

**Guidance Number 052:**

**Table 1: Clean/Pure Steam<sup>4</sup>  
Generation System Sampling Location, Frequency and Test Type**

Generation System Sample Location	Commissioning Tests & Frequency Duration ≈ Varies	Phase 1 Tests & Frequency Duration ≈ 3 days	Phase 2 Tests & Frequency Duration ≈ 1 week	Phase 3 Tests & Frequency Duration ≈ 4 weeks
Feed to the Generator  <sup>1</sup> Note: Water quality should meet defined requirements, but must at minimum meet WHO and regional specifications for drinking water (chemical and microbiological attributes)	1) Verification of feedwater quality (micro, chemical, Certificate of Analysis <sup>1</sup> )			
Outlet of the Generator (Still)	1) Conductivity (daily) 2) EU Chemical Tests (once) 3) EN285 Tests <sup>1</sup> 4) Endotoxin (if required by end use)	1) Conductivity (daily) 2) EU Chemical Tests (once) 3) EN285 Tests <sup>1</sup> (once, if required and not tested during commissioning) 4) Endotoxin (once, if not tested during commissioning)	1) Conductivity (daily) 2) EU Chemical Tests (2x) 3) EN285 Tests <sup>1</sup> (2x, if required) 4) Endotoxin (2x, if required by end use)  <sup>1</sup> Note: The outlet of the Clean Steam Generator sampled at the beginning and the end of this phase (bracketed)	1) Conductivity (daily) 2) EU Chemical Tests (1x/week)

<sup>1</sup> Testing performed specifically to meet international requirements for specific clean steam applications (e.g. "porous load" autoclave sterilization). Process equipment (e.g. autoclave) will need to be operational to perform testing; testing may be performed as part of the process equipment qualification.

**Table 2: Clean/Pure Steam<sup>4</sup>  
Distribution System Sampling Location, Frequency and Test Type**

Distribution System Sample Location	Commissioning Tests & Frequency Duration ≈ Varies	Phase 1 Tests & Frequency Duration ≈ 3 days	Phase 2 Tests & Frequency Duration ≈ 1 week	Phase 3 Tests & Frequency Duration ≈ 4 weeks
Each Use Test Point	1) Conductivity (daily at Generator) 2) EU Chemical Tests (once) 3) EN285 Tests <sup>1</sup> (once, if required) 4) Endotoxin (once, if required by end use)	1) Conductivity (daily at Generator) 2) EU Chemical Tests (once) 3) EN285 Tests <sup>1</sup> (once, if required) 4) Endotoxin (once, if required by end use)	1) Conductivity (daily at Generator) 2) EU Chemical Tests (once) 3) EN285 Tests <sup>1</sup> (once, if required) 4) Endotoxin (once, if required by end use)	1) Conductivity (daily at Generator) 2) EU Chemical Tests (1x/2 weeks) 3) EN285 Tests <sup>1</sup> (1x/2 weeks, if required) 4) Endotoxin (1x/2 weeks, if required by end use)  Note: Sampling of the system should occur on a weekly basis

<sup>1</sup> Testing performed specifically to meet international requirements for specific clean steam applications (e.g. "porous load" autoclave sterilization). Process equipment (e.g. autoclave) will need to be operational to perform testing; testing may be performed as part of the process equipment qualification.