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The approach described is consistent with that described in the ISPE Good Practice Guide: Cold Chain Management. Guidance is provided on Controlled Temperature Chambers used to store raw material, work in progress, or finished product, and which operate under current Good Manufacturing Practices (cGMPs).

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Full Title: ISPE Good Practice Guide: Cold Chain Management . Pages: 140 . Published: 2011-05-09 . Good Practice Guide: Commissioning & Qualification of Pharma Water & Steam Systems (Second Edition)

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This Guide aims to provide an example of how the principles discussed in the ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems and Equipment, and the ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification may be applied to GMP water and steam systems.

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This guide serves as a companion to other ISPE guides available, such as ISPE Baseline Pharmaceutical Engineering Guide, Volume 4-Water and Steam Systems. REFERENCE ISPE Releases ISPE Good Practice Guide: Critical Utilities GMP Compliance [news release]. North Bethesda, MD: International Society for Pharmaceutical Engineering; July 16, 2020.