1.0 **Scope** - This R20.113 applies to medical device companies requiring assessment and/or registration of their management system in accordance with ISO 13485, current edition. Organizations involved in one or more stages of the life-cycle of a medical device, including those providing servicing and technical support, are eligible to use the Medical Device standard.

The following steps represent additions/clarifications to those defined in SRI Procedures QP 4.0 through QP 8.0 with relevant documents (R20.xx) as indicated. The management system requirements specified in ISO 13485 are complementary (not alternative) to the technical specified requirements and applicable law and regulatory requirements where the product is manufactured and distributed. This standard can be integrated, if the organization determines that is a benefit, with other recognized international standards.

1.1 Purpose - The purpose of this document is to define the additional requirements for providing medical device companies with assessment and registration of their management systems as defined by IAF MD9. These requirements are those that are in addition to ISO/IEC 17021. All requirements of ISO/IEC 17021 are applicable.

2.0 **Definitions**

The definitions of ISO 9000:2015 apply, except where in conflict with definitions provided in ISO 13485:2016.

3.0 **General**

Medical Device requirements and supplementation are typically shown in ISO 13485 documents, including IAF MD9. If an organization already has an operative system, (e.g., in relation with ISO 9001 or ISO 14001) it is preferable in most cases to satisfy the requirements of ISO 13485 within the current established standard.

4.0 **Principles**

The following are the additional requirements of IAF MD9 and how these requirements will be addressed by SRI.

4.4 Responsibility

MD.4.4.1

SRI will verify during the Stage 1, Stage 2 and all subsequent surveillance audits that the client has evaluated all applicable statutory and regulatory requirements and can show that appropriate action has been taken in cases of non-compliance with relevant legislation and regulations, including notification to the relevant Regulatory Authority of any incidences that require reporting. The report will reflect this verification.

4.5 Openness

MD.4.5.1

SRI has established appropriate agreements (R20.3) with clients to release audit report information to regulators that recognize ISO 13485.

5.0 General Requirements

5.2 Management of Impartiality

MD 5.2

SRI and its auditors are impartial and free from engagements and influences which could affect their objectivity. All auditors and employees of SRI sign conflicts of interest (R20.10 and R20.29) as well as Secrecy Agreements. In particular auditors and SRI shall not be:

a) involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical device
b) involved in the design, construction, implementation or maintenance of the quality management system being audited
c) an authorized representative of the client organization, nor represent the parties engaged in these activities

SRI requires that the auditor confirms that for a period of at least two (2) years that he/she has not been involved in any of the above consulting activities with a client, if applicable.

6.0 Structural Requirements

6.2 Committee for safeguarding impartiality

MD 6.2.3

SRI's Advisory/Impartiality Committee has an approved representative from the Medical Device industry and has been provided access to that individual(s) who has experience and knowledge related to medical devices in order to gain expert opinions. The Medical Device Representative is listed on the R20.13B as a member of the Advisory/ Impartiality Committee.

7.0 Resource Requirements

7.1 Competence of management and personnel

MD 7.1.1 Management and personnel competence

SRI shall ensure that all management and personnel involved in ISO 13485 certification meet the competency requirements of IAF MD9 (current revision), Annex B.

7.2 Persons involved in the certification activities

MD 7.2.1 Auditor

All auditors used by SRI will meet the requirements of IAF MD9 (current revision), Annex C including the following.

C.1 Education

SRI shall ensure that auditors have the knowledge corresponding to post-secondary education or equivalent work experience. Post-secondary education or equivalent work experience shall be appropriate to the scope of the ISO 13485 registration.

C.2 Work Experience

SRI shall ensure that auditors have a minimum of four years full-time work experience in medical device related industry including at least two years of work experience in one or more of the following:

a) closely related industries and the workplace such as research and development, manufacturing, and also those with cGMP requirements;
b) the application of the device technology and its use in health care services and with patients;
c) testing the devices concerned for compliance with the relevant national or international standards;
d) conducting performance testing, validation, installation, evaluation studies or clinical trials of the devices.
e) if qualified in the Main Technical Areas and Technical Areas or has related experience in one product category, the auditor is deemed qualified for all product categories covered by the Technical Areas.

In some cases, a shorter duration may be considered and SRI shall demonstrate that the experience is equivalent and record the justification for acceptance.

C.3 Auditor Competency

SRI shall ensure the competency of all auditors used in accordance with IAF MD9 (current revision) Annex B, as well as ISO 17021-3. Technical area competency is established in part by direct work experience (for all main technical areas, except Parts and Services). Candidate resume's, showing the applicable main technical areas, are maintained on file. For main technical area Parts and Services, competency in comparable QMS technical areas is used. For example: Parts or Services: Transportation compares directly with QMS technical are 31-1.

C.4 Development and Maintenance of Competency

C.4.1 Continuous Professional Development (CPD)
In addition to Continuous Professional Development required for quality management system auditing, SRI auditors for ISO 13485 perform additional activities to ensure timely awareness of new or modified regulatory requirements appropriate to cover the scope of the audits of the organizations to be audited. (SRI utilizes the ISO 13485 Medical Device Scope - Declared Basis of Competency by Auditor and by Individual Product Classification).

C.4.2 Advanced Training Elements for Auditors

During the annual review of CPD requirements, an evaluation will be performed to determine if any advanced and/or specialized training is required to cover the scope of the audits of the organizations to be audited. All auditor competencies are covered at least annually and address CPDs, Reports, Client Feedback, internal witness if conducted, and external witness results.

MD 7.2.4 Auditor Experience.

Auditors shall be authorized to perform audits after complying with the following criteria.

a) The auditor shall have experience in the entire process of auditing medical device organizations' quality management system including the review of documentation and risk management of medical devices, the performance of the audit and audit reporting. Auditors shall participate as a trainee in a minimum of four (4) audits for a total of at least twenty (20) days in an accredited Quality Management System program. Of this, at least 50% will be against ISO 13485 in an accredited Quality Management System program.

   Audit team leaders shall fulfill the additional following criteria.

b) Experience of an Audit Team Lead under the supervision of a qualified team lead for at least three (3) ISO 13485 audits.

MD 7.2.9 Personnel Making the Accreditation Decision

SRI shall ensure that the individual(s) making the accreditation decision will fulfill the requirements of IAF MD9 (current version Appendix B). If the decision is made by an individual, that individual shall meet all of the requirements. If the decision is made by a group, the group as a whole shall meet all of the requirements.

8.0 Information Requirements

8.1 Publicly accessible information

MD 8.1.3

SRI will provide information about certifications granted, suspended or withdrawn to the relevant Regulatory Authority when required by law.

8.2 Certification documents

MD 8.2.1

SRI will precisely define the scope of certification and will not exclude processes, products or services when those products, processes or services have an influence on safety and the quality of the product. The certificate scope statement will include both a description related to the technical area (per IAF MD 9, Appendix A) and a description of the related medical products. To avoid misleading or unambiguous scope statements, SRI will ensure descriptions of manufactured medical devices / products are clearly tied to their relevant technical area (i.e. A1.1 to A1.6) and that all

others are clearly tie to the appropriate sub category within A.1.7 Parts and Services. Further, when products and services are both with the scope, each shall be described by its own sentence. In no case will terminology associated with a technical area outside of SRI's current accreditation be allowed within the certificate scope statement.

Restrictions: Only 7.3 Design and development can be taken as an exclusion. Only clauses, approved by SRI tables, within sections 6.0, 7.0 & 8.0 can be identified as "not applicable." Auditors are not allowed to approve a "not applicable" status for the Software Validation requirements that follow in the paragraph after 7.5.6 a.-g., as this requirement applies to all organizations.

The scope of the audit will be defined utilizing IAF MD9 Annex A as a guideline.

8.3 Client Websites

SRI is required to exercise control over incorrect or misleading statements or references to certification status and or certification documents, such as their certificate. When MD 13845 client's serve non-medical markets, it is critical that their claims make it clear what medical products are within scope vs. those products not in scope. Of even higher criticality, is medical products that ARE NOT WITHIN THEIR SCOPE. In this case, they must be absolutely clear when making reference to the products outside their medical scope. The intention is to avoid misrepresenting the medical scope in such a way as to make it unclear what is in scope and what is not. This also applies to services, such as a statement that the client can offer DESIGN SERVICES. If design is not within the Medical Scope, it must be clear that design services do not apply to medical products. During the review of the website, focus on four categories, to detect any ambiguous or non-factual statements or claims in categories 2.-4.

1. Medical products / services in scope

2. Medical products / services not in scope

3. Non-Medical products / services

4. Other Manufacturing locations identified on the organization's website that are not listed as addresses on the certificate

   When reviewing the website, follow this sequence:

   a. The website review is conducted at the start of audit concurrent with the other "every time items." Information collected during the review is confirmed against any relevant evidence collected across the balance of the entire audit.

   b. Confirm the accuracy of the MD 13485 medical scope, including any exclusions.

   c. Review the products included in each technical area.

   d. Question the client regarding any medical products / services that are outside the scope of the certified MD 13485 system. Document all products and services that are outside the scope in your auditor notes.

e. Question the client about non-medical products / services that are outside the scope of the certified MD 13485 system.

f. Review the client's website with focused attention on products and services outside the scope and how the client represents the applicability of the certified management system relative to those products and services.

g. Look for generalized statements that may be ambiguous or misleading.

h. Look for pages of the site that link to the certificate vs. pages that do not.

- If the certificate is not linked on a page related to products or services outside the scope, a statement of disclaimer should be included that clarifies that all products are not in scope and directs users toward the location / document that clarifies applicability (i.e., the certificate, other statements that accurately define what is not in scope).

i. Due to the importance of this area, allocate the time needed for sufficient review website, especially when some products and services are not within the certified scope.

j. Use the knowledge gained during the website review to evaluate other public claims related to certification (e.g., printed brochures, business cards, etc.).

k. If any claims related to products / services are ambiguous or misleading, issue a corrective action to the client.

9.0 Process requirements

9.1 General requirements

MD 9.1.3.2

SRI will ensure that the audit team meets all of the competency requirements of IAF MD9 (current version), Annex A for the scope of the audit being performed.

MD 9.1.4.1 Determining audit time

SRI will utilize IAF MD9 (current version), Annex D, Table D.1, for determining the duration of the Stage 1 and Stage 2 audit. The duration of the audit may deviate based on the audit scope, the complexity of the audit and any relevant regulatory requirements. When the deviation is less than the duration defined, the justification shall be documented.

The audit duration will include on site time at the client's premises and off-site time spent for audit planning, documentation review and report writing.

If the medical device management system is integrated with other recognized standards, audit time calculations can consider the discounts described in MD 11 Application of ISO/IEC 17021 for Audits of Integrated Management Systems.

MD 9.1.5 Multi-site sampling

SRI will not sample design, development and manufacturing sites.

MD 9.1.9.6 Identifying and recording audit findings

The SRI audit team will consider the following additional conditions for audit nonconformities:

a) The failure to implement appropriate corrective and preventive actions when there is evidence that post market data indicates a pattern of product defects.
b) The existence of products which do not conform to the product design specifications and/or regulatory requirements. The product design specifications may be defined by the SRI client or the SRI client's customer.
c) The placement of products on the market which may cause undue risk to patients and/or users when the device is used according to product labeling.
d) The repeat of nonconformities from previous audit performed by SRI

9.2.3.1 Stage 1 audit

MD 9.2.3.1

SRI will perform all Stage 1 audits on-site.

Auditors review any areas excluded or identified as "not applicable"

9.3.2 Surveillance audit

MD 9.3.2.1

Every surveillance audit performed by SRI will include a review of actions taken for notification of adverse events, advisory notices, and recalls.

9.5 Special audits

9.5.2 Short notice audits

MD 9.5.2

SRI will evaluate the need to perform a short notice audit when the following occur:

a) Post-market data available to SRI on the subject device indicates a possible deficiency in the quality management system.
b) Safety related information becomes known to SRI.
c) The client informs SRI, or it becomes known to SRI, that significant changes have occurred at the client which could affect the client's state of regulatory compliance.
d) If SRI becomes concerned with the implementation of corrective actions and/or compliance with standard and/or regulatory requirements.