Appendix 2 Prevention and control measures for microbial risks in membrane-based WFI systems

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| Code | Failure mode | Preventive actions and suggestions |
| FM1 | Raw water quality does not meet requirement, such as increased levels of particulates, bacteria, organic matter, minerals, etc. | 1. Regular inspection of raw water supply pipelines;
2. Provide online facility for adding sodium hypochlorite solution to raw water;
3. Routine sampling of the raw water should be carried out.
 |
| FM2 | Unable to filter raw water | 1. Regular maintenance of multi-media filter;
2. Provision of alarm on multi-media filter;
3. Validation and confirmation of sanitation methods and frequency;
4. Defined periodic media replacement.
 |
| FM3 | Unable to filter raw water | 1. Regular maintenance of activated carbon filter;
2. Provision of alarm on activated carbon filter;
3. Validation and confirmation of sanitation methods and frequency;
4. Defined periodic media replacement;
5. Strong recommendation to avoid using carbon filter (ISPE 2021).
 |
| FM4 | Low concentration of chemicals in the antiscalant dosing tank, unable to remove precipitable ions | 1. Alarm provision is provided in case of low chemical;
2. Operation of the Chemical dosing system shall be verified during commissioning;
3. Routine checkup of chemical dosing shall be performed regularly.
 |
| FM5 | Low/high dosing of SMBS/SBS | 1. Alarm provision is provided in case of low/high chemical;
2. Operation of the Chemical dosing system shall be verified during commissioning;
3. Routine checkup of chemical dosing shall be performed regularly.
 |
| FM6 | Water Pressure may not sufficient to feed RO  | 1. Provision of high-pressure pump with VFD;
2. Installation of pressure gauge to monitor RO feed water pressure;
3. Operation of the high-pressure pump shall be verified during commissioning;
4. Routine checkup of chemical dosing shall be performed regularly.
 |
| FM7 | Leakage of the RO membrane | 1. RO system integrity testing;
2. Monitoring instruments (e.g., pressure gauges and thermometers) and interlocks, such as a temperature switch or sensor in RO feed pump line to inhibit pump operation at high feed water temperatures to avoid membrane damage;
3. Calibration of measuring instruments;
4. Monitoring of salt rejection and permeate conductivity;
5. Training of operators and establishment of clear operating procedures.
 |
| FM8 | Damage to RO membrane | 1. Monitoring instruments (e.g., pressure gauges and thermometers) and interlocks, such as a temperature switch or sensor in RO feed pump line to inhibit pump operation at high feed water temperatures to avoid membrane damage;
2. Calibration of monitoring instruments;
3. Monitoring of salt rejection and permeate conductivity;
4. Instrumentation to monitor and alarm for presence of chlorine and interlock, such as online ORP analyzer;
5. Robust control of chlorine removal in pretreatment;
6. Training of operators and establishment of clear operating procedures.
 |
| FM9 | Scaling/fouling of RO membrane | 1. Monitoring of salt rejection and permeate conductivity;
2. Monitoring of operating pressure, transmembrane pressure, permeate flow;
3. regular cleaning of membrane;
4. Installation of alarm to alert abnormal RO process parameters;
5. Increase the flow velocity paralleling membrane surface since rate of membrane fouling is closely related to the velocity (Bilad et al. 2014; Kruschitz & Nidetzky 2020; Pervov 2016).
 |
| FM10 | CEDI cannot provide electric field | 1. Regular check-up and maintenance of system operation;
2. Monitor and interlock dilute conductivity;
3. Recommended to install medium pressure UV light upstream the CEDI (ISPE 2022).
 |
| FM11 | Leakage of CEDI membrane | 1. Provision of conductivity sensor downstream of CEDI to monitor stack resistance and dilute conductivity;
2. Monitoring and maintaining appropriate operating pressure to prevent water hammer;
3. Regular inspection for leakage.
 |
| FM12 | Leakage of UF | 1. Integrity testing of membrane;
2. Monitoring instruments and interlocks, such as monitor flow rate, pressure drop and temperature;
3. Calibration of monitoring instruments.
 |
| FM13 | Damage to UF membrane | 1. Monitoring instruments (e.g., pressure gauges and thermometers) and interlocks, such as a temperature switch or sensor in UF feed pump line to inhibit pump operation at high feed water temperatures to avoid membrane damage;
2. Calibration of monitoring instruments;
3. Robust control of chlorine removal in pretreatment;
4. Define cleaning and sanitation method and frequency;
5. Training of operators and establishment of clear operating procedures.
 |
| FM14 | Fouling of UF  | 1. Provision of a pump with required flow rate for UF backwashing and rapid flushing;
2. Monitoring of operating pressure and permeate flow;
3. Define cleaning and sanitation method and frequency.
 |
| FM15 | Unable remove microorganism in the air | 1. Periodic testing of seal of the vent filter to avoid leakage;
2. The material of vent filter is hydrophobic, high temperature resistant and oxidation resistant;
3. Provision medium pressure UV light in water supply pipeline.
 |
| FM16 | Insufficient sealing | Regular inspection for leaks. |
| FM17 | Unpolished pipeline | 1. Passivation of pipelines after welding;
2. Qualified personnel for polishing operations;
3. Provision of passivation test report.
 |
| FM18 | Insufficient pump power | Regular performance inspection and maintenance of pump. |
| FM19 | Inadequate welding leading to pipeline leakage | 1. Welding by qualified welders;
2. Validation report of welding quality, such as pressure testing.
 |
| FM20 | Materials with water solubility | 1. All metal contact parts (storage tank and distribution pipelines, valves, sampling and user valves) and instrument contact parts should be made of SS 316L stainless steel;
2. Electro-polishing and orbital welding for distribution system pipelines;
3. Use of sanitary or hygienic design for flanges, unions, or valves.
 |
| FM21 | Inability to sanitize the system; ineffective sanitation; infrequent sanitation. | 1. Routine monitoring of the sanitation system;
2. Define sanitation method and frequency;
 |
| FM22 | Critical equipment process parameters cannot be monitored. | Regular performance confirmation and maintenance. |
| FM23 | Water quality cannot be measured. | Regular performance confirmation and maintenance. |
| FM24 | Measuring instruments cannot be calibrated. | Regular performance confirmation and maintenance. |

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