**Document Revision History**

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# Purpose and Scope

(Define the overall objective of what the requirements document is focused on)

# References

(Provide reference to appropriate supporting documentation)

# Definitions, Acronyms, and Abbreviations

| Term | Definition |
| --- | --- |
|  |  |
|  |  |

# Technical Requirements

# User Functional Requirements

The following requirements describe the features and functionality of XXX that are intended for use.

## System Workflow (Outline the basic data flow within the system)

## Functionality required for the System (email alerts, notification of out of specification data, required inputs at each part of the workflow, etc.)

## Reports (Outline the types of reports required by the system in order to evaluate the data within the system)

# Electronic Records / Compliance Requirements

The following requirements describe the electronic record compliance requirements for XXX.

## Security

## Audit Trail

## Electronic Signatures (or Digital Signatures)

## Data Storage and Retrieval

# Approvals