NIST Grant/Contractor Report
NIST GCR 23-043

Demystifying Accreditation

A Framework for Accreditation of Forensic Units

Nicole S. Jones
Erin P. Forry

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A Framework for Accreditation of Forensic Units

Prepared for
U.S. Department of Commerce
Special Programs Office
National Institute of Standards and Technology
Gaithersburg, MD 20899

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Abstract

Accreditation is a formal recognition by an independent third party/accreditation body that a forensic service provider such as a laboratory, unit, or agency,[a] meets standards. A standard is a requirement or guideline used to ensure that a process or service, in this case Crime Scene Investigation (CSI), is conducted consistently within the forensic service provider by competent personnel and is fit for purpose. Forensic service providers are accredited to ISO/IEC 17020, ISO/IEC 17025 and any other relevant sector-specific standards. The accreditation process involves an audit, or assessment, which, when performed, evaluates the unit against one or both of these standards to ensure it has developed and maintains a quality system that aligns with the requirements in an ISO standard. The 2009 National Academy of Sciences (NAS) report, *Strengthening Forensic Science in the United States: A Path Forward*, recommended mandatory accreditation and quality control and quality assurance programs for all units or laboratories that conduct forensic science activities, including those in which police agencies and identification units engage. Accreditation of CSI Units is important because it provides assurances that quality standards are met during scene investigations—the main gateway for recognizing, recording, collecting, transporting, and storing forensic evidence, which can have a lasting impact on the analysis, interpretation, reporting of results, and ultimately, the outcome of the investigation.

Accreditation gives the criminal justice system and the public confidence in a unit's competence and results and ensures that the unit has policies and procedures in place and can demonstrate the unit maintains impartiality. This is particularly important in the practice of crime scene investigation and forensic science because unlike other industries, there is no nationally mandatory regulatory approach to ensuring quality. Therefore, a voluntary standardization approach through accreditation is important for maintaining public trust, transparency, and quality of work. This report reviews the steps a CSI Unit must take to achieve accreditation, discusses the documentation framework that comprises a quality management system, and provides guidance to meet the requirements in ISO/IEC 17020 and ISO/IEC 17025 and any additional requirements included in amplification documents.

Keywords

Accreditation; Certification; International Standards; Quality; Quality Management; Forensic Science Process, Crime Scene Examination.

[a] Throughout this report, we will use "unit" to refer to a laboratory, agency, or unit.

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1. Introduction

Accreditation is a formal recognition that a unit[b] has implemented internationally recognized standards and best practices and demonstrates that they are maintaining competency in forensic examinations with a commitment to continuous process improvement. The 2009 National Academy of Sciences (NAS) report, *Strengthening Forensic Science in the United States: A Path Forward*, recommended mandatory accreditation and a quality control and quality assurance program for all units or laboratories that conduct forensic science activities, including those in which police agencies and identification units engage. [2]. Accreditation of Crime Scene Investigation (CSI) Units is important because it provides assurances that quality standards for processing crime scenes are established and implemented. Crime scene processing and examinations are a gateway for recognizing, recording, collecting, transporting, and storing forensic evidence, which can have a lasting impact on the analysis, interpretation, reporting of results, and ultimately, the outcome of the investigation. Accreditation also increases the confidence of both the criminal justice system and the public in a unit's competence and results. This is important in the practice of forensic science because unlike in other industries, there is no mandatory regulatory approach to ensuring quality. Therefore, a voluntary standardization approach through accreditation is important for maintaining public trust, transparency, and quality of work.

Accreditation is a formal recognition by an independent third party/accreditation body that a unit meets requirements within the scope of ISO/IEC 17020, ISO/IEC 17025, and any other relevant sector-specific standards included in the supplemental documents. The accreditation process ensures that when the accreditation audit, or assessment, is performed, the unit has a quality system in place which is based on a framework of policies and procedures set forth by standards. Accreditation gives an added layer of confidence to the customer, in this case the criminal justice system, that the unit follows best practices in forensic science and quality management. When beginning the accreditation process, it is important for a unit to have commitment from management regarding both human and financial resources. Figure 1 below shows some of the considerations for a unit when developing a roadmap to accreditation. To be successful, the unit should develop a comprehensive accreditation plan and identify individuals internal and external of the unit to participate in an accreditation implementation team. All members of the unit should be involved in the accreditation process so they can understand what will change, and why, and what will stay the same. This will both ensure their understanding and support of the accreditation process, as well as how to maintain the quality management system.

During the planning process, a unit should define the scope of forensic activities in which they plan to pursue accreditation and then identify all requirements for accreditation in those areas. Activities can include things such as collection of items at a crime scene, enhancement of impressions, or quantitative analysis of seized drugs. Accrediting bodies maintain a list of possible activities and scopes in their forensic accreditation program literature. Once that has been determined, and all requirements have been identified, the unit must conduct a gap analysis audit against standards to identify what requirements the unit already meets based on their current policies and procedures, and what new policies and procedures will need to be developed to meet the remaining requirements. The timeline for preparing for the assessment by the

[b] Throughout this report, we will use "unit" to refer to a laboratory, agency, or unit.

accrediting body depends on a variety of factors, including the scope of activities to be accredited, the size of the unit, the number of employees that will fall under accreditation (or not), and the complexity of the unit's operations. A typical time range to prepare all the documentation for the assessment is 6 months to a year, but it can take longer. Once the quality management system is in place, a unit must demonstrate conformance by applying it to casework long enough that the accrediting body has several cases to review during the assessment. In addition, once the assessment by the accrediting body is complete, it can take 8 weeks or more for the resolution of any nonconformances identified during the assessment before receiving an accreditation approval and certificate. Nonconformances occur when a unit does not meet a particular requirement in its quality management system and are not uncommon during an assessment. If these are identified in an assessment, the unit must submit a plan to correct them to be reviewed and approved by the accrediting body. The cost of accreditation can vary based on a variety of factors, including the size of the organization; the number of employees; gaps between the unit's current quality system and those defined in the standard; and the labor costs to develop a quality management system.

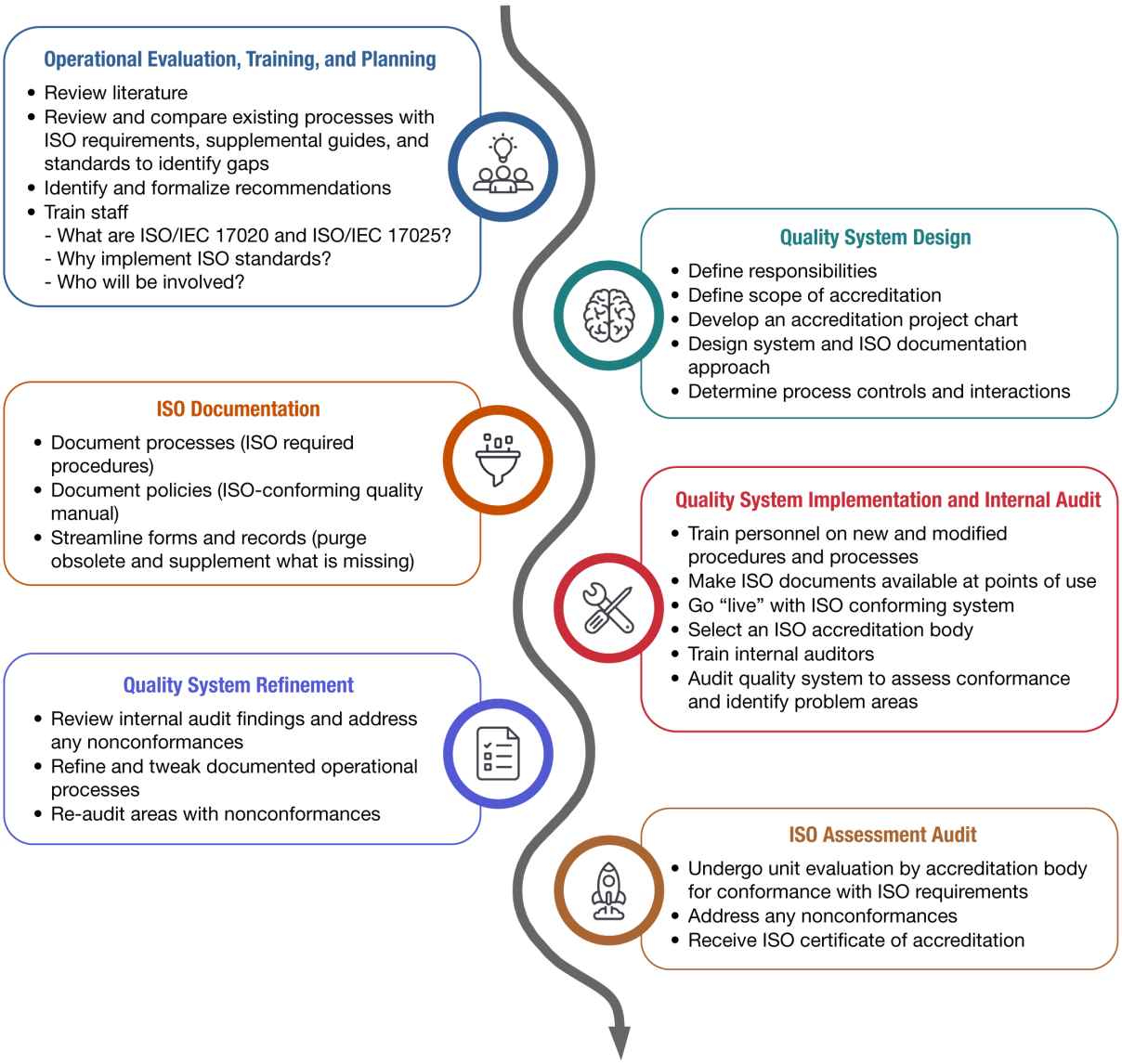


Fig. 1. ISO accreditation roadmap.

2. Literature Review

A forensic unit seeking accreditation should obtain and read a copy of standards used in forensic science and become familiar with the requirements to decide which accreditation standard is the better fit for their organization and the activities the unit seeks to include in their scope of accreditation. The two standards used to accredit forensic units are ISO/IEC 17020 and ISO/IEC 17025. There are many other standards that apply to the forensic science process which can be consulted when constructing a quality system such as ISO 21043-2, a standard about recognition and collection of items and scene investigation. ISO/IEC 17020 specifies the requirements for inspection bodies whereas ISO/IEC 17025 specifies the requirements for the competency of

testing and calibration laboratories; accrediting bodies can only accredit a unit to one of these two standards. Both of these standards have equal status and should be applied as applicable to the activities of the unit. For a unit that falls under the operations of a forensic laboratory already accredited to ISO/IEC 17025, or that is pursing accreditation to this standard, it may be beneficial for that laboratory to expand the scope of accreditation to include CSI. For other CSI units not contained within the organizational structure of a laboratory, it may be more beneficial to pursue accreditation to ISO/IEC 17020. In a 2020 review, Doyle outlines the current quality standards framework supporting forensic science and defines the hierarchy of standards that document the requirements for what needs to be documented and practiced to meet the requirements and provide guidance on how it can be achieved [3]. The review describes a hierarchy of Level 1 standards, which are the ISO standards; Level 2 standards that provide guidance on the application of the standards; Level 3 that provide guidance on the forensic science process; and Level 4, which is essentially a standard operating procedure [3].

The ISO/IEC 17020 document describes standard requirements for the operation of various types of bodies that perform inspections. Inspection involves examining, measuring, and comparing materials or test items. In the realm of forensic science, an inspection body would include CSI services or police forensic units that examine latent prints, friction ridge, firearms, digital multimedia, handwriting, or biological materials. For example, a CSI unit (or other forensic unit) uses professional judgement to examine or inspect a crime scene with the aim of helping determine what, where, when, how, and why a crime happened and who was involved. ISO/IEC 17020 pertains to organizations that use professional judgement to decide if the object being inspected passes or fails conformity. Professional judgement is an important distinction in ISO/IEC 17020 because it relies on the competence, intellectual knowledge, decision making, and the judgement of the trained crime scene investigator to “inspect products provided, processes and services.” A crime scene professional looks in detail to identify potential evidence items such as latent prints for friction ridge detailed comparison. Testing performed by an inspection body can fall into two categories that include functional testing or analytical testing. Functional testing is part of the normal activities of an inspection body and, in the case of forensic science, typically includes activities that take place in the field or at the scene of a crime. Analytical testing typically occurs inside a laboratory under controlled environmental conditions using calibrated equipment and testing methods.

ISO/IEC 17025 is for analytical testing laboratories
ISO/IEC 17020 is for inspection bodies

ISO/IEC 17025 describes competency standards for testing and calibration laboratories and is applied to organizations that perform testing of items that provide a quantifiable result. Testing of materials, products or process that are tested or calibrated may result in a specific value with a documented uncertainty of the measurement. ISO/IEC 17025 focuses on accuracy, precision, traceability, uncertainty of measurement, and method validation. Both ISO/IEC 17020 and ISO/IEC 17025 include scope, normative references, terms and definitions, and general requirements as well as structural, resource, process, and management system requirements. However, the biggest difference between the two standards is in the type of work being conducted. ISO/IEC 17020 focuses on competency of the unit and people performing inspection

whereas ISO/IEC 17025 focuses on the unit's analytical testing laboratory and equipment performing the testing and analysis and has requirements about the competency of personnel.

In addition to ISO/IEC 17020 and ISO/IEC17025, there are other documents that may be required for accreditation by the accrediting body and standards that may not be required but would be beneficial to review when building a quality management system and planning to obtain accreditation. Such documents include:

- ISO 9001:2015 Quality Management Systems - Requirements [4]
- ISO 21043-1:2018 Part 1: Terms and Definitions [5]
- ISO 21043-2:2018 Part 2: Recognition, recording, collecting, transport and storage of items in forensic science [6]
- ISO 20143-3 Part 3: Analysis [7]
- ISO 20143-4 Part 4: Interpretation [8]
- ISO 20143-5 Part 5: Reporting [9]
- ILAC G19 Modules in a Forensic Science Process [10]
- ENFSI EA – 5/03 Guidance for the Implementation of ISO/IEC 17020 in the field of crime scene investigation [11]
- ANAB AR 3120 (accreditation requirements for ISO 17020) [12]
- ANAB AR 3125 (accreditation requirements for ISO 17025) [13]
- A2LA P115 Technical Consensus Decisions from the Forensic Examination Advisory Committee [14]
- A2LA P103e Annex-Policy on Estimating Measurement Uncertainty for Forensic Conformity Assessment Bodies [15]
- Relevant standards on the Organization of Scientific Area Committees [16] for Forensic Science Registry [16]

The International Forensic Strategic Alliance (IFSA) has also published minimum requirements documents for various forensic science disciplines to establish a baseline for building a a quality system foundation by providing a framework that includes personnel competency, equipment and consumables, evidence collection, analysis, interpretation, reporting, procedures, protocols, validation, and quality management [17]. ISO 21043 is a series of standards for the forensic process. ISO 21043-2, Recognition, recoding, collecting, transport, and storage of items in forensic science, aligns with many of the quality management requirements in ISO/IEC 17020 and ISO/IEC 17025. It also contains requirements specific to forensic science that, when followed, would conform to some these quality management system requirements.

Additional information may be published by the accrediting bodies to assist in preparing for accreditation, or consultants may be able to assist an agency in understanding and implementing a standard. It is worthwhile to investigate what resources are available and to identify what are necessary to implement and what could act in a supportive role during the implementation process.

3. Structuring a Quality Management System

Many organizations within various industries seek accreditation to improve quality through transparency, documentation, and systematic approaches to process improvement. A Quality Management System (QMS) should address the CSI unit's unique needs, help the unit achieve their quality goals and objectives, and meet the needs of the unit's stakeholders and responsibilities. A QMS is a set of operational processes that help the unit maintain compliance with requirements of the applicable standards in an accreditation program and consistently ensure stakeholder satisfaction. An effective QMS translates the unit's mission and goals into policies and procedures that demonstrate transparency, impartiality, and define what quality means within the unit. Figure 2 provides the framework of documentation that is encompassed within the QMS. This document will reference ISO/IEC 17020: 2012 and ISO/IEC 17025:2017 specifically when referencing section numbers and content.

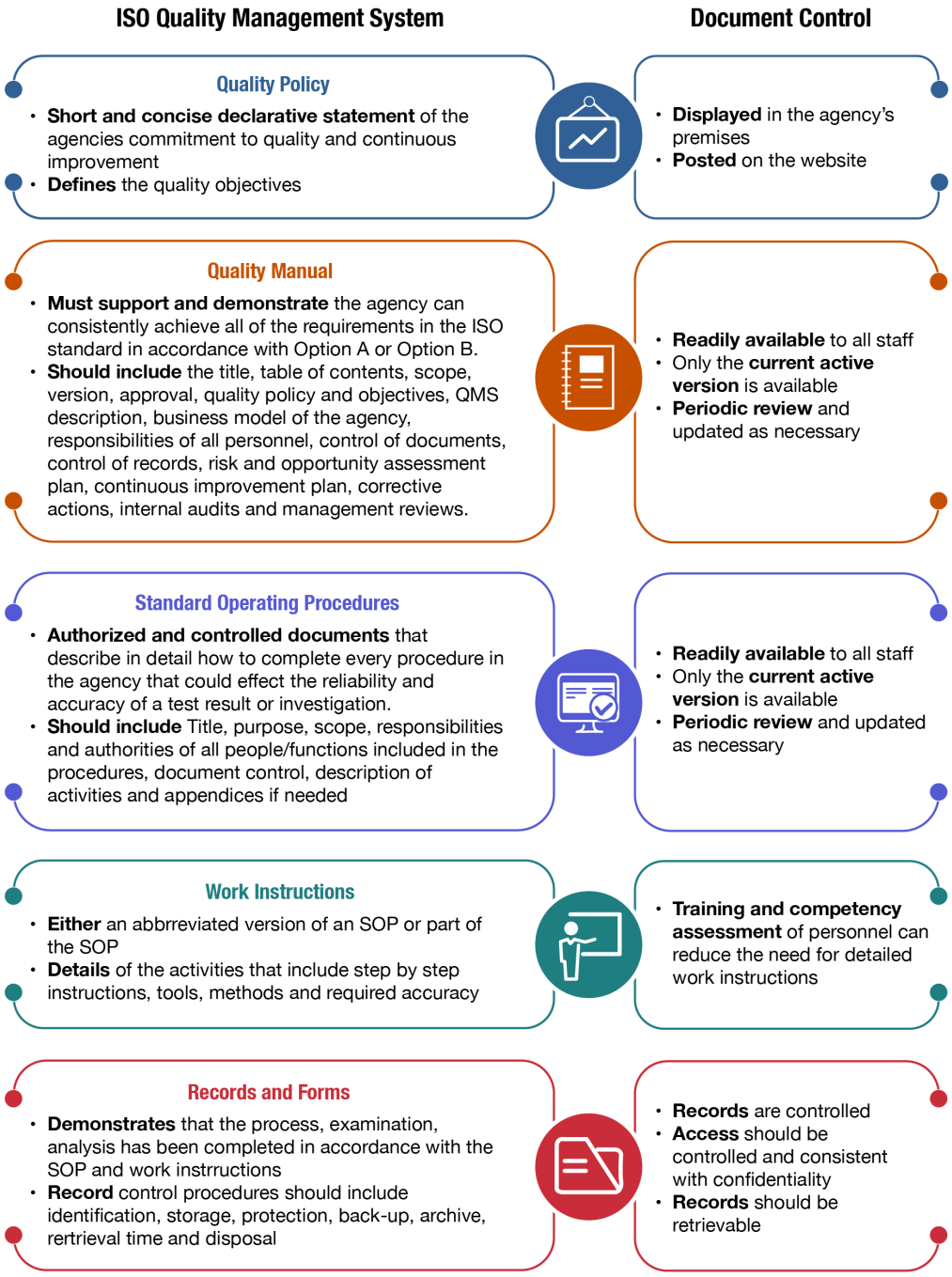


Fig. 2. Framework for a QMS.

3.1. Documentation

To fully understand the following sections, a copy of both ISO/IEC 17020:2012 and ISO/IEC17025:2017 must be available to the unit. It may also be necessary to cross-reference any of the amplification and supplementary documents mentioned in the literature review section. Before diving into the requirements of each standard, it is important to understand some of the basic terminology in the ISO/IEC standards. In these documents, note the following language [18]:

- "Shall" indicates a requirement.
- "Should" indicates a recommendation.
- "May" indicates permission.
- "Can" indicates a possibility or capability.

Other important terminology includes the use of the words policy and procedure, which are different from one another. A policy is a short, concise, declarative statement of the overall direction or course of action that a unit takes with respect to a stated issue. For example, it may be a crime scene unit's policy to provide services for a particular type of crime. A procedure, on the other hand, is a detailed description of how the unit implements a policy and includes statements regarding how it is done, including what is done, who does it, when it is done, and where it is done. For example, the crime scene unit may have a procedure for photographing a scene. Several elements of the standards require that the unit document both a policy and a procedure(s).

A quality policy should state the unit's commitment to both quality and continuous improvement. It may be helpful to display the quality policy at the unit as well as on the unit's website, as applicable, so that all stakeholders and employees are made aware and reminded of the unit's commitment to quality. The quality policy is also documented in a Quality Manual and should include:

- a statement of management's commitment of quality to their customers,
- the unit's standards of service,
- the relation of the management system to quality,
- and compliance to applicable standards.

The quality policy should identify top management in the unit, who are responsible for ensuring that quality policy objectives are:

- established for the QMS,
- compatible with the context and strategic direction of the unit,
- and are integrated into the unit's operational processes.

The overall quality policy, objectives, and any additional policies required by the applicable standards or by the accrediting body are generally documented in the Quality Manual, however named, as required in section 8 of both ISO/IEC 17020 and ISO/IEC 17025. The Quality Manual should include a:

- title;
- table of contents;
- scope of the QMS;
- any exclusions from the standards;
- and the elements required for document control, including documented approval by the appropriate authority, review, change control and version number.

It is often helpful to format the Quality Manual in a way that aligns with the applicable standards for referencing purposes and to easily allow future revisions as necessary when accreditation standards change. Quality procedures can be organized in combinations of different formats or structures whether narrative, structured into tables, or illustrated through flow charts or process maps. Procedures should include:

- title of the procedure,
- purpose,
- scope,
- responsibilities and authority of all people or functions included in the procedure,
- definitions/terminology,
- list of all records that result from the activities described in the procedure,
- document control elements,
- description of the activities,
- and appendices, if needed.

3.2. ISO/IEC Standard Requirements

As previously mentioned, both ISO/IEC 17020 and ISO/IEC17025 both include similar scopes, normative references, terms and definitions, and general requirements as well as structural, resource, process, and management system requirements. The difference between the standards in these two documents is in the type of work being conducted and how it is conducted; ISO/IEC17020 focuses on the competency of the agency and people performing inspection/investigation/examination whereas ISO/IEC17025 focuses on the agency's analytical testing laboratory and equipment performing the testing and analysis.

3.3. Section 4 – General Requirements

Table 1. ISO/IEC 17020 and ISO/IEC17025. Section 4 - General Requirements.

17020 (2012)	17025 (2017)
4 General requirements	
4.1 Impartiality and independence	4.1 Impartiality
4.2 Confidentiality	4.2 Confidentiality

3.3.1. Impartiality

Both ISO/IEC 17020 and ISO/IEC 17025 have general requirements concerning impartiality. The impartiality requirements are particularly important because they ensure that the outcome of any activity performed under the scope of the QMS is performed to minimize external influence or conflict of interest. The impartiality requirements are meant to not only safeguard the validity of the inspection activity, tests, or results, but also to ensure that the management structure, the use of resources, and the execution of processes are implemented and maintained in a manner that is as free from bias as possible and systematically performed to avoid compromising the integrity of the results. The risks of the presence of a conflict of interest can result in vulnerability to the policies and objectives, resulting in damage to the unit's reputation or noncompliance to the standard requirements. Compromising situations can arise from financial, commercial, political, or other pressures.

Some threats to impartiality to consider include the oversight or governing structure of the agency and their relationship with the unit; the relationships among a law enforcement agency, the crime laboratory, and the prosecutor's office; and even the personal relationships and actions of personnel involved in procurement, tenders, and contracts for the unit. When the unit itself resides within the governance of a law enforcement agency, the unit must have a policy that provides safeguards within the organizational structure to ensure that there is sufficient segregation of responsibilities between the unit and the investigative and prosecuting agency. A unit will typically include a statement in the quality manual regarding impartiality and activities it conducts to address it.

Ensuring impartiality includes developing an organizational culture within the unit which promotes awareness of conflicts of interest and bias; this may include a documented code of ethics or code of conduct. When developing this culture, it is important that staff is regularly made aware of the unit's policy and personnel acknowledge the code of conduct and personally declare any conflicts of interest. Management should consider the operations of the unit and where instances of bias, conflict of interest, and impartiality may occur. They should then institute policies and procedures to establish safeguards for monitoring the status and risk of potential bias. One potential risk could be staff who split their duties between casework and quality assurance. If there is a heavy case load, there may be pressure to put more time on casework and less on quality; there should be a plan in place to monitor and mitigate these types of risks. Other examples of risks that can occur because of internal or external pressures can include casework backlogs or special requests from the legal community or investigators.

In addition to impartiality, ISO/IEC 17020 also has requirements related to independence. This may lead some units to think that they cannot meet this standard if it is co-located within the law enforcement agency; however, Annex A of ISO/IEC 17020 further describes the independence

requirements and gives examples of three different types of forensic units. These three types of forensic units are further detailed to how they pertain to forensic examination in A2LA P115 , a supplemental accreditation document for an accrediting body, as noted below [14]. Once the unit determines which type of forensic unit represents their operational structure, they can then refer to the specific independence requirements in Annex A for their type of organization.

- **Type A:** These organizations examine sites and collect, transport, store, or inspect evidence (e.g., fingerprint analysis) at the request of the customer (e.g., prosecution, police agency, private citizen). They do not participate in the investigation (e.g., interview suspects, victims) other than to provide their results/reports to the customer.
- **Type B:** These organizations are included as part of the investigative team and include staff who could be considered a customer (e.g., an individual(s) who review or use inspection results to further the investigation).
- **Type C:** These organizations are included as part of the investigative team (Type B) but are also available to other customers (e.g., other jurisdictions or private citizens) (Type A).

One way to address independence in the QMS is to include an organizational chart within the Quality Manual, but particular attention must be paid to what the organizational chart shows. If the unit is part of a larger organization or department you will need to demonstrate a professional independence from other parts of the organization. The organizational chart(s) should show the position of the unit within the larger organization and the reporting relationship among management, quality assurance staff and operations.

3.3.2. Confidentiality

The unit is responsible for managing all information obtained from their stakeholders or created as part of the business operations, including results or information produced from examining the crime scene or analyzing evidence. This requires that the unit has policies and procedures related to data security regardless of whether that data are on paper or virtually on a local server or the cloud. Access to these data must be stored in limited access, secure locations. A unit may conform to the confidentiality clause in the standard by referencing parent organization policies on information confidentiality, a non-disclosure agreement that staff are required to sign, and/or documented policies and procedures on limiting access to the building or rooms where confidential data are stored.

3.4. Section 5 – Structural Requirements

Table 2. ISO/IEC 17020 and ISO/IEC 17025. Section 5 – Structural Requirements.

17020 (2012)	17025 (2017)
5 Structural requirements	
5.1 Administrative requirements	
5.2 Organization and management	

Section 5 of ISO/IEC 17020 is subdivided into two sections on administrative requirements and organization and management requirements. ISO/IEC 17025 does not identify substandards, but does have requirements in these areas, many of which are common across both ISO/IEC 17020 and ISO/IEC 17025.

3.4.1. Administrative Requirements

Both ISO/IEC 17020 and ISO/IEC 17025 require that the unit is either a legal entity or part of a legal entity that is legally responsible for all activities within the accreditation scope performed by the unit. This can include the agency's charter, articles on incorporation, or legal statute that brought the organization into existence. If a unit is a part of a larger parent organization, a statement stating as such can be included in the Quality Manual; it may be helpful to illustrate this with an organizational chart. The unit must also document the range of activities that conform to the requirements listed in the standard. This can be a statement in the Quality Manual that reflects the scope of accreditation. In addition, ISO/IEC 17020 requires that the unit have insurance or financial reserves to cover liabilities.

3.4.2. Organization and Management

As defined by ISO 19011, *Guidelines for auditing management systems*, competency is the demonstrated ability for personnel to apply both knowledge and skills to particular tasks and activities. Both ISO/IEC 17020 and ISO/IEC 17025 have requirements concerning organization and management structure and require an organization to ensure that personnel are competent to achieve the intended results of examinations. The unit's organizational chart may satisfy the requirement to document the management and reporting structure. These standards also require the unit to specify who has the authority to do particular tasks and activities and who serves as the back-up authority when the primary is unavailable. It also requires all personnel to have the authority and resources to perform their duties regardless of their position in the organization. Although ISO/IEC 17020 and ISO/IEC 17025 have slight differences, both contain requirements for the education, training, technical knowledge, skills, and experience of personnel conducting activities. Section 6 – Resource Requirements

Table 3. ISO/IEC 17020 and ISO/IEC 17025. Section 6 – Resource Requirements.

17020 (2012)	17025 (2017)
6 Resource requirements	
	6.1 General
6.1 Personnel	6.2 Personnel
6.2 Facilities and equipment	6.3 Facilities and environmental conditions
	6.4 Equipment
	6.5 Metrological traceability
6.3 Subcontracting	6.6 Externally provided products and services

ILAC-G19 provides guidance on how to interpret accreditation criteria in a forensic context for the assessment of forensic units. This guidance applies to both ISO/IEC 17020 and ISO/IEC 17025 in areas where the two standards overlap, such as in the resource requirements for personnel, facilities and environmental conditions, equipment, and subcontracting/procurement. The introduction to section 6 of ISO/IEC 17025 states that the unit must have appropriate

resources needed to carry out examinations operations, including personnel, facilities, equipment, systems, and support services. Many agencies will address this requirement with a statement to this effect in their Quality Management Plan.

3.4.3. Personnel

ILAC G-19 defines personnel requirements around competency and includes the documentation of a defined training program that establishes training goals and professional development needs. Although ISO/IEC 17020 and ISO/IEC 17025 standards have slight differences, personnel requirements of education, qualification, training, technical knowledge, skills, and experience are consistent between both documents. Management must assess competence and can do so through a variety of formats including written or oral examinations, practical exercises, or direct observation. Each employee, at all levels of the organization, should have a training record either electronically or in hard copy. The training record may include job descriptions that clearly define employee responsibilities and requirements for minimum education, training, skills, experience, competency, and authority. These qualifications may also be included in the quality manual. The training record may include copies of diplomas, certificates of completion for any trainings, proficiency test results, written or oral examinations, and competency assessments and a signatory authorizing them to conduct specific duties or test methods. Some agencies may require that personnel hold certifications in particular testing or discipline in order to conduct casework; such a requirement or goal should be documented in the quality management system. The OSAC registry also has documentary standards for minimum education and training requirements in certain forensic science disciplines that may be included in the training and competency records as well. In addition to ILAC G19 and the OSAC registry, there are other amplification documents that contain supplemental requirements for training that may be considered when documenting and implementing the training program and procedures. The unit must ensure that any testing and competency procedures they put in place are reviewed on a regular basis (can be part of an annual review cycle) and followed.

Both ISO/IEC ISO 17020 and ISO/IEC 17025 require that the unit have documented job descriptions for each position category in the organization that is involved with the activities that fall under the scope of the accreditation. The job description should be written in enough detail to document the qualifications, training, experience, responsibilities, skills, knowledge, education, competency, and authority to meet the requirements of this standard. Something to consider, however, is that job descriptions can sometimes be written broadly to cover the full gamut of responsibilities for one type of position, which would not meet the intentions of the standard.

Both ISO/IEC 17020 and ISO/IEC 17025 require the unit to define competency requirements. Establishing and maintaining employee competency begins with fit for purpose training programs in the methods used by the unit. The unit must develop, plan, execute, and document a training program for personnel that includes:

- onboarding and the induction period,
- a mentoring period with experienced personnel,
- and continuing education to ensure that competency is maintained as technology changes and methods evolve.

Individual training records should include copies of diplomas, degrees, certifications, and professional development courses and continuing education (both internal and external) that the employee has completed. The training record should include documentation of all supervised training that personnel have completed as on the job training and competency tests such as written exams, mock trials, practical exams, or proficiency testing, including the results of the tests. Competency must be demonstrated for the use of every method that the person is responsible for conducting. ISO 21043-2, *Recognition, recording, collecting, transport, and storage of materials,* includes requirements for competency of forensic personnel.

Units commonly have on the job training where a more senior employee who has demonstrated the necessary competency mentors a newer employee. The trainee may need to review literature, conduct practical exercises, observe testing by another staff member, and courtroom (or mock court) testimony training and observations, as appropriate, depending on the scope and locations of the individual's work activities. Training and competency requirements are activity specific and specific to each discipline. The unit must ensure that training records document competency for every method, test, or examination activity for which the employee is responsible. This includes the development or modification of test methods, validation and verification of test methods, analysis of results, interpretation of results, conformity, reporting of results, and review. The training record should define what must be successfully completed by the trainee to demonstrate competency and who authorized that the individual was competent. A way to meet this requirement is through a formal statement or memo that the employee is authorized to commence casework in a particular type of testing which is then signed and dated by the proper authorizing authority once training and a competency test have been successfully completed. Once the employee is authorized, they must undergo training and competency assessments each time a new method is incorporated into the lab service or significantly changed. The training records can be either hard copy or electronic but must be retained and retrievable.

Personnel must demonstrate ongoing competency through performance monitoring. This is accomplished in several ways for CSI units. Proficiency testing is a specific type of performance monitoring. Proficiency tests are obtained from a provider external to the unit who is accredited to ISO/IEC 17043 for developing proficiency tests. These tests are interlaboratory comparisons meaning that there must be tests taken by other organizations. Intralaboratory tests are different as they are prepared internally and can include observed evidence collection and processing of a real crime scene or a mock crime scene to ensure the investigator demonstrates the expected level of knowledge of evidence collection and processing procedures. External tests for CSI units are currently offered by Collaborative Testing Services, Inc. and Ron Smith and Associates.

Table 4. Currently Offered External Proficiency Tests for CSI Units.

Collaborative Testing Services, Inc (CTS)	Ron Smith & Associates, Inc. (RS&A)
Crime Scene Processing (Mock Crime Scene) **Some skill sets that are tested and observed include: Discovery of Evidence, PPE usage, Documentation, Photography, Sketching, Evidence Collection and Packaging.***	**Crime Scene Processing (Presumptive Blood Testing)** Consists of at least 4 surfaces containing stains of suspected blood. Participants are required to process each surface for the presence of blood using any method they choose. Results are Presumptive Blood Positive (+) or Presumptive Blood Negative [11].
Crime Scene Individual Skill Sets **Tests that represent aspects of crime scene examination, such as the use of firearms at a scene, bloodstain pattern analysis as an investigative tool, the lifting and processing of latent prints on varied surfaces (porous and nonporous), and body fluid identification on various substrates.**	**Crime Scene Processing (Latent Print Processing)** Contains at least 3 NON-POROUS items of evidence. Participants are required to process the items for the presence of latent prints using any processing method(s) they choose. Required to submit at least one photograph of any latent prints discovered.
	Crime Scene Processing (Shooting Incident Doc.) At least one trajectory entry and one trajectory exit in at least one item of evidence. Required to submit 3 results: Entry Side, Horizontal Azimuth including the Horizontal Direction of Measure, Vertical Angle including Vertical Direction of Measure.

*PT tests that are included in the providers Scope of Accreditation to ISO/IEC 17043:2010.

3.4.4. Facilities

In addition to personnel, the standards in section 6 of both ISO/IEC 17020 and ISO/IEC 17025 address facility requirements. ILAC-G19 again provides common guidance for both ISO/IEC 17020 and ISO/IEC 17025 regarding facility and environmental conditions, preventing cross-contamination, controlling access, and equipment requirements. The evidence collected or examined by forensic service providers often includes trace materials, biological evidence at high risk for cross-contamination, and evidence that may be fragile because of decomposition. There may be security issues related to controlling and monitoring access to evidence and maintaining chain of custody. Ensuring the health and safety of the individuals at work sites is also an important consideration.

To evaluate the necessary facility and environmental requirements, it can be helpful to make a list of all the tests and examinations that the unit performs along with a corresponding column noting what environmental conditions can affect the integrity of the evidence (loss, deterioration, and/or contamination) or affect the testing outcome and a third column listing what conditions must be controlled to achieve quality results. Conditions include temperature, humidity, noise, dust, power and light supply, vibration, and water purity. If any of the test methods on the list have environmental conditions that can affect the results, those conditions will need to be controlled as much as possible, monitored, and recorded in a monitoring log, or similar. In addition, the requirements for those conditions will need to be documented in the procedure. Some environmental/testing conditions can be monitored and documented through electronic systems.

When the environmental conditions at the scene cannot be controlled, as in the case of weather conditions at outdoor scenes, then those conditions should be documented as part of the case record and mitigated as best as possible.

Access to the facilities where evidence collection/testing occurs may need to be considered and controlled for security, safety, and cross-contamination purposes. Some amplification documents specify that a procedure must be in place to address security and access to areas where evidence collection, testing, or calibration activities occur. Access to scene investigations must also be controlled.

Most units will have measures in place to account for controlled access, but it can be helpful to go through the list of test methods and possible sources of contamination to ensure that there is a monitoring plan in place for each test that can be affected by cross-contamination. ILAC G19 requires that high-level and low-level work be separated to avoid cross-contamination for example for bulk and trace levels of drugs.

3.4.5. Equipment

Both ISO/IEC 17020 and ISO/IEC 17025 require that the unit has access to equipment necessary to perform the services within their scope of accreditation. Equipment includes consumables, testing reagents (e.g., latent print powder), as well as items such as cameras or alternate light sources. Policies for access to equipment must be defined and controlled. The unit should have a procedure for handling, transport, storage, use, and maintenance of the equipment to ensure that it is functioning properly and to prevent contamination. Both ISO/IEC 17020 and ISO/IEC 17025 require that all equipment that can influence the results be uniquely identified and defined. This should be recorded, whether maintained in hard copy or digitally, and include:

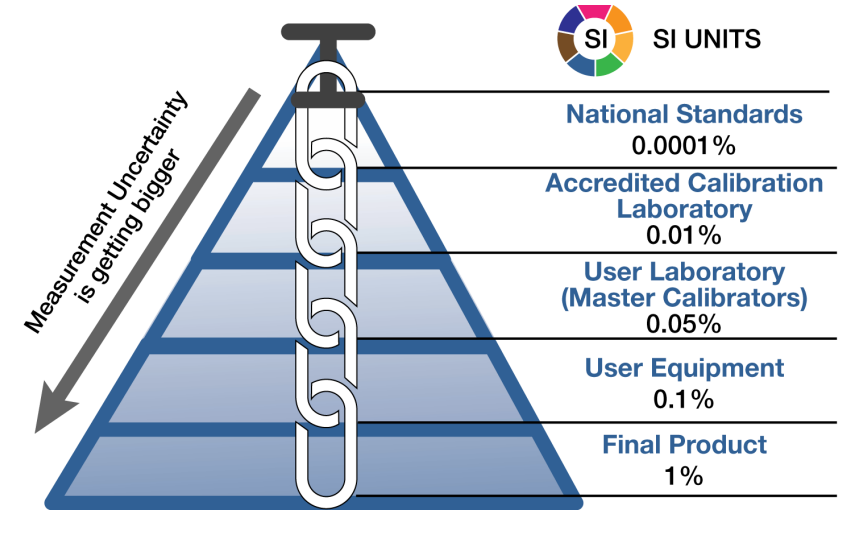
- the identity of the equipment,
- the software version or firmware version,
- the manufacturer's name and model number, serial number,
- evidence of verification that the equipment is functioning properly,
- and its current location.

The equipment record should also document the date that maintenance occurs (regular preventative maintenance and corrective maintenance) when relevant to the performance of the equipment and details of any damage or malfunction of the equipment and its repair. When the equipment is not in compliance with expectation of proper function by the unit because of damage or malfunction, it should be clearly marked and taken out of use. Units often label the equipment with a unique identifier, establish an inventory list of all equipment, and maintain a logbook, whether hard copy or digital, to document these details. Alternatively, they may create a database for equipment records. The unit should also have a procedure for disposable equipment to prevent misuse or reuse that could contribute to contamination.

Both standards require that measurement equipment be calibrated before being put into service and that the unit has a calibration procedure documented and established an ongoing calibration program for such equipment. For measurement equipment, the equipment record should also include calibration dates, calibration results, any adjustments that were necessary, acceptance

criteria and either the due date for the next calibration or the calibration interval. The calibration requirement applies to all measurement equipment from large pieces of instrumentation down to balances, pipettes, and evidence scales.

3.4.6. Metrological Traceability



Source: Adapted from calibrationawareness.com [19]

Metrological Traceability is a measurement result that "can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty" [20]. Unlike ISO/IEC 17025, ISO/IEC 17020 does not have a section dedicated to metrological traceability, but it does include a standard that requires that reference standards and the calibration program be designed to be traceable to a national or international standard of measurement. Calibration is required for all equipment that can impact the accuracy and validity of test results before the equipment can be used in casework. In a laboratory, this includes thermometers, pipettes, micropipettes, balances, and weights. There are three ways to achieve metrological traceability using external services: (1) traceability via a National Metrology Institute, (2) traceability via an accredited calibration laboratory, or (3) traceability via certified reference materials [21]. There is a hierarchy for measurement traceability from the International Standards (SI) Unit at the top to National Metrology Institutes such as the National Institute of Standards and Technology (NIST), down to primary and secondary laboratories and then to industrial measurements. The shorter the measurement chain between the unit and the National Metrology Institute, the smaller the value of measurement uncertainty. Therefore, if a laboratory sends its weights, pipettes, and thermometers to NIST for calibration there will be less uncertainty in the measurement than if the unit sends these items to an ISO/IEC 17025 accredited calibration laboratory or meets the traceability requirement via certified reference materials.

Certified Standard Reference Materials should be obtained for any tests that the unit conducts. Table 5 below provides a list of Standard Reference Materials currently offered by NIST for CSI.

Table 5. Standard Reference Materials available from NIST for CSI.

SRM 2460	Standard Bullet Replica
SRM 2461	Standard Cartridge Case
SRMs	Ethanol Solutions Suite

More information on the metrology traceability can be found in ILAC P10:07/2020 ILAC Policy on Traceability of Measurement Results, NIST Policy on Metrology Traceability, NIST Policy on Traceability Supplemental Materials, and A2LA P102 Policy on Metrological Traceability [22-25]. Additional information for forensic laboratories can be found in ILAC G19 and the supplemental amplification requirements from the accrediting bodies [10].

3.4.7. Subcontracting and Externally Provided Products and Services

Both ISO/IEC 17020 and ISO/IEC 17025 have requirements regarding subcontracting and externally provided goods and services. Subcontracting occurs when a unit offers a particular type of service but has another unit in another organization conduct the work for them. ISO/IEC 17025 requires that units have a procedure and retain records to ensure that subcontractors and all externally provided products and services conform to the unit requirements for being fit for purpose before they are used. The procedure must document the criteria for evaluating selection, monitoring performance, and re-evaluating external providers. These criteria for defining evaluation, selection, performance monitoring, and re-evaluation for external providers and subcontracting may include requiring that the sub-contracted entity be accredited to ISO/IEC 17025, that their scope of accreditation includes accuracy requirements, and that their capabilities are within the required range if calibration and traceability are required by the unit. Accreditation to ISO/IEC 17043 could be monitored for evaluation criteria of proficiency testing providers or ISO 9001 as a certification for general goods and services. Other criteria for monitoring and evaluation of external providers can include supplier audits, evaluation of the goods and services received upon delivery, years in business, and references. Maintaining a list, whether hard copy or digital, of approved providers is one way to document that providers have been approved and have been re-evaluated. There is also a requirement that the unit communicate their confidence requirements and acceptance criteria for products and services, competency requirements for personnel, and any activities that the vendor intends to perform on the providers premises. This can be documented via a purchase order or statement of work that clearly states these criteria.

3.5. Process Requirements

Section 7 of both ISO/IEC 17020 and ISO/IEC 17025 covers the inspection or analytical portion of processes from the time that evidence is collected, submitted for analysis, all the way through to the reporting of results and control of the data. ISO 21043-2:2018 *Forensic sciences - Part 2: Recognition, recording, collecting, transport, and storage of items*, is a useful reference of requirements and recommendations related to forensic science that would assist the unit in developing a QMS. It contains requirements related to what is required to be done at a crime scene, developing an examination strategy, evidence packaging and more.

Table 6. ISO/IEC 17020 and ISO/IEC 17025. Section 7 – Process Requirements.

17020 (2012)	17025 (2017)
7 Process requirements	
7.1 Inspection methods and procedures	7.1 Review of requests, tenders, and contracts
	7.2 Selection, verification, and validation of methods
	7.2.1 Selection and verification of methods
	7.2.2 Validation of methods

17020 (2012)	17025 (2017)
7 Process requirements	
	7.3 Sampling
7.2 Handling inspection items and samples	7.4 Handling of test or calibration items
7.3 Inspection records	7.5 Technical records
	7.6 Evaluation of measurement uncertainty
	7.7 Ensuring the validity of results
7.4 Inspection reports and inspection certificates	7.8 Reporting of results
	7.8.1 General
	7.8.2 Common requirements for reports (test, calibration, or sampling)
	7.8.3 Specific requirements for test reports
	7.8.4 Specific requirements for calibration certificates
	7.8.5 Reporting sampling – specific requirements
	7.8.6 Reporting statements of conformity
	7.8.7 Reporting opinions and interpretations
	7.8.8 Amendments to reports
7.5 Complaints and appeals	7.9 Complaints
7.6 Complaints and appeals process	7.10 Nonconforming work
	7.11 Control of data and information management

3.5.1. Methods and Procedures

Regardless of which ISO/IEC standard (17020 or 17025) the unit implements, the unit must demonstrate that all test methods or examination methods be fit for the intended purpose. One way this is done is through validation and verification studies. A unit must test out a method on the types of items encountered in forensic science casework using the equipment that the unit has and ensure that the method is fit for purpose before using it on actual casework. Validation studies are required for all methods used in collection/testing/calibration activities, including comparison methods. Verification studies are often less complex than a validation study but are also intended to demonstrate that a method is fit for purpose. The data obtained in the validation or verification that shows the method works as intended must be retained by the unit.

These validation studies assist the unit in writing the standard operating procedures (SOP) for the testing. There must be written instructions available for all test methods used in collection/testing/calibration activities. This can include standard operating procedures (SOPs), work instructions, standards, and manuals, all of which should be written in enough detail that any trained employee can follow the method to perform the activity correctly and consistently and an accreditation assessor can follow it to assess technical conformance to the procedure. These documents should include information such as a document identification number, title, effective date, and indication of the authorizing personnel as required by the unit's document control system. They must be kept up to date and readily available to all employees of the unit. Many units will have SOPs available electronically on their server or in the electronic cloud. SOPs must be documented as "uncontrolled" when printed so that employees are aware that the printed version may not be the most up-to-date version available electronically. The methods and SOPs should be periodically reviewed to ensure that they meet the needs of the client.

In forensic service providers, methods can be taken from peer-reviewed or professionally accepted publications, but they must be validated or verified prior to use on casework. A

verification typically entails following a procedure as written using the same equipment and materials ensuring it is fit for purpose. Methods developed in-house can also be used but must be validated prior to use. A validation or verification of a method SOPs online for use in casework should include documentation of the quality control procedures and use of reference materials. When developing methods and documenting processes for CSI, the unit must assess all factors that can influence the outcome and document those factors. It may be helpful to develop a process map to document the strategy and thought process that investigators go through from arriving at the scene of the crime, protecting the scene, identifying, and preserving evidence, and conducting the inspection and interpretation process. This is important for ensuring that the scene investigation process is repeatable and reproduceable regardless of the investigator who is assigned that scene. There are several different process mapping tools and multiple ways to document the process. These can include a top-down flow chart, process flow chart, or a swim lane flow chart, to name a few. Process maps can help identify and graphically represent every part of the procedure to increase the visibility of each component of the process, provide guidance, and help others better understand the process, identify gaps and bottlenecks in the process, and make tracking easier. Figure 3 depicts an example of a top-down process map to document the CSI process. A top-down process map can also be overlayed with swim lanes to show the responsible party for each action in the process map. Process maps can be used to document decision points that can change the workflow.

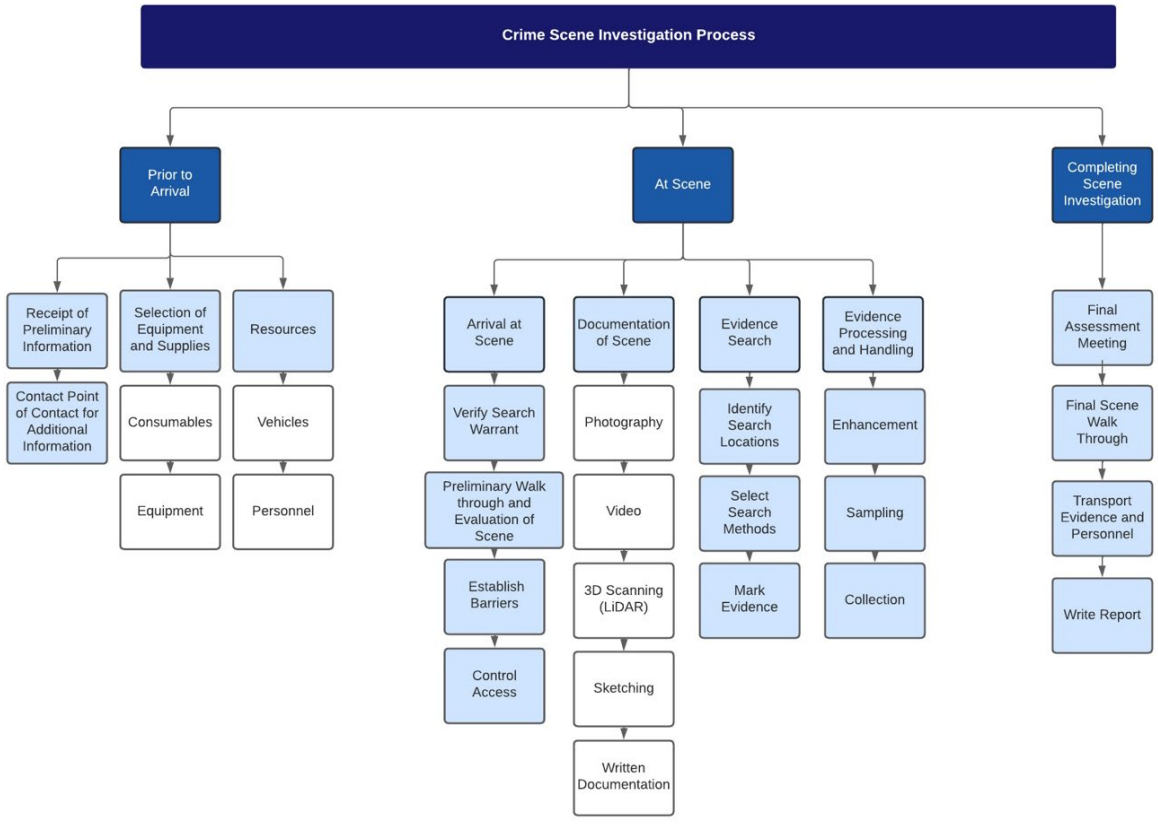


Fig. 3. Example of a top-down process map to document the CSI process.

Some factors to consider when validating test methods are documented in ILAC G19 and listed in Figure 4. ISO/IEC 17025 requires a formal sampling plan, which can be challenging for units that conduct CSI and collect evidence from crime scenes. The unit must have a sampling plan that documents the selection, recovery, and prioritization of evidence items from crime scenes; for example, how representative samples are taken from bulk seized materials such as drugs, questioned documents, and soil or what possible blood stains to collect from an apparent blood trail. Any limitations on the evidence collected or special considerations that were made should be documented as part of the case record. Some factors to consider when developing a sampling plan are included in ILAC G-19 and in Figure 4 below.

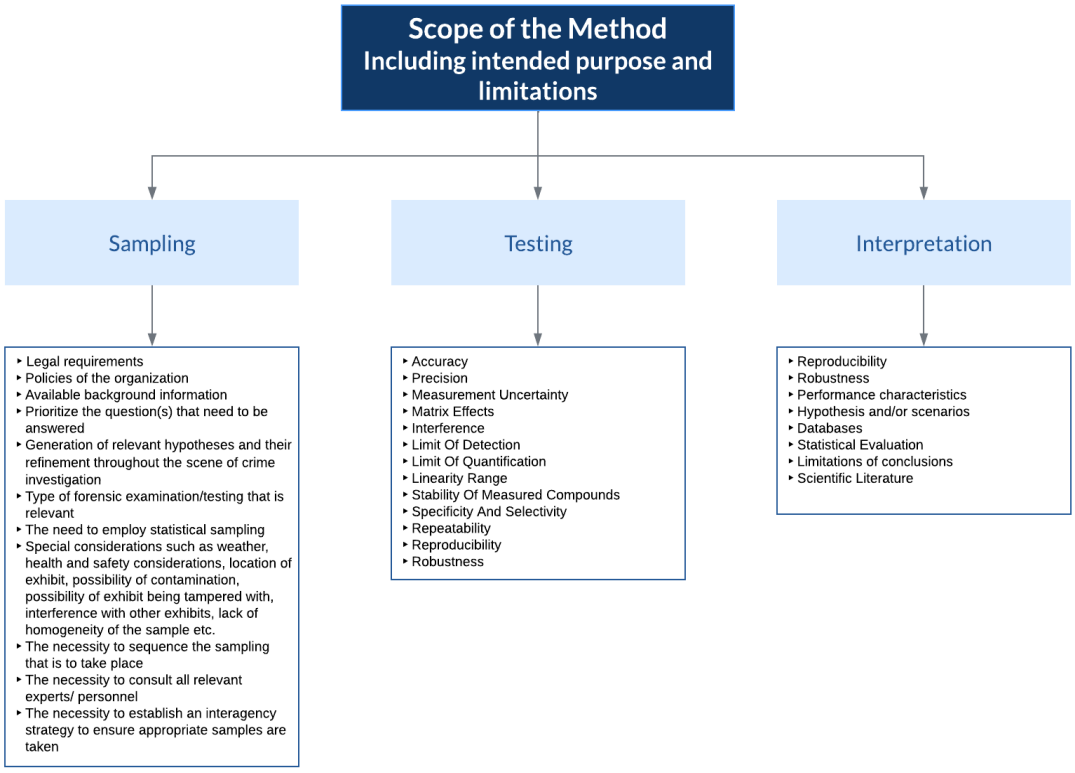


Fig. 4. Factors to consider when validating qualitative and quantitative test methods.

As your unit validates methods, consider any factors that were identified that can affect the method to develop acceptance criteria for the suitability of evidence for testing. These factors may be as simple as and evidence item that does not match the description on the label or chain of custody, or the quantity or the condition of the submitted evidence. ISO 21043-2 contains requirements and recommendations concerning the examination of a scene and what should be recorded.

Section 7.1 of ISO/IEC 17025 speaks to how test requests are received by the unit and the communication between the “client” and the unit to ensure that the unit understands the request for testing made and that the appropriate testing is performed. If the client requests a testing method deemed inappropriate by the unit, the unit needs to communicate that back to the client

and come to an agreement with them on what test methods are appropriate to use. Any disagreements need to be resolved before the unit commences testing.

3.5.2. Handling Exhibits and Evidence

Both ISO/IEC 17020 and ISO/IEC 17025 have requirements for handling evidence or exhibits, although they refer to it in terms of either inspection items and samples (17020), or test and calibration items (17025). Many of the requirements for handling and preserving evidence to prevent deterioration and to ensure chain of custody are likely already in place at the unit, but it is important to ensure they are documented. The ISO standards require that the unit has procedures in place for handling evidence, including the transportation, receipt, handling, protection storage, retention, and disposal or return of evidence. These procedures should also document how the unit takes precautions to avoid contamination and deterioration of evidence. ISO 21043-2 contains requirements and recommendations concerning the handling of evidence items. Amplification documents may require that units have a procedure in place for upholding chain of custody that includes detailed records of the unique identification of the evidence, dates of receipt and transfer, and identification of the person(s) involved. When an electronic evidence tracking system is used, it must be secure, capable of producing personal identifiers, and reproducible in hard copy. Amplification documents may list supplemental requirements for handling of evidence by some accrediting bodies, so it is advised to consult the additional requirements in the amplification documents (such as ANAB AR3125) of the accrediting body or amplification documents in general that your unit is using for accreditation purposes. Records

ISO/IEC 17020 and ISO/IEC 17025 both have requirements for inspection or technical records regarding the information that must be captured in the record and the date and identity of the individual person responsible for the recorded activity. All changes must be tracked, and the original documents and all amended documents must be retained.

3.5.3. Measurement Uncertainty

There is an inherent element of uncertainty in every measurement because whenever a numerical measurement is made, the value of the measurement can never be exactly known—only an estimated value can be given. Metrology has developed several methods of quantifying a measurement's margin of error or uncertainty. A measurement result is complete only when accompanied by a quantitative statement of its uncertainty. Measurement uncertainty (MU) allows the expert and the court to determine the appropriate evidentiary weight of the measurement. The uncertainty is required to decide if the result is adequate for its intended purpose and to ascertain if it is consistent with other similar results. The uncertainty measurement only applies to quantitative analysis and does not apply to qualitative methods [12, 26]. ISO/IEC 17025 requires testing laboratories to have and apply procedures for estimating uncertainty of measurement and to attempt to identify all components of uncertainty and make a reasonable estimation and shall ensure that the way the results are reported does not give a wrong impression of the uncertainty. In certain cases, the nature of the test method may preclude rigorous, metrological, and statistically valid calculations of uncertainty of measurement. An example of where MU is relevant in a forensic service provider is in blood alcohol testing. There is an uncertainty in the measurement of the amount of alcohol in the blood sample. The laboratory must calculate that uncertainty and include it in the test results. If the measurement is

close to the legal limit, the MU may make a difference with respect to whether or not a charge is brought forward.

The measuring system, measurement procedure, operator skill, environment, or other factors may introduce random or systematic errors into the measuring process. A generally accepted approach to estimating the measurement uncertainty involves calculating an expanded interval with an associated coverage probability. Possible sources or components of uncertainty include the methods and materials used, environmental conditions, properties and condition of the test item, and the analysts performing the test. Most measurements made by CSI units are qualitative or approximate, but applicable techniques could use NIST calibrated rulers and evidence scales for fit for purpose evaluation. However, measurement uncertainty generally does not apply to CSI because quantitative methods are not typically performed at the scene.

3.5.4. Validity of Results

ISO/IEC 17025 requires that the agency have a procedure for monitoring the validity of results. ISO/IEC 17020 does not include a requirement for a procedure; however, some amplification documents for specific accrediting bodies do have this requirement regarding the technical review of inspection records to include review of the reports and testimony. These requirements are meant to ensure that the results of the testing methods continue to meet acceptance standards set forth during the validation, that equipment works properly, and that personnel can conduct the tests and obtain expected results. ISO/IEC 17025 requires that quality control materials or reference materials are used to identify, statistically determine, and analyze trends that might indicate the results are not valid. Other ways to ensure validity include using a secondary methodology, recalibration, technical review of reported results, interlaboratory/unit comparison studies and proficiency testing, or blind quality control samples.

3.5.5. Reports and inspection certificates

Section 7.4 of ISO/IEC 17020 and section 7.8 of ISO/IEC 17025 contain requirements for information that is expected to be included in the test reports and certificates issued by the unit. Although neither ISO/IEC document specifies that the unit must have a procedure for reporting, supplementary requirements include this requirement. The amplification documents for both standards require that the procedure for reporting results:

a) *"Identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing and for partial work performed.*
b) *Requires qualifying the significance of associations in the reports whether by a statistic or a qualitative statement.*
c) *Requires communicating the reason(s) in the report when the reported results are inconclusive and.*
d) *Requires reporting of the initial database entry (e.g. DNA profiles, friction ridge, ballistics, biometrics)."* [c] [12, 13]

[c] These requirements for the reporting procedures for both ISO/IEC 17020 and ISO/IEC 17025 are documented in the amplification documents ANAB AR3120 and AR3125. In addition to those requirements listed here, AR3120 also includes a requirement that when statistical sampling is used, the reporting procedure requires the agency to report the confidence level and corresponding inference regarding the population.

In addition, the amplification documents include requirements regarding the measurement uncertainty that must be included if it impacts the reported results. If any requirement in the standard is absent from a report or certificate, there must be a valid reason that must be defined in the unit's procedure for generating and issuing reports. The unit's procedure for reporting case results should include information on how the reports are prepared and distributed. The amplification documents give multiple options for meeting the requirements for reporting test results. The first option is to include all the information required by the standards in the report. The second option is to prepare an annex or appendix to the test report that documents any information not included in the test report but required by the standards. The third option is a simplified report. In simplified reporting, the client must agree, in writing, to the unit omitting some of the requirements from the test report. The fourth option is to include any additional information in the case record, although reference to this fact may need to be made in the report annex or appendix. The opinions and interpretation of findings must be documented either in the report or the case record. If an amended or corrected report is issued, that report must be uniquely identified and include all the information required by the standard to be included in the original report. This may be accomplished by referencing the original report in the amended or corrected report.

3.5.6. Complaints and Appeals

Both ISO/IEC 17020 and ISO/IEC 17025 (Section 7.9) address the customer, or client. In a forensic service provider, and in a CSI unit in particular, the customer is typically an investigator and perhaps a prosecutor. The standards require the unit to have a formal written procedure for documenting a complaint and appeals process, which should include:

- the process for receiving and acknowledging a complaint,
- identifying the individuals responsible for investigating the complaint,
- determining the actions needed to resolve and respond to the complaint,
- and communicating the decision and resolution of the complaint to the appellant.

3.5.7. Nonconforming Work

Both ISO/IEC 17020 (Section 8.7) and ISO/IEC 17025 (Section 7.10) require that the unit have a procedure for addressing nonconformance. Nonconforming work occurs when an aspect of the quality management system, such as a procedure or a policy, is not followed. It can occur despite the best efforts of a unit and its quality management system. Both standards include a list of requirements that must be addressed in the unit's procedure for addressing nonconforming work and includes:

- defining the management responsibilities and authorities,
- actions taken (including halting or repeating work),
- root cause analysis (determining the cause of the nonconformance),
- evaluation of the risks and impact,
- customer notification,

- and authorization of work to resume (if it has been stopped).

When nonconforming work occurs, the unit should determine what caused the nonconformance, what actions should be taken to address it, and what action should be taken to prevent recurrence.

3.5.8. Control of Data and Information Management

ISO/IEC 17025 (Section 7.11) includes requirements for laboratory information systems and control of data in both computerized and non-computerized systems. The unit must ensure that the data are protected from unauthorized access, tampering and loss. This section also addresses calculations and data transfers and requires these to be checked.

3.6. Section 8 - Management System Requirements

Table 7. ISO/IEC 17020 and ISO/IEC 17025. Section 8 – Management System Requirements.

17020 (2012)	17025 (2017)
8 Management system requirements	
8.1 Options	8.1 Options
	8.1.1 General
	8.1.2 Option A
	8.1.3 Option B
8.2 Management system documentation (Option A)	8.2 Management system documentation (Option A)
8.3 Control of documents (Option A)	8.3 Control of management system documents (Option A)
8.4 Control of records (Option A)	8.4 Control of records (Option A)
8.5 Management review (Option A)	8.5 Actions to address risks and opportunities (Option A)
8.6 Internal audits (Option A)	8.6 Improvement (Option A)
8.7 Corrective actions (Option A)	8.7 Corrective actions (Option A)
8.8 Preventive actions (Option A)	8.8 Internal audits (Option A)
	8.9 Management reviews (Option A)

3.6.1. Management System Requirements

Section 8 of both ISO/IEC 17020 and ISO/IEC 17025 defines the management system requirements for supporting and demonstrating the unit's consistent production of quality results and outputs. Both standards allow for implementation of one of two options to meet the management system requirements. Option B allows an agency to demonstrate adherence to ISO 9001 but does not require that the agency achieve ISO 9001 certification; however, if an agency plans to exercise option B it would be advisable to consider ISO 9001 certification. Option A details the management system requirements in sections 8.2–8.8 (ISO/IEC 17020) and 8.9 (ISO/IEC 17025).

3.6.2. Management System Documentation

Both ISO/IEC 17020 and ISO/IEC 17025 require that the unit has a management system that is fully documented and described in the Quality Manual. The Quality Manual should make refence to all policies, procedures, objectives, and systems relevant to the scope of inspections or tests

performed by the unit. This documentation should be readily available to all personnel as it pertains to their responsibilities. The development of the Quality Manual is one of the largest undertakings on the road to accreditation as it is the documentation of the unit's quality management system. The Quality Manual can be documented in an electronic or a hard copy, but it must be accessible to all employees. Therefore, if it is an electronic copy it needs to be stored on a server that is accessible to all employees and all employees must have access to a computer or other interface to access it. If it is a hard copy it needs to be kept someplace where all employees have access such as a break room, library, or other common area. It is generally not considered accessible to keep the hard copy in a locked office or other location that staff would not be able to access it such as in a bookcase located in an office behind the Laboratory Director or Quality Manager's desk. It is important that, if maintained in hardcopy format, the document is maintained in a controlled format where most current version is easily determined, and all previous iterations are marked as archived or indicated as such in a similar manner. See the Control of Documents section below.

It is also beneficial to document that all employees have reviewed the Quality Manual annually and maintain that documentation in the laboratory records. There is no specific required format for the quality manual. Many laboratories/units/agencies format their quality manuals to reflect the order of the applicable accreditation standards. More information about management system documentation can be found in the previous section entitled "Structuring the ISO Quality Management System." The SOPs and instruction methods are much more detailed than the quality manual but may be referenced in the quality manual.

3.6.3. Control of Documents

Document control is important for ensuring only the most up-to-date, approved revisions of the SOPs and test methods are accessible and used. A master list of documents is useful for maintaining control of documents. Each document should have a title and a unique document identifier, be reviewed on a regular basis, authorized by the appropriate authority, dated to ensure that they are reviewed and approved prior to use, and should include page numbers (i.e., pages X of Y) to indicate that the document is present in its entirety. Each subsequent revision should be documented in the document identification. The documents must be readily available and accessible to the staff who need to use them and must be controlled in such a way to prevent use of obsolete documents. If the documents are stored electronically, all obsolete documents should be archived where they are no longer accessible to the staff but maintained for version control. It is also beneficial to include a statement on the documents to indicate that they are "Uncontrolled if printed." If the documents are maintained in hard copy, it is essential to ensure that each copy is up to date and that obsolete or revised documents are archived and replaced with the current version.

There is no specification on how often the documents must be "periodically reviewed"; however, an annual review cycle is typical, or more frequently if needed. Records of the review should be maintained, and previous versions archived in case a need arises to go back and review the procedure in use at the time of a former examination or case. The document control procedure should document the authorizing authority for each document and how the unit controls access to ensure only the current version of the document is accessible and how staff can be assured they are using the most current version.

3.6.4. Control of Records

Along with the control of documents, the control of records is an important part of the agencies overall QMS. Both ISO/IEC 17020 and ISO/IEC 17025 require that the unit have a procedure for control of records that includes how the unit collects, identifies, indexes, stores, maintains, retrieves, and disposes of records. The procedure should also document how long the records will be retained and the procedures for disposition of the records and shall be consistent with all confidentiality requirements. The unit should consider record retention policies of any parent organization as well as any relevant laws. Control of records includes technical records of any examinations or analyses that are conducted as well as operational records and quality assurance and control records. This can include records of instrument maintenance, calibration, personnel records, training, proficiency testing, nonconformance, corrective actions, internal audits, and management reviews. This requirement covers all aspects of the case file, including notes or emails from relevant conversations, chain of custody records, analytical results, interpretations, measurements, and photos. The records included in the case file should be complete enough for a second person to be able to interpret the data or conduct a secondary review. Each page of the records should be uniquely identified and may be numbered to include the total number of pages so an incomplete record can be easily identified. All handwritten notes should be made using permanent ink so they cannot be erased from the record. If a correction is made to a written record, it should be crossed out with a single strikethrough, signed, and dated but still readable. If a correction is made to an electronic record, this record.

The records should be readily retrievable by staff members who need to access them but also securely stored as to limit access to protect the confidentiality and integrity of the records. Most units are in limited-access facilities, which would also secure any records located within the security perimeter; however, there may be some records that require additional security measures such as personnel files.

3.6.5. Management Review

Both ISO/IEC 17020 and ISO/IEC 17025 have a requirement for a formal management review process that must occur at least annually. ISO/IEC 17020 further requires that the review happens within a 12-month period if it occurs on a rolling basis. Both standards have very specific minimum requirements for the inputs that should be reviewed and the expected output, decisions, and actions that result from the management system review, which can be found in Table 8 below. The management review should include a review of the entire QMS and all operations of the unit, and all outputs should be documented, and the records retained based on the Control of Records standards.

Table 8. Management Review Required Inputs and Outputs.

17020 (2012)	17025 (2017)
Required Inputs 1. Results of internal and external audits 2. Feedback from clients and interested parties related to the fulfillment of this international standard. 3. The status of preventive and corrective actions 4. Follow-up actions from previous management reviews 5. The fulfillment of objectives 6. Changes that could affect the management system. 7. Appeals and complaints	**Required Inputs** 1. Changes in internal and external issues that are relevant to the laboratory. 2. Fulfilment of objectives 3. Suitability of policies and procedures 4. Status of actions from previous management reviews 5. Outcome of recent internal audits 6. Corrective actions 7. Assessments by external bodies 8. Changes in the volume and type of the work or in the range of laboratory activities 9. Customer and personnel feedback 10. Complaints 11. Effectiveness of any implemented improvements. 12. Adequacy of resources 13. Results of risk identification 14. Outcomes of the assurance of the validity of results 15. Other relevant factors, such as monitoring activities and training
Required **outputs** shall include decisions and actions related to: • Improvement of the effectiveness of the management system and its processes • Improvement of the inspection body related to the fulfilment of this international standard. • Resource needs	Required **outputs** shall record all decisions and actions related to at least: • The effectiveness of the management system and its processes • Improvement of the laboratory activities related to the fulfilment of the requirements of this document. • Provision of required resources • Any need for change

3.6.6. Actions to Address Risks and Opportunities for Improvement and Preventative Action

One of the foundations of an ISO-based QMS is continuous process improvement. As such, both standards require the unit to have a process by which all staff proactively identifies potential problems and opportunities for improvement within the management system and areas of operation. This requirement is noted in section 8.8 of ISO/IEC 17020 and sections 8.5 and 8.6 of ISO/IEC 17025. ISO/IEC 17025 includes a requirement that the unit consider and take action to address risks and opportunities for improvement, however there is no requirement for implementation of a formal risk management method or a documented risk management process. Nevertheless, agencies may decide to use one of the many tools available to formally address risk. Because ISO defines risk as the "effect of uncertainty on objectives," understanding the level of risk helps units meet their objectives. One simple but effective tool to measure risk is a two-dimensional, basic risk matrix shown in Figure 5. It weighs the severity of an issue or problem against the probability of occurrence in relationship to meeting objectives. Other more complex tools, such as Failure Mode and Effects Analysis, evaluate failures or potential failures using three dimensions and assigns a risk priority number score associated with the level of risk. Failure Mode and Effects Analysis is often used to measure risk related to corrective and

preventative action. Regardless of the method used, formally assessing risk provides units with a more objective understanding of risk to inform decision making.

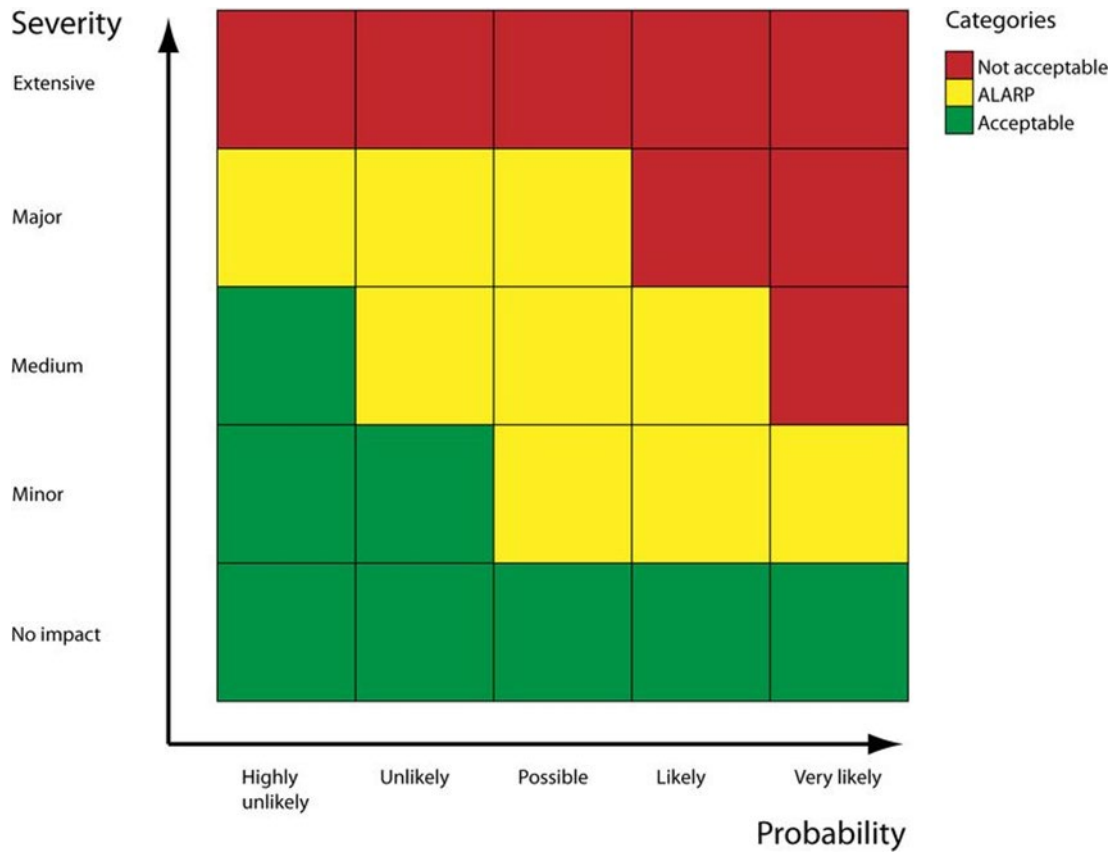


Fig. 5. Risk Matrix-Not Acceptable, As Low as Reasonably Practicable (ALARP) and Acceptable Risk.

Units may decide to make risk management part of their management review process and document actions taken to address risks and opportunities for improvement in the outputs from the management review. Opportunities for improvement may also be identified during internal audits, external assessments, suggestions from staff, as the result of nonconforming work investigations or corrective actions taken, analysis of quality control trends, or through performance monitoring. ISO/IEC 17020 specifically requires a documented procedure for both preventative and corrective actions, but they can both be covered in one procedure. ISO/IEC 17020 requires that the procedure for preventive action include how the unit will identify potential nonconformities and the root cause, evaluate the need to take preventative actions and determine and implement those actions, document the actions taken, and review the effectiveness of those actions.

Preventative actions and opportunities for improvement can be identified through trend analysis, such as monitoring quality control data, and then formulating a proactive approach to address those opportunities. Such activities may include reviewing charts to identify drifting control standards or calibration standards that are approaching failure and proactively remaking those standards before a failure occurs, monitoring turnaround times and proactively implementing

preventive measures when turnaround times start to trend upward, identifying back-up suppliers for key resources such as reagents or protective equipment, tracking equipment to proactively anticipate when critical equipment will need to be replaced, and implementing a plan to budget for those purchases. Opportunities for improvement and preventative actions can be identified by all levels of the organization and can include both administrative and technical activities.

3.6.7. Internal Audits

Both ISO/IEC 17020 and ISO/IEC 17025 require that the unit have a procedure for conducting internal audits. ISO/IEC 17020 requires that these audits take place annually, and although 17025 does not list a required frequency, an annual audit cycle (or more frequent) is typically expected. The internal audit should evaluate the unit's adherence to the ISO standard they are accredited to and their QMS to ensure that the QMS is fully implemented, followed, and appropriately documented. The QMS of the unit includes any policies and procedures and if the unit states that they follow particular standards, the internal audit may include checking for conformance to those standards. The internal audit should also evaluate the implementation of corrective actions from previous audit findings or for documented nonconformance. All corrections and findings and corrective actions from the internal audit must be documented and the record retained in accordance with the unit's control of records and retention policy. Internal auditors should be trained in all standards to which the unit is accredited. Internal audits are also beneficial as a gap assessment tool to prepare the unit for an initial or any subsequent, accreditation assessment. Additional guidance on internal audits can be found in ISO 19011 [27].

3.6.8. Corrective Actions

Both ISO/IEC 17020 (Sections 8.7 and 8.8) and ISO/IEC 17025 (Section 7.10) require that the unit have a procedure for identifying and implementing corrective action when a nonconformance occurs. This procedure must include:

- root cause analysis to identify the nonconformance and the cause,
- what action is needed to correct and address the consequences,
- action to prevent it from reoccurring,
- an implementation plan,
- documentation of all actions taken,
- and a review of the effectiveness of the corrective actions at resolving the issue.

Some examples of nonforming work that may initiate the corrective action procedure include a failed calibration, failed quality control, or failed proficiency test or because of internal or external audit findings.

4. Developing a Roadmap to Implementation of a Quality Management System

The development and adoption of a quality management system needs to be the strategic decision made by the whole organization with support from top management. It is vital that senior management is involved in the decision and creation process of the quality management

system because they decide the business strategy and resource allocation. In addition, a dedicated team is needed to develop and implement the quality management system. When beginning the accreditation process, a unit should develop a comprehensive plan that identifies members of the accreditation team, an accreditation implementation project leader, and that defines the scope of the accreditation. When choosing a project leader for the accreditation initiative, a unit should choose someone with strong communication skills who can help leadership understand the importance of accreditation, administrative challenges, and available and needed resources. The project leader should believe in the importance and value of accreditation and unit the accreditation team and others in the organization. The team members responsible for implementing and maintaining the quality management system will need to understand the full details of the applicable standard(s). There is a wide range of courses, workshops, and seminars available designed to offer training on the individual standards and how to audit to the standard, which is important for conducting internal audits and gap assessments. Given the unit's resources, it may be beneficial to use an independent consultant to advise a workable, realistic, and cost-effective strategic plan for accreditation implementation. In collaboration with the National Institute of Justice, the American Society of Crime Laboratory Directors (ASCLD) leads an accreditation initiative that provides a toolkit to aid in implementation of a quality management system. This initiative may provide mentors to help publicly funded units with the accreditation process.

Once a unit has determined which of the two ISO accreditation standards they wish to be accredited to and the project leader, the unit should define the scope of accreditation. The scope of accreditation is a document that contains information related to the testing and inspection activities that the unit requests to be covered by accreditation {reference ANAB GD3064}.

When defining the scope, it is important to consider:

- what testing and inspection activities are conducted in the unit,
- equipment, consumables, and reagents used to conduct testing and inspection activities,
- where testing and inspection activities occur,
- and who conducts these testing and inspection activities.

An accrediting body may have a list of testing and inspection activities related to forensic units that it accredits. Such a document can be helpful as the unit determines what activities it conducts, and the equipment used. The location in which the unit conducts its activities can be in the field such as at a scene or in a mobile laboratory, or in a permanent facility. Locations should be listed for each activity.

Once a unit has determined the scope of accreditation, it is important to conduct a gap assessment of the unit's quality management system and operational processes using the ISO standard it will be accredited to and identify areas in which the unit is currently meeting the requirements and areas that will need adjusting in order to meet the requirements. One way to do this is to create a checklist of the requirements from the standard and then conduct an internal audit against it to identify areas where the unit is already meeting the requirements, where a procedure is in place that could meet the requirements with some minor revisions, and where a new policy or procedure is needed to meet the requirement. The gap assessment should include:

- the general requirements for impartiality, confidentiality, and independence,

- structural requirements for administration, organization, and management,
- resource requirements for personnel, facilities, equipment, and any subcontractors the agency may use,
- process requirements for methods, procedures, records, reports, and certificates,
- and management system requirements for documentation, control of records, management review, internal audits, nonconformance, and preventative actions.

Once the gap assessment has been completed, it is important to develop a workplan inclusive of everyone in the unit. Some important tools to create the workplan include an Accreditation Project Chart that describes why your unit is pursuing accreditation, describes the costs and benefits of accreditation, and defines the goals of the project as well as what success looks like. The Accreditation Project Chart should also define how to manage possible setbacks, what reports need to be generated, and who is responsible for generating them to keep people informed and hold them accountable. The Accreditation Project Chart should also include the commitment from management, what resources management agreed to provide, and which units are contributing which resources, and what needs to be procured.

4.1. Developing Quality Management System Documentation

Decide on an appropriate platform for your management system documentation (e.g., specific software, process map–based software, SharePoint). It is important to give this some thought because selecting the best platform for the unit is important to ensure effective management, communication, and implementation of your quality management system. The QMS should describe the policies and operations of the unit. The documentation includes relevant processes and other documented information needed to support you in meeting your intended outcomes and the requirements of the applicable accreditation standard. An important step in establishing your management system is to determine the needed processes and their interactions in accordance with the unit policies, strategy, and objectives. These processes should cover areas such as the following:

- Operational processes,
- Meeting relevant needs and expectations of stakeholders,
- Management processes, including measurement, analysis, improvement, and innovation.

Specifics on what should be included in these processes are described throughout this document.

Communication and training are key to successful implementation. During the implementation phase, the unit will be working according to the established processes and connected criteria to document and demonstrate the effectiveness of the management system.

4.2. Steps to Accreditation

The business relationship with the accreditation body will exist for many years, or as long as accreditation is maintained. To have an efficient quality management system, continuous improvement is key to get the maximum value out of the accreditation process - evaluating strengths and identify opportunities for improvement. When selecting an accreditation body, it is

important to consider their credentials, reputation, and financial stability. Because forensic science is a specialized field it is also important to consider if the accreditation body has assessors who are qualified to conduct assessments in the scope of the accreditation that the unit is seeking. The unit may also want to consider if the accrediting body is an ILAC signatory, which can be found by searching the ILAC signatory database [28]. It is important to also understand the accrediting body's timeline to ensure that it is in sync with the timeline of the unit. The typical steps to accreditation are shown in Figure 6.

Fig. 6. Steps to accreditation.

While preparing for accreditation, the unit will need to ensure that management has allowed enough time for all staff to become familiar with the implemented QMS and time to develop sufficient evidence to document that the QMS has been fully implemented in casework. In addition to the foundational documentation of the QMS such as the Quality Manual and standard operating procedures, the unit must demonstrate that it is applying that QMS in its testing and inspections activities (casework). In order for the accreditation body to conduct an assessment, it

will need to review case files that demonstrate the unit is applying the QMS in its technical records and reports. This QMS documentation will be submitted to the accrediting body for the documentation review, which typically takes place 4 to 6 weeks before the assessment so that any deficiencies or nonconformances identified during this stage can be corrected before the assessment to prevent any delays.

Many accrediting bodies will allow the unit to request an optional preliminary assessment of the QMS to identify any weakness that may exist before the initial assessment. The preliminary assessment provides the unit with an opportunity to correct any potential areas for concern before the accreditation assessment begins. This can save the unit time on the back end of the assessment by identifying any deficiencies or nonconformances and possibly address them before they become documented as nonconformances during the accreditation assessment. Nonconformances require follow-up corrective actions and by participating in a preliminary assessment, the unit mitigates the time and expense associated with those corrective actions.

Before the assessment, a Lead Auditor/Assessor will be assigned by the accreditation body. This individual will work with the unit's Management Representative (usually the Quality Manager) to develop the agenda for the on-site assessment. On the first day of the assessment, there will be an opening briefing with the assessment team and the unit management staff who are directly involved with the laboratory management system. The assessment team will review the assessment scope and objectives and confirm the assessment schedule and an overview of the assessment process.

Following the opening briefing, it is typical to provide the assessment team with a walkthrough of the facility before they begin the assessment. During the assessment, assessors may interview personnel and request documents and records to inspect for completeness and to confirm that personnel know where to locate and how to retrieve the records. The assessors may also ask to review personnel training records and witness personnel perform their duties to ensure that they have documented demonstration of competencies and that they are following the standard operating procedures. It is important for management of the unit to talk with the lead assessor and ask how they would like to communicate throughout the assessment. For example, a lead assessor may wish to only communicate with the Quality Manager as a point of contact. It is also beneficial to request that the unit be updated daily with any potential nonconformances. If nonconformances are identified, they may be able to be addressed at the time by ensuring that the assessors have been provided with the appropriate records and information. Sometimes a nonconformance is identified because of a miscommunication and can be quickly resolved. If it cannot be resolved during the assessment, the assessor will record the nonconformance in the assessment report with a specific description of the nonconforming work and the corresponding section of the relevant standard. When the on-site assessment has been completed, an exit meeting will be held where the Lead Auditor/Assessor will provide a summary of the assessment, detailed explanation of any nonconformances, a copy of the draft assessment report, and a recommendation regarding the agency's eligibility for accreditation.

If the assessment team identifies nonconformances, they will allow the unit a reasonable amount of time to take corrective action. All accrediting bodies must have an appeal process. If the unit feels the assessors may have misinterpreted the standard or were missing information, and that the unit is in conformance with the standard, the unit can appeal or take corrective action. All nonconformances must be addressed and corrective actions implemented and evaluated before accreditation can be granted, but they are not a cause for alarm. The unit will need to provide a

corrective action response that includes a copy of objective evidence that the corrective actions have been implemented and completed. Depending on the nature and severity of the nonconformance, the Lead Auditor/Assessor may be able to confirm that the problem has been resolved based on the corrective action response or it may require a follow-up assessment limited to the area of concern. Once all nonconformances have been corrected and verified by the Lead Auditor/Assessor, the accreditation documents are sent to the accrediting body for staff who are independent of the initial assessment to review. Assessment documentation and the Lead Auditor/Assessor's recommendation whether to grant accreditation to the unit will be reviewed. Once the unit has attained ISO/IEC accreditation, annual surveillance assessments will be required to ensure that the unit is still in conformance with the relevant standards and is continually working to improve and maintain the QMS. It is important to recognize and accept that mistakes will happen, and it is through the process of conducting internal audits and surveillance assessments that these mistakes and nonconformances can be identified and addressed for continuous process improvement [3].

Developing a QMS and participating in the accreditation process are monumental tasks and investments of time and money. Many resources are available to assist a unit undertaking both. There are hundreds of accredited forensic service providers, including CSI units, in the United States alone. Many of their QMS documents are publicly available for reference. In addition, many forensic service providers are more than willing to support another organization in this process. Regional, national, and international forensic science professional organizations provide networking and collaboration opportunities as well as mentoring programs for accreditation. Federal grants are available to help defer initial accreditation costs as well. ISO/IEC 17020 and ISO/IEC 17025 are both customer-driven management system models that aim to control quality costs, improve measurement accuracy, and guarantee consistency of results. When implemented correctly, the elements of ISO/IEC 17020 and ISO/IEC 17025 work meticulously together to ensure that required quality levels are met and that the criminal justice system's needs are satisfied.

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