1. Purpose

This document describes the policies and procedures of <company>’s (<COMPANY>’s) controlled document and records management system.

2. Scope

This procedure applies to all documents and records that are part of <COMPANY>'s product development, product manufacturing, clinical research, quality system and regulatory activities.

This procedure may be applied to documents generated by other designated activities.

3. Responsibility

All <COMPANY> personnel are responsible for following this procedure and applying it to their daily work.

Department and functional managers are responsible for ensuring personnel under their supervision follow this procedure.

Executive Management is responsible for ensuring that this procedure is understood, implemented, and maintained at all levels of the organization.

Configuration Management is responsible for establishing, implementing, practicing, and maintaining this procedure.

4. Related and/or Reference Documents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Title</th>
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<tbody>
<tr>
<td>920-0009</td>
<td>Change Control Procedure</td>
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</table>

5. Definitions

**Configuration Management**: (IEEE) A discipline applying technical and administrative direction and surveillance to identify and document the functional and physical characteristics of a configuration item, control changes to those characteristics, record and report change processing and implementation status, and verifying compliance with specified requirements. Within <COMPANY> Configuration Management is a designated job function.

**Current**: The status given to the most recent and/or effective versions of documents.

**Dispose**: The process of destroying a document after it is no longer required to be maintained.


- **Note 1**: Medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.
- **Note 2**: A set of documents, for example specifications and records, is frequently called “documentation”.
- **Note 3**: Some requirements (e.g. the requirement to be readable) related to all types of documents, however there can be different requirements for specifications (e.g. the requirement to be revision controlled) and records (e.g. the requirement to be retrievable).