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Version #3/ External

November 17, 2010

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REGULATION 5.20 Methodology for Determining the Benchmark Ambient Concentration of a Toxic Air Contaminant

**Louisville Metro Air Pollution Control District ~~of Jefferson County~~
Jefferson County, Kentucky**

Pursuant To: KRS Chapter 77 Air Pollution Control

Relates To: KRS Chapter 77 Air Pollution Control

Pursuant To: ~~KRS Chapter 77 Air Pollution Control~~

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

SECTION 1 Use of Benchmark Ambient Concentration

A benchmark ambient concentration (BAC) ~~forof~~ a toxic air contaminant (TAC) developed pursuant to this regulation shall be used ~~in Regulation 5.21 Environmental Acceptability for Toxic Air Contaminants~~ to determine compliance with the environmental acceptability goals established in Regulation 5.21.

SECTION 2 Determination that a TAC Toxic Air Contaminant is a Carcinogen

2.1 A ~~toxic air contaminant (TAC)~~ shall be determined to be a carcinogen for purposes of determining the BAC if ~~any of the following provisions is met:~~

2.1.1 A carcinogenic unit risk estimate (URE), or ~~alternatively,~~ a concentration represent~~ing~~ative of a specifi~~ced~~ level of additional lifetime cancer risk, for the TAC is ~~listed by~~included in any of the information a sources ~~identified in sub~~sections 3.3.1 to 3.3.3,

2.1.2 The TAC is ~~designated~~listed as ~~either~~—Aknown to be a human carcinogen ~~or~~ Reasonably anticipated to be a human carcinogen ~~in the most recent Report on Carcinogens published by the National Toxicology Program (NTP) pursuant to Section 301(b)(4) of the Public Health Service Act as Amended by Section 262, PL 95-622, available on the Internet at <http://ehp.niehs.nih.gov/roc/>,~~

2.1.3 The TAC is ~~designated~~declassified as to potential carcinogenic risk to humans as a AGroup 1: ~~The agent (mixture) is~~ (carcinogenic to humans), ~~or~~ AGroup 2A: ~~The agent (mixture) is~~ (probably carcinogenic to humans), ~~or~~ AGroup 2B: ~~The agent (mixture) is~~ (possibly carcinogenic to humans) ~~or~~ agent or mixture by the International Agency for Research on Cancer (IARC). ~~The IARC list is available on the Internet at <http://www.iarc.fr/monoeval/erthall.html>,~~

2.1.4 The TAC is ~~designated~~identified as a carcinogen by the Agency for Toxic Substances and Disease Registry (ATSDR), ~~available on the Internet at <http://www.atsdr.edc.gov/toxpro2.html>,~~ or and

2.1.5 After providing an opportunity for public review and ~~written~~ comment, the District determines that the TAC should be considered to be a carcinogen for purposes of determining the BAC because~~any of the following criteria is met:~~

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- 44 2.1.5.1 ~~The TAC is K~~"known to be a human carcinogen": There is sufficient peer-
45 reviewed evidence of carcinogenicity from studies in humans ~~indicating which~~
46 ~~indicates~~ a causal relationship between exposure to the ~~TAC agent, substance, or~~
47 ~~mixture~~ and human cancer,
- 48 2.1.5.2 ~~The TAC is R~~"reasonably anticipated to be a human carcinogen"~~based on peer-~~
49 ~~reviewed evidence~~: There is limited ~~peer-reviewed~~ evidence of carcinogenicity
50 from studies in humans ~~indicating, which indicates that a~~ causal ~~interpretation is~~
51 ~~credible~~ relationship between exposure to the TAC and human cancer, but ~~that~~
52 alternative explanations, such as chance, bias, or confounding factors, could not
53 adequately be excluded,
- 54 2.1.5.32.2 There is sufficient ~~peer-reviewed~~ evidence of ~~the TAC's~~ carcinogenicity from
55 studies in experimental animals ~~indicating which indicates there is~~ an increased
56 incidence of malignant or a combination of malignant and benign tumors: (1) in
57 multiple species, ~~or (2)~~ at multiple tissue sites, ~~or (32)~~ by multiple routes of
58 exposure, or ~~(43)~~ to an unusual degree with regard to incidence, site, or type of
59 tumor, or age at onset, or
- 60 2.1.5.42.3 There is less than sufficient ~~peer-reviewed~~ evidence of ~~the TAC's~~ carcinogenicity
61 in humans or laboratory animals, ~~however; but:~~
- 62 ~~2.1.5.4.1~~ ~~†The TAC agent, substance, or mixture~~ belongs to a well-defined,
63 structurally-related class of substances whose members are listed in the
64 most recent *Report on Carcinogens* published by the ~~NTP-National~~
65 ~~Toxicology Program~~ as ~~either a~~ known to be human carcinogen or
66 reasonably anticipated to be a human carcinogen, or
- 67 ~~2.1.5.4.2~~ ~~—†There is convincing relevant information that the agent acts through~~
68 mechanisms indicating it would likely cause cancer in humans.
- 69 2.2 In making a determination pursuant to section 2.1.5, ~~the following provisions shall apply:~~
- 70 2.2.1 Conclusions regarding carcinogenicity in humans or experimental animals ~~shall be~~
71 based on relevant peer-reviewed scientific evidence, ~~including. Relevant peer-~~
72 ~~reviewed scientific evidence includes, but is not limited to,~~ dose response, route of
73 exposure, chemical structure, ~~—~~metabolism, pharmacokinetics, sensitive sub
74 populations, genetic effects, and other data relating to mechanism of action or factors
75 that may be unique to a given substance. ~~This applies to both the Aknown to be a~~
76 ~~human carcinogen@ and the Areasonably anticipated to be a human carcinogen@~~
77 ~~categories, and~~
- 78 2.2.2 For a TAC ~~an agent~~ to be determined ~~to be a~~ Aknown to be a human carcinogen,
79 evidence from peer-reviewed studies of humans is required. ~~—~~This may include
80 traditional cancer epidemiology studies, data from clinical studies, or data derived
81 from the study of tissues from humans exposed to the ~~TAC substance in question~~ and
82 useful for evaluating whether a relevant cancer mechanism is operating in humans.
- 83 ~~2.3 The Board~~~~District~~ may determine, through rulemaking pursuant to Regulation 1.08, that a
84 TAC is not a carcinogen for the purposes of determining the BACC.
- 85 ~~2.4 In making a determination pursuant to section 2.3, the Board shall revise this regulation~~
86 ~~and list any~~those TACs determined not to be a carcinogen in this section.

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~~, following public notice and comment, that a TAC is not a carcinogen for purposes of determining the BAC if:~~

~~2.3.1 The carcinogenic URE or the BAC concentration representative of a specified level of additional lifetime cancer risk relied upon by the District pursuant to section 2.1.1 is delisted by one of the sources in subsections 3.3.1 to 3.3.3;~~

~~2.3.2 A designation relied upon by the District pursuant to sections 2.1.2 to 2.1.4 is reevaluated and the TAC is no longer designated as a known or possible carcinogen by the designating agency.~~

~~2.3.3 The TAC was determined to be a carcinogen pursuant to section 2.1.5 and the District determines that there is sufficient, credible information that the TAC is not a carcinogen for purposes of determining the BAC; or~~

~~2.3.4 The District determines that there is sufficient, credible information supported by peer-reviewed scientific data that the TAC is not a carcinogen for purposes of determining the BAC.~~

SECTION 3 Determination of the BAC ~~Cancer Risk Benchmark Determination Methodology~~

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

$$BAC_C = \frac{1 \times 10^{-6}}{URE}$$

Where:

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

URE = ~~Unit Risk Estimate~~—The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of $1 \mu\text{g}/\text{m}^3$ in air, in units of $(\mu\text{g}/\text{m}^3)^{-1}$. The URE shall be determined according to the methodology in section 3.3, and

~~1×10^{-6}~~ = An upper bound additional lifetime cancer risk of 1 in 1,000,000.

3.2 ~~Alternatively, if a source in any of the sources of information identified in subsections 3.3.1 to 3.3.3 lists, the a concentration of a carcinogen, expressed in $\mu\text{g}/\text{m}^3$, as that is representative of an additional lifetime cancer risk of 1×10^{-6} is identified instead of the URE, then that concentration may be used as the BAC_C; is that identified concentration. The URE can be calculated by using Equation 1.~~

3.3 ~~The following provisions shall apply to the derivation of a unit risk estimate (URE), or alternatively a BAC_C directly, shall be derived as follows for a TAC determined to be a carcinogen:~~

3.3.1 If a URE for ~~the~~ a TAC ~~is~~ has been developed by the U.S. Environmental Protection Agency (EPA) and included in the EPA's Integrated Risk Information System (IRIS), ~~(available on the Internet at <http://www.epa.gov/iris>)~~, then that URE shall

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- 128 be used to determine the BAC_C .
- 129 3.3.2 If a URE for a TAC has not been derived pursuant to section 3.3.1 but a URE for that
130 TAC has been developed by the California Office of Environmental Health Hazard
131 Assessment, ~~(available on the Internet at <http://www.arb.ca.gov/toxics/healthval/contable.pdf>),~~ then that URE, found in the column Inhalation Unit Risk ($\mu\text{g}/\text{m}^3$)⁻¹,
132 shall be used to determine the BAC_C .
- 134 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
135 Initial Risk Screening Level (IRSL) for that TAC has been developed by the
136 Michigan Air Quality Division, ~~(available on the Internet at <http://www.deq.state.mi.us/documents/deq-aqd-toxics/itsleas.pdf> sorted by
137 Chemical Abstract Services (CAS) number or
138 <http://www.deq.state.mi.us/documents/deq-aqd-toxics/itslalph.pdf> sorted in
139 alphabetical order,~~ then that IRSL shall be used as the BAC_C .
- 141 3.3.4 If a ~~TAC has been determined to be a carcinogen,~~ but a URE, or a BAC_C directly, has
142 not been derived pursuant to subsections 3.3.1, 3.3.2, or to 3.3.3, then the URE may
143 be derived using one of the following:
- 144 3.3.4.1 The methodology in ~~EPA's~~ the Guidelines for Carcinogen Risk Assessment, U.S.
145 Environmental Protection Agency, EPA/630/P-03/001F, (March 2005), and
146 Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to
147 Carcinogens, U.S. Environmental Protection Agency, EPA/630/R-03-003F,
148 (March 2005), both of which are hereby adopted and incorporated by reference;
- 149 3.3.4.2 The methodology in EPA's Air Toxics Risk Assessment Reference Library,
150 Volume 1, Technical Resource Manual, Chapter 12 Inhalation Toxicity
151 Assessment, U.S. Environmental Protection Agency, EPA 453-K-04-001A,
152 (April 2004), which is hereby adopted and incorporated by reference;
- 153 3.3.4.3 The methodology in EPA's Guidelines for Carcinogen Risk Assessment, U.S.
154 Environmental Protection Agency, NCEA-F-0644, July 1999, Review Draft (July
155 1999), which is hereby adopted and incorporated by reference;
- 156 3.3.4.4 The methodology in EPA's Guidelines for Carcinogen Risk Assessment, U.S.
157 Environmental Protection Agency, EPA/630/R-00/004, September 24, 1986, 51
158 Fed. Reg. 33992-34003 (September 24, 1986), which is hereby adopted and
159 incorporated by reference;
- 160 3.3.4.5 The methodology in R 336.1231 Cancer Risk Assessment Screening
161 Methodology (2)(b) and (3) of the Michigan Administrative Code, which is
162 hereby adopted and incorporated by reference; or
- 163 3.3.4.6 Any alternative cancer risk assessment methodology that can be demonstrated to
164 the ~~satisfaction of the~~ District to be more appropriate based on biological grounds
165 and that is supported by peer-reviewed scientific data.
- 166 3.3.5 If a URE for a TAC has not been derived pursuant to subsections 3.3.1, 3.3.2, 3.3.3,
167 or 3.3.4 to 3.3.4, then the BAC_C shall be the default value $0.0004 \mu\text{g}/\text{m}^3$.
- 168 3.4 An annual average time period shall be used to determine ~~for~~ a BAC_C .

170 **SECTION 4 Determination of the BAC_{NC} Chronic Noncancer Risk Benchmark**

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Determination Methodology

The benchmark ambient concentration for the noncarcinogenic effects of a ~~TAC s toxic air contaminant (the BAC_{NC}); is the a~~ concentration that is likely to be without an appreciable risk of deleterious effects during a lifetime. ~~The BAC_{NC} shall be used to determine compliance with the EA goals established in Regulation 5.21 and~~ shall be determined as follows:

4.1 If a Reference Concentration (RfC) for a TAC has been developed by the EPA and included in ~~the EPA's Integrated Risk Information System (IRIS), available on the Internet at <http://www.epa.gov/iris/>~~, then that RfC shall be used as the BAC_{NC}, in units of $\mu\text{g}/\text{m}^3$.

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

Where:

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

~~RfC = Reference Concentration, in units of $\mu\text{g}/\text{m}^3$.~~

4.1.1 An annual average time period shall be used to determine for the a BAC_{NC} ~~determined~~ pursuant to this subsection.

~~4.1~~

4.2 If a BAC_{NC} for a TAC has not been determined pursuant to subsection 4.1 but a Reference Exposure Level (REL) has been developed by the California Office of Environmental Health Hazard Assessment, that REL, expressed in units of $\mu\text{g}/\text{m}^3$, found in the column AChronic Inhalation ($\mu\text{g}/\text{m}^3$), shall be used as the BAC_{NC}.

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

Where:

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

~~REL = Reference Exposure Level, in units of $\mu\text{g}/\text{m}^3$.~~

4.2.1 An annual average time period shall be used to determine the for a BAC_{NC} ~~determined~~ pursuant to this subsection 4.2.

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

$$BAC_{NC} = \text{Oral RfD} \times \frac{70 \text{ kg}}{20 \frac{\text{m}^3}{\text{day}}}$$

Where:

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

RfD = ~~Reference Exposure Level, in units of $\mu\text{g}/\text{kg}\text{-day}$~~ Oral Reference Dose, in units of $\mu\text{g}/\text{kg}\text{-day}$,

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214 70 kg = The average body weight of a human, and
215 20 m³/day = The average daily inhalation rate for a human.

216 4.3.1 An annual average time period shall be used to determine thefor a BAC_{NC} ~~determine~~
217 ~~d~~ pursuant to this subsection 4.3.

218 4.4 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.3 but an
219 Initial Threshold Screening Level (ITSL) for that TAC has been developed by the
220 Michigan Air Quality Division, ~~available on the Internet at [http://www.deq.state.mi.us/](http://www.deq.state.mi.us/documents/deq_aqd_toxics_itlscas.pdf)~~
221 ~~documents/deq_aqd_toxics_itlscas.pdf@ sorted by Chemical Abstract Services (CAS)~~
222 ~~number or http://www.deq.state.mi.us/documents/deq_aqd_toxics_itlslalph.pdf@ sorted in~~
223 ~~alphabetical order, then,~~ that ITSL, expressed in units of µg/m³ shall be ~~used as the~~
224 BAC_{NC}.

225 ~~$$BAC_{NC} = ITSL$$~~ [Equation 5]

226 Where:

227 BAC_{NC} = ~~Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units~~
228 ~~of µg/m³, and~~

229 ITSL = ~~Initial Threshold Screening Level, in units of µg/m³.~~

230 4.4.1 The average time period ~~as listed for a specific ITSL shall be used to determine for~~
231 ~~at the BAC_{NC} determined~~ pursuant to this subsection 4.4.

232 4.5 If a BAC_{NC} for a TAC has not been determined pursuant to subsections 4.1 to 4.4 but an
233 occupational exposure level (OEL) exists for that TAC, ~~then~~ the OEL may be used to
234 calculate the BAC_{NC} as follows:

235
$$BAC_{NC} = \frac{OEL}{100}$$

236 Where:

238 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a
239 TAC, in units of µg/m³,

240 OEL = Occupational Exposure Level, that, for the TAC, is the lowest value of
241 either the National Institute of Occupational Safety and Health
242 (NIOSH)-recommended exposure level listed in the current edition of
243 the NIOSH pocket guide to chemical hazards or the time-weighted
244 average Threshold Limit Value (~~TLV~~) listed in the current edition of
245 the American Conference of Governmental and Industrial Hygienists
246 Threshold Limit Value (~~TLV~~) booklet, in units of µg/m³, and

247 100 = A composite safety factor to account for differences in susceptibility
248 between the healthy, adult worker population compared to the general
249 population that is more diverse and may contain individuals or
250 subpopulations more sensitive to the effects of the toxic air pollutant
251 (safety factor of 10). Additionally, the composite safety factor
252 accounts for the difference in exposure duration (in hours per week
253 and years working versus a lifetime) for the worker population
254 compared to the general population:

255
$$\frac{1}{10} \theta \frac{40 \text{ hours} \blacktriangle \text{ week}}{168 \text{ hours} \blacktriangle \text{ week}} \theta \frac{30 \text{ years}}{70 \text{ years}} \cdot \frac{1}{100}$$

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256 4.5.1 An 8-hour average time period shall be used ~~to determine thefor a~~ BAC_{NC} ~~determined~~
257 pursuant to ~~this subsection-4.5~~ based upon a time-weighted OEL.

258 4.6 If a BAC_{NC} for a TAC has not been determined pursuant to ~~sub~~sections 4.1 to 4.5 but a 7-
259 day, inhalation, no observed adverse effect level (NOAEL) or lowest observable adverse
260 effect level (LOAEL) is available for that TAC, ~~then~~ the NOAEL or LOAEL may be
261 used to calculate the BAC_{NC} as follows:
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$$BAC_{NC} = \frac{NOAEL}{35 \times 100} \times \frac{Hr Exposed/Day}{24 Hr/Day}$$

263
264

$$BAC_{NC} = \frac{LOAEL}{35 \times 100 \times UF} \times \frac{Hr Exposed/Day}{24 Hr/Day}$$

265
266 Where:

267 BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of
268 a TAC, in units of µg/m³,

269 NOAEL = No observed adverse effect level (inhalation study), in units of µg/m³,

270 LOAEL = Lowest observed adverse effect level (inhalation study), in units of
271 µg/m³,

272 35 = A safety factor to account for using a NOAEL or LOAEL from a 7-
273 day exposure period to estimate a NOAEL or LOAEL for a lifetime
274 study,

275 100 = A standard composite safety factor comprised of a safety factor of 10
276 to account for differences between animals and humans and a safety
277 factor of 10 to account for the differences between individuals in the
278 human population, and

279 UF = Uncertainty Factor, a value from 1 to 10, applicable when using a
280 LOAEL (lowest effect) instead of a NOAEL (no effect), determined
281 by the District on a case-by-case basis, considering the type and
282 severity of effect. For example, a value of 1 would be used when the
283 lowest effect was a skin rash; a value of 10 would be used when the
284 lowest effect was death.

285 4.6.1 If approved by the District, the BAC_{NC} may be determined on a case-by-case basis
286 using a NOAEL or LOAEL from repeated dose studies other than 7-day studies. An
287 annual average time period shall be used ~~to determinefor thea~~ BAC_{NC} ~~determined~~
288 pursuant to ~~this subsection-4.6~~.

289 4.7 If a BAC_{NC} for a TAC has not been determined pursuant to ~~sub~~sections 4.1 to 4.6 but a 7-
290 day, oral NOAEL or oral LOAEL is available for that TAC, ~~and there is peer reviewed~~
291 ~~data are not available to indicatinge that oral route to inhalation route extrapolation is~~
292 ~~inappropriate, then~~ the oral NOAEL or oral LOAEL may be used to calculate the BAC_{NC}
293 as follows:
294

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$$BAC_{NC} = \frac{\text{Oral NOAEL}}{35 \times 100} \times \frac{W_A}{I_A} \times \frac{b}{a}$$

$$BAC_{NC} = \frac{\text{Oral LOAEL}}{35 \times 100 \times UF} \times \frac{W_A}{I_A} \times \frac{b}{a}$$

Where:

- BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of µg/m³,
- NOAEL = No observed adverse effect level (oral study), in units of µg/kg-day,
- LOAEL = Lowest observed adverse effect level (oral study), in units of µg/kg-day,
- 35 = A safety factor to account for using a NOAEL or LOAEL from a 7-day exposure period to estimate a NOAEL or LOAEL for a lifetime study,
- 100 = A standard composite safety factor comprised of a safety factor of 10 to account for differences between animals and humans and a safety factor of 10 to account for the differences between individuals in the human population,
- UF = Uncertainty Factor, a value from 1 to 10, applicable when using a LOAEL (lowest effect) instead of a NOAEL (no effect), determined by the District on a case-by-case basis, considering the type and severity of effect. For example, a value of 1 would be used when the lowest effect was a skin rash; a value of 10 would be used when the lowest effect was death,
- W_A = Body weight of experimental animal in kilograms (kg),
- I_A = Daily inhalation rate of experimental animal in m³/day,
- b = Absorption efficiency (percent absorbed) by the oral route of exposure, and
- a = Absorption efficiency (percent absorbed) by the inhalation route of exposure.

4.7.1 If approved by the District, the BAC_{NC} may be determined on a case-by-case basis using an oral NOAEL or oral LOAEL from repeated dose studies other than 7-day studies. An annual average time period shall be used for ~~the~~ BAC_{NC} determined pursuant to ~~this sub~~section ~~4.7~~.

4.8 If a BAC_{NC} for a TAC has not been determined pursuant to sections 4.1 to 4.7 but an inhalation LC₅₀ from a study that is 4 or more hours in duration is available for that TAC, ~~then~~ the LC₅₀ may be used to calculate the BAC_{NC} as follows:

$$BAC_{NC} = \frac{LC_{50}}{500 \times 100}$$

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331

Where:

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

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LC_{50} = Concentration of material used in an inhalation study that causes death of 50% of the group of test animals when administered as a single dose in a specific time period, in units of $\mu\text{g}/\text{m}^3$,

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500 = A factor to account for using an LC_{50} to estimate a no observed adverse effect level (NOAEL) for a lifetime study, and

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

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4.8.1 An annual average time period shall be used ~~for to determine thea~~ BAC_{NC} ~~determined~~ pursuant to this subsection ~~4.8~~.

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

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$$BAC_{NC} = \frac{(1 - HR)LC_{50}}{500 \times 100 \times 40}$$

349

350

Where:

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

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353

LC_{50} = Concentration of material used in an inhalation study that causes death of 50% of the group of test animals when administered as a single dose in a specific time period, in units of $\mu\text{g}/\text{m}^3$,

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500 = A factor to account for using an LC_{50} to estimate a no observed adverse effect level (NOAEL) for a lifetime study,

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358

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

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40 = A safety factor to account for the uncertainty of using a one-hour inhalation LC_{50} compared to an exposure duration of four hours or more.

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4.9.1 An annual average time period shall be used ~~for to determine thea~~ BAC_{NC} ~~determined~~ pursuant to this subsection ~~4.9~~.

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4.10 If a BAC_{NC} for a TAC has not been determined pursuant to subsections 4.1 to 4.9 but an animal oral LD_{50} is available for that TAC, ~~and there is peer reviewed data are not available to indicatinge that oral route to inhalation route extrapolation is inappropriate,~~ ~~then~~ the LD_{50} may be used to calculate the BAC_{NC} as follows:

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$$BAC_{NC} = \frac{LD_{50} (mg/kg)}{500 \times 100 \times 40 \times 0.167} \times \frac{W_A}{I_A}$$

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**This version has been technically corrected to add certain equations in sections 3.1, 4.3, 4.5, 4.6, 4.7, 4.8, 4.9, and 4.10 that were inadvertently omitted due to a formatting error.*

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November 17, 2010

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Where:

- BAC_{NC} = Benchmark Ambient Concentration for the noncarcinogenic effects of a TAC, in units of $\mu\text{g}/\text{m}^3$,
- LD₅₀ = Amount of material administered in a single dose by a route other than inhalation, e.g., oral, that causes death of 50% of the group of test animals, in units of $\mu\text{g}/\text{kg}$,
- 500 = A factor to account for using an LC₅₀ to estimate a no observed adverse effect level (NOAEL) for a lifetime study,
- 100 = A standard composite safety factor comprised of a safety factor of 10 to account for differences between animals and humans and a safety factor of 10 to account for the differences between individuals in the human population,
- 40 = A safety factor to account for the uncertainty of estimating an LC₅₀ from an LD₅₀,
- 0.167 = A factor to convert the daily dose to a 4-hour time frame ($4 / 24 = 0.167$),
- W_A = Body weight of experimental animal in kilograms (kg), and
- I_A = Daily inhalation rate of experimental animal in m^3/day .

4.10.1 An annual average time period shall be used ~~for to determine the~~ BAC_{NC} ~~determined~~ pursuant to this subsection 4.10.

4.11 If a BAC_{NC} for a TAC has not been determined pursuant to subsections 4.1 to 4.10, ~~then~~ the BAC_{NC} shall be the default value of 0.04 $\mu\text{g}/\text{m}^3$.

~~$$\text{BAC}_{\text{NC}} = 0.04 \mu\text{g}/\text{m}^3 \quad [\text{Equation 14}]$$~~

Where:

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

4.11.1 An annual average time period shall be used ~~for to determine the~~ BAC_{NC} ~~determined~~ pursuant to this subsection 4.11.

4.12 ~~Notwithstanding the methodologies in sections 4.3, 4.7, and 4.10, a~~ BAC_{NC} shall not be derived from a methodology in section 4.3, 4.7 or 4.10 ~~one of these methodologies, which consider based on route to route extrapolation,~~ unless the District ~~has affirmatively determined~~ that the use of oral toxicity data is appropriate. The use of oral toxicity data is not appropriate when in the following cases:

4.12.1 ~~When g~~ Groups of chemicals have different toxicity by the two different routes (e.g., metals, irritants, and sensitizers),

4.12.2 ~~When a~~ first-pass effect by the respiratory tract is expected,

4.12.3 ~~When a~~ first-pass effect by the liver is expected,

4.12.4 ~~When a~~ respiratory tract effect is established, but dosimetry comparison cannot be clearly established between the two routes,

4.12.5 ~~When t~~ The respiratory tract is not adequately studied in the oral studies, and

4.12.6 ~~When s~~ Short-term inhalation studies, dermal irritation, in vitro studies, or characteristics of the chemical indicate potential for portal-of-entry effects at the respiratory tract, but the studies themselves are not adequate for the development of a BAC benchmark ambient concentration.

**This version has been technically corrected to add certain equations in sections 3.1, 4.3, 4.5, 4.6, 4.7, 4.8, 4.9, and 4.10 that were inadvertently omitted due to a formatting error.*

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419 | **SECTION 5 ___ Consideration of Acute Noncancer Effects**

420 | If the District determines that compliance with the BAC_{NC} over the applicable averaging time
421 | ~~specified in Section 4~~ does not provide adequate protection from the acute effects of a TAC, ~~then~~
422 | the District may establish an ~~different~~ acute ~~BAC_{NC} benchmark ambient concentration~~ (BAC_{NCA})
423 | ~~using and a~~ shorter averaging time ~~and that would provide adequate protection, using~~ a
424 | methodology consistent with the guidance provided in EPA's Air Toxics Risk Assessment
425 | Reference Library, Volume 1, Technical Resource Manual, Section 12.6 Acute Exposure
426 | Reference Values, U.S. Environmental Protection Agency, EPA-454-K-04-001A, (April 2004).

427 | **~~SECTION 6 — Available Documents~~**

428 | ~~The District will maintain on its web page, <http://www.apcd.org>, links to the documents~~
429 | ~~identified as available on the Internet and maintain at its office a copy of all documents identified~~
430 | ~~in this regulation. In addition, the District will maintain a current list of the benchmark ambient~~
431 | ~~concentrations that have been developed pursuant to this regulation and maintain this current list~~
432 | ~~on its web page.~~

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434 | Adopted v1/6-21-05, effective 7-1-05; amended v2/7-19-06; v3/