

# ILAC-G19 06/2022 Gap Analysis - August 2022

**Introduction** – This document serves as an informative guide correlating the clauses in ILAC-G19 06/2022 to the previous issue.

**Summary** – ILAC-G19 06/2022 was published in June 2022 and replaces the subsequent version (08/2014). UKAS have eluded that they expect organisations to be compliant with the new version by November 2022. They have also indicated if your assessment is just prior to November, there will be an expectation that progress has been made on a gap analysis. Changes are generally minor in nature, with no major changes noted. There are some new requirements, however most changes seem to relate to aligning with practices already adopted through compliance with other Quality Standards. Annex D provides clarification around expectations when testing is carried out as part of an inspection activity and which clauses of ISO/IEC 17025 are related.

| ILAC G19 06/2022 Clause No. | Emphasis of change | Summary of text/extract from ILAC G19 06/2022   | Comments |
|-----------------------------|--------------------|---|----------|
| 2.7 – Examination/Test      | Minor              | Definition expanded. ‘Opinions’ removed from this definition  |          |
| 2.9 – Forensic investigator | New                | Forensic investigator defined as ‘A person, however named, trained to perform scene of crime examinations and/or investigations. Other names used for this function are, for example, Scene of Crime Officer, Crime Scene Investigator, Scene of Crime investigator and Scene of Crime Examiner.’   |          |
| 2.10 – Forensic Report      | New                | Forensic Report defined as ‘A forensic report (however named) includes the results and interpretations of forensic examinations/tests. Such reports may be hard copy or electronic and may be in a format prescribed in relevant legislation. Forensic reports may be submitted to law enforcement investigators, members of the judiciary and other interested parties.’   |          |
| 2.12 – Impartiality         | Minor              | Definition expanded to include ‘The forensic unit shall undertake all activities impartially; some examples of the aspects of the forensic science process related to the demonstration of impartiality are the use of alternative hypotheses when developing strategies for scene of crime or laboratory examination or testing (4.3 and 4.7.2), the provision of background information (4.4.1 and 4.7.1) and the use of balanced scales of opinion (4.9).’ |          |

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| 2.13 – Item                 | New                | Item defined as ‘An item is an object, substance or sample recovered as part of an investigation. This includes everything recovered in the forensic science process including, whole objects, and debris and may include derived samples such as swabs, casts of footprints, and finger mark lifts. Items may sometimes be referred to as exhibits or evidence.’   |   |
| 2.16 Reference material     | Minor              | Definition expanded to include ‘Some reference materials may be certified reference materials in that the reference material is characterized by a metrologically valid procedure for one or more specified properties accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability.’  |   |
| 2.17 – Sampling             | Minor              | Definition updated to ‘Sampling is a defined process whereby a part of a substance, material or product is taken to provide for examination or testing. For the purpose of examinations/tests to determine the attributes of the whole, the process should be based on statistically valid techniques.<br>In forensic science, ‘sample’ is also used to describe physical objects collected as items, or sub-sets of these. These items may be collected using criteria other than conventional statistical criteria, for example, samples collected at a scene of crime. In this document the term sampling will be used for both purposes.’ |   |
| 2.21 - Testing              | New                | Testing defined as ‘Testing is used in the document when there is an activity including measurements and analytical techniques.’  |   |
| 3.2 – Complaints            | Minor              | ‘appeals or opportunities’ removed from this section to focus the requirements solely on complaints.  |   |
| 3.3 – Competence            | Minor              | ‘The forensic unit shall ensure that all staff working in the forensic unit are competent and authorized to perform the work required, and where their role requires it, to report the work.’   | Introduces the term ‘authorized’ in addition to competent and draws out authorization for reporting separately. |

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| 3.5 - Records                 | Minor              | <p>'The procedure in place should ensure that all of the components, both hard copy and electronic, are coordinated such that they are identified as a part of the case record and their locations are defined. In determining the retention period of the records associated with the forensic activity the forensic unit shall consider the legal requirements and customer expectations of the applicable economy or region. See ISO/IEC 17025 7.11 for more information regarding data and information management.'</p> <p>'If records are stored electronically, controls shall be in place to prevent unauthorized access, loss of files/data and to ensure the continued integrity of the records.'</p> | <p>Introduces the term 'coordinated' in this section.</p> <p>Also now includes further reference to electronic records around data integrity.</p> <p>Also, some expansion of the text to include electronic records as equivalent to case records.</p>  |
| 3.6 – Risks and Opportunities | New                | New section.   | <p>Introduces risk and opportunities and risk-based thinking, which aligns with ISO 17000 standards. This section also provides a bullet point list of some examples of risks to consider. Suggest reviewing this list against internal risk registers to ensure all risks in ILAC G19 have been considered within your organisation.</p> <p>Health and safety risks are built into the bullet points in this section. The health and safety section (formerly 3.6) has been removed.</p> |

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| 3.10 – Methods and Method<br>Validation                           | Minor                 | 'In demonstrating the suitability of a non-analytical discipline e.g., fingerprint enhancement, marks comparison, the forensic unit will need to review the list above and determine which aspects are appropriate to consider, whether there are additional considerations and how these would be evaluated for the method that they are reviewing.<br>For example:<br>range – does the technique work for typical items and/or surfaces<br>accuracy – can the technique capture and/or reproduce the item to the required level of detail for future use<br>repeatability – do all examiners get the same outcomes (within defined and acceptable limits)<br>robustness – does the technique work as effectively in different conditions, types of scenes<br>limitations – are there scenarios when the technique could not or should not be used, are there potentials for false positives and/or false negatives' | Additional information provided to assist with validation of non-analytical methods. |
| 3.12.1 – Equipment and<br>Measurement Traceability -<br>General   | New                   | 'The forensic unit shall define and document its procedures for the selection and use of purchased external services, equipment and consumable supplies that affect the quality of its service. There shall be procedures and criteria for acceptance, rejection and storage of equipment and/or materials, for example, consumables used at the scene, during analysis and personal protective equipment. Appropriate quality records of external services, supplies and purchased products shall be established and maintained for a period of time, as defined in the management system.'  |  |
| 3.12.2 – Equipment and<br>Measurement Traceability -<br>Equipment | Minor                 | Addition of 'Equipment that could be re-used at another scene should be cleaned after use, the rationale for the cleaning regime should be based on the potential risk to contaminate subsequent items and/or scenes.'  |  |

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| 3.12.5 – Equipment and Measurement Traceability - Equipment                               | Minor              | ‘Consumables, for example, swabs, chemicals, gel lifts, glassware, PPE, scalpels, scissors, packaging etc., shall be demonstrably suitable, stored correctly and monitored (if required). Consideration could be given to the compliance of the supplier of relevant supplies with ISO 18385:2016 Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes — Requirements.’  | This section has been amended to distinguish consumables from reference materials and reagents.                                 |
| 4.4.1 – Scene of crime examination procedures   | Minor              | Addition of ‘Additionally, the provision of this information should not compromise the impartiality of the forensic unit.’  | Suggest adding to impartiality risk register and taking appropriate mitigating action if required.                              |
| 4.5.2 – Determine what should be examined further and assurance of the integrity of items | Minor              | Addition of ‘When the forensic unit is responsible for the transportation and storage of the items prior to further examination or testing they shall ensure that the identified items are recovered, stored, and transported without contamination (from the environment, weather, people etc.), deterioration and with due regard to the integrity and the ‘chain of custody’ of the items. Where perishable items are handled any deterioration of the items shall be minimised.<br><br>If the forensic unit is handing over the items to the customer or other organization for the transportations and storage of the items prior to further examination or testing the forensic unit shall make them aware of any issues with respect to the aspects indicated above.<br><br>If the forensic unit is responsible for determining which items are sent on for examination or testing, they should have an agreement regarding this with their customer.’ | 4.5.2 and 4.5.3 (Subsequent laboratory examination/tests) have been condensed into this section and 4.5.3 has now been removed. |
| 4.6 – Interpret and Report Results and Observations from the Scene of Crime               | Minor              | Addition of ‘Outcomes from the scene of crime may be available to customers via an internal database rather than through more formal reports or customers may request a simplified report. It is important that the extent of any simplification does not lead to ambiguity in reporting, and the records held by the forensic unit shall be such that a comprehensive report could be produced if later required.’   |   |

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| 4.8.2 – Peer review  | Minor              | Addition of ‘Peer review shall be performed by an authorized person with the appropriate competence in the technique in order to confirm the validity of the results and/or to assess that there is an appropriate and sufficient basis for the conclusions and/or opinions.’ |          |
| 4.9 – Report of Examinations/Tests Including Interpretation of Results | Minor              | Addition of ‘Opinion scales shall be designed to demonstrate impartially, for example, that they are sufficiently balanced and should be communicated within the report and/or be available to the customer.’   |          |

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| Annex D                        | New                   | <p>‘The forensic science process (as detailed in this document) includes several stages from the initial discussion regarding scene of crime attendance through to the reporting of examinations/tests conducted in a laboratory environment. Accreditation Bodies have opted to have accreditation schemes based on ISO/IEC 17020 and/or ISO/IEC 17025 for different parts of the forensic science process. Consequently, the same activity conducted at a specific part of the forensic science process could be assessed using different standards by different Accreditation Bodies, and the same activity could be assessed by the same Accreditation Body under different standards depending on where in the overall forensic science process it takes place e.g., presumptive testing of blood at a crime scene or in a laboratory. Therefore, to ensure that equal confidence can be applied to all activities irrespective of the stage of the forensic science process at which they are conducted or if accredited by different Accreditation Bodies using different standards, consistent expectations are required. This document indicates, in the Scope, that any examinations/tests conducted as part of scene of crime investigation shall be carried out according to documented procedures and ISO/IEC 17020 may cover these procedures provided that the relevant clauses of ISO/IEC 17025 are considered. Examples of examination or testing activities that can be conducted at scenes include detection and recovery of body fluids, enhancement and recovery of footwear or finger marks, and determination of blood pattern analysis. The table below outlines the key relevant areas of ISO/IEC 17025 that should be met by the forensic unit if they are completing examinations/tests as part of an inspection activity.’</p> | See ILAC G19 for the table. |