Table 1: Risk Assessment											
		Risk Identification			Risk Evaluation			Risk Control			
Sample Valve (SPV)	Description	Failure Mode	Effect	Cause	Impact (C, M, m, b)	Detectability (H, M, L)	Initial Risk (H, M, L)	Risk Mitigation	Final Risk (H, M, L)	Risk Verification	Risk Acceptance (H, M, L)
1	Incoming water	Not applicable, since the incoming water is controlled by city regulation laws	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as total organic carbon (TOC,) conductivity, and ultraviolet (UV) data measurements.	M	Verified during PQ and routine QC sampling phase (post-PQ phase, the moment the system is accepted or handed over to operations within the operational phase). Refer to rationale in Table 2 for additional explanation.	L
2	Filtered incoming water – cartridge filter product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	H	L	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
3	Water softening unit S-1 product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	H	M	From the midpoint to the final stages of purification process there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
4	Water softening unit S-2 product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	M	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
5	Activated carbon cartridge filtration system product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	M	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
6	Post-pretreatment cartridge filter product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	L	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
7	Reverse osmosis product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	L	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
8	Reverse osmosis product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	L	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
9	Reverse osmosis product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	L	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
10	Reverse osmosis product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	L	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
11	Reverse osmosis product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	L	From the mid-point to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
12	Reverse osmosis product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	M	M	L	From the mid-point to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
13	Reverse osmosis product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	M	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	L	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
14	USP purified water distribution loop return	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
15	USP purified water storage tank water (pump discharge)	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
16	Loop rechargeable mixed bed canister system product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
17	Loop rechargeable mixed bed canister system product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
18	Loop inline ultraviolet sanitization unit product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
19	0.1-micron final membrane filter 1st, product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
20	0.1-micron final membrane filter, 2nd, product water	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L
21	USP purified water distribution loop feed water (points of use)	Equipment not reducing impurities per design	No sampling	Unknown, since no sampling	C	H	H	From the midpoint to the final stages of the purification process, there are quality indicators in place such as TOC, conductivity, and UV data measurements.	M	Verified during PQ and routine QC sampling phase. Refer to rationale in Table II for additional explanation.	L

Legend
Impact codes: C = critical for GMP applications (direct Impact); M = major (indirect impact); m = Minor (no impact); b - business application only
Detectability: H (high), M (medium), L (low)
Risk assessment code: H (high), M (medium), L (low)

Definitions
Detectability: The ability to discover or determine the existence, presence, or fact of a hazard.
Harm: Damage to health, including the damage that can occur from loss of product quality or availability.
Hazard: The potential source of harm.[3]