

Title: Clean/Pure Steam System Commissioning and Qualification -Sampling Plans					
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Clean/Pure Steam System Commissioning and Qualification - Sampling Plans

Introduction

This document recommends sampling locations, frequencies, and testing activities associated with the commissioning and qualification of new installations or major revisions of Clean/Pure Steam Systems (e.g. the addition of new subloops or other system wide retrofitting).

This guidance defines the sampling location, frequency, and testing activities utilizing a risk based approach for supporting the commissioning and qualification for a clean/pure steam system. The recommended practices are derived from the latest edition of the ISPE Good Practices Guide “*Commissioning and Qualification of Pharmaceutical Water and Steam Systems*”.

Clean Steam is defined to be steam that does not contain any additives (e.g., boiler additives), ¹ is used where the steam and/or condensate have direct contact with product, and the steam condensate meets USP/EP WFI requirements. In addition, clean steam that is used for sterilization applications of “porous loads” for international manufacturing also should meet the requirements of European Standard EN 285. The USP states that “Pure Steam [Clean] is prepared from suitably pre-treated source water analogously to either the pre-treatment used for Purified Water or Water for Injection”.

This guidance does not cover the additional commissioning and qualification activities associated with other aspects of system validation (e.g., drawing development, system equipment/component installation/testing activities, cleaning/passivation, monitoring equipment, etc.). Ongoing operations (i.e. routine monitoring) after qualification activities are also outside of the scope of this guidance.

Recommendations & Rationale

The results of the commissioning and qualification demonstrate the equipment, personnel, and operating procedures are capable of consistently providing Clean Steam meeting the necessary steam quality requirements.

Regarding the quality of water feeding the clean steam generator, consider the requirements for Bacterial Endotoxin Testing (BET) validation studies in order to assure that there is no Bacterial Endotoxin being carried over in the steam during generation for those applications that have an endotoxin specification.

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developed for qualification if the acceptance criterion has been pre-approved by the appropriate Quality Assurance representative.

Phase 1 (approximately 3 Days)

Per current industry practice, the Phase 1 Qualification study lasts a minimum of three days with samples being taken at least once from each point of use and the outlet of the generation system.

The Phase 1 or “start-up” activities are to demonstrate production and delivery of clean steam meeting the necessary quality requirements. It is also very important during Phase 1 activities to finalize appropriate operating ranges for critical process parameters and to finalize Standard Operating Procedures (SOPs) for the system operation, cleaning, and maintenance.

Phase 2 (approximately 1 Week)

The Phase 2 or “system consistency/stability” activities typically last for one week following completion of Phase 1 sampling. The sampling and testing frequency are nearly identical to the activities in Phase 1 with the exception of the sampling of the outlet of the generator. Current industry practice is to sample the outlet of the clean steam generator more than once during the Phase 2 testing activities such as a bracketing approach (*e.g.* once during the start of Phase 2 sampling and again at the end of Phase 2 sampling).

The purpose of Phase 2 is to further demonstrate stable and consistent production and delivery of clean steam of the required quality with consistent operation within the established ranges when using SOPs. The use of steam for production is permissible during the qualification phase as long as the data collected demonstrates system stability, the steam produced is of the appropriate quality and that this approach has been approved by the appropriate site Quality Assurance representative.

Phase 3 (approximately 4 weeks)

The Phase 3 or “deviations” portion of the clean steam system qualification activities generally continue for an additional four weeks. Typically, the Phase 3 sampling plan is modified from the Phase 1 and Phase 2 schedule with the sampling and testing activities consisting of sampling the outlet of the clean steam generator on a weekly basis with additional samples being taken from the use test points on a weekly basis such that each use test point is sampled at a minimum of every 2 weeks during the Phase 3 studies.

As for clean steam quality tests, prior to plant usage of the clean steam within autoclaves for “porous loads” (as defined by the site) for products marketed in Europe, there needs to be testing of the following quality attributes, with the test conditions and specifications being listed within

Health Technical Memorandum (HTM) 2010s:

- 1) Superheat
- 2) Dryness Fraction
- 3) Noncondensable Gases