Document Authorization:

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Changes from previous version:

Section	Summary of Changes	Change Control Number
ALL	1. New document	

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1. PURPOSE

The purpose of this document is to describe the process for reviewing controlled documents on a periodic basis in compliance with industry standards. Periodic document reviews are intended to ensure continued accuracy of the controlled document content and process.

2. SCOPE

This procedure includes Policies, Standard Operating Procedures (SOPs), and associated Forms.

Documents outside of this scope are not included in this SOP because by nature of the document type, the content of the document type is reviewed on a much more regular frequency against known standards and compliance regulations than is described in this SOP.

3. INTERNAL REFERENCES

Document ID	Title
QUA001	Quality Manual
QUA006	Record Retention Policy

4. EXTERNAL REFERENCES

Document ID	Title
	21 CFR Part 820, Medical Device; Current Good Manufacturing Practice (cGMP) Final Rule; Quality System Regulation, Food and Drug Administration, Federal
	ISO 9001, Quality management systems -Requirements, International Organization for
	ISO 13485, Medical Devices – Quality Management Systems – Requirements for Regulatory

5. RESPONSIBILITIES

Job Function and/or Department	Responsibility
All Personnel	It is the responsibility of all employees, including temporary employees and consultants, involved in recording, or reviewing information on documents to provide clear and consistent details on record keeping and follow good documentation practices to support the quality of work.

6. DEFINITION

Term	Definition

7. CONTEXT OF THE ORGANIZATION

7.1. Controlled Document Periodic Review Frequency

7.1.1. Policy, SOPs and analytical methods are reviewed at least every two (2) years by the department responsible for the oversight.

7.2. Controlled Document Periodic Review Notifications

7.2.1. Quality Assurance issues notifications at least 90 days prior to the two-year anniversary of the effective date of the document.

7.2.2. Each notification will require a verdict from the document owner or department delegate.

- “keep effective”
- “need revision”
- “need to be made obsolete”

7.3. Responding to a Controlled Document Periodic Review Request

7.3.1. If “keep effective” is selected, this periodic review is complete, and no further action is required of the document owner or department.

7.3.2. If “need revision” is selected, document owners or delegates are required to initiate a Change Control Request per QUA003.

7.3.3. If “need to be made obsolete” is selected, the document owner is required to initiate a Change Control Request per QUA003.

7.3.4. If a Change Control Request is initiated, the justification for changes should indicate the Periodic Review as a reason in addition to justification related to the edits to the document.

7.4. Controlled Document Periodic Review Escalation Steps

7.4.1. If a Change Control Request is not initiated by the department or delegate within 30-day period after the anniversary of the document effective date, Quality Assurance will facilitate the initiation of the Change Control Request with a document owner or delegate for each outstanding document. This effort will also trigger an escalation notification from Quality Assurance to the responsible department’s executive management.

7.5. Controlled Document Periodic Review Reporting

7.5.1. Controlled document periodic reviews are tracked and trended by Quality Assurance.

7.5.2. The document review status and trends are reported to executive management at least quarterly.

7.5.3. The date of the most recent periodic document review verdict sets the new baseline date for the next consecutive periodic review date.