certain that they are sending results to a party that is entitled to them by a fax number that the sender reasonably believes to be appropriate.)
 - 15.10. The fax of an examination report addresses a particular person and includes a confidentiality notice and the total number of pages being sent. A record of what was faxed is retained in the case file. This record indicates the phone number the fax was sent to, the total number of pages in the transmission, and the success of the transmission.
 - 15.10.7.3 The sender verifies that the fax of an examination report was successful by reviewing the fax transmission report for the number of pages sent and an indication that the transmission was successfully sent.
- **5.10.8** The report format is designed to accommodate the examinations performed. The format should have a clear presentation and allow for ease of assimilation by the reader to

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minimize the possibility of misunderstanding or misuse.

- **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 obligation to ensure that an incorrect report does not leave the laboratory. However, if it is necessary to make material amendments to a report, an amended report shall be issued. The heading for the amended report shall contain the words "Amended Report." At the beginning of the amended report, a paragraph shall be inserted that describes the changes made in the amended report. 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. 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 amended 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 amended." Only the amended report shall be stored electronically in the evidence tracking system.

6.1 PERSONNEL POLICIES

- 6.1.1 Offices shall observe Official State of Idaho business hours, which are Monday through Friday from 8:00 A.M. until 5:00 P.M. The standard work schedule may be altered if authorized by the Major/Manager.
- **6.1.2** Identification shall be worn at the ISP facility in Meridian.
- 6.1.3 Guidelines for interns (Laboratory managers can make exceptions to these guidelines if appropriate.):
- 6.1.3.1 Shall be non-funded positions.
- Chosen on a first-come, first-serve basis. 6.1.3.2
- Chosen on a mst-come, mst-serve basis.

 Shall be college juniors and above interning for college credit toward a degree in Chemistry, 6.1.3.3 Biology, Molecular Biology, or a closely related science or shall already possess a degree in one of the above areas.
- Have a recommendation from a professor, faculty advisor, or other professional. 6.1.3.4
- Pass background check and polygraph. 6.1.3.5
- Shall only be accepted if a forensic scientist or Laboratory Manager volunteers to supervise 6.1.3.6 and mentor the individual. Upon approval from the Laboratory Manager, specific duties of interns shall be left to the discretion of their supervising forensic scientist.
- Shall remain under the close supervision of a forensic scientist at all times. 6.1.3.7
- Shall become familiar with ISP Procedures governing conduct and confidentiality and 6.1.3.8 Forensic Services health and safety policies.
- Shall not participate in crimes scene investigations including clandestine drug 6.1.3.9 laboratories unless accompanied by a forensic scientist. Access to very sensitive or hazardous areas shall not be permitted.
- May attend autopsies when accompanied by a forensic scientist. 6.1.3.10
- Shall not be allowed in any area of the laboratory after business hours unless 6.1.3.11 accompanied by a forensic scientist.
- Shall not be involved in the analysis of evidence. No exceptions are permitted. 6.1.3.12

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 Intoxilyzer or Alco-Sensor 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.
- 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.

6.3 CRIME SCENES AND CLANDESTINE LABORATORY CALL-OUT AND ASSISTANCE

- 6.3.1 The Idaho State Police Forensic Services shall provide support at crime/clan-lab scenes subject to the following guidelines.
- **6.3.2** The following are recommended guidelines for responding to crime scenes:
- When assistance is requested, determine the nature of the crime, the agency and officer requesting laboratory assistance, and any other information that may help identify the needs of personnel at the scene. Notify the Major/Manager or his designee, relaying the above information. The forensic scientist, Lab Manager, or Major/Manager may then contact the regional captain of ISP Investigations and communicate pertinent information and request for assistance.
- 6.3.2.2 If Forensic Services elects to respond, they shall notify additional forensic scientists who may be of assistance at the scene and proceed to the laboratory to collect any required supplies.
- 6.3.2.3 Forensic Services personnel shall identify themselves to law enforcement personnel who are present at a crime scene.
- 6.3.3 When crime scenes represent a security threat, law enforcement personnel shall secure the scene prior to laboratory personnel becoming involved on-site. Forensic Services personnel shall not remain at a crime scene or clandestine lab if insufficient law enforcement officers are present to maintain security. When the security of a crime scene or clan lab becomes uncertain or safety conditions become compromised, Forensic Services personnel may immediately leave the premises. The forensic scientist shall notify the appropriate authorities as to the reason the departure was necessary.
- 6.3.4 Only trained clandestine laboratory personnel shall be allowed to enter a suspected clandestine laboratory site. Forensic scientists so trained shall have completed the requisite course-work as outlined by Forensic Services and the Department. Prior to entry into such, Forensic Services personnel shall put on clothing and safety equipment commensurate to the circumstances. Prior to entering a potential laboratory, Forensic Services personnel shall ensure that fire and safety personnel have been notified or are present.
- 6.3.5 Only the minimum quantities of clandestine laboratory products, precursors, or equipment shall be collected by Forensic Services personnel assisting at these scenes. Samples collected at clandestine laboratories shall consist of only a few milliliters of liquids or a very few grams of solids.
- 6.3.6 Forensic Services shall not accept responsibility for, or transport of, chemicals, equipment, etc. collected at clandestine laboratory scenes. To maintain a safe work environment, Forensic Services will not accept large quantities of chemicals, solutions or equipment seized at

6.3 – Crime Scene and Clandestine Laboratory Call-Out Page 1 of 2

clandestine laboratories. Forensic Services shall not accept responsibility for destruction or storage of any chemicals collected at such scenes.

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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 Jeans or other casual pants are acceptable in the laboratory. Pants shall be in good condition with no holes and no stains.
- Polo shirts are acceptable for wear in the laboratory. They shall be in good condition with no holes or stains. T-shirts are not acceptable.
- 6.4.3.3 Shoes (conservative in appearance) shall be protective of the feet, provide support and cushion when working or standing on hard surfaces, and provide a gripping surface on the floor.
- 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). However, FES shall wear a smock or laboratory coat over the their casual attire while in the front office.
- 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.