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POLICY FOR AUDITING & CERTIFICATION TO ISO 13485

In addition to the General Policy which applies to all Standards, this policy describes interpretations of the requirements for auditing and certification of medical device based quality management systems to IS0 13485 made by TQCSI's Certification Approval Panel. It complements TQCSI Work Instruction 37 (ISO 13485) which should also be referred to by auditors when auditing clients' quality management systems.

A **major nonconformance** is to be raised where:

- there is a very significant breach of legislation or a regulatory requirement
- there is a failure to address and implement applicable requirements for quality management systems (see ISO 9001 ISO Systems Policy)
- there is a failure to implement appropriate corrective and preventive action when an investigation of post market data indicates a pattern of product defects
- 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 labelling
- there is existence of products, which clearly do not comply with the client's specifications and/or the regulatory requirements.
- repeated nonconformances exist from previous audits.

All major nonconformances require acceptance and verification of the effectiveness of correction and corrective action.

General Policies:

- Short notice or unannounced audits may be required when:
  - External factors apply, eg available post-market surveillance data known to TQCSI on the subject devices indicate a possible significant deficiency in the QMS or significant safety related information becoming known to TQCSI.
  - Significant changes occur which have been submitted as required by the regulations or become known to TQCSI and which could affect the decision on the client's state of compliance with the regulatory requirement.
  - Examples of when a short notice or unannounced audit may be required include new ownership; extension to manufacturing and/or design control; new facility, site change, modification of the site operation involved in the manufacturing activity; new processes or significant process changes, significant modifications to special processes; modifications to the defined authority of the management representative that impact QMS effectiveness or regulatory compliance, the capability and authority to assure that only safe and effective medical devices are released; new products or categories, addition of a new device category to the manufacturing scope within the QMS; changes in standards or regulations, post market

surveillance; or if TQCSI has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

Approved: ***approved through TQCSI Track, Documentation***

Craig Bates
Managing Director & President, TQCSI

Date: 5 May 2025