Operations Division
Specification
Title: Pure Steam Generation Equipment and Distribution system

Purpose: The definition of Pure Steam is that it is free of Pyrogen, and endotoxins, to meet the requirements for water injection (WFI)
This specification is to be used as the basis for the maintenance, service, repair and emergency call out agreement to the following system:

- Pure Steam Generation and Distribution System, consisting of the following:
  - Mueller Pure Steam Generator – Model: P7145
  - Celester Pure Steam Generator – Model GVP 500 (CPS 400)
  - Stilmas Degasser – Model TK09-1
  - Pure Steam Distribution System

The specification should be used as a minimum requirement, and any additional recommended works should be agreed between NIBSC and the service provider.

The specification will cover the entire system, and a current equipment list will be attached to this specification if applicable (Equipment List attached YES/NO, delete as necessary)

The Services required are:

- **Annual site/service visits** - to carry out routine and planned preventative maintenance (PPM). (Completed certificates/service sheets of examination to confirm this). To consist of two visits at six and twelve month intervals
- **Telephone Support Available** – 24/7 365 days of the year, response should be within 2 hours of receipt of phone call from NIBSC.
- **Emergency Call Outs** – Attendance on site for emergency repairs/fault diagnosis should be within 1 working days of notification of emergency.

Associated Documents

Please refer to Workbench Document Serial No 6598 for contractor general requirements
Please refer to Workbench Document Serial No 6721 Planned Preventive Maintenance and Calibration Administration
HPA/RA/02001 Clean steam generators, degasser and distribution system
Health Technical Memorandum (HTM) 2010 Sterilization
BS EN 285:2006+A2:2009 Sterilization. Steam sterilizers. Large sterilizers
USP 29

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Health and Safety

Parts of Steam generating plant when in use, or under test conditions will be hot and care must be taken not to come in contact with these parts of the equipment , any breaks or missing insulation should be highlighted and reported.
Compressed air is used for the control system at high pressure, up to 6 bar.
Work is undertaken in a plant room which houses other equipment, contractors should be aware of this plant, and must not touch or interfere with the safe running of other equipment.

Planned Maintenance and Service

NIBSC maintains equipment to ensure it is in an efficient state and order, and also in good repair. The frequency and type of maintenance carried out is assessed taking into account the following points:

- the manufacturer's recommendations
- the intensity of use
- Legal Requirements
- operating environment (e.g. the effect of temperature, corrosion, weathering)
- user knowledge and experience
- Industry practice including specified guidance
- the risk to health and safety from any foreseeable failure or malfunction
- the risk to institute work

The maintenance regime at NIBSC is not only to keep equipment safe to use, but also to maintain its reliability, and ensure it is running at its most efficient.

Because of this, NIBSC has developed the service requirements, and service period using knowledge and experience of this type of specialist equipment, and Industry good practice, as well as using the expertise of specialist contractors, to develop the specification that we work to.

Note: Insurance Inspection by a third party when required will be organised to coincide with strip

NIBSC will make equipment available, and understand there will be a requirement for the plant to be shut down for duration of the work.
There will be a formal hand over procedure to the service provider before work has commenced.
There will also be a formal hand back on completion of work.

The conductivity of the condensate sample must meet WFI quality requirements in accordance with HTM2010, BS EN 285, and USP29 standards and guidelines.

The service visits must consist of the following for each item of plant:

Mueller Pure Steam Generator Model P7145

6 Month Service Visit:

Pre-Work Inspection and Test

- With the Generator running carry out pre-work inspection and testing – monitor and record operational values, settings and Blow Down against Qualified Values.

Shut Down

- Shut down Pure Steam Generator and isolate all Utility and Electrical supplies.
- Allow Pure Steam Generator to cool and drain down.

Service work

- Strip Level Control Valves LCV-1760 and LCV-1770 and replace Process diaphragms.
- Remove Plant Steam, Plant Steam Condensate and Cooling Water Strainers, Clean and Replace.
- Start Up and Re-Validation
- Re-start Pure Steam Generator and bring up to operating temperature checking for leaks rectifying as necessary.
- Carry out operational testing of Critical Alarms and Operations against Qualified Set Points.
- With the Pure Steam Generator running carry out visual integrity checks on all joints, valves and Heat Exchangers for leaks and correct operation.

Post-Work Inspection and Test

- With the Pure Steam Generator running carry out post-work inspection and testing, monitor and record operational values, settings and Blow Down against Qualified Values.

12 Month Service and Calibration Visit:

Pre-Work Inspection and Test

With the Pure Steam Generator running carry out pre-work inspection and testing:

- Monitor and record operational values, settings and Blow Down against Qualified Values.

Shut Down

- Shut down Pure Steam Generator and isolate all Utility and Electrical supplies.
- Allow Pure Steam Generator to cool and drain down.

Calibration

Carry out calibration on the following:

- Temperature Loops Tags: TE-5110, TE-5925.
- Conductivity Loops Tags: AE-5935
- Pressure Switches Tags: PSL-4030
- Pressure Gauges: PI-4020, PI-4110, PI-5110, PI-2020, PI-2070, PI-5120

Note: Calibration must be of complete loops where applicable. Control and Recording loops will be checked for operation as part of the calibration.

Service Work

- Strip Down - as necessary, Inspect/Service – Plant Steam/Plant Steam Condensate
- Inspect Plant Steam and Condensate Lines generally for signs of leaks and general condition.
- Remove Strainer Mesh from NN-2030, clean and re-fit.
- Dismantle Steam Trap FCV-2220 from Condensate Line and inspect internals.
- Strip Down - as necessary, Inspect/Service Evaporator/Separator
- Remove top of Evaporator and Inspect internals of Evaporator and Separator Column, re-assemble with new gaskets.
- Dismantle Blow-Down Cooler and Inspect internals, re-assemble with new gaskets.
- Dismantle Level Indicator Assembly and Inspect Float Ball assembly and internals, re-assemble with new gaskets.
- Strip Down as necessary, Inspect/Service Feed water
- Inspect Feed Water Lines generally for signs of leaks and general condition.
- Pressure test all associated pressure relief valves, and document their set pressures and the pressure at which they operate.
- Strip Level Control Valves LCV-1760 and LCV-1770 and replace Process diaphragms.
- Strip Down - as necessary, Inspect/Service Cooling Water
- Inspect Cooling Water Lines generally for signs of leaks and general condition.
- Remove Strainer NN-3015 Inspect Clean and Replace.
- Strip Down - as necessary, Inspect/Service Waste/Domestic Water
- Inspect Waste Water Lines generally for signs of leaks and general condition.
- Strip Down - as necessary, Inspect/Service Condensed Pure Steam
- Inspect Lines generally for signs of leaks and general condition.
- Dismantle Condensing assembly and inspect internally re-assemble with new Diaphragm and gaskets.
- Dismantle Sample Valve Tag HV-5945 and inspect, re-assemble with new Diaphragm and gaskets.
- Strip Down - as necessary, Inspect/Service Pneumatics
- Inspect Pneumatic Lines generally for signs of leaks and general condition.
- Inspect filter units for contamination and replace as necessary.

Start Up and Re-Validation

- Re-start Pure Steam Generator and bring up to operating temperature checking for leaks rectifying as necessary.
- Carry out operational testing of Critical Alarms and Operations against Qualified Set Points.

- With Pure Steam Generator running carry out visual integrity checks on all joints, valves and Heat Exchangers for leaks and correct operation.

Post-Work Inspection and Test

With the Pure Steam Generator running carry out post-work inspection and testing:

- Monitor and record operational values, settings and Blow Down against Qualified Values.
- Completion

Celester Pure Steam Generator Model GVP 500 (CPS400)

6 Month Service Visit:

Pre-Work Inspection and Test

With the Generator running carry out pre-work inspection and testing:

- Monitor and record operational values, settings and Blow Down against Qualified Values.

Shut Down

- Shut down Pure Steam Generator and isolate all Utility and Electrical supplies.
- Allow Pure Steam Generator to cool and drain down.

Service work

- Strip Level Control Valves and replace Process diaphragms.
- Remove Plant Steam, Plant Steam Condensate and Cooling Water Strainers, Clean and Replace.

Start Up and Re-Validation

- Re-start Pure Steam Generator and bring up to operating temperature checking for leaks rectifying as necessary.
- Carry out operational testing of Critical Alarms and Operations against Qualified Set Points.
- With the Pure Steam Generator running carry out visual integrity checks on all joints, valves and Heat Exchangers for leaks and correct operation.

Post-Work Inspection and Test

- With the Pure Steam Generator running carry out post-work inspection and testing, monitor and record operational values, settings and Blow Down against Qualified Values.
- Completion

12 Month Service and Calibration Visit:

Pre-Work Inspection and Test

With the Pure Steam Generator running carry out pre-work inspection and testing:

- Monitor and record operational values, settings and Blow Down against Qualified Values.

Shut Down

- Shut down Pure Steam Generator and isolate all Utility and Electrical supplies.
- Allow Pure Steam Generator to cool and drain down.

Calibration

Carry out calibration on the following:

- Temperature Loops
- Conductivity Loops
- Pressure Switches
- Pressure Gauges

Note: Calibration will be of complete loops where applicable. Control and Recording loops will be checked for operation as part of the calibration.

Service Work

- Strip Down - as necessary, Inspect/Service Plant Steam/Plant Steam Condensate
- Inspect Plant Steam and Condensate Lines generally for signs of leaks and general condition.
- Remove Strainer Mesh, clean and re-fit.

- Dismantle Steam Trap from Condensate Line and inspect internals.
- Strip Down - as necessary, Inspect/Service Evaporator/Separator
- Remove top of Evaporator and Inspect internals of Evaporator and Separator Column, re-assemble with new gaskets.
- Dismantle Blow-Down Cooler and Inspect internals, re-assemble with new gaskets.
- Dismantle Level Indicator Assembly and Inspect assembly and internals, re-assemble with new gaskets.
- Pressure test all associated pressure relief valves, and document their set pressures and the pressure at which they operate.

Strip Down - as necessary, Inspect/Service – Feed water

- Inspect Feed Water Lines generally for signs of leaks and general condition.
- Strip Level Control Valves and replace Process diaphragms.

Strip Down - as necessary, Inspect/Service – Cooling Water

- Inspect Cooling Water Lines generally for signs of leaks and general condition.
- Remove Strainer Inspect, Clean and Replace.

Strip Down - as necessary, Inspect/Service – Waste/Domestic Water

- Inspect Waste Water Lines generally for signs of leaks and general condition.

Strip Down - as necessary, Inspect/Service – Condensed Pure Steam

- Inspect Lines generally for signs of leaks and general condition.
- Dismantle Condensing assembly and inspect internally, re-assemble with new Diaphragm and gaskets.
- Dismantle Sample Valve and inspect, re-assemble with new Diaphragm and gaskets.

Strip Down - as necessary, Inspect/Service – Pneumatics

- Inspect Pneumatic Lines generally for signs of leaks and general condition.
- Inspect filter units for contamination and replace as necessary.

Start Up and Re-Validation

- Re-start Pure Steam Generator and bring up to operating temperature checking for leaks rectifying as necessary.
- Carry out operational testing of Critical Alarms and Operations against Qualified Set Points.
- With Pure Steam Generator running carry out visual integrity checks on all joints, valves and Heat Exchangers for leaks and correct operation.

Post-Work Inspection and Test

With the Pure Steam Generator running carry out post-work inspection and testing:

- Monitor and record operational values, settings and Blow Down against Qualified Values.
- Completion

Stillmas Degasser Model TK09-1

6 Month Service Visit:

Pre-Work Inspection and Test

With the Degasser running carry out pre-work inspection and testing:

- Monitor and record operational values, settings and outputs against Qualified Values.

Shut Down

- Shut down Degasser and isolate all Utility and Electrical supplies.
- Allow Degasser to cool and drain down.

Service Work

- Remove Plant Steam Strainer, Clean and Replace.
- Check Steam Traps for correct operation.

Start Up and Re-Validation

- Re-start Degasser and bring up to operating temperature checking for leaks rectifying as necessary.

- Carry out operational testing of Critical Alarms and Operations against Qualified Set Points.
- With Degasser running carry out visual integrity checks on all joints, valves and Heat Exchangers for leaks and correct operation.

Post-Work Inspection and Test

With the Degasser running carry out post-work inspection and testing:

- Monitor and record operational values, settings and outputs against Qualified Values.
- Completion

12 Month Service and Calibration Visit:

Pre-Work Inspection and Test

With the Degasser running carry out pre-work inspection and testing:

- Monitor and record operational values, settings and outputs against Qualified Values.

Shut Down

- Shut down Degasser and isolate all Utility and Electrical supplies.
- Allow Degasser to cool and drain down.

Service Work

- Remove Plant Steam Strainer, Clean and Replace.
- Strip Steam Traps and replace internals.
- Remove Heads from Heat Exchanger and Inspect, re-assemble with new gaskets.
- Strip pneumatic valves and replace valve seats/diaphragms.
- Check Pump Seals and bearings.
- Strip pipe work and replace gaskets as deemed necessary.
- Note: All O.E.M. Specific parts to be supplied by NIBSC

Calibration

Carry out calibration on the following:

- Temperature Loops Tags: TE-09-52B, TE-09-52A
- Pressure Gauges Tags: PI-09-53, PI-09-22
- Note: Calibration will be of complete loops. Control and Recording loops must be checked for operation as part of the calibration.

Start Up and Re-Validation

- Re-start Degasser and bring up to operating temperature checking for leaks rectifying as necessary.
- Carry out operational testing of Critical Alarms and Operations against Qualified Set Points.
- With Degasser running carry out visual integrity checks on all joints, valves and Heat Exchangers for leaks and correct operation.

Post-Work Inspection and Test

- With the Degasser running carry out post-work inspection and testing, monitor and record operational values, settings and outputs against Qualified Values.
- Completion

Pure Steam Distribution System

6 Month Service Visit:

Pre-Work Inspection and Test

With the Pure Steam Generator running and Distribution System Operational carry out pre-work inspection and testing:

- Monitor and record operational values, settings and outputs against Qualified Values.

Service Work

- Inspect Lines generally for signs of leaks and general condition.
- Check all Tri-Clamp connections are tight.
- Check all Steam Traps and Air Vents for correct operation.

- Check operation of Regulating Control Valve Tag PCV-501

Re-Validation

- Carry out Steam Quality Testing (Non condensable Gases only) at each Autoclave and record results.

Post-Work Inspection and Test

With the Pure Steam Generator running and Distribution System Operational carry out post-work inspection and testing:

- Monitor and record operational values, settings and outputs against Qualified Values.
- Completion

12 Month Service and Calibration Visit:

Pre-Work Inspection and Test

With the Pure Steam Generator running and Distribution System Operational carry out pre-work inspection and Testing:

- Monitor and record operational values, settings and outputs against Qualified Values.

Calibration

Carry out calibration on the following:

- Pressure Transmitters: PE-501
- Pressure Gauges: PI-501, PI-502, PI-401, PI-402
- Pressure Control Valve: PCV-501

Service Work

- Inspect Lines generally for signs of leaks and general condition.
- Strip all Steam Traps and Air Vents and replace internal elements.
- Replace all Tri-clamp gaskets.
- Check operation of all Ball Valves.
- Pressure test all associated pressure relief valves, and document their set pressures and the pressure at which they operate.

Start Up and Re-Validation

- Service Provider and NIBSC engineers to sign report confirming that it is safe to re-start the Pure Steam Generator and commence re-pressurization of the Pure Steam Distribution System.
- Re-start Pure Steam Generator and bring the Distribution System up to operating pressure checking for leaks rectifying as necessary.
- With Pure Steam Distribution System up to pressure, carry out visual integrity checks on all joints, valves and Steam Traps for leaks and correct operation.
- Carry out Steam Quality Testing (Non condensable Gases only) at each Autoclave and record results.

Post-Work Inspection and Test

With the Pure Steam Generator running and Distribution System Operational carry out post-work inspection and testing:

- Monitor and record operational values, settings and outputs against Qualified Values.
  Completion

Administration Process

The procedure used to administer the service and documentation is detailed in a workbench document SN6721

END