

[If adopted, this would be a new regulation]

[Approved by the Committee of the Whole on January 13, 2005, for Public Review]

[Changes to Draft #2 (the proposed regulation) are redlined and double underlined]

1 **REGULATION 5.20 Methodology for Determining Benchmark Ambient Concentration of a**
2 **Toxic Air Contaminant**

3 **Air Pollution Control District of Jefferson County**
4 **Jefferson County, Kentucky**

5 **Relates To:** KRS Chapter 77 Air Pollution Control

6 **Pursuant To:** KRS Chapter 77 Air Pollution Control

7 **Necessity and Function:** KRS 77.180 authorizes the Air Pollution Control Board to adopt and
8 enforce all orders, rules, and regulations necessary or proper to accomplish the purposes of KRS
9 Chapter 77. This regulation establishes the methodology for determining the benchmark ambient
10 concentration for a toxic air contaminant.

11 **SECTION 1 Use of Benchmark Ambient Concentration**

12 A benchmark ambient concentration for a toxic air contaminant developed pursuant to this
13 regulation shall be used in Regulation 5.21 *Environmental Acceptability for Toxic Air Contaminants*
14 to determine environmental acceptability.

15 **SECTION 2 Determination that a Toxic Air Contaminant is a Carcinogen**

16 2.1 A toxic air contaminant (TAC) shall be determined to be a carcinogen if any of the following
17 provisions is met:

18 2.1.1 A carcinogenic unit risk estimate, or alternatively, a concentration representative of a
19 specified level of additional lifetime cancer risk, for the TAC is included in any of the
20 information sources identified in sections 3.3.1 to 3.3.3 or derived by using one of the
21 methodologies listed in section 3.3.45,

22 2.1.2 The TAC is listed as either “known to be a human carcinogen” or “reasonably
23 anticipated to be a human carcinogen” in the most recent *Report on Carcinogens*
24 published by the National Toxicology Program pursuant to Section 301(b)(4) of the
25 Public Health Service Act as Amended by Section 262, PL 95-622, available on the
26 Internet at “<http://ehp.niehs.nih.gov/roc>”,

27 2.1.3 The TAC is classified as to potential carcinogenic risk to humans as “Group 1: The
28 agent (mixture) is carcinogenic to humans,” “Group 2A: The agent (mixture) is probably
29 carcinogenic to humans,” or “Group 2B: The agent (mixture) is possibly carcinogenic
30 to humans” by the International Agency for Research on Cancer (IARC). The IARC list
31 is available on the Internet at “<http://www-cie.iarc.fr/monoeval/crthall.html>”, or

32 2.1.4 The District determines that the TAC should be considered to be a carcinogen because
33 there is sufficient, credible information that any of the following criteria is met:

34 2.1.4.1 Known to be a human carcinogen: There is sufficient evidence of carcinogenicity
35 from studies in humans which indicates a causal relationship between exposure to
36 the agent, substance, or mixture and human cancer,

37 2.1.4.2 Reasonably anticipated to be a human carcinogen:

38 2.1.4.2.1 There is limited evidence of carcinogenicity from studies in humans, which
39 indicates that causal interpretation is credible, but that alternative explanations,
40 such as chance, bias, or confounding factors, could not adequately be excluded,

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- 41 2.1.4.2.2 There is sufficient evidence of carcinogenicity from studies in experimental
 42 animals which indicates there is an increased incidence of malignant or a
 43 combination of malignant and benign tumors: (1) in multiple species or at
 44 multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual
 45 degree with regard to incidence, site, or type of tumor, or age at onset, or
 46 2.1.4.2.3 There is less than sufficient evidence of carcinogenicity in humans or laboratory
 47 animals, however; the agent, substance, or mixture belongs to a well defined,
 48 structurally-related class of substances whose members are listed in the most
 49 recent *Report on Carcinogens* published by the National Toxicology Program as
 50 either a known to be human carcinogen or reasonably anticipated to be human
 51 carcinogen, or there is convincing relevant information that the agent acts
 52 through mechanisms indicating it would likely cause cancer in humans.
- 53 2.2 In making a determination pursuant to section 2.1.43, the following provisions shall apply:
- 54 2.2.1 Conclusions regarding carcinogenicity in humans or experimental animals are based on
 55 scientific judgment, with consideration given to all relevant information. Relevant
 56 information includes, but is not limited to, dose response, route of exposure, chemical
 57 structure, metabolism, pharmacokinetics, sensitive sub populations, genetic effects, and
 58 other data relating to mechanism of action or factors that may be unique to a given
 59 substance. This applies to both the “known to be a human carcinogen” and the
 60 “reasonably anticipated to be a human carcinogen” categories, and
- 61 2.2.2 For an agent to be determined “known to be a human carcinogen,” evidence from studies
 62 of humans is required. This may include traditional cancer epidemiology studies, data
 63 from clinical studies, or data derived from the study of tissues from humans exposed to
 64 the substance in question and useful for evaluating whether a relevant cancer mechanism
 65 is operating in humans.

66 SECTION 3 Cancer Risk Benchmark Determination Methodology

- 67 3.1 The benchmark ambient concentration for a toxic air contaminant (TAC) determined to be
 68 a carcinogen (BAC_C) shall be calculated as follows:

$$69 \quad BAC_C = \frac{1 \otimes 10^{-6}}{URE} \quad [Equation 1]$$

70 Where:

71 BAC_C = Benchmark Ambient Concentration for a carcinogen, a concentration
 72 representative of an additional lifetime cancer risk of 1 in 1,000,000 ($1 \otimes 10^{-6}$),
 73 in units of micrograms per cubic meter ($\mu\text{g}/\text{m}^3$),

74 URE = Unit Risk Estimate - The upper-bound excess lifetime cancer risk estimated
 75 to result from continuous exposure to an agent at a concentration of $1 \mu\text{g}/\text{m}^3$
 76 in air, Additional lifetime cancer risk occurring in a population in which all
 77 individuals are exposed continuously for life (70 years) to a concentration of
 78 $1 \mu\text{g}/\text{m}^3$ of the chemical in the air they breathe, in units of $(\mu\text{g}/\text{m}^3)^{-1}$. The
 79 URE shall be determined according to the methodology in section 3.3, and

80 $1 \otimes 10^{-6}$ = An upper bound additional lifetime cancer risk of 1 in 1,000,000.

- 81 3.2 Alternatively, if in any of the sources of information identified in section 3.3, the

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- 82 concentration of a carcinogen, expressed in $\mu\text{g}/\text{m}^3$, that is representative of an additional
 83 lifetime cancer risk of 1×10^{-6} is identified instead of the URE, then the BAC_C is that
 84 identified concentration. The URE can be calculated by using Equation 1.
- 85 3.3 The following provisions shall apply to the derivation of a unit risk estimate (URE), or
 86 alternatively a BAC_C directly, for a TAC determined to be a carcinogen:
- 87 3.3.1 If a URE for a TAC has been developed by the U.S. Environmental Protection Agency
 88 (EPA) and included in the EPA's Integrated Risk Information System (IRIS), available
 89 on the Internet at "http://www.epa.gov/iris/", then that URE shall be used to determine
 90 the BAC_C .
- 91 3.3.2 If a URE for a TAC has not been derived pursuant to section 3.3.1 but a URE for that
 92 TAC has been developed by the California Office of Environmental Health Hazard
 93 Assessment, available on the Internet at "http://www.arb.ca.gov/toxics/healthval/
 94 contable.pdf", then that URE, found in the column "Inhalation Unit Risk ($\mu\text{g}/\text{m}^3$)⁻¹", shall
 95 be used to determine the BAC_C .
- 96 3.3.3 If a URE for a TAC has not been derived pursuant to section 3.3.1 or 3.3.2 but an Initial
 97 Risk Screening Level (IRSL) for that TAC has been developed by the Michigan Air
 98 Quality Division, available on the Internet at "http://www.deq.state.mi.us/
 99 documents/deq-aqd-toxics-itlscas.pdf" sorted by Chemical Abstract Services (CAS)
 100 number or "http://www.deq.state.mi.us/documents/deq-aqd-toxics-itlslalph.pdf" sorted
 101 in alphabetical order, then that IRSL shall be used as the BAC_C .
- 102 3.3.4 If a TAC has been determined to be a carcinogen, but a URE, or a BAC_C directly, has
 103 not been derived pursuant to section 3.3.1, 3.3.2, or 3.3.3, then the URE may be derived
 104 using one of the following:
- 105 3.3.4.1 The methodology in the *Guidelines for Carcinogen Risk Assessment*, U.S.
 106 *Environmental Protection Agency*, EPA/630/P-03/001F, March 2005, and
 107 *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to*
 108 *Carcinogens*, U.S. Environmental Protection Agency, EPA/630/R-03-003F, March
 109 2005, both of which are hereby adopted and incorporated by reference..
- 110 3.3.4.~~21~~ The methodology in *Air Toxics Risk Assessment Reference Library, Volume 1,*
 111 *Technical Resource Manual, Chapter 12 Inhalation Toxicity Assessment*, U.S.
 112 Environmental Protection Agency, EPA-453-K-04-001A, April 2004, which is
 113 hereby adopted and incorporated by reference,
- 114 3.3.4.~~32~~ The methodology in *Guidelines for Carcinogen Risk Assessment*, U.S.
 115 Environmental Protection Agency, NCEA-F-0644, July 1999, Review Draft, which
 116 is hereby adopted and incorporated by reference,
- 117 3.3.4.~~43~~ The methodology in *Guidelines for Carcinogen Risk Assessment*, U.S.
 118 Environmental Protection Agency, EPA/630/R-00/004, September 24, 1986, 51 FR
 119 33992-34003, which is hereby adopted and incorporated by reference,
- 120 3.3.4.~~54~~ The methodology in *R 336.1231 Cancer risk assessment screening methodology*
 121 *(2)(b) and (3) of the Michigan Administrative Code*, which is hereby adopted and
 122 incorporated by reference, or
- 123 3.3.4.~~65~~ Any alternative cancer risk assessment methodology that can be demonstrated to the
 124 satisfaction of the District to be more appropriate based on biological grounds and
 125 that is supported by peer-reviewed the scientific data.

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- 126 3.3.5 If a URE for a TAC has not been derived pursuant to section 3.3.1, 3.3.2, 3.3.3, or 3.3.4,
127 then the BAC_C shall be the default value $0.0004 \mu\text{g}/\text{m}^3$.
128 3.4 An annual average time period shall be used for a BAC_C .

129 SECTION 4 Chronic Noncancer Risk Benchmark Determination Methodology

130 The benchmark ambient concentration for the noncarcinogenic effects of a toxic air contaminant
131 (BAC_{NC}), a concentration that is likely to be without an appreciable risk of deleterious effects during
132 a lifetime, shall be determined as follows:

- 133 4.1 If a Reference Concentration (RfC) for a TAC has been developed by the EPA and included
134 in the EPA's Integrated Risk Information System (IRIS), available on the Internet at
135 "<http://www.epa.gov/iris/>", then that RfC shall be used as the BAC_{NC} :
136

$$BAC_{NC} = RfC \quad [Equation 2]$$

137 Where:

- 138 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
139 TAC, in units of $\mu\text{g}/\text{m}^3$, and
140 RfC = Reference Concentration, in units of $\mu\text{g}/\text{m}^3$.

141 An annual 24-hour average time period shall be used for a BAC_{NC} determined pursuant to
142 section 4.1.

- 143 4.2 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 but a Reference
144 Exposure Level (REL) for that TAC has been developed by the California Office of
145 Environmental Health Hazard Assessment, available on the Internet at
146 "<http://www.arb.ca.gov/toxics/healthval/contable.pdf>", then that REL, found in the column
147 "Chronic Inhalation ($\mu\text{g}/\text{m}^3$), shall be used as the BAC_{NC} :
148

$$BAC_{NC} = REL \quad [Equation 3]$$

149 Where:

- 150 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
151 TAC, in units of $\mu\text{g}/\text{m}^3$, and
152 REL = Reference Exposure Level, in units of $\mu\text{g}/\text{m}^3$.

153 An annual 24-hour average time period shall be used for a BAC_{NC} determined pursuant to
154 section 4.2.

- 155 4.3 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 or 4.2 but an Oral
156 Reference Dose (RfD) for that TAC has been developed by the EPA and included in the
157 EPA's IRIS, available on the Internet at "<http://www.epa.gov/iris/>", and data are not
158 available to indicate that oral-route to inhalation-route extrapolation is inappropriate, then
159 that RfD shall be used to calculate the BAC_{NC} as follows:
160

$$BAC_{NC} = Oral\ RfD \otimes \frac{70\ \text{kg}}{20\ \frac{\text{m}^3}{\text{day}}} \quad [Equation 4]$$

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161 Where:
 162 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
 163 TAC, in units of $\mu\text{g}/\text{m}^3$,
 164 RfD = Reference Exposure Level, in units of $\mu\text{g}/\text{kg}\text{-day}$,
 165 70 kg = The average body weight of a human, and
 166 20 m³/day = The average daily inhalation rate for a human.

167 An annual 24-hour average time period shall be used for a BAC_{NC} determined pursuant to
 168 section 4.3.

169 4.4 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.3 but an Initial
 170 Threshold Screening Level (ITSL) for that TAC has been developed by the Michigan Air
 171 Quality Division, available on the Internet at “[http://www.deq.state.mi.us/
 172 documents/deq-aqd-toxics-itlscas.pdf](http://www.deq.state.mi.us/documents/deq-aqd-toxics-itlscas.pdf)” sorted by Chemical Abstract Services (CAS) number
 173 or “<http://www.deq.state.mi.us/documents/deq-aqd-toxics-itlslalph.pdf>” sorted in alphabetical
 174 order, then that ITSL shall be used as the BAC_{NC}:

$$BAC_{NC} = ITSL \quad [Equation 5]$$

176 Where:
 177 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
 178 TAC, in units of $\mu\text{g}/\text{m}^3$, and
 179 ITSL = Initial Threshold Screening Level, in units of $\mu\text{g}/\text{m}^3$.

180 The average time period as listed for a specific ITSL shall be used for a BAC_{NC} determined
 181 pursuant to section 4.4.

182 4.5 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.4 but an
 183 occupational exposure level (OEL) exists for that TAC, then the OEL may be used to
 184 calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{OEL}{100} \quad [Equation 6]$$

186 Where:
 187 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
 188 TAC, in units of $\mu\text{g}/\text{m}^3$,
 189 OEL = Occupational Exposure Level, that, for the TAC, is the lowest value of
 190 either the National Institute of Occupational Safety and Health (NIOSH)-
 191 recommended exposure level listed in current edition of the NIOSH
 192 pocket guide to chemical hazards or the time-weighted average or ceiling
 193 Threshold Limit Value (TLV) listed in the current edition of the
 194 American Conference of Governmental and Industrial Hygienists
 195 Threshold Limit Value (TLV) booklet, in units of $\mu\text{g}/\text{m}^3$, and
 196 100 = A composite safety factor to account for differences in susceptibility

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197 between the healthy, adult worker population compared to the general
198 population that is more diverse and may contain individuals or
199 subpopulations more sensitive to the effects of the toxic air pollutant
200 (safety factor of 10). Additionally, the composite safety factor accounts
201 for the difference in exposure duration (in hours per week and years
202 working versus a lifetime) for the worker population compared to the
203 general population:

$$204 \quad \frac{1}{10} \otimes \frac{40 \text{ hours/week}}{168 \text{ hours/week}} \otimes \frac{30 \text{ years}}{70 \text{ years}} \approx \frac{1}{100}.$$

205 An 8-hour average time period shall be used for a BAC_{NC} determined pursuant to section 4.5
206 based upon a time-weighted OEL and a 1-hour average time period shall be used for a
207 BAC_{NC} determined pursuant to section 4.5 based upon a ceiling OEL.

- 208 4.6 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.5 but a 7-day,
209 inhalation, no observed adverse effect level (NOAEL) or lowest observable adverse effect
210 level (LOAEL) is available for that TAC, then the NOAEL or LOAEL may be used to
211 calculate the BAC_{NC} as follows:

$$212 \quad BAC_{NC} = \frac{NOAEL}{35 \otimes 100} \otimes \frac{Hr \text{ Exposed / Day}}{24 \text{ Hr / Day}} \quad [Equation 7]$$

$$213 \quad BAC_{NC} = \frac{LOAEL}{35 \otimes 100 \otimes UF} \otimes \frac{Hr \text{ Exposed / Day}}{24 \text{ Hr / Day}} \quad [Equation 8]$$

214 Where:

- 215 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
216 TAC, in units of $\mu\text{g}/\text{m}^3$,
217 NOAEL = No observed adverse effect level (inhalation study), in units of $\mu\text{g}/\text{m}^3$,
218 LOAEL = Lowest observed adverse effect level (inhalation study), in units of
219 $\mu\text{g}/\text{m}^3$,
220 35 = A safety factor to account for using a NOAEL or LOAEL from a 7-day
221 exposure period to estimate a NOAEL or LOAEL for a lifetime study,
222 100 = A standard composite safety factor comprised of a safety factor of 10 to
223 account for differences between animals and humans and a safety factor
224 of 10 to account for the differences between individuals in the human
225 population, and
226 UF = Uncertainty Factor, a value from 1 to 10, applicable when using a
227 LOAEL (lowest effect) instead of a NOAEL (no effect), determined by
228 the District on a case-by-case basis, considering the type and severity of
229 effect. For example, a value of 1 would be used when the lowest effect
230 was a skin rash; a value of 10 would be used when the lowest effect was
231 death.

232 If approved by the District, the BAC_{NC} may be determined on a case-by-case basis using a

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233 NOAEL or LOAEL from repeated dose studies other than 7-day studies.

234 An annual average time period shall be used for a BAC_{NC} determined pursuant to section 4.6.

235 4.7 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.6 but a 7-day,
236 oral NOAEL or oral LOAEL is available for that TAC, and data are not available to indicate
237 that oral-route to inhalation-route extrapolation is inappropriate. then the oral NOAEL or
238 oral LOAEL may be used to calculate the BAC_{NC} as follows:
239

$$BAC_{NC} = \frac{\text{Oral NOAEL}}{35 \otimes 100} \otimes \frac{W_A}{I_A} \otimes \frac{b}{a} \quad [\text{Equation 9}]$$

240

$$BAC_{NC} = \frac{\text{Oral LOAEL}}{35 \otimes 100 \otimes UF} \otimes \frac{W_A}{I_A} \otimes \frac{b}{a} \quad [\text{Equation 10}]$$

241 Where:

242 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
243 TAC, in units of $\mu\text{g}/\text{m}^3$,

244 NOAEL = No observed adverse effect level (oral study), in units of $\mu\text{g}/\text{kg}\text{-day}$,

245 LOAEL = Lowest observed adverse effect level (oral study), in units of $\mu\text{g}/\text{kg}\text{-day}$,

246 35 = A safety factor to account for using a NOAEL or LOAEL from a 7-day
247 exposure period to estimate a NOAEL or LOAEL for a lifetime study,

248 100 = A standard composite safety factor comprised of a safety factor of 10 to
249 account for differences between animals and humans and a safety factor
250 of 10 to account for the differences between individuals in the human
251 population,

252 UF = Uncertainty Factor, a value from 1 to 10, applicable when using a
253 LOAEL (lowest effect) instead of a NOAEL (no effect), determined by
254 the District on a case-by-case basis, considering the type and severity of
255 effect. For example, a value of 1 would be used when the lowest effect
256 was a skin rash; a value of 10 would be used when the lowest effect was
257 death,

258 W_A = Body weight of experimental animal in kilograms (kg),

259 I_A = Daily inhalation rate of experimental animal in m^3/day ,

260 b = Absorption efficiency (percent absorbed) by the oral route of exposure,
261 and

262 a = Absorption efficiency (percent absorbed) by the inhalation route of
263 exposure.

264 If approved by the District, the BAC_{NC} may be determined on a case-by-case basis using an
265 oral NOAEL or oral LOAEL from repeated dose studies other than 7-day studies.

266 An annual average time period shall be used for a BAC_{NC} determined pursuant to section 4.7.

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- 267 4.8 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.7 but an
 268 inhalation LC_{50} from a study that is 4 or more hours in duration is available for that TAC,
 269 then the LC_{50} may be used to calculate the BAC_{NC} as follows:
 270

$$BAC_{NC} = \frac{LC_{50}}{500 \otimes 100} \quad [Equation 11].$$

271 Where:

- 272 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
 273 TAC, in units of $\mu\text{g}/\text{m}^3$,
 274 LC_{50} = Concentration of material used in an inhalation study that causes death
 275 of 50% of the group of test animals when administered as a single dose
 276 in a specific time period, in units of $\mu\text{g}/\text{m}^3$,
 277 500 = A factor to account for using an LC_{50} to estimate a no observed adverse
 278 effect level (NOAEL) for a lifetime study, and
 279 100 = A standard composite safety factor comprised of a safety factor of 10 to
 280 account for differences between animals and humans and a safety factor
 281 of 10 to account for the differences between individuals in the human
 282 population.
 283

An annual average time period shall be used for a BAC_{NC} determined pursuant to section 4.8.

- 284 4.9 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.8 but an LC_{50}
 285 from a 1-hour inhalation study is available for that TAC, then the 1-hour LC_{50} may be used
 286 to calculate the BAC_{NC} as follows:
 287

$$BAC_{NC} = \frac{(1-Hr) LC_{50}}{500 \otimes 100 \otimes 40} \quad [Equation 12].$$

288 Where:

- 289 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
 290 TAC, in units of $\mu\text{g}/\text{m}^3$,
 291 LC_{50} = Concentration of material used in an inhalation study that causes death
 292 of 50% of the group of test animals when administered as a single dose
 293 in a specific time period, in units of $\mu\text{g}/\text{m}^3$,
 294 500 = A factor to account for using an LC_{50} to estimate a no observed adverse
 295 effect level (NOAEL) for a lifetime study,
 296 100 = A standard composite safety factor comprised of a safety factor of 10 to
 297 account for differences between animals and humans and a safety factor
 298 of 10 to account for the differences between individuals in the human
 299 population, and
 300 40 = A safety factor to account for the uncertainty of using a one-hour
 301 inhalation LC_{50} compared to an exposure duration of four hours or more.

302 An annual average time period shall be used for a BAC_{NC} determined pursuant to section 4.9.

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303 4.10 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.9 but an animal
304 oral LD_{50} is available for that TAC, and data are not available to indicate that oral-route to
305 inhalation-route extrapolation is inappropriate, then the LD_{50} may be used to calculate the
306 BAC_{NC} as follows:
307

$$BAC_{NC} = \frac{LD_{50} \text{ (mg/kg)}}{500 \otimes 100 \otimes 40 \otimes 0.167} \otimes \frac{W_A}{I_A} \quad [\text{Equation 13}].$$

308 Where:
309 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
310 TAC, in units of $\mu\text{g}/\text{m}^3$,
311 LD_{50} = Amount of material administered in a single dose by a route other than
312 inhalation, e.g., oral, that causes death of 50% of the group of test
313 animals, in units of $\mu\text{g}/\text{kg}$,
314 500 = A factor to account for using an LC_{50} to estimate a no observed adverse
315 effect level (NOAEL) for a lifetime study,
316 100 = A standard composite safety factor comprised of a safety factor of 10 to
317 account for differences between animals and humans and a safety factor
318 of 10 to account for the differences between individuals in the human
319 population,
320 40 = A safety factor to account for the uncertainty of estimating an LC_{50} from
321 an LD_{50} ,
322 0.167 = A factor to convert the daily dose to a 4-hour time frame ($4 \div 24 =$
323 0.167),
324 W_A = Body weight of experimental animal in kilograms (kg), and
325 I_A = Daily inhalation rate of experimental animal in m^3/day .

326 An annual average time period shall be used for a BAC_{NC} determined pursuant to
327 section 4.10.

328 4.11 If a BAC_{NC} for a TAC has not been determined pursuant to section 4.1 to 4.10, then the
329 BAC_{NC} shall be the default value:
330

$$BAC_{NC} = 0.04 \mu\text{g}/\text{m}^3 \quad [\text{Equation 14}].$$

331 Where:
332 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
333 TAC, in units of $\mu\text{g}/\text{m}^3$.

334 An annual average time period shall be used for a BAC_{NC} determined pursuant to
335 section 4.11.

336 4.12 Notwithstanding the methodologies in sections 4.3, 4.7, and 4.10, a BAC_{NC} shall not be
337 derived from one of these methodologies, which consider route-to-route extrapolation, unless
338 the District has affirmatively determined that the use of oral toxicity data is appropriate. The

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- 339 use of oral toxicity data is not appropriate in the following cases:
- 340 4.12.1 When groups of chemicals have different toxicity by the two different routes (e.g.,
- 341 metals, irritants, and sensitizers),
- 342 4.12.2 When a first-pass effect by the respiratory tract is expected,
- 343 4.12.3 When a first-pass effect by the liver is expected,
- 344 4.12.4 When a respiratory tract effect is established, but dosimetry comparison cannot be
- 345 clearly established between the two routes,
- 346 4.12.5 When the respiratory tract is not adequately studied in the oral studies, and
- 347 4.12.6 When short-term inhalation studies, dermal irritation, in vitro studies, or characteristics
- 348 of the chemical indicate potential for portal-of-entry effects at the respiratory tract, but
- 349 studies themselves are not adequate for the development of a benchmark ambient
- 350 concentration.

351 **SECTION 5 Consideration of Acute Noncancer Effects**

352 If the District determines that compliance with the BAC_{NC} over the applicable averaging time

353 specified in Section 4 does not provide adequate protection from the acute effects of a TAC, then

354 the District may establish a different acute benchmark ambient concentration (BAC_{NCA}) and shorter

355 averaging time that would provide adequate protection, using a methodology consistent with the

356 guidance provided in Air Toxics Risk Assessment Reference Library, Volume 1, Technical Resource

357 Manual, Section 12.6 Acute Exposure Reference Values, U.S. Environmental Protection Agency,

358 EPA-454-K-04-001A, April 2004.

359 **SECTION 6 Available Documents**

360 The District will maintain on its web page, "http://www.apcd.org", links to the documents identified

361 as available on the Internet and maintain at its office a copy of all documents identified in this

362 regulation. In addition, the District will maintain a current list of the benchmark ambient

363 concentrations that have been developed pursuant to this regulation and maintain this current list on

364 its web page.

365 Adopted v1/_____ ; effective _____.