**NOTES:**

**1. This working document is intended as a checklist for the assessor when conducting both ISO/IEC 17025: 2017 and ASCA Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program. This standard incorporates all elements of ISO 9001:2015 relevant to testing laboratories and Sampling Organizations. Organizations that already have ISO 9001:2015 for their scope of service similar to their accreditation scope will be held to the requirements as referenced in Clause 8, Option B which eliminates a full assessment to clauses 8.2-8.9. However, assessors should ensure that the laboratory has incorporated this standard in their quality system regardless of their ISO 9001:2015 certification and meet ASCA specific requirements related to QMS documentation as referenced in this checklist.**

**1a.) Clauses highlighted in green are Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program**

**1b) Items highligted in gray and italized are notes directly from the ISO/IEC 17025:2017 standard.**

**2. Please make notes in the Comments column any deficiencies in the laboratory's management system identified during the assessment (see item #3). These observations may be useful when preparing the assessment report and indicate to the reviewer that a thorough assessment was conducted. It is also imperative to note evidence of compliance, making reference to procedures/work instructions, dates, and other specific observations. At a minimum should be 1 comment per major element of the checklist.**

**3. Do not recommend specific solutions to deficiencies, as this would constitute a conflict of interest.**

**4. If additional questions arise during the assessment, indicate them (and the appropriate responses) either in the blank working document pages at the end of this document or in the empty rows included in some of the sections.**

**5. Please read the questions carefully, as the "preferred" answer in some cases may be "no" or "not applicable."**

**6. If, at any time, the assessment team requires assistance in the interpretation of the requirements of ISO/IEC 17025: 2017 or the ASCA Biocompatibility Testing of Medical Devices Guidance Document, contact the PJLA office immediately.**

| | |
|---|---|
| **Organization Name:** | |
| **Address:** | |
| **Telephone:** | |
| **E-mail:** | |
| **Web Address:** | |
| **Assessment Location (If different):** | |
| **Assessment Number:** | |
| **Assessment Date:** | |
| **Assessors(s):** | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| 4 | **General Requirements** | | | |
| 4.1 | **Impartiality** | | | |
| 4.1.1 | Has the laboratory undertaken impartially and structured and managed activities so as to safeguard impartiality? | | | |
| 4.1.2 | Is the laboratory management committed to impartiality? | | | |
| 4.1.3 | Is the laboratory responsible for the impartiality of it's laboratory activities and do not allow commercial, financial or other pressures to compromise impartiality? | | | |
| 4.1.4 | Does the laboratory identify risks to it's impartiality on an on-going basis? Including those risks that arise from its activities, or from its relationships, or from the relationships of it's personnel? However, such relationships do not necessarily present a laboratory with a risk to impartiality. | | | |
| ASCA | Does the laboratory have any services, such as consulting, design, or research offered? | | | |
| ASCA | Does the lab have a policy and procedure for maintaining impartiality through separation of those services from its testing activities? | | | |
| ASCA | Does the device manufacturer's internal testing laboratory have policies and procedures that specifically ensure and protect the impartiality regarding the laboratory to test or otherwise evaluate devices manufactured by the laboratory's parent organization and if applicable, other manufacturers without regard to the impact of the test results on the parent organization's business interest? | | | |
| 4.2 | **Confidentiality** | | | |
| 4.2.1 | Is the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities? | | | |
| 4.2.1 | Does the laboratory inform the customer in advance, of the information it intends to place in the public domain? Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. | | | |
| 4.2.2 | When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is the customer or individual concerned, unless prohibited by law, be notified of the information provided? | | | |
| 4.2.3 | Does the laboratory ensure that Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) is confidential between the customer and the laboratory? | | | |
| 4.2.3 | Is the provider (source) of this information confidential to the laboratory and not be shared with the customer, unless agreed by the source? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **4.2.4** | Does personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities? | | | |
| **5** | **Structural Requirements** | | | |
| **5.1** | Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities? | | | |
| **Note** | *For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.* | | | |
| **5.2** | Does the laboratory identify management that has overall responsibility for the laboratory? | | | |
| **5.3** | Does the laboratory define and document the range of laboratory activities for which it conforms with this document? | | | |
| **5.3** | Does the laboratory only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis? | | | |
| **5.4** | Are laboratory activities carried out in such a way as to meet the requirements of the standard, the laboratory's customers, regulatory authorities and organizations providing recognition including activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility? | | | |
| **5.5** | Does the laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: | | | |
| **5.5** | a) implementation, maintenance and improvement of the management system? | | | |
| **5.5** | b) identification of deviations from the management system or from the procedures for performing laboratory activities? | | | |
| **5.6** | c) initiation of actions to prevent or minimize such deviations? | | | |
| **5.6** | d) reporting to laboratory management on the performance of the management system and any need for improvement? | | | |
| **5.6** | e) ensuring the effectiveness of laboratory activities? | | | |
| **5.6** | c) initiation of actions to prevent or minimize such deviations; | | | |
| **5.6** | d) reporting to laboratory management on the performance of the management system and any need for improvement; | | | |
| **5.6** | e) ensuring the effectiveness of laboratory activities? | | | |
| **5.7** | Does the laboratory management ensure that: | | | |
| **5.7** | a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; | | | |
| **5.7** | b) the integrity of the management system is maintained when changes to the management system are planned and implemented. | | | |
| **6** | **Resource Requirements** | | | |
| **6.1** | **General** | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **6.1.1** | Does the laboratory have available the personnel, facilities, equipment, systems, and suppport services necessary to manage and perform its laboratory activities? | | | |
| **6.2** | **Personnel** | | | |
| **6.2.1** | Does all personnel of the laboratory, either internal or external, that could -<br>influence the laboratory activities<br>- act impartial?<br>- are competent?<br>- work in accordance with the laboratory's management system? | | | |
| **6.2.2** | Does the laboratory document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience? | | | |
| **6.2.3** | Does the laboratory ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations? | | | |
| **6.2.4** | Does the management of the laboratory communicate to personnel their duties, responsibilities and authorities? | | | |
| **6.2.5** | Does the laboratory have procedure(s) and retain records for: | | | |
| **6.2.5** | a) determining the competence requirements? | | | |
| **6.2.5** | b) selection of personnel? | | | |
| **6.2.5** | c) training of personnel? | | | |
| **6.2.5** | d) supervision of personnel? | | | |
| **6.2.5** | e) authorization of personnel? | | | |
| **6.2.5** | f) monitoring of competence of personnel? | | | |
| **6.2.6** | Does the laboratory authorize personnel to perform specific laboratory activities, including but not limited to, the following? | | | |
| **6.2.6** | a) development, modification, verification and validation of methods? | | | |
| **6.2.6** | b) analysis of results, including statements of conformity or opinions and interpretations? | | | |
| **6.2.6** | c) report, review and authorization of results? | | | |
| **ASCA** | Does the testing laboratory maintain competent technical personnel that are knowledgeable in appropriate test method for the requested scope of accreditation? | | | |
| **Invitro Testing** | Do technicians performing in vitro tests have 1 year of relevant test experience with each standard test included in the ASCA program to which technicians are assigned, **OR** demonstrated proficiency through completion minimally of 25 tests, **OR** 25 phases as outlined in each study specific training? | | | |
| **Invitro Testing** | Do technicians performing in vitro tests have a Bachelor's or associate degree in relevant science areas to the in vitro/in vivo biocompatibility testing included in the ASCA Pilot? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **ISO 10993-12:2012 Sample preparation for all test types** | Do technicians performing any test specific sample preparation have 1 year of sample preparation experience with the relevant standard test included in the ASCA program to which technicians are assigned, OR demonstrated proficiency through completion of sample preparation for minimally 25 tests as outlined in each study specific training? | | | |
| **ISO 10993-12:2012 Sample preparation for all test types** | Do technicians performing any test specific sample preparation have a Bachelor's or associate degree in science? | | | |
| **ISO 10993-12:2012 Sample preparation for all test types** | Do technicians performing sample preparation that is applicable for various tests (e.g., technicians in general sample preparation lab who prepare samples/extracts for various tests) have 1 year sample preparation experience with any standard test included in the ASCA program OR demonstrated proficiency through completion of sample preparation for minimally 25 of any of the standard tests in the ASCA program? | | | |
| **ISO 10993-12:2012 Sample preparation for all test types** | Do technicians performing sample preparation that is applicable for various tests (e.g., technicians in general sample preparation lab who prepare samples/extracts for various tests) have a Bachelor's or associate degree in science? | | | |
| **ASCA** | Do study directors:<br>Have a Bachelor's or higher degree in scientific discipline? **AND**<br>Have 2 years of relevant test experience with each standard test? **AND**<br>Have a direction of at least 25 studies in each relevant test, **OR**<br>management of 25 studies with someone who has directed at least 25 studies in each relevant test? | | | |
| **ASCA** | Is the testing laboratory's management knowledgeable in applicable aspects of the FD&C Act and 21 CFR regulations pertinent to the oversight of medical devices and the criteria set out in ISO/IEC 17025 and ASCA program specifications? | | | |
| **ASCA** | Does the testing laboratory have a list of laboratory managers and contact information? | | | |
| **ASCA** | Does the testing laboratory document and maintain a training program for new and previously trained technical personnel? | | | |
| **ASCA** | Does the testing laboratory maintain a training program that includes the proper procedures for applying new/updated test procedures and performing required tests? | | | |
| **ASCA** | Does the testing laboratory provide new and previously trained technical personnel relevant test-specific requalification training (e.g., cytotoxicity subjective scoring): Every 6-12 months? When responsibilities have changed.When test standards or procedures are updated or developed? | | | |
| **ASCA** | Does the testing laboratory conduct training on a periodic basis through application of training approaches, such as on-the-job training and formal classroom training, as appropriate? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **ASCA** | Does the testing laboratory maintain records of training demonstrating that technical personnel who participate in the conduct of ASCA testing have been trained and evaluated to be competent in the performance of each ASCA test? | | | |
| **ASCA** | Does the training include the ability to follow test-related standard operating procedures (SOPs) and documentation, and in person hands-on or classroom or online training? | | | |
| **ASCA** | Does the testing laboratory have procedures for periodic internal test lab proficiency checks of technicians for the tests performed under the ASCA Pilot with subjective analyses, to include when staff would require retraining? | | | |
| **ASCA** | Does the testing laboratory maintain records demonstrating trainers have qualifications and at least 2 years' experience (routinely performing each relevant ASCA test) to train the technical personnel who will perform the ASCA tests? | | | |
| **ASCA** | Does the testing laboratory have procedures to establish how test and control samples are prepared? | | | |
| **ASCA** | Does the testing laboratory agree to have procedures to establish how test and control samples are prepared and training that includes the following: | | | |
| **ASCA** | • Procedures for device preparation, including:<br>- Cutting samples (if appropriate) and documentation (e.g., photographs) of any particle generation prior to extraction,<br>- Determination of device surface area for extraction ratio, and the volume required to complete the study,<br>- Use of non-standard surface area approaches (e.g., porous devices),<br>- Exclusion of non-contacting components from extraction,<br>- Selection of representative portions for direct contact hemocompatibility studies (i.e., hemolysis, complement activation), | | | |
| **ASCA** | Selection of extraction conditions (i.e., time, temperature, and extraction vehicle),<br>• Assessment and documentation of changes (e.g., photographs) after extraction to sample (e.g., color changes, integrity, swelling) or extract conditions (e.g., pH, particles/precipitates, color changes, or turbidity),<br>• General and/or test-specific follow-up procedures when changes are noted (e.g., extract settling techniques to allow particle-free IV injections),<br>• Use of non-standard extraction approaches (e.g., fluid path approaches, approaches for extremely large devices, procedures to maintain contact with extraction vehicle), and<br>• Handling of extracts prior to testing (e.g., filtration, centrifugation, storage time and temperature). | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **Invivo Testing** | Does the lab have training which includes:<br>• **Guinea Pig Maximization (GPMT) and Closed Patch Sensitization:**<br>- Shaving techniques (e.g., to avoid razor burn)<br>- Mixing of extract and adjuvant, if applicable<br>- Intradermal injection (GPMT) including criteria to confirm avoidance of subcutaneous injections<br>- Sample application (GPMT and Closed Patch)<br>- Animal wrapping<br>- Differentiation for source of redness (e.g., true sensitization versus mechanical/adhesive irritation)<br>- Minimally, quarterly periodic technician proficiency check of positive control scoring (in live animals at least once annually)<br>- Technician retraining, if needed<br>• **Intracutaneous Reactivity and Dermal Irritation:**<br>- Shaving techniques (e.g., to avoid razor burn)<br>- Application of test samples<br>- Injection technique and signs to confirm appropriate injection location<br>- Differentiation for source of redness (e.g., true irritation versus possible irritation from shaving)<br>- Minimally, biannual periodic technician proficiency check of positive response scoring (in live animals at least once annually)<br>- Technician retraining, if needed<br>• **Acute Systemic Toxicity:**<br>- Balance use and calibration to ensure appropriate sensitivity<br>- Intraperitoneal (IP) and intravenous (IV) injection techniques and signs to confirm appropriate injection location<br>- Minimally, technician proficiency check on injection techniques prior to conduct of next test if it has been more than one month between technician conduct of a study<br>- Technician retraining, if needed | | | |
| **6.3** | **Facilities and Environmental Conditions** | | | |
| **6.3.1** | Are facilities and environmental conditions suitable for the laboratory activities and not adversely affect the validity of results? | | | |
| **Note** | *Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.* | | | |
| **6.3.2** | Are requirements for facilities and environmental conditions necessary for the performance of the laboratory activities documented? | | | |
| **6.3.3** | Does the laboratory monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results? | | | |
| **6.3.4** | Are measures to control facilities implemented, monitored and periodically reviewed? | | | |
| **6.3.4** | Does it include, but not be limited to?: | | | |
| **6.3.4** | a) access to and use of areas affecting laboratory activities? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **6.3.4** | b) prevention of contamination, interference or adverse influences on laboratory activities? | | | |
| **6.3.4** | c) effective separation between areas with incompatible laboratory activities? | | | |
| **6.3.5** | When the laboratory performs laboratory activities at sites or facilities outside its permanent control, does it ensure that the requirements related to facilities and environmental conditions of this document are met? | | | |
| **6.4** | **Equipment** | | | |
| **ASCA** | Does the testing laboratory ensure that all equipment used for testing and evaluating devices is available and in proper working order for requested scope of accreditation? | | | |
| **6.4.1** | Does the laboratory have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result? | | | |
| **Note 1** | *A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. Reference materials from producers meeting the requirements of ISO 17034 come with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.* | | | |
| | *Reference materials should be used from producers that meet ISO 17034.* | | | |
| **Note 2** | *ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in house quality control materials.* | | | |
| **6.4.2** | In those cases where the laboratory uses equipment outside its permanent control, does the laboratory ensure that the requirements for equipment of this document are met? | | | |
| **6.4.3** | Does the laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration? | | | |
| **6.4.4** | Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service? | | | |
| **6.4.5** | Is the equipment used for measurement capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result? | | | |
| | Is measuring equipment calibrated when: | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **6.4.6** | a) the measurement accuracy or measurement uncertainty affects the validity of the reported results? | | | |
| | b) calibration of the equipment is required to establish the metrological traceability of the reported result? | | | |
| **Note** | *Types of equipment having an effect on the validity of the reported results can include:* | | | |
| | *— those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;* | | | |
| | *— those used to make corrections to the measured value, e.g. temperature measurements;* | | | |
| | *— those used to obtain a measurement result calculated from multiple quantities.* | | | |
| **ASCA** | Does the testing laboratory ensure that its procedures specify the steps for establishing calibration intervals for each type or item of equipment, and specify criteria, steps, and approvals for extending the calibration interval of an instrument? | | | |
| **6.4.7** | Does the laboratory establish a calibration programme which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration? | | | |
| **6.4.8** | Does all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity? | | | |
| **6.4.9** | Is equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, taken out of service? | | | |
| **6.4.9** | Is It isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly? | | | |
| **6.4.9** | Does the laboratory examine the effect of the defect or deviation from specified requirements and initiate the management of nonconforming work procedure? (see 7.10) | | | |
| **6.4.10** | When intermediate checks are necessary to maintain confidence in the performance of the equipment, are these checks shall be carried out according to a procedure? | | | |
| **6.4.11** | When calibration and reference material data include reference values or correction factors, does the laboratory ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements? | | | |
| **ASCA** | Does the testing laboratory ensure that its procedures address adding, deleting, modifying, or maintaining information in equipment records in an accurate and timely manner, and specify the personnel responsible for these task? | | | |
| **6.4.12** | Does the laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **6.4.13** | Are records retained for equipment which can influence laboratory activities? | | | |
| **6.4.13** | Does the laboratory records include the following where applicable? | | | |
| **6.4.13** | a) the identity of equipment, including software and firmware version? | | | |
| **6.4.13** | b) the manufacturer's name, type identification, and serial number or other unique identification? | | | |
| **6.4.13** | c) evidence of verification that equipment conforms with specified requirements? | | | |
| **6.4.13** | d) the current location? | | | |
| **6.4.13** | e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval? | | | |
| **6.4.13** | f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity? | | | |
| **6.4.13** | g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment? | | | |
| **6.4.13** | h) details of any damage, malfunction, modification to, or repair of, the equipment? | | | |
| **ASCA** | Does the testing laboratory have procedures to examine the effects of equipment operation outside the equipment tolerances or study specified limits (e.g., temperature excursions) on test results?<br>• Procedures for device preparation, including:<br>- Cutting samples (if appropriate) and documentation (e.g., photographs) of any particle generation prior to extraction,<br>- Determination of device surface area for extraction ratio, and the volume required to complete the study,<br>- Use of non-standard surface area approaches (e.g., porous devices),<br>- Exclusion of non-contacting components from extraction,<br>- Selection of representative portions for direct contact hemocompatibility studies (i.e., hemolysis, complement activation), | | | |
| **ASCA** | Does the procedure identify the personnel responsible for such examination of the equipment (e.g., technicians) and determination of acceptability with respect to test validity (e.g., study directors/toxicologists), specify their responsibilities, and provide the steps for determining if the equipment variation would impact the study results, including:<br>• Determining whether the effects are unacceptable (including the accept/reject criteria)<br>• Identifying the conducted tests affected<br>• Analyzing the results impacted for these particular tests<br>• Determining whether retesting is required. | | | |
| **6.5** | **Metrological Traceability** | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **6.5.1** | Does the laboratory establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference? | | | |
| **Note 1** | *In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".* | | | |
| **Note 2** | *See Annex A for additional information on metrological traceability.* | | | |
| **ASCA** | Does the testing laboratory use specified methods and/or standards that clearly describe the following:<br>• Calibration to three decimal places for spectrophotometer absorbance readings for hemolysis and complement activation?<br>• Particle ranges for calibration of coulter counter use for cell counting? | | | |
| **6.5.2** | Does the laboratory ensure that measurement results are traceable to the International System of Units (SI) through one of the following: | | | |
| | a) calibration provided by a competent laboratory? | | | |
| **Note 1** | *Laboratories fulfilling the requirements of this document are considered to be competent.* | | | |
| **6.5.2** | b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI? | | | |
| **Note 2** | *Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.* | | | |
| **ASCA** | Does testing laboratory have procedures to qualify new controls if test-specified positive, negative, and/or reference controls are no longer able to distinguish between positive and negative responses? | | | |
| **ASCA** | Does the testing laboratory ensure that controls (positive/negative/reagent, if applicable) meet assay-specific acceptance criteria? | | | |
| **ASCA** | Have any periodic postive contols conducted using biannual testing to detect positive sensitization reponses been deemed no longer vaild?<br>**Note: All testing conducted after the last validated positive control run cannot be submitted as part of the ASCA Pilot.** | | | |
| **6.5.2** | c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards? | | | |
| **Note 3** | *Details of practical realization of the definitions of some important units are given in the SI brochure?* | | | |
| **6.5.3** | When metrological traceability to the SI units is not technically possible, does the laboratory demonstrate metrological traceability to an appropriate reference ? | | | |
| **6.5.3** | Is the reference assocated with? | | | |
| **6.5.3** | a) certified values of certified reference materials provided by a competent producer? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **6.5.3** | b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison? | | | |
| **6.6** | **Externally Provided Products and Services** | | | |
| **ASCA** | Are all subcontractors utilized to conduct testing under the scope of ASCA Accreditation, ASCA-accredited testing laboratories? | | | |
| **6.6.1** | Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used? | | | |
| **6.6.1** | Does this include product and sevices that: a) are intended for incorporation into the laboratory's own activities? | | | |
| **6.6.1** | b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider? | | | |
| **6.6.1** | c) are used to support the operation of the laboratory? | | | |
| **Note** | *Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.* | | | |
| **6.6.2** | Does the laboratory have a procedure and retain records for: | | | |
| **6.6.2** | a) defining, reviewing and approving the laboratory's requirements for externally provided products and services? | | | |
| **6.6.2** | b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers? | | | |
| **6.6.2** | c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer? | | | |
| **6.6.2** | d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers? | | | |
| **6.6.3** | Does the laboratory communicate its requirements to external providers for: | | | |
| **6.6.3** | a) the products and services to be provided? | | | |
| **6.6.3** | b) the acceptance criteria? | | | |
| **6.6.3** | c) competence, including any required qualification of personnel? | | | |
| **6.6.3** | d) activities that the laboratory, or its customer, intends to perform at the external provider's premises? | | | |
| **7** | **Process Requirements** | | | |
| **7.1** | **Review of Requests, Tenders and Contracts** | | | |
| **7.1.1** | Does the laboratory have a procedure for the review of requests, tenders and contracts. | | | |
| **7.1.1** | Do the procedure shall ensure: | | | |
| **7.1.1** | a) the requirements are adequately defined, documented and understood? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **7.1.1** | b) the laboratory has the capability and resources to meet the requirements? | | | |
| **7.1.1** | c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval? | | | |
| **Note 1** | It is recognized that externally provided laboratory activities can occur when: | | | |
| | *— the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;* | | | |
| | *— the laboratory does not have the resources or competence to perform the activities.* | | | |
| **7.1.1** | d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements. | | | |
| **Note 2** | *For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.* | | | |
| **7.1.2** | Does the laboratory inform the customer when the method requested by the customer is considered to be inappropriate or out of date? | | | |
| **7.1.3** | When the customer request a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), isthe decision rule shall be clearly defined? Unless inherent in the requested specification or standard, is the decision rule selected shall be communicated to, and agreed with, the customer? | | | |
| **Note** | *For further guidance on statements of conformity, see ISO/IEC Guide 98-4.* | | | |
| **7.1.4** | Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Do deviations requested by the customer not impact the integrity of the laboratory or the validity of the results? | | | |
| **7.1.5** | Is the customer shall be informed of any deviation from the contract? | | | |
| **7.1.6** | If a contract is amended after work has commenced, us contract reviewrepeated and any amendments communicated to all affected personnel? | | | |
| **7.1.7** | Does laboratory cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed? | | | |
| **Note** | *Such cooperation can include: a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;* | | | |
| | *b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.* | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **7.1.8** | Are records of reviews, including any significant changes retained including records of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities? | | | |
| **7.2** | **Selection, Verification and Validation of Methods** | | | |
| **7.2.1** | **Selection and Verification of Methods** | | | |
| **7.2.1.1** | Does the laboratory use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data? | | | |
| **Note** | *"Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.* | | | |
| **7.2.1.2** | Do all methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and made readily available to personnel (see 8.3)? | | | |
| **7.2.1.3** | The laboratory ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so? | | | |
| **7.2.1.3** | When necessary, is the application of the method supplemented with additional details to ensure consistent application? | | | |
| **Note** | *International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.* | | | |
| **7.2.1.4** | When the customer does not specify the method to be used, the does the laborator select an appropriate method and inform the customer of the method chosen? | | | |
| **7.2.1.5** | Does the laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance? | | | |
| **7.2.1.5** | Are records of the verification retained? | | | |
| **7.2.1.5** | If the method is revised by the issuing body, is verification repeated to the extent necessary? | | | |
| **7.2.1.6** | When method development is required, is this a planned activity and assigned to competent personnel equipped with adequate resources? | | | |
| **7.2.1.6** | As method development proceeds, does the lab conduct periodic reviews to confirm that the needs of the customer are still being fulfilled? | | | |
| **7.2.1.6** | Are any modifications to the development plan approved and authorized? | | | |
| **7.2.1.7** | Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **Note** | *Customer acceptance of deviations can be agreed in advance in the contract.* | | | |
| **7.2.2** | **Validation of Methods** | | | |
| **ASCA** | Does the management system include procedures governing the development, maintenance, and use of test procedures? | | | |
| **ASCA** | Does the management system procedures include steps for:<br>• Identifying the personnel responsible for developing, reviewing, and maintaining these documents<br>• Specifying the frequency of review by technical personnel and management<br>• Ensuring consistency with applicable standard(s)<br>• Ensuring test modifications are reviewed by personnel who are competent to the applicable standard(s)<br>• Identifying and documenting the types of modifications to the test procedures that do not need to be reviewed by FDA for confirmation prior to implementation. | | | |
| **ASCA** | **Note**: Any procedures regarding the following as well as any unanticipated changes will be confirmed with FDA and PJLA prior to implementation:<br>- Changes to sample for retesting to achieve a “passing” result<br>- pH adjustments<br>- Sample filtration or other extract manipulation<br>- Removal or modification of documentation associated with color, turbidity or particles in the test extract, or swelling/degradation of the test article<br>- Frequency of non-concurrent control testing<br>- Changes to acceptance criteria outside the validated/qualified laboratory-specific limits (e.g., for complement activation where the standard methods do not specify acceptable limits)<br>- Changes to data calculations and presentation, if applicable (e.g., hemolytic index, irritation index, complement activation plots)<br>- Changes in the criteria for re-challenge or retesting<br>- Changes in the criteria for reportable adverse clinical observations or animal deaths | | | |
| **7.2.2.1** | If the the laboratory validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified, is the validation extensive as is necessary to meet the needs of the given application or field of application? | | | |
| **Note 1** | *Validation can include procedures for sampling, handling and transportation of test or calibration items.* | | | |
| | *The techniques used for method validation can be one of, or a combination of, the following:* | | | |
| | *a) calibration or evaluation of bias and precision using reference standards or reference materials;* | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **Note 2** | *b) systematic assessment of the factors influencing the result;* | | | |
| | *c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;* | | | |
| | *d) comparison of results achieved with other validated methods;* | | | |
| | *e) interlaboratory comparisons;* | | | |
| | *f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.* | | | |
| **ASCA** | The test procedures must include or specify, as appropriate, the following:<br>• Unique identification, including title, document number, revision, and effective date<br>• Specific test equipment to use along with their required ratings<br>• Warnings/caution statements to alert the operators of potential hazards<br>• Normal and any unusual ambient conditions (including tolerances) for tests<br>• Test data to be obtained and recorded<br>• Objective acceptance criteria for results including the essential performance required to be maintained<br>• Testing techniques (i.e. test methods) required to ensure consistent results<br>• Instructions on test conduct, including equipment operation, reagent preparation, cell line and animal handling, techniques, preparation of test samples (including instructions for sample traceability during testing, if applicable), conduct of each step of the test, data recording, and scoring assessment procedures<br>• Deviations from the SOP, as well as any equipment deviations and discussion of why deviations will not impact the validity of the study results | | | |
| **ASCA** | Does the test procedure include relevant information from the intended use of the device to ensure that the types of biological evaluation assessments recommended by FDA are considered based on tissue type and duration of contact with the device? | | | |
| **ASCA** | Does each test procedure include relevant information from the manufacturers essential performance specifications, including any **metrological stability,** to ensure that the test procedures (e.g., extraction temperature and time) are compatible with the device? | | | |
| **ASCA** | Does each test procedure adequately address all the applicable specifications of the standard for the devices being tested? | | | |
| **7.2.2.2** | When changes are made to a validated method, are the influence of such change determined and where they are found to affect the original validation, is a new method validation performed? | | | |
| **7.2.2.3** | Are the performance characteristics of validated methods as assessed for the intended use, relevant to the customers' needs and consistent with specified requirements? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **Note** | *Performance characteristics can include, but are not limited to, the measurement range, accuracy, the measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.* | | | |
| **7.2.2.4** | Does the laboratory retain the following records of validation:<br>a) the validation procedure used? | | | |
| **7.2.2.4** | b) specification of the requirements? | | | |
| **7.2.2.4** | c) determination of the performance characteristics of the method? | | | |
| **7.2.2.4** | d) results obtained? | | | |
| **7.2.2.4** | e) a statement on the validity of the method, detailing its fitness for the intended use? | | | |
| **7.3** | **Sampling** | | | |
| **ASCA** | Does the testing lab's procedure(s) for sample preparation meet the specifications of ISO 10993-12 and FDA’s guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process" | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **ASCA** | Does the testing lab sample preparation include the following:<br>• Use of surface area/extraction volume ratio (unless mass/extract volume ratio results in equivalent or higher amount of test sample)<br>• No dilutions of extract or test solutions, unless required for dose-dependent cytotoxicity studies<br>• No filtration/centrifugation<br>• No pH/osmolality adjustment<br>• Documentation of any color changes, turbidity or particles in the extract<br>• How representative portions are selected for testing, if the test system cannot accommodate all of the direct and indirect tissue contacting device components, to include documentation of what was excluded<br>• How extraction vehicle volume will be determined and documented for absorbent devices (e.g., spongy devices)<br>• How sample extraction ratios will be selected for devices having multiple components with different thicknesses<br>• How components with different types and durations of contact will be separated for sample preparation and testing<br>• Situations when pooled component samples (with same or different types or duration of tissue contact) will be allowed<br>• Inclusion of only tissue contacting components (unless procedure describes how inclusion of non-tissue contacting components will be addressed in determination of extraction ratios)<br>• Submersion of large devices completely in extraction vehicle<br>• How extractions will be conducted for devices containing fluid path components<br>• That the following types of devices are excluded for the ASCA Pilot: absorbable and in situ polymerizing devices, liquid devices, creams, gels, hydrogel devices, and devices containing nanomaterials. | | | |
| **7.3.1** | Does the laboratory have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration? | | | |
| **7.3.1** | Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results? | | | |
| **7.3.1** | Does the sampling plan and method available at the site where sampling is undertaken? | | | |
| **7.3.1** | Are sampling plans , whenever reasonable, based on appropriate statistical methods? | | | |
| **7.3.2** | Does the sampling method describe: | | | |
| **7.3.2** | a) the selection of samples or sites? | | | |
| **7.3.2** | b) the sampling plan? | | | |
| **7.3.2** | c) preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration? | | | |
| **Note** | *When received into the laboratory, further handling can be required as specified in 7.4.* | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **7.3.3** | Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken? | | | |
| **7.3.3** | Do these records include, where relevant: | | | |
| **7.3.3** | a) reference to the sampling method used? | | | |
| **7.3.3** | b) date and time of sampling? | | | |
| **7.3.3** | c) data to identify and describe the sample (e.g. number, amount, name)? | | | |
| **7.3.3** | d) identification of the personnel performing sampling? | | | |
| **7.3.3** | e) identification of the equipment used? | | | |
| **7.3.3** | f) environmental or transport conditions? | | | |
| **7.3.3** | g) diagrams or other equivalent means to identify the sampling location when appropriate? | | | |
| **7.3.3** | h) deviations, additions to or exclusions from the sampling method and sampling plan? | | | |
| **7.4** | **Handling of Test or Calibration Items** | | | |
| **7.4.1** | Does the laboratory have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer? | | | |
| **7.4.1** | Are precautions taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for, testing or calibration? | | | |
| **7.4.1** | Are handling instructions provided with the item followed? | | | |
| **7.4.2** | Does the laboratory have a system for the unambiguous identification of test or calibration items? | | | |
| **7.4.2** | Is the identification retained while the item is under the responsibility of the laboratory? | | | |
| **7.4.2** | Does the system ensure that items will not be confused physically or when referred to in records or other documents? | | | |
| **7.4.2** | Does the system, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items? | | | |
| **7.4.3** | Upon receipt of the test or calibration item, are deviations from specified conditions recorded? | | | |
| **7.4.3** | When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does the laboratory consult the customer for further instructions before proceeding and record the results of this consultation? | | | |
| **7.4.3** | When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does the the laboratory include a disclaimer in the report indicating which results may be affected by the deviation? | | | |
| **7.4.4** | When items need to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **7.5** | **Techinical Records** | | | |
| **7.5.1** | Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original? | | | |
| **7.5.1** | Do the technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results? | | | |
| **7.5.1** | Are original observations, data and calculations recorded at the time they are made and are identifiable with the specific task? | | | |
| **7.5.2** | Does the laboratory ensure that amendments to technical records can be tracked to previous versions or to original observations? | | | |
| **7.5.2** | Are both the original and amended data and files kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations? | | | |
| **7.6** | **Evaluation of Measurement Uncertainty** | | | |
| **7.6.1** | Does the laboratory identify the contributions to measurement uncertainty? | | | |
| **7.6.1** | When evaluating measurement uncertainty, are all contributions which are of significance, including those arising from sampling, taken into account using appropriate methods of analysis? | | | |
| **7.6.2** | Does a laboratory performing calibrations, including of its own equipment, evaluate the measurement uncertainty for all calibrations? | | | |
| **7.6.3** | Does a laboratory performing testing evaluate measurement uncertainty? | | | |
| **7.6.3** | Where the test method precludes rigorous evaluation of measurement uncertainty, is an estimation made based on an understanding of the theoretical principles or practical experience of the performance of the method? | | | |
| **Note 1** | *In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.* | | | |
| **Note 2** | *For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.* | | | |
| **Note 3** | *For further information, see ISO/IEC Guide 98-3, ISO 5725 and ISO 21748.* | | | |
| **7.7** | **Ensuring the Validity of Results** | | | |
| **7.7.1** | Does the laboratory have a procedure for monitoring the validity of results? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **7.7.1** | Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results? | | | |
| **7.7.1** | Is monitoring planned and reviewed and include, where appropriate, but not be limited to: | | | |
| **7.7.1** | a) use of reference materials or quality control materials? | | | |
| **7.7.1** | b) use of alternative instrumentation that has been calibrated to provide traceable results? | | | |
| **7.7.1** | c) functional check(s) of measuring and testing equipment? | | | |
| **7.7.1** | d) use of check or working standards with control charts, where applicable? | | | |
| **7.7.1** | e) intermediate checks on measuring equipment? | | | |
| **7.7.1** | f) replicate tests or calibrations using the same or different methods? | | | |
| **7.7.1** | g) retesting or recalibration of retained items? | | | |
| **7.7.1** | h) correlation of results for different characteristics of an item? | | | |
| **7.7.1** | i) review of reported results? | | | |
| **7.7.1** | j) intralaboratory comparisons? | | | |
| **7.7.1** | k) testing of blind sample(s)? | | | |
| **ASCA** | Does the laboratory confirm the validity of the testing methods, any test-specified positive, negative, and/or reference controls allow for distinguishing between positive and negative responses? | | | |
| **ASCA** | Does the testing laboratory havet pre-defined criteria for positive/negative/reference control values as follows: | | | |
| **ASCA** | **For cytotoxicity testing (per ISO 10993-5**):<br>- each positive control material replicate is ≥ Grade 3<br>- each negative control material replicate is Grade 0<br>- each vehicle control replicate is Grade 0 | | | |
| **ASCA** | **For intracutaneous reactivity irritation testing:**<br>- each of five sodium chloride control sites in each animal at all timepoints is Grade 0<br>- each of five oil control sites in each animal at all timepoints is ≤ Grade 1 | | | |
| **ASCA** | **For primary skin (dermal) irritation testing**, each sodium chloride and oil control site is Grade 0 | | | |
| **ASCA** | **For guinea pig maximization sensitization testing (per ASTM F720)**:<br>- all sodium chloride and oil vehicle control animals have Grade 0 results at all sites<br>- the positive controls are run at least biannually (for each animal source) and each animal is at least one grade higher than concurrently run sodium chloride and oil vehicle controls in at least 8 out of 10 positive control animals (for strong sensitizers such as 0.1-0.5% dinitrochlorobenzene (DNCB) at induction and 0.05-0.1% DNCB at challenge) | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **ASCA** | **For closed patch sensitization testing:**<br>- all negative control animals (e.g., sodium chloride or oil vehicles or negative control materials) are Grade 0.<br>- the positive controls are run at least biannually (for each animal source) and each animal is at least one Grade higher than concurrently run sodium chloride and oil vehicle controls in at least 8 out of 10 positive control animals (for strong sensitizers such as 0.1-0.5% DNCB at induction and 0.05-0.1% DNCB at challenge) | | | |
| **ASCA** | **For acute systemic toxicity testing**, all sodium chloride and oil control animals result in no adverse clinical findings, no decrease in body weight > 10% per animal, and no deaths | | | |
| **ASCA** | **For material-mediated pyrogenicity testing** there are no predefined criteria | N/A | N/A | |
| **ASCA** | **For hemolysis testing (per ASTM F756)**:<br>- the positive control material mean hemolytic index is ≥ 5%<br>- the negative control material mean hemolytic index is < 2% | | | |
| **ASCA** | **For complement activation testing using SC5b-9 (a product of the terminal pathway for complement activation),**<br>- the positive control meets one of the following criteria:<br>o the mean value for the cobra venom factor positive control (if applicable) is at least 10X greater than both the mean values for the negative control material and the activated normal human serum, plasma, or whole blood, or<br>o the positive material control (if applicable) is statistically significantly higher than both the negative control material and the activated normal human serum, plasma, or whole blood,<br>- any kit-specific high and low controls meet the kit specifications. | | | |
| **7.7.2** | Does the laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate? | | | |
| **7.7.2** | Is this monitoring planned and reviewed and include, but not be limited to, either or both of the following: | | | |
| **7.7.2** | a) participation in proficiency testing? | | | |
| **Note** | *ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.* | | | |
| **7.7.2** | b) participation in interlaboratory comparisons other than proficiency testing? | | | |
| **7.7.3** | Is the data from monitoring activities analysed, used to control and, if applicable, improve the laboratory's activities ? | | | |
| **7.7.3** | If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, is appropriate action taken to prevent incorrect results from being reported? | | | |
| **7.8** | **Reporting of Results** | | | |
| **7.8.1** | **General** | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **7.8.1.1** | Are reviewed and authorized prior to release? | | | |
| **7.8.1.1** | Are the results provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling) and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used? | | | |
| **7.8.1.1** | Are all issued reports retained as technical records? | | | |
| **Note 1** | *For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.* | | | |
| **Note 2** | *Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met* | | | |
| **7.8.2** | **Common Requirements for Reports (Test, Calibration or Sampling)** | | | |
| **ASCA** | Does the laboratory have procedures for each test conducted to include:<br>• Test procedure(s) and test standard(s) used<br>• Product or component(s) tested<br>• Test equipment used for testing, measurement, or review (including the equipment's ratings and accuracies, unless otherwise readily available)<br>• Date of the test(s). For example, periodic controls may have different test dates<br>• Test report number, including revision number and amendment date, if applicable, and any related sub-contracted test report number(s)<br>• Names of the personnel performing the test(s) and the names of all supervisory personnel involved in the study and for biological studies, the signature of the study director and quality assurance unit personnel (i.e., per 21 CFR part 58, Good Laboratory Practices for Nonclinical Laboratory Studies, requirements)<br>• The test conditions as specified by the test standard, if applicable, (e.g., required voltage, power, temperature, or humidity for the test) | | | |
| **ASCA** | Does the lab ensure that all testing conducted by subcontractors comply with the above test report specifications, as applicable? | | | |
| **ASCA** | Does the laboratory provide a complete test report and an ASCA Summary Test Report to the client at the end of testing activities? | | | |
| **7.8.2.1** | Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse: | | | |
| **7.8.2.1** | a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling"); | | | |
| **7.8.2.1** | b) the name and address of the laboratory; | | | |
| **7.8.2.1** | c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities; | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
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| **7.8.2.1** | d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; | | | |
| **7.8.2.1** | e) the name and contact information of the customer; | | | |
| **7.8.2.1** | f) identification of the method used; | | | |
| **7.8.2.1** | g) a description, unambiguous identification, and, when necessary, the condition of the item ; | | | |
| **7.8.2.1** | h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results; | | | |
| **7.8.2.1** | i) the date(s) of performance of the laboratory activity; | | | |
| **7.8.2.1** | j) the date of issue of the report; | | | |
| **7.8.2.1** | k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; | | | |
| **7.8.2.1** | l) a statement to the effect that the results relate only to the items tested, calibrated or sampled; | | | |
| **7.8.2.1** | m) the results with, where appropriate, the units of measurement; | | | |
| **7.8.2.1** | n) additions to, deviations, or exclusions from the method; | | | |
| **7.8.2.1** | o) identification of the person(s) authorizing the report; | | | |
| **7.8.2.1** | p) clear identification when results are from external providers. | | | |
| **Note** | *The laboratory should include a statement specifying that the report shall not be reproduced except in full, without approval of the laboratory.* | | | |
| **7.8.2.2** | Does the laboratory take responsibility for all the information provided in the report, except when information is provided by the customer? Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), does it state in the report that the results apply to the sample as received? | | | |
| **7.8.2.2** | Is the data provided by a customer clearly identified? | | | |
| **7.8.2.2** | In addition, to clearly identified data does the laboratory ensure that a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results? | | | |
| **7.8.3** | **Specific Requirements For Test Reports** | | | |
| **7.8.3.1** | In addition to the requirements listed in 7.8.2, do test reports , where necessary for the interpretation of the test results, include the following: | | | |
| **7.8.3.1** | a) information on specific test conditions, such as environmental conditions? | | | |
| **7.8.3.1** | b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6)? | | | |
| **7.8.3.1** | c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: | | | |
| **7.8.3.1** | 1) it is relevant to the validity or application of the test results? | | | |
| **7.8.3.1** | 2) a customer's instruction so requires? | | | |
| **7.8.3.1** | 3) the measurement uncertainty affects conformity to a specification limit? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **7.8.3.1** | d) where appropriate, opinions and interpretations (see 7.8.7)? | | | |
| **7.8.3.1** | e) additional information which may be required by specific methods, authorities, customers or groups of customers? | | | |
| **7.8.3.2** | Where the laboratory is responsible for the sampling activity, do test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results? | | | |
| **7.8.4** | **Specific Requirements for Calibration Certificates** | | | |
| **7.8.4.1** | In addition to the requirements listed in 7.8.2, do calibration certificates include the following: | | | |
| **7.8.4.1** | a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent)? | | | |
| **Note** | *According to JCGM 200:2012, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.* | | | |
| **7.8.4.1** | b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results? | | | |
| **7.8.4.1** | c) a statement identifying how the measurements are metrologically traceable (see Annex A); | | | |
| **7.8.4.1** | d) the results before and after any adjustment or repair, if available; | | | |
| **7.8.4.1** | e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); | | | |
| **7.8.4.1** | f) where appropriate, opinions and interpretations (see 7.8.7). | | | |
| **7.8.4.2** | Where the laboratory is responsible for the sampling activity, do calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of test results? | | | |
| **7.8.4.3** | Does the lab avoid any recommendation on the calibration interval on calibration certificate or calibration labels, except where it has been agreed by the customer? | | | |
| **7.8.5** | **Reporting Sampling – Specific Requirements** | | | |
| **7.8.5.1** | Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, do reports include the following, where necessary for the interpretation of results? : | | | |
| **7.8.5.1** | a) the date of sampling; | | | |
| **7.8.5.1** | b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); | | | |
| **7.8.5.1** | c) the location of sampling, including any diagrams, sketches or photographs; | | | |
| **7.8.5.1** | d) a reference to the sampling plan and sampling method; | | | |
| **7.8.5.1** | e) details of any environmental conditions during sampling that affect the interpretation of the test results; | | | |
| **7.8.5.1** | f) information required to evaluate measurement uncertainty for subsequent testing or calibration. | | | |
| **7.8.6** | **Reporting Statements of Conformity** | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **7.8.6.1** | When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule? | | | |
| **Note** | Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary. | | | |
| **7.8.6.2** | Does the laboratory report on the statement of conformity, such that the statement clearly identifies: | | | |
| **7.8.6.2** | a) to which results the statement of conformity applies? | | | |
| **7.8.6.2** | b) which specifications, standards or parts thereof are met or not met? | | | |
| **7.8.6.2** | c) the decision rule applied (unless it is inherent in the requested specification or standard)? | | | |
| **Note** | *For further information, see ISO/IEC Guide 98-4.* | | | |
| **7.8.7** | **Reporting Opinions and Interpretations** | | | |
| **7.8.7.1** | When opinions and interpretations are expressed, the laboratory does the laboratory ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement? | | | |
| **7.8.7.1** | Does the laboratory document the basis upon which the opinions and interpretations have been made? | | | |
| **Note** | *It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.* | | | |
| **7.8.7.2** | Are the opinions and interpretations expressed in reports based on the results obtained from the tested or calibrated item and shall be clearly identified as such? | | | |
| **7.8.7.3** | When opinions and interpretations are directly communicated by dialogue with the customer, is a record of the dialogue retained? | | | |
| **7.8.8** | **Amendments to Reports** | | | |
| **7.8.8.1** | When an issued report needs to be changed, amended or re-issued, is any change of information clearly identified and, where appropriate, the reason for the change included in the report? | | | |
| **7.8.8.2** | Are amendments to a report after issue made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording? | | | |
| **Note** | *Such amendments shall meet all the requirements of this document.* | | | |
| **7.8.8.3** | When it is necessary to issue a complete new report, is it uniquely identified and contain a reference to the original that it replaces? | | | |
| **7.9** | **Complaints** | | | |
| **7.9.1** | Does the laboratory have a documented process to receive, evaluate and make decisions on complaints? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **7.9.2** | Is a description of the handling process for complaints available to any interested party on request? | | | |
| **7.9.2** | Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, deal with it? | | | |
| **7.9.2** | Is the laboratory responsible for all decisions at all levels of the handling process for complaints? | | | |
| **7.9.3** | Does the laboratory's process for handling complaints include at least the following elements and methods? | | | |
| **7.9.3** | a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it? | | | |
| **7.9.3** | b) tracking and recording complaints, including actions undertaken to resolve them? | | | |
| **7.9.3** | c) ensuring that any appropriate action is taken? | | | |
| **7.9.4** | Does the laboratory take responsibilty for gathering and verifying all necessary information to validate a complaint once received? | | | |
| **7.9.5** | Whenever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome? | | | |
| **7.9.6** | Are the outcomes communicated to the complainant made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question? | | | |
| **Note** | *This can be performed by external personnel.* | | | |
| **7.9.7** | Whenever possible, does the laboratory give formal notice of the end of the complaint handling to the complainant? | | | |
| **7.10** | **Nonconforming Work** | | | |
| **7.10.1** | Does the laboratory have a procedure implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)? | | | |
| **7.10.1** | Does the procedure ensure that: | | | |
| **7.10.1** | a) the responsibilities and authorities for the management of nonconforming work are defined? | | | |
| **7.10.1** | b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory? | | | |
| **7.10.1** | c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results? | | | |
| **7.10.1** | d) a decision is taken on the acceptability of the nonconforming work? | | | |
| **7.10.1** | e) where necessary, the customer is notified and work is recalled? | | | |
| **7.10.1** | f) the responsibility for authorizing the resumption of work is defined? | | | |
| **7.10.2** | Does the laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f)? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **7.10.3** | Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, does the laboratory implement corrective action? | | | |
| **7.11** | **Control of Data and Information Management** | | | |
| **7.11.1** | Does The laboratory have access to the data and information needed to perform laboratory activities? | | | |
| **7.11.2** | Does the laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction? | | | |
| **7.11.2** | Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorized, documented and validated before implementation? | | | |
| **Note 1** | *In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.* | | | |
| **Note 2** | *Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.* | | | |
| **7.11.3** | Is the laboratory information management system(s): | | | |
| **7.11.3** | a) protected from unauthorized access? | | | |
| **7.11.3** | b) safeguarded against tampering and loss? | | | |
| **7.11.3** | c) operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription? | | | |
| **7.11.3** | d) maintained in a manner that ensures the integrity of the data and information? | | | |
| **7.11.3** | e) include recording system failures and the appropriate immediate and corrective actions? | | | |
| **7.11.4** | When a laboratory information management system is managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document? | | | |
| **7.11.5** | Does the laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel? | | | |
| **7.11.6** | Are calculations and data transfers checked in an appropriate and systematic manner? | | | |
| **8** | **Management System Requirements** | | | |
| **8.1.1** | **General** | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **8.1.1.1** | Does the laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results? | | | |
| **8.1.1.1** | In addition to meeting the requirements of Clauses 4 to 7, has the laboratory implemented a management system in accordance with Option A or Option B? | | | |
| **Note** | See Annex B for more information. | | | |
| **8.1.2** | **Option A** | | | |
| **8.1.2** | At a minimum, does the management system of the laboratory address the following: | | | |
| **8.1.2** | — management system documentation (see 8.2)? | | | |
| **8.1.2** | — control of management system documents (see 8.3)? | | | |
| **8.1.2** | — control of records (see 8.4)? | | | |
| **8.1.2** | — actions to address risks and opportunities (see 8.5)? | | | |
| **8.1.2** | — improvement (see 8.6)? | | | |
| **8.1.2** | — corrective action (see 8.7)? | | | |
| **8.1.2** | — internal audits (see 8.8)? | | | |
| **8.1.2** | — management reviews (see 8.9)? | | | |
| **8.1.3** | **Option B** | | | |
| | If a laboratory has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, does it fulfill at least the intent of the management system requirements specified in 8.2 to 8.9? | | | |
| **ASCA** | Regardless of the option selected (i.e., ISO/IEC 17025 Option A or Option B),does the testing laboratory maintain an index of standard operating procedures (SOPs) and any relevant ASCA test-related documents (e.g., SOPs, test methods, work instructions, master protocols, test-specific protocols, data collection worksheets, training information) applicable to any of the standards included in the ASCA Pilot for basic safety and essential performance of medical devices and laboratory equipment program specifications in the ASCA Guidance Document Appendix? | | | |
| **8.2.1** | Does the Laboratory management establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization? | | | |
| **8.2.2** | Do the policies and objectives address the competence, impartiality and consistent operation of the laboratory? | | | |
| **8.2.3** | Does the laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **8.2.4** | Is all documentation, processes, systems, records, related to the fulfilment of the requirements of the standard included in, referenced from, or linked to the management system? | | | |
| **8.2.5** | Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities? | | | |
| **8.3** | **Control of Management System Documents (Option A)** | | | |
| **8.3.1** | Does the laboratory control the documents (internal and external) that relate to the fulfilment of this document? | | | |
| **Note** | *In this context, "document" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.* | | | |
| **8.3.2** | Does the laboratory ensure that: | | | |
| **8.3.2** | a) documents are approved for adequacy prior to issue by authorized personnel? | | | |
| **8.3.2** | b) documents are periodically reviewed, and updated as necessary? | | | |
| **8.3.2** | c) changes and the current revision status of documents are identified? | | | |
| **8.3.2** | d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled? | | | |
| **8.3.2** | e) documents are uniquely identified? | | | |
| **8.3.2** | f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose? | | | |
| **8.4** | **Control of Records (Option A)** | | | |
| **8.4.1** | Does the laboratory establish and retain legible records to demonstrate fulfilment of the requirements in this document? | | | |
| **8.4.2** | Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records? | | | |
| **8.4.2** | Does the laboratory retain records for a period consistent with its contractual obligations? | | | |
| **8.4.2** | Is access to these records consistent with the confidentiality commitments and readily available? | | | |
| **Note** | *Additional requirements regarding technical records are given in 7.5.* | | | |
| **8.5** | **Actions to address risks and opportunities (Option A)** | | | |
| **8.5.1** | Does the laboratory consider the risks and opportunities associated with the laboratory activities in order to: | | | |
| **8.5.1** | a) give assurance that the management system achieves its intended results? | | | |
| **8.5.1** | b) enhance opportunities to achieve the purpose and objectives of the laboratory? | | | |
| **8.5.1** | c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities? | | | |
| **8.5.1** | d) achieve improvement? | | | |
| **8.5.2** | Does the laboratory plan: | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **8.5.2** | a) actions to address these risks and opportunities? | | | |
| **8.5.2** | b) how to: | | | |
| **8.5.2** | integrate and implement the actions into its management system? | | | |
| **8.5.2** | evaluate the effectiveness of these actions? | | | |
| **Note** | *Although this document specifies that the organization plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.* | | | |
| **8.5.3** | Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results? | | | |
| **Note 1** | *Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.* | | | |
| **Note 2** | *Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.* | | | |
| **8.6** | **Improvement (Option A)** | | | |
| **8.6.1** | Does the laboratory identify and select opportunities for improvement and implement any necessary actions? | | | |
| **Note** | *Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.* | | | |
| **8.6.2** | Does the laboratory seek feedback, both positive and negative, from its customers? | | | |
| **8.6.2** | Is the feedback analysed and used to improve the management system, laboratory activities and customer service? | | | |
| **Note** | *Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.* | | | |
| **8.7** | **Corrective Action (Option A)** | | | |
| **8.7.1** | When a nonconformity occurs, does the laboratory: | | | |
| **8.7.1** | a) react to the nonconformity and, as applicable? | | | |
| **8.7.1** | take action to control and correct it? | | | |
| **8.7.1** | address the consequences? | | | |
| **8.7.1** | b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: | | | |
| **8.7.1** | reviewing and analysing the nonconformity? | | | |
| **8.7.1** | determining the causes of the nonconformity? | | | |
| **8.7.1** | determining if similar nonconformities exist, or could potentially occur? | | | |
| **8.7.1** | c) implement any action needed? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **8.7.1** | d) review the effectiveness of any corrective action taken? | | | |
| **8.7.1** | e) update risks and opportunities determined during planning, if necessary? | | | |
| **8.7.1** | f) make changes to the management system, if necessary? | | | |
| **8.7.2** | Are corrective actions appropriate to the effects of the nonconformities encountered? | | | |
| **8.7.3** | Does the laboratory retain records as evidence of: | | | |
| | a) the nature of the nonconformities, cause(s) and any subsequent actions taken? | | | |
| | b) the results of any corrective action? | | | |
| **8.8** | **Internal Audits (Option A)** | | | |
| **8.8.1** | Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system: | | | |
| **8.8.1** | a) conforms to: | | | |
| **8.8.1** | — the laboratory's own requirements for its management system, including the laboratory activities; | | | |
| **8.8.1** | — the requirements of ISO/IEC 17025:2017; | | | |
| **8.8.1** | b) is effectively implemented and maintained. | | | |
| **8.8.2** | Does the laboratory: | | | |
| **8.8.2** | a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits? | | | |
| **8.8.2** | b) define the audit criteria and scope for each audit? | | | |
| **8.8.2** | c) ensure that the results of the audits are reported to relevant management? | | | |
| **8.8.2** | d) implement appropriate correction and corrective actions without undue delay? | | | |
| **8.8.2** | e) retain records as evidence of the implementation of the audit program and the audit results? | | | |
| **Note** | *ISO 19011 provides guidance for internal audits.* | | | |
| **8.9** | **Management reviews (Option A)** | | | |
| **8.9.1** | Does the laboratory management review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of ISO/IEC 17025:2017? | | | |
| **8.9.2** | Are the inputs to management review recorded and shall include information related to the following: | | | |
| **8.9.2** | a) changes in internal and external issues that are relevant to the laboratory? | | | |
| **8.9.2** | b) fulfilment of objectives? | | | |
| **8.9.2** | c) suitability of policies and procedures? | | | |
| **8.9.2** | d) status of actions from previous management reviews? | | | |
| **8.9.2** | e) outcome of recent internal audits? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| **8.9.2** | f) corrective actions? | | | |
| **8.9.2** | g) assessments by external bodies? | | | |
| **8.9.2** | h) changes in the volume and type of the work or in the range of laboratory activities? | | | |
| **8.9.2** | i) customer and personnel feedback? | | | |
| **8.9.2** | j) complaints? | | | |
| **8.9.2** | k) effectiveness of any implemented improvements? | | | |
| **8.9.2** | l) adequacy of resources? | | | |
| **8.9.2** | m) results of risk identification? | | | |
| **8.9.2** | n) outcomes of the assurance of the validity of results? | | | |
| **8.9.2** | o) other relevant factors, such as monitoring activities and training? | | | |
| **8.9.3** | Do the outputs from the management review l record all decisions and actions related to at least: | | | |
| **8.9.3** | a) the effectiveness of the management system and its processes? | | | |
| **8.9.3** | b) improvement of the laboratory activities related to the fulfilment of the requirements of this document? | | | |
| **8.9.3** | c) provision of required resources? | | | |
| **8.9.3** | d) any need for change. | | | |
| **Additional Requirements (Required for surveillance and re-accreditation assessments) *Objective Evidence of Laboratory's utilization of PJLA's accreditation symbol must be included in the package. This includes but not limited to (Website page, letterhead, test or calibration report including subcontracted results if utilized and calibration** | | | | |
| **Use of the Symbol** | | | | |
| | For applicant laboratories:<br>Does the applicant laboratory use the PJLA Logo?<br><br>Note: Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive committee approval. | | | |
| | Is the accredited laboratory utilizing the correct symbol (i.e. testing and/or calibration)? | | | |
| | Is the symbol reproduced in a size that is clearly distinguishable? | | | |
| | Is the symbol reproduced in a single-color (black or a single color belonging to the house-style of the accredited lab)? | | | |
| | Is the symbol identifiable? | | | |
| | Is the accredited laboratory properly stating their accreditation status? | | | |
| | Is the accredited laboratory properly using the symbol on:<br><br>a) promotional material and business stationary?<br><br>b) test or calibration certificates or labels? (See note 1)<br><br>c) website?<br><br>d) technical literature? | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| | Is the accredited laboratory appropriately using the symbol by not placing the symbol on:<br><br>a) legal documents (i.e. contracts or checks)?<br><br>b) on test/calibration certificates or any other material referencing work or items not covered by scope of accreditation?<br><br>c) any documentation of sites that are not accredited by PJLA?<br><br>d) on subcontractor's certificates or documentation?<br><br>e) on products or items which laboratory has tested or calibrated (except calibration labels)?<br><br>Where tests or calibrations outside the scope of the accreditation are included on reports, certificates or enclosed letters with results, has the laboratory clearly defined "This laboratory is not accredited for the tests or calibrations marked"? | | | |
| **Subcontracted Tests or Calibrations** | | | | |
| | If the accredited laboratory included the results of subcontracted tests or calibrations on reports or certificates can they demonstrate that they have:<br><br>a) obtained approval from the subcontracted laboratory?<br><br>b) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate?<br><br>c) objective evidence that the subcontractor itself is accredited for the specific tests or calibrations concerned and results have been included in the subcontractor's endorsed report or certificate? | | | |
| | Does the laboratory use any oversight or recognition body logo or symbol on their certificates, reports or any other material? If yes, which body's logo or symbol are they using? | | | |
| ****To be reviewed at all assessments (Accreditation, Surveillance and Reaccreditation**** | | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| | For applicant laboratories:<br>Is there objective evidence for PT activity for each item to be included within proposed scope of accreditation?<br><br>Are the results meaningful i.e. demonstrating the laboratory's competence in performing specified tests or calibrations? | | | |
| | For accredited laboratories:<br>Is there a documented proficiency testing plan or schedule?<br><br>Does this plan or schedule include all items included on the scope of accreditation to be tested within a four year period?<br><br>Has the laboratory completed at least one proficiency test each year?<br><br>Has the proficiency plan or schedule been approved by PJLA? | | | |
| | For any unfavorable results gathered during proficiency testing, was appropriate corrective action taken? | | | |
| **PL-2 Measurement Traceability Policy** | | | | |
| | Does the laboratory have documented policies and procedures regarding measurement traceability and reference this traceability on test/calibration reports?<br><br>Does the laboratory have documented procedures detailing the verification, transport and storage of reference standards? | | | |
| | Has the laboratory employed the services of an external calibration provider(s) that are accredited to ISO/IEC 17025:2005 for the calibration(s) performed?<br><br>If not, can the laboratory demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI? | | | |
| | Does the laboratory have on file and available the current certificates and scopes of accreditation for the external calibration laboratories employed? | | | |
| **PL-3 Policy on Measurement Uncertainty for Calibration and Testing Laboratories** | | | | |

| Section | Assessment | Yes | No | Comments/Policy/Procedure/Record |
|---|---|---|---|---|
| | For applicant laboratories:<br>Has the laboratory applied its documented procedure to provide measurement uncertainties for every measured quantity, instrument or gage listed in its scope of accreditation?<br><br>(Well recognized test methods or calibration procedures that specify limits to the values of major sources of uncertainties will meet this requirement) | | | |
| | For accredited laboratories:<br>Are stated uncertainties periodically reviewed and updated to evaluate changes to be made to any influence listed in an uncertainty budget?<br><br>Does the laboratory include a metrological statement or reference estimated uncertainties on calibration/test reports? | | | |
| PJLA SOP-1-ASCA /ASCA | If any citations were issued to the laboratory by the FDA Bioresearch Monitoring Program per 21 CFR Part 58 – GLP, has the laboratory fully corrected and implemented appropriate corrective action? | | | |
| **Surveillance of Previous Nonconformities and Corrective Action** | | | | |
| | The assessor shall verify that previous nonconformities have been resolved and that corrective actions have been effectively implemented. | | | |