

Table 2: Sampling Plan Summary for the Generic Reverse Osmosis (RO) / Deionized Water (DI) Skid			
Tag #	Description	Test	Rationale
SPV-01	Incoming water	Frequency: twice during three weeks pH, total chlorine concentration, free chlorine concentration, total iron, manganese, total organic carbon (TOC), turbidity, conductivity at 25° C, total alkalinity as calcium carbonate, sulfate, barium, total hardness as calcium carbonate, sodium, chloride, total suspended solids, silica, total viable bacteria count	Since the output of the incoming water will undergo further purification steps, it is suggested to test twice during a three-week period to determine the quality of the water prior to any pretreatment purification/processing steps. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-02	Filtered incoming water – cartridge filter product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-01, and testing would provide very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-03	Water softening unit S-1 product water	Frequency: two days/week for three weeks Total hardness as calcium carbonate	Only suggested to test for total hardness as calcium carbonate during this purification processing step. It is important to ensure consistency in sample output/data at the beginning and end of the week during a three-week period. Performing this test daily would not necessarily provide any added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-04	Water softening unit S-2 product water	Frequency: two days/week for three weeks Total hardness as calcium carbonate	Only suggested to test for total hardness as calcium carbonate during this purification processing step. It is important to ensure consistency in sample output/data at the beginning and end of the week during a three-week period. Performing this test daily would not necessarily provide any added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-05	Activated carbon cartridge filtration system product water	Frequency: two days/week for three weeks Total chlorine concentration	To ensure that the total chlorine concentration remains in control within acceptable range based on its previous purification processing steps coupled with its design function. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-06	Post-pretreatment cartridge filter product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-13, and testing would provide very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-07	Reverse osmosis product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-13, and testing would provide very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-08	Reverse osmosis product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-13, and testing would provide very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-09	Reverse osmosis product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-13, and testing would provide very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-10	Reverse osmosis product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-13, and testing would provide in very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-11	Reverse osmosis product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-13, and testing would provide very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-12	Reverse osmosis product water	Not applicable	No need to perform this test (the water generation system is new) since it has been tested for water quality at sample site SPV-13, and testing would provide very little to no added value since other sampling points at further purification stages will capture the quality output. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-13	Reverse osmosis product water	Frequency: two days/week for three weeks Conductivity @ 25° C, pH, TOC	Only TOC and conductivity tests are needed at this point since there would be no added value to test for other parameters such as total alkalinity as calcium carbonate and total viable bacteria due to the fact that they have been previously removed during the purification processing steps and tested. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-14	USP purified water distribution loop return	Frequency: two days/week for three weeks TOC per USP Physical Tests section <643>, conductivity per USP Physical Tests section <645>, total viable bacteria	To ensure that critical testing components such as TOC, bconductivity, and total viable bacteria remain within acceptable limits. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-15	USP purified water storage tank water (pump discharge)	Frequency: two days/week for three weeks Conductivity @ 25° C, TOC, total viable bacteria	To ensure that critical testing components such as TOC, conductivity, and total viable bacteria remain within acceptable limits. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-16	Loop rechargeable mixed bed canister system product water	Not applicable	No added value to test (the water generation system is new) at this point since it will be tested at the output of the UV unit sample site (SPV-18) for a better representative sample. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-17	Loop rechargeable mixed bed canister system product water	Not applicable	No added value to test (the water generation system is new) at this point since it will be tested at the output of UV unit sample site (SPV-18) for a better representative sample. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).t the output of UV unit sample site (SPV-18) for a better representative sample.
SPV-18	Loop inline ultraviolet sanitization unit product water	Frequency: two days/week for three weeks Total viable bacteria	To ensure that at the loop inline ultraviolet sanitization unit product water component purification stage, the total viable bacteria remains in control within acceptable range based on its previous purification processing steps coupled with its design function. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).
SPV-19	0.1-micron final membrane filter 1st, product water	Not applicable	No added value to test at this point (the water generation system is new) since it will be tested at sample site (SPV-21) prior to points of use. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-20	0.1-micron final membrane filter, 2nd, product water	Not applicable	No added value to test (the water generation system is new) at this point since it will be tested at sample site (SPV-21) prior to points of use. Risk control: The sampling activities and frequency shall be done in routine sampling phase (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring).
SPV-21	USP purified water distribution loop feed water (points of use)	Frequency: two days/week for three weeks TOC per USP Physical Tests section <643>, Conductivity per USP Physical Tests section <645>, total viable bacteria	To ensure that the USP purified water distribution loop feed water component purification stage is maintaining the TOC and conductivity are within acceptable range based on its previous purification processing steps coupled with its design function. Risk control: The sampling activities and frequency shall be done per test instruction within the PQ phase in addition to the routine sampling (e.g., sample randomization in order to ensure that the sample output remains consistently within specifications during routine monitoring over and above).