Subject: Procedure for Conducting ISO 13485 Assessments

1.0 **PURPOSE**: To provide the controls necessary to assure that the assessment and certification processes ISO 13485 complies with all applicable rules and regulations of the applicable accreditation or approval body and these management system requirements.

Note: The requirements of this CQAM are in addition to the requirements of CQAM-102 (Initial Stage 1 & Stage 2) and CQAM103 (Surveillance, Recertification, Scope Changes and Upgrades).

2.0 **SCOPE**: This procedure is to be used by all Smithers Quality Assessments, Inc. (SQA) auditors in the evaluation of a client's ISO 13485 quality management system and the design, manufacture and supply of medical devices. *For transition audits or initial audits to ISO 13485:2016, refer to CQAM-111T- Procedure for Transitioning to ISO 13485:2016.*

2.1 Definitions

2.1.1 ISO 9000:2015, "Quality management systems — Fundamentals and vocabulary

2.1.2 IAF MD 9:*2015*

2.1.3 Regulatory Authority (RA)

A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with legal requirements.

Note: Within the European Medical Devices Regulation the Regulatory Authority as defined above is titled "Competent Authority".

3.0 **RESPONSIBILITY**: The General Manager is responsible to the President for ensuring all ISO 13485 related audits are conducted in accordance with this CQAM.

4.0 **AUTHORITY**: The General Manager is authorized by the President to take appropriate actions to assure the proper and complete implementation of this CQAM.

5.0 **PROCEDURES**: (Ref: CQAM-102, Procedure for Conducting Quality System Assessment.)

5.1 ***Management Of Impartiality***

5.1.1 The President shall ensure that SQA and auditing staff are impartial and free from engagements and influences which could affect their objectivity, and in particular shall not be:

5.1.2 Involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device

5.1.3 Involved in the design, construction, implementation or maintenance of the quality management system being audited

5.1.4 An authorized representative of the client organization, nor represent the parties engaged in these activities

5.1.5 The situations hereafter are examples where impartiality is compromised in reference to the criteria defined in 5.1.1) to 5.1.3):

5.1.5.1 The auditor having a financial interest in the client organization being audited (e.g. holding stock in the organization)

5.1.5.2 The auditor being employed currently by a manufacturer producing medical devices

5.1.5.3 The auditor being a member of staff from a research or medical institute or a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices.

5.1.6 In order to meet these requirements personnel involved with SQA auditing activities (including SQA Office personnel, auditors, technical experts or interpreters) shall have abstained from any of the above listed activities for a minimum of 2 years. Confirmation of such is achieved through:

5.1.6.1 The completion of Form SQA-4 at the time of hire.

5.1.7 *The Technical Expert shall have access to individual(s) who have experience and knowledge related to medical devices in order to get expert opinions.*

5.2 Responsibility

5.2.1 *SQA is responsible and verifies the client organization has evaluated statutory and regulatory compliance by the use of SQA-05.*

5.2.2 *Evidence that appropriate action has been taken in cases of non-compliance with relevant legislation and regulations, including the notification to the Regulatory Authority of any incidences that require reporting is the identificaiton of CARs as needed.*

5.3 Openness

5.3.1 *SQA's agreement for services establishes contractual agreement with our clients to release audit report information to regulators that recognize 13485 (CGI-02)*.

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5.3.2 *Where it is required by law or by relevant regulatory authority, SQA will provide information about certificates granted, suspended, or withdrawn to the regulatory authority.*

5.4 Competence Of Management Personnel

5.4.1 *All personnel involved in ISO 13485 certification will meet the requirements of Annex B in MD-09.*

5.4.2 *Auditor competency will be as defined in CQAM-009.*

5.4.2.1 *Audit team will have the competency for the Techncial Area (Annex A) and Skills (Annex B).*

5.4.3 *ECP personnel making the certification decision must fulfill the competency requirements of Annex B in MD-09. This does not mean that each individual in the group needs to comply with all requirements, but the group as a whole shall meet all requirements. When the certification decision is made by an individual, the individual must meet all the requirements.*

5.4.5 *When the client has outsourced processes, SQA will determine and document whether specific competence in the audit team is necessasry to evaluate the outsourced process(es).*

5.5 Audits

5.5.1 Audits shall be conducted in accordance with the requirements of the following documents in addition to the requirements stated herein. Where conflicting requirements are present the requirements of this procedure shall take precedence

5.5.1.1 CQAM102 - Conduction Initial Mgmt Systems Assessments

5.5.1.2 CQAM103 - Conduction Srv, Recert, Scope Changes and Upg Assessments

5.5.1.3 CQAM104 - Confirmation of CAR

5.5.2 *Audit time is determined per CQAM-016.15 'Estimating time required for 13485 audits' and is based on Annex D in MD-09 as a starting point.*

5.5.3 *Sufficient time will be planned to allow the audit team to determine the conformity status of a client's quality management system with respoect to relevant regulatory requirements.*

5.5.3.1 Additional time required to audit national or regional relevant regulatory requirements and dossier reviews must be justified.

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5.5.4 *Multisite sampling is not permitted.*

5.5.5 Stage 1 audit

1.1.1.1 Where higher risk medical devices are concerned, the stage 1 audit shall be performed on-site.

5.5.6 Surveillance

5.5.6.1 Shall also include a review of actions taken for notification of adverse events, advisory notices, and recalls.

5.5.7 Short Notice Audits

Short notice audits may be required when:

5.5.7.1 external factors apply such as:

a. Available post-market surveillance data known to SQA (or the assigned auditor) on the subject devices indicate a possible significant deficiency in the quality management system.

b. A significant safety related information becomes known to SQA (or the assigned auditor)

5.5.7.2 Significant changes occur which have been submitted as required by the regulations or become known to SQA (or the assigned auditor), and which could affect the decision on the client's state of compliance with the regulatory requirements.

The following are examples of such changes which could be significant and relevant to the when considering that a special audit is required, although none of these changes should automatically trigger a special audit:

5.5.7.2.1 QMS – impact and changes:

- New ownership
- Extension to manufacturing and/or design control
- New facility, site change, such as a modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites)
- New processes, process changes, such as significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization.

5.5.7.2.2. Quality management system personnel, such as modifications to the defined authority of the management representative that impact

- Management system effectiveness or regulatory compliance
- The capability and authority to assure that only safe and effective medical devices are released

5.5.7.2.3 Product related changes such as:

- New products, categories or
- Addition of a new device category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to hemodialysis equipment
- Or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment)

5.5.7.2.4 Quality management system and Product related changes such as

- Changes in standards
- Changes in regulations
- Post market surveillance, vigilance

5.5.7.2.5 An unannounced or short-notice audit may also be necessary if SQA (or the assigned auditor) have justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

5.6 **Major and minor nonconformities**:

5.6.1 For purposes of this CQAM, SQA shall adhere to the definition of “major” and “minor” nonconformities and “open” as stated in CQAM-102.

5.6.2 The following additional examples are provided as guidance on determine potential nonconformity to product/process.

a) Failure to address applicable requirements for quality management systems (e.g. failure to have a complaint handling or training system).

b) Failure to implement applicable requirements for quality management systems.

c) Failure to implement appropriate corrective and preventative action

when an investigation of post market data indicates a pattern of product defects.

d) Products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labeling.

e) The existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements.

f) Repeated nonconformities from previous audits.

g) An excessive number of MINOR nonconformities against a particular requirement for quality management systems.

5.7 References

1.2 ISO 13485:2003
1.3 ISO 17021-1, "Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems
1.4 IAF MD 9:2015, "Mandatory Document for the Application of ISO/IEC 17021 in Medical device Quality management Systems (ISO 13485), Issue 2.

END OF DOCUMENT