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Idaho State Police

Forensic Services

Quality Manual

Quality Manual
ISP Forensic Services

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1
INTRODUCTION

1.1 Quality assurance is a basic function and responsibility of each member of ISP Forensic Services. A rigorous quality assurance program is a major tool to ensure that ISP Forensic Services is providing quality services to the criminal justice system. This quality manual is issued to describe the quality assurance system of the ISP Forensic Services in compliance with the general quality system requirements of ASCLD/LAB.

1.2 The staff of ISP Forensic Services is expected to adhere to the current, approved documents of the quality system including but not limited to the ISP Forensic Services Procedure Manual, the Quality Manual, Training Plans, the analytical SOPs, etc.

1.3 The purpose of ISP Forensic Services is to provide quality and impartial scientific analysis, testimony, crime scene investigation, education, and research to the criminal justice system.

1.4 Forensic Services provides scientific analysis on physical evidence. At the time this section of the quality manual was last revised, it provided examinations in the following areas:

1.4.1 Examination of fire evidence and other volatiles.
1.4.2 Alcohol program: performing quantitation of alcohol in blood, urine, other body fluids, liquor samples, and administration of the breath alcohol program.
1.4.3 Forensic biology (DNA and serology).
1.4.4 Identification of drugs in liquid and solid form.
1.4.5 Firearm and tool/toolmark examinations.
1.4.6. Trace evidence examinations. Examples are hairs, fibers, and filament on/off.
1.4.7 Impression evidence (footwear and tiretracks) to determine type and/or brand, and comparisons of questioned to known.
1.4.8 Toxicology analysis such as analysis of urine and blood for drugs and/or metabolites.
1.4.9 Latent print comparisons.

1.5 ISP Forensic Services provides services to the following agencies:

1.5.1 Law enforcement agencies, primarily state and local agencies.
1.5.2 Prosecutors.
1.5.3 Public defenders.
1.5.4 Other entities by court order.

1.6 The basic components of the quality assurance program are as follows:

1.6.1 Audits and inspections.
1.6.2 Case documentation and review.
1.6.3 SOPs and training manuals.
1.6.4 Employee training, both initial and on-going.
1.6.5 Identification and correction of problems.
1.6.6 Competency testing and proficiency testing.
1.6.7 Documented instrument calibration and maintenance.
1.6.8 Technical leaders and technical groups.
1.6.9 User agency feedback.
1.6.10 Validation of new procedures.
1.6.11 Quality control of standards, controls, and reagents.
1.6.12 Monitoring court testimony.

2
QUALITY ASSURANCE POLICY STATEMENT AND OBJECTIVES

2.1 Policy Statement: ISP Forensic Services is committed to providing excellent service to the criminal justice system. To accomplish this, a quality system has been established by ISP Forensic Services. This applies not only to casework analysis, but also to written reports, testimony, training provided, and support of the breath alcohol program.

The management of ISP Forensic Service fully supports the objectives of the quality program as outlined below. The position of quality manager was created to provide leadership in achieving these objectives and to serve as quality manager for all three laboratories of ISP Forensic Services.

2.2 The objectives of the quality assurance program are to:

2.2.1 Maintain and continuously improve the quality of service provided to the criminal justice system in Idaho.

2.2.2 Develop and utilize new technology to improve the quality and efficiency of the analysis of physical evidence.

2.2.3 Take appropriate measures to protect all evidence from contamination, deleterious effects, and loss. Ensure that an appropriate chain of custody is maintained for all evidence.

2.2.4 Enhance the analytical capabilities of the professional staff through training, etc.

2.2.5 Identify quality related problems in all areas of operation and take corrective action to prevent their reoccurrence.

3
ORGANIZATION AND MANAGEMENT STRUCTURE

3.1 The organization and structure of ISP Forensic Services appears in the most current edition of the ISP Forensic Services Procedure Manual.

3.2 The relationship of ISP Forensic Services to the parent agency, ISP, appears in the departmental procedure manual.

4
JOB DESCRIPTIONS, EDUCATION, TRAINING, AND TRAINING RECORDS

4.1 Job descriptions for all positions are available at the DHR Website.

4.2 The education of each employee who ultimately will perform case analysis will be verified prior to being hired by ISP Forensic Services. A copy of the college transcript and proof of graduation shall be retained by the quality manager for those individuals for whom college graduation and/or proof of taking specific college courses is a requirement of employment.

4.3 Training:

4.3.1 All the steps in the training plan will be documented as they are completed. Training should include but is not limited to the following items (Training does not have to proceed in the order of 1, 2, etc, but all aspects of training must be covered to the extent necessary with a particular analyst to ensure that he/she understands and knows the material):

4.3.1.1 General knowledge of forensic science and ISP Forensic Services practices and procedures such as maintaining chain of custody, writing notes and reports, safety, observation, quality practices, etc.

4.3.1.2 The scientific theory on which the examination(s) is based.

4.3.1.3 The theory and operation of the instrument(s) used.

4.3.1.4 Practice in using the standard operating procedure/standard operating procedures(SOP).

4.3.1.5 Performance of the SOP(s) on actual case material under close supervision.

4.3.1.6 Competency tests on simulated case material.

4.3.1.7 Mock court or proof of experience in testifying.

4.3.2. Documentation: The technical leader/supervisor will review all the documentation regarding the training of an individual for a specific examination once the training is completed. The technical leader/supervisor will either approve an analyst to perform casework analysis in the area for which the training was provided or recommend additional training. The written approval along with the training checklist shall be forwarded to the appropriate lab manager, the quality manager, and the ISP Forensic Services major/manager for review and acknowledgement.

4.4 The quality manager will maintain the documentation for all training of each employee, if practical. A summary, only, of casework training will be in this central file if it is impractical to store all of the documentation in this central training file.

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

4.5 Training plan:

4.5.1 A training plan shall be developed and updated as required by the technical leader/supervisor. The training plan will be based on the relevant SOP(s). All the knowledge, skills and abilities necessary to perform casework analysis should be included in the training program.

This quality policy applies only to training plans created or revised after the approval date for this quality policy.

4.5.2 Format:

4.5.2.1 Cover.

4.5.2.2 History page. This would provide a list of revisions, the revision date, and the date accepted.

4.5.2.3 The training plan will be in the form of a checklist that can be signed or initialed containing a list of appropriate topics.

4.5.2.4 The numbering system: Section one will be 1; Topic 1 will be 1.1; and Item 1 will be 1.1.1, etc.

4.5.2.5 Table of contents: Each training plan will have a table of contents after the history page (s).

4.5.2.6 Introduction: Each training plan will have an introduction on the third page inside the cover.

4.5.2.7 If the sign-off is for a section of an SOP rather than a task, the SOP section should be listed.

4.5.2.8 References may be included at the end of each training section. If included, they can be general reference books or references to very specific sections of literature. At the discretion of the technical leader/supervisor, literature references may include a sign-off.

4.5.2.9 Each page of a training manual will have the date issued and the revision number (rev. #) in the bottom right hand corner.

4.5.2.10 An approval page.

4.5.3 An on-site trainer or the technical leader/supervisor may administer the training plan to an individual. However, the technical leader/supervisor will be ultimately responsible for insuring that the individual who was trained has obtained the knowledge, skills, and ability needed to perform a particular casework analysis and testify in regards to that analysis.

4.5.4 Approval:

4.5.4.1 The draft of the training plan will be circulated to all the managers, the quality manager, and the staff who will be using the training plan for review and comment before the training plan is finalized.

4.5.4.2 The final draft of the training plan will be approved when the appropriate technical leader/supervisor and the quality manager approve the document by

signing and dating it. The technical leader/supervisor should inform the appropriate staff, the managers, and the major/manager when the training plan is approved. The training plan will be implemented only after it has been approved.

4.6 Each staff member is responsible for updating his/her training record on file with the quality manager.

5
EMPLOYEE DEVELOPMENT PROGRAM

5.1 ISP Forensic Services encourages staff members to develop their potential by identifying training needs and taking advantage of opportunities for professional development. ISP Forensic Services management in conjunction with the technical leaders/supervisors, will conduct an annual training needs assessment of employees and laboratories.

5.2 Employee development plan: An employee development plan shall be written as part of the annual evaluation of each employee. The employee is responsible for developing the plan and is encouraged to seek input from the supervisor. This plan must be compatible with the mission of the laboratory, ISP Forensic Services, and the department. It should be included with the annual evaluation. The plan should be based on mutually accepted objectives and should include provisions independently addressed by the employee as well as provisions requiring agency support. The plan from the previous year should be assessed as part of the evaluation process. The new plan may build on or enhance the plan from the previous year.

5.3 Career advancement/enhancement opportunities:

5.3.1 Career advancement/career enhancement is available from a wide variety of sources.

5.3.1.1 Professional meetings such as the NWAFS or AAFS.

5.3.1.2 Seminars.

5.3.1.3 Short courses such as those provided by instrument companies.

5.3.1.4 Training provided by the DEA, FBI, CCI, or other governmental entities.

5.3.1.5 Private vendors offering courses in computer software use, career enhancement, etc.

5.3.1.6 Department and the Division of Human Resources training.

5.3.1.7 College courses.

5.3.1.8 Annual discipline meetings.

5.3.1.9 On-the-job training.

5.3.2 ISP Forensic Services will pay all costs associated with taking the ABC test and the annual certification fee for maintaining certification. Forensic Services will also pay for approved attendance at seminars, etc., necessary to maintain certification.

5.3.3 ISP Forensic Services supports the training of its employees in supervision and management to facilitate succession planning and career enhancement.

5.4 Application and Follow-up to employee development opportunities:

5.4.1 Typical application process:

5.4.1.1 Staff members interested in attending training should apply for training using the

ISP training request or its current equivalent. The immediate supervisor must approve this training request.

5.4.1.2 The technical leader/supervisor must approve employee training for personnel in his/her area of leadership.

5.4.1.3 The training request should be submitted to the quality manager who will forward it to the major/manager for approval.

5.4.1.4 The request will be approved or denied by the major/manager based on considerations such as need, budget (current funding situation), and caseload demand.

5.4.1.5 Applicant will be informed whether his/her request for training was approved or denied.

5.4.1.6 Application for college classes will follow ISP procedure.

5.4.2 Standard follow-up to development opportunities:

5.4.2.1 Forward the Record of Training, a description of the training and a short evaluation of the training to the quality manager.

5.4.2.2 Summarize the training for other staff members who would benefit. You will typically prepare a written report for other staff members. However, you could make a verbal report by conference call or at a meeting should that prove to be a better way to present the training.

5.5 Certification:

5.5.1 ABC certification as a Diplomate should be obtained after two years of performing forensic scientist responsibilities.

5.5.2 Obtain appropriate advanced certification as employees progress through the ISP Forensic Services job series.

6
STANDARDS, CONTROLS, AND REAGENTS

6.1 Definitions:

6.1.1 Reference Standard (standard): "A sample acquired or prepared that has known properties (e.g., concentration, chemical composition) for the purpose of calibrating equipment and /or for use as a control in experiments." This definition is from the glossary of the 2000 version of the ASCLD/LAB manual.

6.1.2 Quality control sample (control): Evaluation sample used to check, test, or verify.

6.1.3 Reagent: "A substance used because of its chemical or biological activity." This definition is from the glossary of the 2000 version of the ASCLD/LAB manual.

6.1.4 Critical reagent: "Determined by empirical studies or routine practice to require testing on established samples before use in order to prevent unnecessary loss of sample." This definition is taken from the FBI DNA Quality Assurance Audit Document, issue date 08/29/00 (Rev. #3).

6.2 Standards and quality controls specimens:

6.2.1 Whether prepared in-house or obtained from commercial sources, standards and control specimens must be authenticated.

6.2.2 A record must be maintained in the casework documentation of the results obtained for standards and quality control specimens.

6.2.3 Each standard operating procedure (SOP) should specify the standards and quality controls to be used, how standards/quality control specimens are authenticated, and the range of acceptable results for the standard and control specimen(s) if appropriate.

6.3 Reagents:

6.3.1 All reagents must be labeled with the identity of the reagent and the date of preparation or lot number. The initials of the preparer are suggested but not mandatory.

6.3.2 Length of time the reagent is dependable and special storage or handling requirements should also be noted on the container if applicable.

6.3.3 Reagents must be tested to determine if they work as expected to check the reliability of the reagent.

6.3.3.1 Some reagents are prepared in batch and used for extended periods of time without being tested with a standard or control each time they are used. Examples of this type of reagent are the Marquis reagent or the Duquenois reagent. These reagents must be tested before use and on a periodic basis to be determined by the appropriate technical leader/supervisor.

6.3.3.2 Other reagents are tested with a control each time they are used such as phenolphthalein. Therefore, these reagents do not require periodic testing. These results must be documented.

6.3.3.3 A critical reagent must be tested prior to use in casework analysis. It is the responsibility of each technical leader/supervisor to determine which reagents are critical as defined above in the SOPs performed by his/her area of responsibility.

6.3.4 Record(s) must be maintained for reagent preparation containing, at a minimum the following components (These records are not necessarily in the same place.):

6.3.4.1 The name and recipe for the reagent.

6.3.4.2 The date of preparation.

6.3.4.3 Identification of the preparer.

6.3.4.4 The results of testing the reagent.

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

6.3.6 Reagents of questionable reliability or that are expired will be discarded.

7
CALIBRATION AND MAINTENANCE OF EQUIPMENT

7.1 Definitions:

7.1.1 Calibration: For the purposes of this quality manual, calibration refers to the checking, adjusting, or standardizing of any instrument and/or equipment to ensure agreement with a measurement standard of known value.

7.1.2 Maintenance: For the purposes of this quality manual, preventive maintenance refers to actions taken to ensure that equipment continues to operate properly. Repairs are performed on items to restore them to proper operation.

7.2 Calibration and maintenance standards:

7.2.1 Standards traceable to national or international standards, certified reference materials, or well-documented materials provided by the manufacturer or a third party will be used for calibration if possible. When commercial reference materials are not available, a laboratory-prepared calibration standard may be used. The technical leader/supervisor of the discipline will ensure that the properties and characteristics of the laboratory-prepared calibration standard are suitable for its intended purpose.

7.2.2 The materials used as references for maintenance checks must either be well documented by the supplier or be checked prior to using.

7.3 Instruments that have undergone repair or preventive maintenance that could change the calibration will be calibrated before being used in casework analysis.

7.4 All calibrations will be performed in accordance with the documented calibration procedure on or close to the scheduled interval if the instrument is being used for casework analysis. This procedure will reflect the current calibration requirements based on the use of the instrument/equipment. A calibration procedure may be included in the standard operating procedure (SOP) in which the instrument/equipment is used, may be an in-house procedure included with the calibration log, or may be a manufacturer supplied procedure for calibration.

7.5 A calibration log must be kept for all pieces of equipment for which calibration should either be checked or adjusted on some routine basis.

7.5.1 The log will be used to document all calibrations.

7.5.2 This log must contain the following documentation, at a minimum:

7.5.2.1 The type of instrument and its unique identification.

7.5.2.2 The calibration procedure or a copy if from an external source and not in the appropriate SOP(s).

7.5.2.3 The acceptance criteria for calibrations, if applicable.

7.5.2.4 Appropriate interval of calibration.
7.5.2.5 Regarding each calibration: date of calibration, results of calibration, reference standard, and initials of individual performing calibration.

7.6 Preventive maintenance procedures should be performed in accordance with the procedure and on or close to the schedule documented in the maintenance log.

7.7 A maintenance log must be kept for all pieces of equipment that may require preventive maintenance or repair.
7.7.1 The log will be used to document all maintenance performed on the piece of equipment.
7.7.2 The log must contain the following documentation at a minimum:
7.7.2.1 Type of instrument and unique identifier.
7.7.2.2 The preventive maintenance procedure (s) or a copy if from an external source.
7.7.2.3 Schedule for preventive maintenance.
7.7.2.4 The acceptance criteria if applicable for a maintenance procedure.
7.7.2.5 Preventive maintenance performed, date, and initials of individual performing preventive maintenance.
7.7.2.6 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.

7.8 New instrument/equipment shall not be used for casework analysis until the technical leader/supervisor has approved the calibration procedure and log, the maintenance procedure and log, and confirmed that the validation and the appropriate calibration and maintenance has been performed.

7
CALIBRATION AND MAINTENANCE OF EQUIPMENT

7.1 Definitions:

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7.2.2 The materials used as references for maintenance checks must either be well documented by the supplier or be checked prior to using.

7.3 Instruments that have undergone repair or preventive maintenance that could change the calibration will be calibrated before being used in casework analysis.

7.4 All calibrations will be performed in accordance with the documented calibration procedure on or close to the scheduled interval if the instrument is being used for casework analysis. This procedure will reflect the current calibration requirements based on the use of the instrument/equipment. A calibration procedure may be included in the standard operating procedure (SOP) in which the instrument/equipment is used, may be an in-house procedure included with the calibration log, or may be a manufacturer supplied procedure for calibration.

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7.5.2.1 The type of instrument and its unique identification.

7.5.2.2 The calibration procedure or a copy if from an external source and not in the appropriate SOP(s).

7.5.2.3 The acceptance criteria for calibrations, if applicable.

7.5.2.4 Appropriate interval of calibration.
7.5.2.5 Regarding each calibration: date of calibration, results of calibration, reference standard, and initials of individual performing calibration.

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7.7.1 The log will be used to document all maintenance performed on the piece of equipment.
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7.7.2.1 Type of instrument and unique identifier.
7.7.2.2 The preventive maintenance procedure (s) or a copy if from an external source.
7.7.2.3 Schedule for preventive maintenance.
7.7.2.4 The acceptance criteria if applicable for a maintenance procedure.
7.7.2.5 Preventive maintenance performed, date, and initials of individual performing preventive maintenance.
7.7.2.6 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.

7.8 New instrument/equipment shall not be used for casework analysis until the technical leader/supervisor has approved the calibration procedure and log, the maintenance procedure and log, and confirmed that the validation and the appropriate calibration and maintenance has been performed.

7.9 Some instruments are used by multiple disciplines. These disciplines may have different calibration and/or maintenance procedures for the same instrument. These multiple disciplines may perform calibration and/or maintenance using the procedures for only one discipline if those calibration and/or maintenance procedures meet the needs of all the users of the instrument.

7.10 Instruments or equipment known to be out of calibration or not in proper working order must be clearly tagged to so indicate.

8
WRITING STANDARD OPERATING PROCEDURES

8.1 Standard operating procedure (SOP): A written document that specifies the steps, equipment, and materials necessary to perform a task properly. SOPs are written to provide instruction and standardization for activities affecting quality. In ISP Forensic Services, they are used primarily to describe the accepted manner of performing casework analysis. There may be a series of SOPs to cover a discipline.

This quality policy applies only to SOPs created or revised after the approval date for this quality policy.

8.2 Contents of an SOP manual:

8.2.1 Cover.

8.2.2 History page. This will provide a list of revisions, the revision date, and the date accepted.

8.2.3 Table of contents.

8.2.4 Introduction.

8.2.5 Series of SOPs with approvals.

8.2.6 The numbering system: Topic 1 will be 1.1; and Item 1 will be 1.1.1, etc.

8.3 Contents of an SOP:

8.3.1 Background: This section is required but it may be brief. It may refer to the manufacturer's protocol or some other source from which this method was derived. It could in practice contain a variety of openings by way of providing background.

8.3.2 Scope: A description of the purpose of the standard operating procedure. Stated another way, what the SOP is trying to accomplish.

8.3.3 Equipment: This will be a list of the procedure specific equipment needed to perform this procedure. The list of equipment should be as generic as possible. For instance, do not list a piece of equipment as an H-P 6890 gas chromatograph if in fact any GC could perform this procedure. However, if the procedure is based on a specialized piece of equipment that can be obtained only from one source, then that specific piece of equipment should be listed.

8.3.4 Reagents: The next section would be a list of reagents. List the name of a prepared solution or reagent where recipes are described elsewhere. The reagents and equipment section can be combined if both sections are short.

8.3.5 The step by step procedure: This section will vary depending on the SOP and the discipline.

8.3.5.1 The writer needs to strive for the right level of detail. Too much detail makes a SOP too cumbersome. Too little detail leaves out important information that the

person following the SOP needs in order to perform the procedure properly.

8.3.5.2 Include quality criteria as applicable:

8.3.5.2.1 Calibration.

8.3.5.2.2 Blanks, duplicates, standards, and controls.

8.3.5.2.3 Acceptance criteria in regards to quality measures if applicable.

8.3.5.2.4 Other quality measures as dictated by a particular SOP.

8.3.5.3 Instrumental parameters: They should be written as generally as possible, consistent with good laboratory practices. For instance, instead of giving a temperature ramp in full detail for gas chromatography, the writer should focus on the minimum retention time for an analyte of interest or the minimum separation required for two or more analytes of interest.

8.3.6 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 SOP or in some cases, a totally separate SOP. The identification criteria must be included in one of these locations.

8.3.7 References: Often a SOP will be based on some literature reference. If it is not listed in the introduction, then it should be listed here. The references can be listed in the background section if they are few in number and fairly simple. Other suggested references include relevant technical documents, published/accepted methods, in-house manuals, and equipment manuals.

8.3.8 Limitations to the method: Does not need to be a separate section. However, limitations to a method must be listed somewhere in the SOP.

8.3.9 Safety Concerns: Specific or unique safety hazards should be listed as part of the SOP.

8.4 Each page of a SOP will have the date issued and the revision number (rev. #) in the bottom right hand corner.

8.5 Approval:

8.5.1 Each SOP will be approved individually. This will allow individual SOPs to be amended without re-approving the whole SOP manual.

8.5.2 The draft of the SOP will be circulated to all the managers and the staff that will be using the SOP electronically or as a hard copy. The length of time for review is at the discretion of the discipline leader/supervisor, but adequate time should be given for a thorough review by all those concerned.

8.5.3 The final draft of a SOP will be formally approved when the technical leader/supervisor or temporary designee and the quality manager or temporary designee have signed and dated it. The review by the quality manager is to ensure that the SOP has been validated as required, contains the appropriate sections outlined above, and is written to the appropriate level of detail. The analysts who will use the SOP, managers, and the major/manager will be notified of the new/revised SOP.

9
VALIDATION OF NEW OR MODIFIED STANDARD OPERATING PROCEDURES

9.1 New standard operating procedures (SOPs) must be validated prior to being used in casework.

9.2 Modifications of approved SOPs that could potentially have an effect on the outcome of casework analysis performed with the SOP must also be validated. The technical leader/supervisor must decide if a modification to an SOP requires validation.

9.3 The extent and depth of validation studies must be consistent with the novelty of the proposed SOP. Novel SOPs developed independently by ISP Forensic Services would require extensive validation. SOPs widely accepted in the forensic science community that are being adopted by ISP Forensic Services require demonstration that the SOP is accurate and reliable when used by trained ISP Forensic Services personnel.

9.4 The discipline leader/supervisor must approve validation studies. The documentation for this validation must be available for review and will be retained by the technical leader/supervisor.

9.5 New or modified SOPs must be approved according to policy.

9.6 Validation will be carried out following ASCLD/LAB guidelines for validation studies:

9.6.1 The person or team performing the validation must have a complete understanding of the theoretical basis for the method.

9.6.2 The new and the old method must be compared using split samples if a method parallels or supercedes an existing method.

9.6.3 The method should be tested using known samples.

9.6.4 The known samples should be designed to resemble actual evidence materials as closely as possible so that the effects of such factors as matrix, 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.

9.6.5 If the analysis provides quantitative data, the validation study should include an estimation of its accuracy and precision at concentrations which are representative of casework samples.

9.6.6 Exchange of blind and reference samples with another competent laboratory is useful for detecting internal systematic error and is recommended for validation involving quantitative data.

10
PROTOCOL PERMITTING DEPARTURES FROM STANDARD OPERATING PROCEDURES

10.1 The nature of the work in forensic science sometimes presents atypical situations where a Standard Operating Procedure (SOP) does not exactly fit. This policy describes the steps that an analyst must take before departing from an approved SOP.

10.2 Definitions:

10.2.1 Minor deviation: A deviation that would not affect the validation study for the SOP or the accuracy of casework analysis performed using the SOP.

10.2.2 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.

10.3 Practices:

10.3.1 Minor deviation:

10.3.1.1 Analyst realizes that for some reason he/she must depart from the approved SOP. The analyst assesses the situation and decides that the deviation is a minor deviation only.

10.3.1.2 The analyst documents in his/her notes that a minor departure was made, the reasons for the departure, and then initials and dates that note.

10.3.2 Major deviation:

10.3.2.1 The analyst contacts the technical leader/supervisor and explains the deviation. Together they decide whether the departure is a major or minor deviation.

10.3.2.2 If they decide that the deviation is a major deviation, then they must decide if validation is required.

10.3.2.3 If validation is necessary, a validation study following the quality policy for validating new or modified SOPs is performed.

10.3.2.5 The case file must contain authorization for the departure from the SOP by the technical leader/supervisor including a statement about whether validation was needed or not. A report of the validation study should either be in the case file or referenced in the case file if performed.

10.4 SOPs that are created/revised as a result of following this policy should be added to the SOP manual if the SOP has applicability to future casework.

11
PROFICIENCY TESTING

11.1 Proficiency testing is an integral part of a quality program. However, it is not the only indicator of satisfactory performance. To obtain the maximum benefits from proficiency testing, ISP Forensic Services will emphasize the educational aspects of the program rather than punitive aspects when taking any corrective action.

11.2 A proficiency test (s) should 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, analyzing it like a routine case, and performing the normal administrative and peer review.

11.3 Proficiency testing objectives:
11.3.1 Verify that standard operating procedures are valid.
11.3.2 Ensure that quality work is being performed.
11.3.3 Identify areas where additional training would be beneficial.
11.3.4 Demonstrate the competence of the analytical system, i.e. examiner and peer reviewer.

11.4 Accuracy of results: ASCLD/LAB and the proficiency review committees (PRC) have agreed that results are correct if they meet any of the following criteria:
11.4.1 Results agree with the target values.
11.4.2 The answer is correct within the limits of qualifying statements in the conclusion.
11.4.3 The results are consistent with a consensus of the participants from accredited laboratories. A consensus of participants from accredited laboratories is defined as at least 75 per cent of participants from accredited laboratories obtaining the same answer(s) on the proficiency test.
11.4.4 If there is not a consensus of the participants from accredited laboratories, then results cannot be evaluated for discrepancies.
11.4.5 The technical leader/supervisor is responsible for determining the accuracy of the results This is accomplished by comparing the results of an individual to the correct results as defined above.

11.5 Responsibilities of the quality manager:
11.5.1 Procuring tests.
11.5.2. Distributing and tracking tests.
11.5.3 Coordinating responses to the test provider.
11.5.4 Maintaining documentation of proficiency test activities of analysts including the documents from the test provider and the reports submitted to the provider.

11.5.5 In the case where the analyst is also the technical leader, the quality manager will issue the report regarding the accuracy of results obtained in a proficiency test by a particular individual.
11.5.6 Makes certain that the results of proficiency tests are released to ASCLD/LAB as necessary.
11.5.6 Make certain that all criminalists participate in appropriate and timely proficiency tests.

11.6 Responsibilities of the technical leader/supervisor:
11.6.1 Decide what proficiency tests are required for his/her area of responsibility.
11.6.2 Review proficiency test results in his/her area of responsibility.
11.6.2 Issue a report to the analyst's supervisor and the quality manager regarding the accuracy of the results obtained by an individual.

11.7 Responsibilities of the laboratory manager:
11.7.1. Stores the complete proficiency test records for the laboratory.
11.7.2 Ensures proficiency tests are done in a timely manner and forwarded to the quality manager for submission to the external provider and ASCLD/LAB.

11.8 Responsibilities of analysts:
11.8.1 Non DNA analysts: Participate in at least one proficiency test per year in each casework area (controlled substances, hairs, fiber, firearms, etc.) in which he/she performs casework analysis.
11.8.2 DNA analysts: Participate in proficiency tests in accordance with the current national guidelines.
11.8.3 Except for justifiable circumstances, proficiency tests must be completed in time to be submitted to the provider by the stated due date. An analyst must notify his supervisor before the due date and get an extension for completing a proficiency test if for some reason the analyst believes he/she cannot complete the proficiency test on time.

11.9 Proficiency test files will be kept for at least the current year and previous five years.

11.10 A proficiency test may be used for a training exercise or for competency testing. If the proficiency test is so used, the results will be treated like a training exercise or competency test and not a proficiency test.

11.11 Records will not be retained for scientific research tests.

12
CORRECTIVE ACTION

12.1 Analytical deficiencies can be discovered as a result of external or internal audits, proficiency testing, customer complaints, instrumental malfunction (operational difficulties, maintenance problems, or calibration problems), controls giving inappropriate results, peer review, etc. Corrective action will be initiated to correct and prevent the reoccurrence of deficiencies pertaining to the quality of work performed in ISP Forensic Services. Immediate action will be taken to ensure that no analytical results with deficiencies leave the laboratory and/or to prevent additional analytical results from leaving if the result has already been distributed outside of ISP Forensic Services.

12.2 Deficiencies will be classified into one of three classes:

12.2.1 Class one deficiency: The nature and cause of the deficiency raises immediate concern regarding the quality of work. Often these deficiencies are false positives. If these deficiencies are analyst based, proficiency/competency testing will be done as part of the corrective action.

12.2.2 Class two deficiencies: The deficiency is due to a problem which may affect the quality of the work, but is not persistent or serious enough to cause immediate concern for the over all quality of the work product. Often, these deficiencies are false negatives. Proficiency testing/competency testing may be done depending on the nature of the deficiency and the circumstances.

12.2.3 Class three deficiency: The deficiency is determined to have only minimal effect or significance, be unlikely to reoccur, is not systemic, and does not significantly effect the fundamental reliability of the work product. Often, these deficiencies are administrative errors. Typically, they do not require a proficiency test/competency test or formal corrective action.

12.3 Any employee of ISP Forensic Services who identifies a deficiency must report the deficiency to his/her technical leader/supervisor and his/her immediate supervisor immediately. The technical leader/supervisor and the immediate supervisor will evaluate the deficiency. Possible class one discrepancies and possible class two discrepancies will be reported to the laboratory manager, the quality manager, and to the major/manager as soon possible.

12.4 Typical deficiency /corrective action process:

12.4.1 Identification of deficiency, reported through the chain of command, ultimately to the major/manager.

12.4.2 Immediate action to prevent current or future deficient analytical results from being released from ISP Forensic Services. The laboratory manager or his/her

designee should take this action.

12.4.3 A preliminary investigation is performed by a combination of analyst, technical leader/supervisor, immediate supervisor, and/or quality manager.

12.4.4. If the discrepancy is deemed to be a class three discrepancy, the analyst, technical leader/supervisor, and the immediate supervisor can resolve it. The resolution can be informal but documented in writing, and copied to the lab manager and the quality manager.

12.4.5 If the deficiency is deemed to be a class one or class two deficiency, the quality manager will issue a corrective action request (CAR) to the individual (s) most directly involved.

12.4.5.1 The analyst, his/her immediate supervisor, and the technical leader/supervisor will first try to determine the root cause of the discrepancy if possible. This means going beyond the immediate reason and finding the single thing that, if changed, would have prevented the deficiency and others like it, if possible.

12.4.5.2 A corrective action plan (CAP) will be written by a combination of the analyst, his/her immediate supervisor, and the technical leader/supervisor with the technical leader/supervisor having the responsibility to ensure it is prepared. The plan will contain a list of actions to resolve the deficiency and ensure the deficiency does not reoccur. The CAP should include actions already taken to resolve the deficiency. The CAP will also contain specific target dates by which each activity will be completed.

12.4.5.3 The CAP will be submitted to the quality manager for approval. The technical leader/supervisor will direct the plan.

12.4.5.4 If the CAP has to be modified, it should be done in writing and re-approved.

12.4.5.5 A report attached to the CAP will be sent to the quality manager when the CAP is fully completed as written. The quality manager will notify the major/manager that the corrective action is complete.

12.5 Typical activities used to resolve deficiencies.

12.5.1 Stop performing casework analysis utilizing a particular SOP, in a discipline, or totally, depending on an evaluation of the deficiency. Casework analysis should not be resumed until it can be assured that the results obtained are valid. Depending on the circumstances, a group of individuals or one analyst may have to stop performing casework analysis until corrective action is taken.

12.5.2 Procedure or instrument based:

12.5.2.1 Investigate the problem.

12.5.2.2. One time problem such as bad reagent: Correct problem, and if appropriate, modify in such a way as to prevent the reoccurrence of the problem.

12.5.2.3 Decide if old cases have to be reanalyzed.
12.5.2.4 Modify standard operating procedure (SOP) or adopt new SOP and validate, as necessary.
12.5.2.5 Repair or replace instrument and validate.
12.5.2.6 Competency test staff with new/revised SOP if necessary.
12.5.3 Analyst based:
12.5.3.1 Investigate problem.
12.5.3.2 Train/retrain.
12.5.3.3 Review completed cases.
12.5.3.4 Competency test.
12.5.3.5 Review all cases for a period of time or a specific number of cases.

13
PEER REVIEW, ADMINISTRATIVE REVIEW, AND CONFLICT RESOLUTION

13.1 Peer review policy: Procedure manual, chapter 5.2.2

13.2 Administrative review policy: Procedure manual, chapter 5.2.3

13.3 Conflict resolution:

13.3.1 If differences in opinions between the casework analyst and either the peer reviewer or technical leader/supervisor cannot be resolved during a review of casework analysis, the following process will be used to mediate the dispute:

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

13.3.1.2 Formation of a review committee: The parties shall notify their immediate supervisor and lab manager that they cannot resolve their dispute after mediation. The lab manager will contact the other lab managers 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.

13.3.1.3 The decision of the review committee may include reanalysis, issuance of an administrative report by the immediate supervisor of the analyst, or other suitable action based on an evaluation by the review committee. The decision of the review committee concerning the resolution of the casework analysis conflict shall be binding provided that the Major/Manager approves the decision. However, in no instance, shall an individual be compelled to sign a case report containing opinions and/or conclusions with which the individual disagrees.

13.3.2 Technical issues resolved during conflict resolution should be shared with other analysts as feasible.

14
MONITORING COURT TESTIMONY

The procedure to be followed in monitoring courtroom testimony is documented in chapter/section 7.1 of the procedure manual for ISP Forensic Services.

15
EVIDENCE HANDLING AND CASEWORK DOCUMENTATION

15.1 Handling of evidence is documented in chapter three of the procedure manual for ISP Forensic Services. It includes the following topics: receiving evidence; handling evidence in the laboratory; returning evidence; and protecting evidence from loss, contamination, and deleterious change.

15.2 The procedures to be following in writing notes, documenting observations, and writing conclusions is contained in chapter 5.1 of the procedure manual for ISP Forensic Services.

16
MAINTAINING EVIDENCE STORAGE AREAS

16.1 All evidence in the vault and elsewhere must be sealed, stored, handled, and protected in accordance with chapter three of the ISP Forensic Services Procedure manual.

16.3 All evidence must be properly logged into the evidence inventory system.

16.4 The evidence storage areas should be kept clean and tidy. This includes keeping the evidence well organized.

16.5 The vault must be kept locked when someone is not in it.

16.6 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.

16.7 An audit of evidence shall be performed any time a custodian of the vault ceases maintaining custody over the vault but no less than one time each calendar year.

17
DOCUMENT CONTROL AND MAINTENANCE

17.1 All documents will be maintained and destroyed according to the department record retention policy.

All case files will be maintained permanently. Current case files, two years minimum, and all homicide case files are maintained at the laboratory where they were created. All other case files may be transferred to the ISP warehouse in Meridian for permanent storage. Card files and/or electronic databases that are used to reference case files will also be stored permanently. Card files and/or electronic databases will be stored in a manner and location most appropriate for the specific file to ensure continued accessibility.

17.2. All Forensic Services policy manuals, standard operating procedures (SOPs), training manuals, ASCLD/LAB manuals, and other casework related documents of long term value will be managed consistent with appropriate document control. Current documents will be available for use by the staff and all obsolete documents will be archived and removed from general usage.

17.2.1 Obsolete policy manuals, safety manuals, SOPs, training plans, ASCLD/LAB manuals, and supporting documents cited in these documents will be retained by the quality manager.

17.2.2 The management assistant for Forensic Services will maintain the current ISP Forensic Services Procedure manual.

17.2.3 Discipline leaders/supervisors will maintain current SOPs and training plans.

17.2.4 The quality manager will maintain the current quality manual.

17.2.5 Laboratory managers will maintain the current safety manual and the current ASCLD/LAB manual.

17.2.6 Proficiency test files will be retained for a minimum of five years. The full documentation will be retained at the appropriate laboratory. The quality manager will retain the submitted proficiency test report, summaries from the manufacturer, and the evaluation of the results of analysts prepared by the technical leader.

17.2.7 The quality manager will maintain training records.

17.3 Training plans, SOPs, policy manuals, and safety manuals should be reviewed regularly (annually recommended). These documents will be revised as necessary to ensure that they reflect current policies, practices, and technology.

17.4 The ISP Forensic Services procedures manual, chapter five, has additional policies which

govern the generation and storage of case records and notes.
Casework documentation. (5.1)
Casework review. (5.2)
Releasing case results to authorized individuals only. (5.3)
Case record storage and disposition. (5.4.1)
Destroying documents. (5.5)

18
HANDLING COMPLAINTS AND DISCLOSURE OF INFORMATION

18.1 ISP Forensic Services considers valid complaints to be indicators of customer dissatisfaction and an opportunity for improvement. Forensic Services will take appropriate steps to address complaints regarding its services in order to provide the highest quality service to its customers.

18.2 The ISP complaint procedure should be followed when a complaint is made against any department employee.

18.3 Disclosure of Information:

18.3.1 Section 5.3 of the procedure manual of ISP Forensic Services contains the ISP Forensic Services procedure for the release of reports prepared as a result of casework analysis and the related documentation.

18.3.2 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.

18.3.3 The procedure for release of information through discovery in criminal cases is contained in the Idaho Criminal Rules, 16 (b)(8).

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

19
QUALITY AUDITS AND QUALITY SYSTEM REVIEW

19.1 A variety of audits and inspections are performed internally by staff and externally as required to fulfill accreditation standards. The purpose of these audits is to identify noncompliance with the applicable standards whether they are internal or external and remediate those areas of noncompliance through corrective action both formal and informal.

19.2 Quality audits: A quality audit will be conducted on no less than an annual basis of all three ISP Forensic Services laboratories. Each laboratory will be audited for compliance with established ISP Forensic Services quality policies and ASCLD/Lab accreditation criteria. This quality audit will be based on an objective checklist developed by the quality manager and reviewed by the management and staff of ISP Forensic Services prior to its being used.

19.2.1 The quality manager will issue a report to the laboratory manager and to the major/manager of Forensic Services detailing recommendations for change in the form of recommendations and corrective action requests (CAR).

19.2.2 The lab manager will respond with a report containing remediation, corrective action plans (CAP) for long term and /or more serious deficiencies, and rebuttal/explanation regarding specific recommendations.

19.2.3 The quality manager will make a closeout report to the lab manager and to the major/manager when all issues raised in the audit are resolved.

19.2.4 Each laboratory manager should maintain appropriate documentation of the quality audits performed in his/her laboratory.

19.3. Technical audits: Technical leaders/supervisors must review annually each regional laboratory in which casework analysis is performed over which he/she has technical leadership. On-site audits are preferable. However, review through the exchange of documents is acceptable. Suggested tasks for this technical review include:

19.3.1 Insuring that analysts are using the current SOPs and training plans.

19.3.2 Review of casework.

19.3.2.1 SOPs, appropriate use and method drift.

19.3.2.2 Conclusions.

19.3.2.3 Documentation.

119.3.3 Discuss issues and problems with individual analysts and with groups.

19.3.4 Calibration and maintenance procedures.

19.3.5 Assessment of equipment.

19.4 DNA audits will be performed annually following the applicable standards. Every other year an external audit must be performed.

19.5 Review of the quality system: Each year, the management team will review the quality system to ensure that measures are being taken to provide the highest quality services using state-of-the art forensic technology. This review will include one or more of the following:

19.5.1. Management team review of the annual reports submitted to ASCLD/LAB regarding the self-evaluation of each lab for compliance with the ASCLD/LAB accreditation criteria.

19.5.2 Review of the quality audits of the three laboratories by the management team.

19.5.3 Discussion of quality issues at management meetings.

19.5.4 Report regarding the state of the quality system in ISP Forensic Services prepared by the quality manager to the Major/Manager and to the laboratory managers.

20
HEALTH AND SAFETY

20.1 It is important that a forensic science laboratory establishes and maintains a health and safety program that is designed to safeguard employees from work related injury and health problems. ISP Forensic Services health and safety program is documented in its health and safety manual (s).