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Table 27.9 Quantitative risk assessment data requirements

Study type	Preferred criteria	
Required studies		
gene mutation assay ¹	bacterial reverse mutation assay performed with and without exogenous metabolic activation using <i>Salmonella typhimurium</i> (preferred strains are TA97, TA98, TA100, TA102, TA1535, and TA1537) or <i>Escherichia coli</i> (preferred strains are WP2 <i>uvrA</i> or WP2 <i>uvrA</i> (pKM101)	
chromosomal aberration assay ¹ (<i>in vitro</i> preferred)	metaphase analysis in mammalian cells and without exogenous metabolic activation	
(in vivo)	metaphase analysis or micronucleus assay in mammalian species	
subchronic toxicity ¹	90-d assay in rodent species by oral route of exposure	
Additional studies (required as indicated)		
reproduction assay ²	two generation reproductive assay in a rodent species	
developmental assay ²	teratology study (two species, one rodent and one non-rodent, are preferred)	
chronic study ³	2-yr bioassay in rodent species by oral route of exposure	
Supplemental studies		
supplemental genotoxicity studies	mouse lymphoma, SCE, ⁴ UDS, ⁵ HGPRT, ⁶ DNA binding (post labeling assay)	
bioaccumulation potential	octanol / water partition coefficient	
pharmacokinetics	absorption, distribution, metabolism, and excretion data in humans, other mammalian species, or both	
structural/functional assessment	structure / activity relationship analysis	
acute or short-term toxicity7	1- to 14-d or 14- to 28-d study using oral exposure	
cell proliferation / cell cycle assays	proliferating cell nuclear antigen (PCNA)	
sensitization	guinea pig intradermal injection	
in vivo gene mutation assay	transgenic gene mutation assays	
endocrine disruption assays	receptor binding / transcriptional activation assays, frog metamorphosis assay, steroidogenesis assay	
human data	epidemiological, occupational, or clinical studies	

¹ The gene mutation assay, the chromosomal aberration assay (*in vitro* or *in vivo*), and the subchronic toxicity study shall constitute the minimum data set required to perform a quantitative risk assessment. When one or both *in vitro* genotoxicity studies are positive, the *in vivo* assay shall be required to be reviewed.

² It is recommended that results of a screening assay, such as OECD No. 422, *Combined repeated dose toxicity study with reproduction/developmental toxicity screening test*, or data from other repeated dose assays that include histopathological examination of the reproductive tissues of each sex be reviewed prior to a determination that these assays are required for evaluation.

³ A chronic study with evaluation of carcinogenic endpoints is required when review of the minimum data set concludes that the substance is likely to be a human health hazard at exposures of 10 μg/L or less.

⁴ Sister chromatid exchange assay; SCEs are not considered to be mutagenic effects because the exchange is assumed to be reciprocal with no gain, loss, or change of genetic material. However, they do indicate that the test material has interacted with the DNA in a way that may lead to chromosome damage. In *in vitro* studies, SCEs do not provide adequate evidence of mutagenicity, but do identify the need for definitive chromosomal aberration studies. When evidence of *in vitro* clastogenicity exists, the induction of SCEs is often used as evidence of likely *in vivo* clastogenic activity because the *in vitro* aberration data demonstrate the clastogenic activity of the compound and the *in vivo* SCE data demonstrate that the compound interacted with the DNA in the target tissue.

Table 27.9 Quantitative risk assessment data requirements

Study type	Preferred criteria
⁵ Unscheduled DNA synthesis assay.	
⁶ Hypoxanthine guanine phosphoribosyl transferase assay.	

⁷ Minimum reported parameters include clinical observations, hematology and clinical chemistry, and gross pathology.

Table 27.10 **Uncertainty factors**

Areas of uncertainty	Factor
Intraspecies extrapolation (species variation) : This factor accounts for variations in chemical sensitivity among individuals in a species including toxicokinetic and toxicodynamic parameters.	1, 3, or 10
Interspecies extrapolation (animal to human) : This factor accounts for variations in chemical sensitivity between experimental animals and humans, including toxicokinetic and toxicodynamic parameters.	1, 3, or 10
Less than lifetime duration of exposure : This factor is intended to extrapolate experimental results from subchronic to chronic exposure.	1, 3, or 10
Use of LOAEL rather than NOAEL ¹ : This factor addresses the uncertainty in developing a reference dose from a LOAEL rather than a NOAEL.	1, 3, or 10
Lack of database completeness: This factor accounts for the absence of data for specific toxic endpoints.	1, 3, or 10
¹ This adjustment is not required for BMD calculations	

adjustment is not required for BMD calculations.

NOTE — When uncertainties exist in four areas, a 3,000-fold composite uncertainty factor is appropriate. When uncertainties exist in five areas, a 10,000-fold composite uncertainty factor is appropriate. This consolidation of individual factors recognizes that each individual factor is conservative, and multiplication of four or five uncertainty factors is likely to result in an overly conservative RfD. Datasets that would result in a composite uncertainty factor of greater than 10,000-fold are considered too weak for quantitative risk assessment (Dourson, 1994).

Normative Annex 1

(formerly Annex A)

Materials review and qualification methods

N-1.1 Purpose

The purpose of these methods is to document that the materials used in contact with pool or spa / hot tub (product) water do not impart undesirable levels of contaminants or color to the product water.

It is recognized that the product water is not intended for human consumption; that it is not feasible or cost-effective to identify every contaminant that might be contributed to the product water; and that there may not be complete toxicological information available on each contaminant identified. Therefore, these methods are designed to:

- determine from the material formulation those contaminants of toxicological concern likely to be contributed to the product water;

 determine the general level of contaminants contributed to the product water by the material, using screening tests; and

- determine the levels of specific contaminants, particularly regulated metals and organics, contributed to the product water by the material.

N-1.2 Formulation review

Where required for conformance to Section 4.2, complete material formulation information shall be reviewed to determine whether a material is suitable for contact with the product water, to assess the potential for contaminants to be contributed to the product water from the material, to determine whether extraction testing is warranted, and to select the appropriate extraction testing parameters.

The complete formulation information may be omitted for a component material if:

— the generic material type is contained in NSF/ANSI/CAN 61, Table 3.1, and the material is not a coating or filtration media, and the material is tested to the requirements of NSF/ANSI/CAN, Table 3.1; or

— if the material is not listed in NSF/ANSI/CAN 61, Table 3.1 and the material is not a coating or filtration media, and the material is tested to the requirements of NSF 61/ANSI/CAN, Table 3.2.

N-1.3 Exposure testing

N-1.3.1 General description

When extraction testing is warranted based on a material formulation, a multiple exposure procedure shall be followed. Under this procedure, material samples shall be submerged for specific durations in water having defined characteristics (exposure water). Upon completion of the exposures, the water (extraction water) shall be analyzed for the selected contaminants of concern. The contaminant concentrations observed shall be normalized to represent exposure conditions in the field. The normalized concentration (estimated exposure level or remove this statement) shall be compared to an established maximum contaminant level or a level of toxicological concern for drinking water. Chemical feeders and generators may be tested according to the requirements of NSF/ANSI/CAN 61 utilizing tap water and the

manufacturer's recommended chemicals, or specific components requiring testing may be evaluated to this Annex.

N-1.3.2 Selection of parameters for exposure testing

The selection of potential contaminants for which testing is warranted shall be based on the review of the material formulation, the toxicological significance of the ingredients, and the likelihood of their migration. Analysis for phenolic substances and total organic carbon (TOC) may be used as screening tests to determine whether additional testing is warranted for specific potential contaminants. Exposure testing may also be conducted to determine whether a material may impart color to water.

If the formulation has been omitted for a component material as allowed through Section N-1.2, testing shall include the material specific analyses in NSF/ANSI/CAN 61, Table 3.1, or as directed in NSF/ANSI/CAN 61. Table 3.2.

N-1.3.3 Exposure water

The condition of exposure water shall be based on the nature of the contaminant of concern. Exposure water having the following characteristics shall be prepared (note that parameters, especially temperature, may change during the exposure period):

	Extraction of metals / inorganics / organics
pH range	7.2 to 7.4
chlorine	2.0 ± 0.2 mg/L
hardness (as CaCO3)	150 ± 10 mg/L
temperature	100 ± 10 °F (38 ± 5 °C)

N-1.3.4 Exposure conditions

Samples shall be exposed to exposure water in three successive intervals according to the following schedule:

1	24 ± 1 h
2	24 ± 1 h
3	72 ± 4 h

After each of the first two exposure periods, the extraction water shall be discarded, and the sample exposed to fresh exposure water. The extraction water from the third exposure interval shall be analyzed for the selected contaminants. All exposures shall be conducted at an ambient air temperature of $73 \pm 3 \,^{\circ}$ F ($23 \pm 2 \,^{\circ}$ C).

N-1.3.5 Ratio of sample surface area to exposure water volume

When material or component samples are evaluated the ratio of the sample surface area to the volume of exposure water shall be 1,000 in² (6,500 cm²) to 1 gal (4 L).

Filtration and adsorption medias shall be exposed at the manufacturer's recommended use ratio of weight of media per unit void volume.

Precoat media shall be exposed at 10 times the manufacturer's recommended use ratio.

N-1.3.6 Analytical methods

Analyses of extraction water shall be conducted in accordance with the procedures in the following:

APHA/AWWA/WEF, Standard Methods for the Examination of Water and Wastewater;⁷

— US EPA-600/4-79-020, Methods for Chemical Analysis of Water and Wastes;

— US EPA, Methods for the Determination of Organic Compounds in Drinking Water, Supplement 1; or

— US EPA, Methods for the Determination of Inorganic Substances in Environmental Samples.

N-1.3.7 Normalization

The normalized extraction level for a contaminant shall be calculated by:

$$C_F = C_L \left(SA_F / V_F \right) \left(V_L / SA_L \right)$$

where:

 C_F = contaminant concentration in field

 C_L = contaminant concentration in lab

- SA_F = surface area of material in the field
- SA_L = surface area of material in the lab
- V_F = volume of water in the field
- V_L = volume of water in the lab

If the surface area to volume ratio in the field is not known the normalized extraction level is calculated by dividing the concentration in the extraction water by a factor of 10. This is based on the assumption that the worst-case surface area to volume ratio of the material is $25 \text{ in}^2/\text{L}$. All medias shall be normalized to the manufacturer's recommended use ratio.

N-1.3.8 Acceptance criteria

The normalized extraction concentration of a potential contaminant shall not exceed the total acceptable concentration (TAC) established by NSF/ANSI/CAN 61.

The color rating of the extraction water, as determined in accordance with *Standard Methods*⁷ 2120B, shall not exceed that of the exposure water (control).

Certification listings and manufacturer's literature for swimming pool materials (excluding components and devices) shall contain surface area to volume restrictions associated with the evaluation.

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Normative Annex 2

(formerly Annex B)

Test methods for the evaluation of filters

NOTE — The test conditions specified in this Annex are not intended to represent recommended field use conditions.

N-2.1 Hydrostatic pressure test (pressure service filters)

N-2.1.1 Purpose

The purpose of this test is to verify the hydrostatic integrity of a pressure service filter tank.

N-2.1.2 Apparatus

- a pressure testing rig capable of delivering and regulating hydrostatic pressure on a filter tank;
- temperature-indicating device (required accuracy: ± 2 °F [± 1 °C]);
- timer (required accuracy: ± 0.5 s); and
- pressure gauges sized to yield the measurement within 25% to 75% of full scale (required accuracy: \pm 2% of reading or \pm 1 psi [7 kPA], whichever is greater).

Electronic transducers may be used for recording test data. Transducers shall meet the accuracy requirements for gauges, but the measurement does not need to be within 25% to 75% of the range of the transducer.

N-2.1.3 Challenge water

	Swimming pool / spa / hot tub filters
water temperature	75 ± 10 °F (24 ± 6 °C)

N-2.1.4 Hydrostatic pressure test method (pressure service filters)

a) Install filter media or elements, or both, and all integral components according to the manufacturer's instructions. Connect the filter to the pressure-testing rig.

b) Fill the unit with the appropriate challenge water and bleed off all air.

c) Adjust the pressure regulator to apply a hydrostatic pressure equal to 1.5 times the working pressure of the unit. Maintain the pressure for 300 ± 30 s. Slowly release the pressure and examine the tank and its integral components for evidence of a rupture, leak, burst, or other deformation.

d) Adjust the pressure regulator to apply a hydrostatic pressure of 30 ± 1 psi (207 ± 7 kPa) and maintain it for 2 ± 0.5 s. The pressurization rate shall not exceed 30 psi/s. Slowly release the pressure and maintain a hydrostatic pressure of 0 psi (0 kPa) for 2 ± 0.5 s. Automatic timers shall be used to ensure that the proper pressures are applied and maintained for the required intervals. Repeat this cycle 20,000 times and examine the tank and its integral components for evidence of a rupture, leak, burst, or other deformation.

e) After the cycle test in step d, adjust the pressure regulator so that the pressure applied on the filter increases steadily and reaches a hydrostatic pressure equal to twice the working pressure within 60 to 70 s. Slowly release the pressure, drain the filter, and examine the tank for evidence of a rupture, leak, burst, or other deformation.

N-2.1.5 Acceptance criteria

There shall be no rupture, leakage, burst, or permanent deformation of the filter tank or its integral components during the three phases of the test, except that leakage from integral components such as valves and fittings during the third phase of the test (as described in Section N-2.1.4.e shall not constitute a failure.

N-2.2 Vacuum test (vacuum service filters)

N-2.2.1 Purpose

The purpose of this test is to verify the integrity of vacuum service filter tanks whose inlets may be closed during part of the operating cycle.

N-2.2.2 Apparatus

- vacuum source capable of creating a vacuum on a filter tank as required by this test;
- temperature-indicating device (required accuracy is ± 2 °F [± 1 °C]);
- timer (required accuracy is ± 0.5 s); and

— vacuum gauges sized to yield the measurement within 25% to 75% of full scale (required accuracy is \pm 2% of reading or \pm 1 psi [7 kPa], whichever is greater).

NOTE — Electronic transducers may be used for recording test data. Transducers shall meet the accuracy requirements for gauges, but the measurement does not need to be within 25% to 75% of the range of the transducer.

N-2.2.3 Challenge water

	Swimming pool / spa / hot tub filters
water temperature	75 ± 10 °F (24 ± 6 °C)

N-2.2.4 Vacuum test method (vacuum service filters)

a) Install filter media or elements, or both, and all integral components according to the manufacturer's instructions. Connect the filter to the vacuum source.

b) Adjust the pressure regulator to apply a vacuum of 25 ± 1 in Hg (85 ± 3.4 kPa) to the filter tank. Maintain the vacuum for 300 ± 30 s. Slowly release the vacuum and examine the tank for evidence of a rupture, collapse, leak, or other deformation.

N-2.2.5 Acceptance criteria

There shall be no rupture, collapse, leak, or other deformation of the filter tank.

N-2.3 Head loss test

N-2.3.1 Purpose

The purpose of this test is to verify that the initial head loss from the filter inlet to the filter outlet does not exceed the maximum head loss as specified by the manufacturer, and to verify that the initial head loss for an alternate sand-type media does not exceed the initial head loss of sand.

N-2.3.2 Apparatus

— pressure-recording device (required accuracy is \pm 0.5 of the smallest division used in the manufacturer's claimed pressure loss);

— turbidimeter (required accuracy from 0 to 10 NTU is \pm 0.5 NTU; required accuracy above 10 NTU is \pm 5% of the reading or \pm 1 NTU, whichever is greater);

temperature-indicating device (required accuracy is ± 2 °F [± 1 °C]);

— flow meter (required accuracy is ± 1 GPM (± 4 LPM) or $\pm 2\%$ of reading, whichever is greater);

- water tank and pump system capable of delivering water at the design flow rate and proper temperature through the filter;

pressure measurement taps sized to the filter's inlet and outlet; and

— for testing the initial head loss of an alternate sand-type media, the media shall be installed in a 24 in (624 mm) diameter sand-type filter for which the head loss with sand is known.

N-2.3.3 Challenge water

	Swimming pool / spa / hot tub filters
water temperature	75 ± 10 °F (24 ± 6 °C)
turbidity	≤ 2 NTU

N-2.3.4 Method

a) Install a pressure measurement tap at the filter inlet and the filter outlet. The taps shall be connected by a hose to the pump outlet and return. Determine the head loss due to any restriction between the filter inlet or outlet and the installed pressure measurement taps. This head loss shall be subtracted from the head loss measured during operation.

b) Condition filter per the manufacturer's instructions and initiate a filter cycle at the design flow rate.

c) Operate the unit at the design flow rate for 300 ± 30 s. See special instructions in Section N-2.3.4.f for testing sand filters.

d) Measure and record the inlet and outlet static pressures.

e) Calculate the head loss using one of the following equations:

$$HLF = (P_1 - P_2) + [Z_1 \times (9.81) W] / 1,000 - HLP$$

$$HLF = [(144 \times (P_1 - P_2)) / W] + Z_1 - HLP$$

where:

 $\begin{array}{ll} HLF &= \mbox{head} \mbox{loss} \mbox{due to filter (ft)} \\ P_1 &= \mbox{inlet static pressure (psig)} \\ P_2 &= \mbox{outlet static pressure (psig)} \\ W &= \mbox{specific weight of water (lb/ft^3)} \\ Z_1 &= \mbox{height of inlet centerline above outlet centerline (ft)} \end{array}$

HLP = head loss due to piping from P_1 to P_2 (ft)

NOTE - conversions:

 $\begin{array}{l} HLF (m) \times 9.81 = HLF (kPa) \\ HLF (ft) \times 0.4335 = HLF (psi) \\ P (psi) \times 2.307 = P (ft) \end{array}$

or

where:

HLF = head loss due to filter (kPa)

 P_1 = inlet static pressure (kPa)

 P_2 = outlet static pressure (kPa)

W = density of water (kg/m³)

 Z_1 = height of inlet centerline above outlet centerline (m)

HLP = head loss due to piping from P_1 to P_2 (kPa)

This analysis assumes that the inlet and outlet piping are of the same size, material, and general condition. If this is not the case, these factors shall be taken into account.

f) When testing sand filters, operate the filter at the design flow rate for an additional 6 h. Slowly reduce the flow to zero, shut down the system, and slowly drain the filter. Sudden reductions in flow can invalidate this test, as the water surge (including reversal of flow) can re-settle the sand bed. Examine the surface of the filter media bed for conformance to Section 6.3.5.3.

N-2.3.5 Acceptance criteria

The measured head loss shall not exceed the design head loss specified by the filter manufacturer.

N-2.4 Filter media cleanability test

N-2.4.1 Purpose

The purpose of this test is to verify the effectiveness of the manufacturer's recommended procedures for the cleaning of filter media, and to verify that the cleanability of an alternate sand-type media is at least equivalent to that of sand.

N-2.4.2 Apparatus

- pressure-recording device (required accuracy is ± 0.5 of the smallest division used in the