

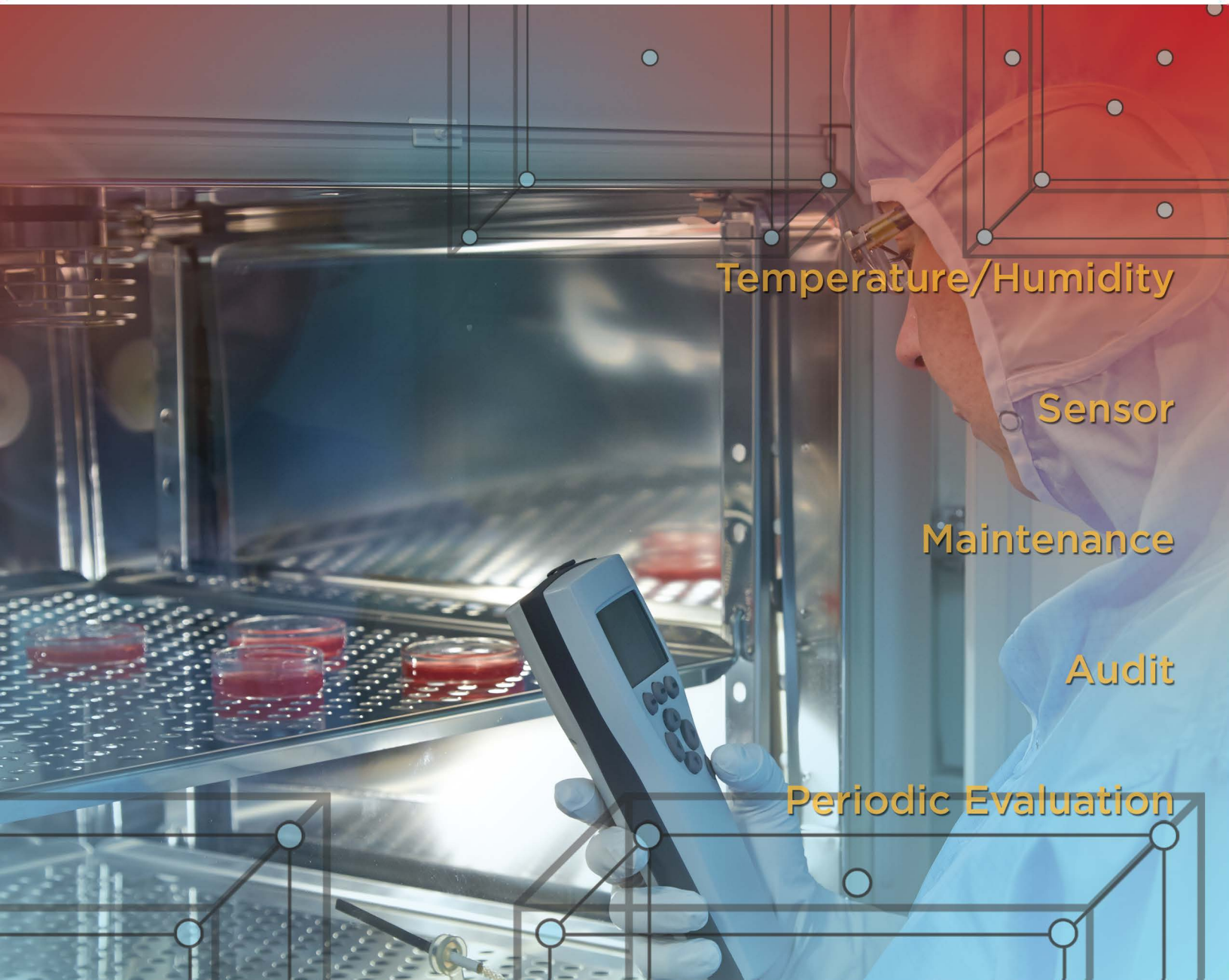


GOOD PRACTICE GUIDE:

Controlled Temperature Chambers

Commissioning and Qualification, Mapping and Monitoring

Second Edition



Temperature/Humidity

Sensor

Maintenance

Audit

Periodic Evaluation



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Preface

Global distribution of medicines requiring controlled temperatures has only increased in complexity since the first edition of this Guide was published. In order to meet changing industry practices, the second edition of this *ISPE Good Practice Guide: Controlled Temperature Chambers – Commissioning and Qualification, Mapping and Monitoring* was undertaken.

The primary purpose of this revision was to align with the *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification (Second Edition)*. Revising the Guide provided the opportunity to consider a periodic review frequency based on risk of failure to maintain uniform temperature and criticality of product stored rather than a standard, one-size-fits-all time span. In addition, the Guide was expanded to include ultra-low freezers, decommissioning a unit, and a discussion on using ocean reefers.

Together these improvements present a cost-effective way of demonstrating and maintaining compliance.

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Company affiliations are as of the final draft of the Guide.

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1 Introduction

A Controlled Temperature Chamber (CTC) is defined as a system, unit, equipment, or room in which the environmental conditions (typically temperature, sometimes temperature and humidity) of a chamber are controlled to meet specific user requirements.

ISPE Good Practice Guides are reviewed periodically to ensure alignment with industry best practices and other ISPE guidance documents. This *ISPE Good Practice Guide: Controlled Temperature Chamber – Commissioning and Qualification, Mapping and Monitoring* has been updated to align with the *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification (Second Edition)* [1].

The most significant changes are:

- Improvements to the commissioning and qualification activities resulting in more efficient processes
- Determining the periodic review frequency based on risk of failure to maintain uniform temperature and criticality of product stored

Additional revisions include:

- Expansion of freezer types to include ultra-low freezers and duration of storage needs
- Discussion on how materials of construction may impact cold rooms
- GxP storage facilities and warehouses descriptions
- Enhanced descriptions of monitoring systems
- High-level overview of decommissioning a unit
- Considerations for using ocean reefers (air-conditioned containers)

These revisions and other edits ensure that the Guide reflects current best practice and provides relevant guidance to industry, presenting a cost effective way of demonstrating and maintaining compliance.

Topics covered in this Guide include:

- Commissioning and Qualification
- Test Strategies
- Acceptance Criteria
- Qualification Approaches
- System Monitoring
- Periodic Evaluation
- Maintenance