



**Summary of Substantive Changes
between the 2020 and the 2021 (with Errata date June 2022) edition of
NSF/ANSI 58 “Reverse Osmosis Drinking Water Treatment Systems”**

Presented to the IAPMO Standards Review Committee on September 12, 2022

General: The changes to this standard should not have an impact on currently listed products. The substantive changes are:

- Updated the minimum 2-L sample requirement to a recommendation in Section 4.4.3.3 (see Sections 4.4.3.2, and 4.4.3.3)
- Updated the lower edge of the drinking water outlet to be at least 25 mm (1 in) above the flood rim of the waste receptacle instead of 50 mm (2 in) (see Section 6.5.1.4)
- Expanded the scope to include nitrosodimethylamine (NDMA) reduction testing (see Section 7.1.4N)

Section 2, Normative references

21 CFR, Food and Drugs, [Subchapter B, Food for Human Consumption](#), Parts 170-1993

~~US-EPA~~, 40 CFR Part 141, *National Primary Drinking Water Regulations*³

~~US-EPA~~, 40 CFR Part 143, *Other Safe Drinking Water Act Regulations, Subpart A, National Secondary Drinking Water Regulations*³

*EPA-600/4B-79-020, Methods for the Chemical Analysis of Water and Wastes, March 1983*⁵

*[EPA-600/R-05-054, Method 521: Determination of Nitrosamines in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography With Large Volume Injection and Chemical Ionization Tandem Mass Spectrometry \(MS/MS\), September 2004](#)*⁵

*EPA-600/RB-93-100, Methods for the Determination of Inorganic Substances in Environmental Samples, August 1993*⁵

Section 4, Materials: updated the minimum 2-L sample requirement to a recommendation in Section 4.4.3.3 as follows:

4.4.3.2 *After flushing and conditioning in accordance with Section 4.4.3.1, systems shall be refilled with exposure water as specified in Section 4.4.2 and maintained for 24 h at an ambient temperature of 23 ± 2 °C (73 ± 3 °F). A ~~2-L~~ water sample shall be collected for analysis by emptying the storage tank completely and then sub-sampling ~~a 2-L volume~~. If the water holding volume of the storage tank is less than 2 L, sufficient samples shall be exposed to provide the required volume of extractant water. The system outlet shall then be closed, and the system shall be maintained for another 24 h at an ambient temperature of 23 ± 2 °C (73 ± 3 °F).*

A ~~2-L~~ water sample shall again be collected for analysis by emptying the storage tank completely and then sub-sampling ~~a 2-L volume~~. This process shall be repeated to give a total of three 24-h exposures ~~and 2-L samples~~. Systems without storage tanks shall be exposed as membrane elements, except that the recovery shall be dictated by the system. Samples collected shall be composited and analyzed in accordance with Section 4.4.1.

This sequence is summarized as follows:

a) Install the test system(s) on the test stand.



- b) Flush and condition with exposure water.
- c) Close the system outlet and maintain for 24 h.
- d) Empty the storage tank(s), if applicable, and sample.
- e) Repeat steps c and d for a total of three sampling events.
- f) Composite the three samples and analyze.

Components other than membrane elements shall follow the same process but shall be flushed according to the manufacturer's instructions prior to each 24-h exposure. A ~~minimum sample volume of daily 2-L shall be collected at each sample point~~ collection volume is recommended to ensure there is sufficient volume in the composite sample to conduct the requested analyses. If the water holding volume of the product is greater than 2 L, the entire volume shall be collected in a suitable collection vessel, and a 2-L subsample obtained from this volume. If the water holding volume of the product is less than 2 L, sufficient samples shall be exposed to provide ~~the required 2-L volume of extractant water at least 1/3 of the volume required for analysis of extractant water at each sample point.~~ Samples collected shall be composited and analyzed in accordance with Section 4.4.1.

.....

4.4.3.3 A ~~minimum sample volume of daily 2-L shall be collected at each sample point~~ collection volume is recommended to ensure there is sufficient volume in the composite sample to conduct the requested analyses. If the water holding volume of the product is greater than 2 L, the entire volume shall be collected in a suitable collection vessel, and a 2-L subsample obtained from this volume. If the water holding volume of the product is less than 2 L, sufficient samples shall be exposed to ~~the required 2-L volume of extractant water at least 1/3 of the volume required for analysis of extractant water at each sample point.~~ The maximum number of samples exposed shall not exceed 16 with 125 mL of extractant water drawn from each sample. If the components with a water holding volume that is less than 250 mL and is able to be identified as one that will only occur once in the flow path of dispensed treated water (such as diverters, faucets, RO shutoff valves, or specialty components) then a volume of 250 mL shall be drawn from each sample using a maximum number of eight samples.

Section 6.5, Product water dispensing outlets: Updated the lower edge of the drinking water outlet to be at least 25 mm (1 in) above the flood rim of the waste receptacle instead of 50 mm (2 in) as follows: Product water dispensing outlets other than drinking fountain outlets, if provided, shall be designed, constructed, and located so that the discharge orifice is directed downward. The lower edge of the outlet shall be at an elevation not less than 51 mm (2 in) above the flood rim of the waste receptacle.

6.5.1.4 The lower edge of the drinking water outlet shall be at least ~~51-25~~ mm (~~2-1~~ in) above the flood rim of the waste receptacle.



7.1.4 N-nitrosodimethylamine (NDMA) reduction testing

7.1.4.1 NDMA reduction claim

Claims for NDMA reduction may be made when tested in accordance with Section 7.1.4.1, so long as maximum effluent concentrations denoted in Table 7.4 are not exceeded.

<u>Contaminant</u>	<u>Individual influent sample point limits (ng/L)</u>	<u>Average influent challenge level (ng/L)</u>	<u>Maximum allowable product water level1 (ng/L)</u>	<u>US EPA Method</u>	<u>Compound</u>
<u>NDMA</u>	<u>40 ± 20%</u>	<u>40 ± 10%</u>	<u>6 ng/L</u>	<u>5212</u>	<u>NDMA</u>

¹ Since n-nitrosamines (NDMA) are not yet regulated by EPA, the effluent level of 6 ng/L was chosen as it is the latest TAC value under NSF/ANSI/CAN 600. The influent challenge of 40 ng/L is based on the 90th percentile of occurrence data from UCMR-2.

² An alternate validated method of equivalent sensitivity to US EPA Method 521 is permissible.

7.1.4.2 Apparatus

A test apparatus capable of providing specified flow rates and pressures shall be used. An example of an appropriate test apparatus appears in Figure 2.

7.1.4.3 Analytical methods

All analysis shall be conducted in accordance with the applicable methods referred to in Table 7.4. It is highly recommended that validation of US EPA Method 521 be undertaken prior to the actual testing, with the following precautions (an alternate validated method of equivalent sensitivity to US EPA Method 521 is permissible):

- a) Use RO/UV water for preparing the challenge water for verification of the stability of the NDMA concentration. UV treatment of the RO water needs to be optimized to eliminate all NDMA background. Alternatively, any challenge water that has no NDMA background is acceptable.
- b) In a 10-L tank, use 9 L of the above treated RO/UV water, add the chemicals in the modified (TOC > 1 ppm and TDS- 350 ± 50 mg/L) chemical test water given in Section 7.1.2.4.2.
- c) For pH adjustment use HCl, NaOH, and a small amount of Na₂CO₃ for stability. For TDS adjustment use NaCl and for TOC use tannic acid.
- d) Add 40 ng/L NDMA to the RO/UV water. Test to see if this concentration can be maintained within ± 10% during a 24-h period, taking samples at 2, 4, 8, 12, 18, and 24 hours.
- e) Make a 20× dilution of the sample at 2 and 24 hours and analyze to show that NDMA at 2 ng/L concentration can be detected in the presence of chemicals present in the test water.

7.1.4.4 Test water

A RO/UV treated water without any NDMA background described above shall be maintained throughout the test for NDMA reduction claim:

<u>turbidity</u>	<u>≤ 1 NTU</u>
<u>pH</u>	<u>7.5 ± 0.5</u>
<u>temperature</u>	<u>25 ± 1 °C (77 ± 2 °F)</u>
<u>total dissolved solids (TDS)</u>	<u>350 ± 50 mg/L</u>
<u>total organic carbon (TOC)</u>	<u>> 1 mg/L</u>



7.1.4.5 Challenge water

Using the test water described in Section 7.1.4.4, a solution of NDMA at a concentration of $40 \pm 10\%$ ng/L should be used as a challenge water.

7.1.4.6 Method

Two systems shall be conditioned in accordance with the manufacturer's instructions using the test contaminant specified in Table 7.4 and the appropriate test water specified in Section 7.1.4.4. The systems shall be tested using the appropriate influent challenge water at an initial dynamic pressure of 350 ± 18 kPa (50 ± 3 psig). The pressure shall not be readjusted, although the system may experience some change in dynamic pressure. Premembrane and postmembrane filters shall be removed prior to testing.

7.1.4.7 Sampling

7.1.4.7.1 Systems with storage tank and automatic shutoff

Product water samples shall be collected from the first water out of the system in the amount of 250 mL or total volume needed for analysis, whichever is greater. Influent and product samples shall be analyzed for all test contaminants. On Day 1 of testing, the storage tank shall be emptied after each collection at 4 h and 12 h. On Days 2 to 4 of testing, 5% of the first day's production rate shall be withdrawn from the storage tank after each collection at the beginning of the day and after an elapsed time of 6 h and 12 h. Days 5 and 6 represent a 54-h stagnation period, under pressure, during which no product water shall be withdrawn.

At the start of Day 7, 144 h into the test, a sample shall be collected and analyzed, followed by emptying of the storage tank. A final sample shall be collected and analyzed on Day 7 for the first 4-h period. After the last sample for test contaminants is collected, the storage tank shall be emptied.

7.1.4.7.2 Countertop systems with storage tanks or reservoirs

Product water samples shall be collected from the first water out of the system in the amount of 250 mL or total volume needed for analysis, whichever is greater. Influent and product samples shall be analyzed for all test contaminants. On Day 1, the storage tank shall be emptied after each collection at 4 h and 8 h. On Days 2 to 4 of testing, 5% of the first day's production rate shall be withdrawn from the storage tank after each collection at the beginning of the day and after an elapsed time of 6 h and 12 h. Days 5 and 6 represent a 54-h stagnation period, under pressure, during which no product water shall be withdrawn. At the start of Day 7, 144 h into the test, a sample shall be collected and analyzed, followed by emptying of the storage tank. A final sample shall be collected and analyzed on Day 7 for the first 4-h period. After the last sample for test contaminants is collected, the storage tank shall be emptied.

7.1.4.7.3 Systems without storage tanks

Product water samples shall be collected from the first water out of the system in the amount of 250 mL or total volume needed for analysis, whichever is greater. Influent and product samples shall be analyzed for all test contaminants. On Day 1 of testing, samples shall be collected at 4 h and 8 h. On Days 2 to 4 of testing, samples shall be collected at the beginning of the day and after an elapsed time of 6 h and 12 h. Days 5 and 6 represent a 54-h stagnation period, under pressure, during which no product water shall be withdrawn. At the start of Day 7, 144 h into the test, a test contaminant sample shall be collected and analyzed. A final sample shall be collected and analyzed on Day 7 for the first 4-h period.

7.1.4.7.4 Systems with no shutoff provisions

Product water samples shall be collected from the first water out of the system in the amount of 250 mL or total volume needed for analysis, whichever is greater. Influent and product samples shall be analyzed for test contaminants. On Day 1 of testing, samples will be collected in 4 h intervals including 4 h, 8 h, 12 h, and 16 h. The storage tank shall be emptied after each collection and the product water volume shall be recorded in liters (gallons). On Days 2 to 4 of testing, 5% of the first day's production rate shall be withdrawn from the storage tank after each collection at the beginning of the day and after an elapsed



time of 6 h and 12 h. Days 5 and 6 represent a 54-h stagnation period, under pressure, during which no product water shall be withdrawn. At the start of Day 7, 144 h into the test, a sample shall be collected and analyzed, followed by emptying of the storage tank. A final sample shall be collected and analyzed on Day 7 for the first 4-h period. After the last sample for test contaminants is collected, the storage tank shall be emptied.

Informative Annex 6 was added as follows:

Informative Annex 6

Explanation of scope and purpose of N-nitrosodimethylamine (NDMA) reduction claim

The information contained in this annex is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this annex may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to this standard.

N-nitrosamines are currently not regulated by the United States Environmental Protection Agency (US EPA) but are considered an emerging contaminant for future regulations. Six N-nitrosamines were monitored as a part of the Second Unregulated Contaminant Monitoring Rule (UCMR-2):

- N-nitrosodimethylamine (NDMA)
- N-nitrosodiethylamine (NDEA)
- N-nitrosopyrrolidine (NPYR)
- N-nitroso-di-n-butylamine (NDBA)
- N-nitroso-N-methylethylamine (NMEA)
- N-nitroso-di-N-propylamine (NDPA)

Of these six N-nitrosamines, NDMA is by far the most important contaminant in occurrence and concentration, as shown by UCMR-2. According to the US EPA's Integrated Risk Information System (2002), NDMA is a member of a family of extremely potent, genotoxic, carcinogenic N-nitrosamines. Its potential for cancer is much higher than that of trihalomethanes.

NDMA serves as an indicator for remaining N-nitrosamine compounds in water contamination, usually in much lower concentration. The test method is specific to NDMA only, though it is likely that the same considerations may apply to the other N-nitrosamines listed above.

The purpose of this protocol is to certify drinking water treatment POU and POE devices using activated carbon (AC) and reverse osmosis (RO) technologies for the reduction of NDMA.

While this protocol suggests US EPA Method 521 for analysis of NDMA, any other validated method of equal sensitivity may be used.

Since N-nitrosamines (NDMA) are not yet regulated by the EPA, the effluent level of 6 ng/L was chosen as it is the latest TAC value under NSF/ANSI/CAN 600. The influent challenge of 40 ng/L is based on the 90th percentile of occurrence data from UCMR-2.

Table 4.2 and Table 8.1: Added n-nitrosodimethylamine to both tables.