Qualification of Purified Water and Water for Injection

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PW & WFI
IQ tests

- Documentation check
- Check of each elements of PW system and its documentation
- Check of technical service documentation
- Check of the welding documentation
  - Welder certificate
  - Calibration certificate of welding machine (automatic welding machine should be periodically calibrated on amperage)
  - Welding machine setting protocol
  - Method of welding (SOP)
  - Quality control method for welding
  - Welding machine printouts for each orbital joint
  - Welding joint sample of each working day
- Check of hydraulic tests results
- Check of passivation results

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IQ tests

- Pipeline slope check
- Sampling valves check
- Check of connection to feed-water
- Check of system cleaning SOP
- Check of measuring and regulation elements and relevant documents
- Check of electrical connection and relevant documents
- Check of accessories completeness, special tools and spare parts, required for operation
- Check of measuring-and-recording apparatus certificates
- Other tests based on RA

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OQ tests

- System operation tests
- Interlocks and safety elements tests
- Management system (PLC) tests
- Recording device tests
- System operation in emergency situations such as on / off power, water, comp. air tests
- Conducting of sanitation or sterilization cycles tests
- Check of thermal sanitation and sterilization cycles
- Water speed tests at its maximum consumption
- Check of personnel training
- Check of SOP on system maintenance, sampling, etc.
- Temperature stability tests
- Water quality control (In Line and Off Line)
- Other tests based on RA

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Qualification Phase 1

- Intensive monitoring of the system, duration 2-4 weeks, during this period the system should operate continuously without failures
- The scope of testing should include the following:

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Qualification Phase 1

- Testing of chemical and microbiological criteria in accordance with the approved plan
- Daily sampling of feed-water
- Daily sampling in each consumption point
- Daily sampling after each cleaning stage
- Determine the level of alarm and action
- Develop CPM on system operation and maintenance, and system sanitization/ sterilization
- Demonstrate the production and supply of water to consumers in the appropriate quantity and quality
- Develop and update operating procedures, required to be taken in identifying deviations

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Qualification Phase 2

- The subsequent period of 2-4 weeks
- Use all updated during phase 1 CPM
- Sampling scheme is generally identical to the used one during phase 1
- Water may be used for production purposes
- Purpose:

  -Demonstrate continuous operation within established ranges

  - Demonstrate continuous production and delivery to the consumption points of water in the required volume and quality in the corresponding operating system in accordance with SOP

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Qualification Phase 3

Duration 1 year, after the successful phase 2completion, purposes:

- Demonstrate long-term and stable operation
- Ensure that seasonal fluctuations are estimated
- Location of sampling points, the frequency of sampling and testing are reduced to normal, corresponding to a routine procedure

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PQ tests

Operational qualification for water treatment system is monitoring the stability of the system parameters for one year

- Determination of sampling points
- Sampling frequency
- On-line monitoring

N.B. Register sanitation cycles, deviation, failures, etc.'

- Analysis (stat. analysis)
- Recommendations for the frequency of sanitation, frequency and sampling points
- Conclusions

Monitoring

- After phase 3 qualification completion, system revision should be carried on. Routine revision plan should be developed based on results of phase 3 qualification
- Monitoring should include combination of on-line data, such as meter readings (e.g. flow, pressure, temperature, conductivity, TOC), and testing of the samples off-line on the physical, chemical and microbiological characteristics
- Test are to be performed to ensure that requirements of specification for water are met (as a rule: conductivity, pH, heavy metals, nitrates, TOC, microbial purity, the presence of specific pathogens and endotoxins)
- Monitoring data should be subjected to trend analysis

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Quality monitoring

Quality monitoring is performed based on the recommendations of the qualification

USP recommends to install for monitoring of microbial contamination:

- Alert Level (upper acceptance limit)
- Action Level

➢ Monitoring parameters

- Temperature
- Speed
- Integrity, the installation tightness and breathing filter change intervals
- The frequency of the ion-exchange columns regeneration
- pH
- Conductivity
- Total organic carbon (TOC)
- UV light (PW)
- System tightness

Re-qualification – annual system review

- Changes made since the last revision
- System operation
- System reliability
- Trend quality analysis
- Cases of failures
- Investigations
- OOS results
- Updated technical documentation
- Record/ log book
- The status of relevant SOPs list

Thank you for your attention

Feel free to contact me in case of any questions!

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