

The Division of Water Resources (DWR) Standard Operating Procedure (SOP) for Reviewing Groundwater Standards Established Pursuant to 15A NCAC 02L .0200

The DWR will use the protocol outlined in this SOP to review groundwater standards and make appropriate recommendations to the NC Environmental Management Commission (EMC or Commission) for the revision of groundwater standards and establishment of new groundwater standards.

Administrative Code Rule

In accordance with “Classifications and Water Quality Standards Applicable to the Groundwaters of North Carolina” (15A NCAC 02L .0202 (d)), “except as provided in paragraph (f) of this Rule, the groundwater quality standards shall be established as the least of:

1. Systemic threshold concentration calculated as follows: $[\text{Reference Dose (mg/kg/day)} \times 70 \text{ kg (adult body weight)} \times \text{Relative Source Contribution (0.10 for inorganics; 0.20 for organics)}] / [\text{2liters/day (avg. water consumption)}]$;
2. Concentration which corresponds to an incremental lifetime cancer risk of 1×10^{-6} ;
3. Taste threshold limit value;
4. Odor threshold limit value;
5. Maximum contaminant level; or
6. National secondary drinking water standard.”

15A NCAC 02L .0202 (e) further establishes that, “the following references, in order of preference, shall be used in establishing concentrations of substances which correspond to levels described in Paragraph (d) of this Rule:

1. Integrated Risk Information System (U.S. EPA);
2. Health Advisories (U.S. EPA Office of Drinking Water);
3. Other health risk assessment data published by the U.S. EPA; or
4. Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.”

15A NCAC 02L .0202 (f) provides that, “the Commission may establish groundwater standards less stringent than existing maximum contaminant levels or national secondary drinking water standards if it finds, after public notice and opportunity for hearing in accordance with G.S. 150B, that:

1. more recent data published in the EPA health references listed in Paragraph (e) of this Rule results in a standard which is protective of public health, taste threshold, or odor threshold;
2. the standard will not endanger the public health and safety, including health and environmental effects from exposure to groundwater contaminants; and
3. compliance with a standard based on the maximum contaminant level or national secondary drinking water standard would produce substantial hardship without equal or greater public benefit.”

Note: 15A NCAC 02L .0202 (f) currently is only applicable to the regulation of 1,1-DCE.

Procedure

1. Calculate systemic threshold concentration following the equation in the 02L rule: [Reference Dose (RfD) (mg/kg/day) x 70 kg (adult body weight) x Relative Source Contribution (0.10 for inorganics; 0.20 for organics)]/[2liters/day (avg. water consumption)]. Obtain the RfD from the following sources listed in priority order, (for more information on these sources of information, see section below “References for Toxicity Values”):
 1. EPA Integrated Risk Information System (IRIS)
 2. EPA Health Advisories
 3. Other health risk assessment data published by the U.S. EPA, such as, but not limited to:
 - i. EPA Regional Table Toxicity Values (Regional Screening Levels for Chemical Contaminants at Superfund Sites)
 - ii. EPA Provisional Peer Reviewed Toxicity Values (PPRTVs)
 - iii. EPA Health Effects Assessment Summary Tables (HEAST, 1997)
 4. Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.
 - i. Agency for Toxic Substances and Disease Registry (ATSDR) Chronic oral minimal risk levels (MRLs)
 - ii. California EPA (CalEPA) Public Health Goals (PHGs)
 - iii. Other published relevant toxicological data.

2. Calculate the concentration which corresponds to an incremental lifetime cancer risk of 1×10^{-6} . Obtain the cancer risk level or oral cancer slope factor (CSF).

When using a cancer risk level, calculate 1×10^{-6} risk using the following equation:

$$1 \times 10^{-6} \text{ risk level (mg/L)} = 1 \times 10^{-4} \text{ risk level (mg/L)} \times 0.01$$

When using a CSF, a 1×10^{-6} risk level is calculated assuming a 70-kg body weight and a 2 Liter per day drinking water consumption rate. This narrative is represented by the following equation:

$$1 \times 10^{-6} \text{ Risk} \times \frac{1}{\text{CSF (Risk/mg/kg-day)}} \times 70 \text{ kg} \times \frac{1 \text{ day}}{2\text{L}} = \text{X mg/L}$$

The cancer risk level or oral cancer slope factor shall be obtained from the following sources listed below in priority order:

1. EPA Integrated Risk Information System (IRIS)
2. EPA Health Advisories (Cancer risk levels for 1×10^{-4} risk for oral exposure sometimes provided).
3. Other health risk assessment data published by the U.S. EPA, such as, but not limited to:
 - i. EPA Regional Table Toxicity Values (Regional Screening Levels for Chemical Contaminants at Superfund Sites)
 - ii. EPA Provisional Peer Reviewed Toxicity Values (PPRTVs)
 - iii. EPA Health Effects Assessment Summary Tables (HEAST, 1997)
4. Other relevant, published health risk assessment data, and scientifically valid peer-reviewed published toxicological data.

- i. Agency for Toxic Substances and Disease Registry (ATSDR) Chronic oral minimal risk levels (MRLs)
 - ii. California EPA (CalEPA) Public Health Goals (PHGs)
 - iii. Other published relevant toxicological data.
 3. Check the following reference for taste threshold values:
 - i. Young, W.F., Horth, H., Crane, R., Ogden, T. and Arnott, M. 1996. Taste and Odour Threshold Concentrations of Potential Potable Water Contaminants. *Water Research*, 30:2, pp.331-340.
 - Record the “geometric mean taste threshold concentration”.
 - ii. Other appropriate, scientifically valid peer-reviewed published data for taste threshold values.
 4. Check the following references for odor threshold values:
 - i. Young, W.F., Horth, H., Crane, R., Ogden, T. and Arnott, M. 1996. Taste and Odour Threshold Concentrations of Potential Potable Water Contaminants. *Water Research*, 30:2, pp.331-340
 - Record the “geometric mean odor threshold concentration”.
 - ii. Amoores, J.E. and Hautala, E. 1983. Odor as an Aid to Chemical Safety; Odor Thresholds Compared with Threshold Limit Values and Volatilities for 214 Industrial Chemicals in Air and Water Dilution. *Journal of Applied Toxicology*, Volume 3, No. 6, 1983.
 - Record the “water odor threshold” but do not record the value if it is listed in parentheses (these values are considered to be very uncertain).
 - iii. Other appropriate, scientifically valid peer-reviewed published data for odor threshold values.
- *** Note: If taste or odor threshold values are provided in more than one reference, record all but use the lower of the values for determining the revised 02L.
5. Record the Maximum Contaminant Level (MCL) from the EPA Office of Ground Water and Drinking Water internet site: <https://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information>
 6. Record the Secondary Maximum Contaminant Level (SMCL) from the EPA Office of Ground Water and Drinking Water internet site: <https://www.epa.gov/dwstandardsregulations/secondary-drinking-water-standards-guidance-nuisance-chemicals>

Use the lowest of the above six values as the proposed revised 02L Groundwater Standard value (report values to an appropriate number of significant figures).

References for Toxicity Values

- EPA Integrated Risk Information System (IRIS) database: (<https://www.epa.gov/iris>) EPA database of human health effects that may result from exposure to various substances found in the environment. IRIS consists of individual files on over 200 chemicals that contain oral Reference Doses (RfDs), inhalation Reference Concentrations (RfCs), hazard identification, oral cancer slope factors, and oral and inhalation unit risks for carcinogenic effects. The information contained in IRIS represents the consensus opinion of health scientists at the EPA.
- EPA Health Advisories: EPA Office of Water’s non-enforceable, technical guidance values for unregulated chemicals found in drinking water based on noncancer health effects for different

durations of exposure (1-day, 10-day, and lifetime). Chronic oral reference doses, carcinogenic classification, and drinking water levels corresponding to 1×10^{-4} risk provided at:

<https://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information>

- EPA Regional Screening Levels (RSLs) Values (*Screening Levels for Chemical Contaminants at Superfund Sites*): The EPA Regional Table lists toxicity values that are used by EPA to calculate Screening Levels for five direct contact exposure pathways (residential soil, industrial soil, residential air, industrial air, and tap water). The Regional Table lists the source of the toxicity values used: EPA's IRIS; EPA's PPRTVs; ATSDR; California EPA; PPRTV Appendix Values; and HEAST. Validate the origin and supporting documentation for public records. <https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables>
- EPA Provisional Peer Reviewed Toxicity Values (PPRTVs): EPA's National Center for Environmental Assessment, Superfund Health Risk Technical Support Center calculates provisional toxicity values (<https://hhpprtv.ornl.gov/>). These values are for EPA internal use and are also provided to State risk assessors (upon request). They have not been verified through the EPA's formal review process.
- Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels (MRLs): ATSDR MRLs - estimates of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure. They are calculated for acute, intermediate, and long-term exposures and for the oral and inhalation pathways. MRLs are intended to be used by public health professionals as screening levels to help determine areas and populations potentially at risk for health effects from exposure to a particular chemical. ATSDR's chronic oral minimum risk level may be used as a chronic oral reference dose. <http://www.atsdr.cdc.gov/mrls/index.html>
- California Environmental Protection Agency (CalEPA) Office of Environmental Health Hazard Assessment (OEHHA) chronic reference exposure levels and cancer potency values (<http://www.oehha.ca.gov/risk/ChemicalDB/index.asp>). Public Health Goals (PHGs), estimates of the levels of contaminants in drinking water that would pose no significant health risk to individuals consuming the water on a daily basis over a lifetime, are also available.
- EPA PPRTVs Screening Toxicity Values: These are screening values located in the appendix of certain PPRTV assessments. EPA has less confidence in a screening toxicity value than in a PPRTV; however, current EPA methodologies are used to derive them and they also receive external peer review. PPRTV documents can be found at <https://hhpprtv.ornl.gov/>
- Health Effects Assessment Summary Tables (HEAST): EPA Superfund 1997 table of provisional risk values. The risk values in this table have generally been replaced by PPRTV values. https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=NCEA&dirEntryID=2877

Recommendations and Public Input Processes

The DWR will proceed through rulemaking and public input processes in accordance with North Carolina General Statute (NCGS) 150B to revise and establish groundwater standards. Public input opportunities will always be offered, at a minimum, in accordance with the requirements outlined in the Administrative Procedures Act (APA) NCGS 150B (as amended).

Before presenting a groundwater standard proposal to the Groundwater and Waste Management Committee of the EMC to commence with rulemaking, NC Department of Environmental Quality (DEQ) DWR will notify the NC Department of Health and Human Services (DHHS) Division of Public Health (DPH) and the DEQ Division of Waste Management (DWM) by a letter that includes enough information to provide a clear indication of the basis and process used to determine the proposed standard(s). The supporting information used to develop the proposal will also be included: if a reference is available on the internet, the link will be provided; if a reference is not available on the internet, the document will be provided. DWR will make every effort to send letter notification to DPH and DWM thirty (30) days prior for single standards and sixty (60) days prior for proposals involving more than one standard. It is the intent that information on all proposals received by DPH and DWM will be treated as sensitive and internal material not to be distributed, subject to requests for information. The purpose of the written notice is to request the DPH and DWM to review and provide comment on 02L standards development to DWR prior to the initiation of the rulemaking process and prior to the NC Administrative Procedures Act (NC APA) public comment period. Comment and/or information are to be provided to DWR on the specific proposal within the timeframe requested. DWR will consider the provided information prior to the DWR decision to make a recommendation to the Groundwater and Waste Management Committee for rulemaking.

The agencies (DWR, DWM and DPH) recognize that the additional comment period will lengthen the process for revising and establishing groundwater standards. Therefore, there may be, at the judgment of the DWR Director or at the agreement of the three agencies, a good reason to move forward to the Groundwater and Waste Management Committee of the EMC, or otherwise, with any specific proposal without the additional thirty-day or sixty-day comment period between the agencies, and the Director of DWR may deem a shorter timeframe as appropriate. Nothing in this SOP document binds DWR or the Director's authorities established pursuant to the North Carolina Administrative Code.

Secretaries' Science Advisory Board (SSAB) Involvement

The DWR may consult with the Secretaries' Science Advisory Board (SSAB), at the discretion of the DWR and the SSAB, for professional toxicological input on any potential or existing groundwater standard. (<https://deq.nc.gov/about/boards-and-commissions/secretaries-science-advisory-board>)

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