R 336.1224 T-BACT requirement for new and modified source of air toxics; exemptions.

Rule 224. (1) A person who is responsible for any proposed new or modified emission unit or units for which an application for a permit to install is required by part 2 of these rules and which emits a toxic air contaminant shall not cause or allow the emission of the toxic air contaminant from the proposed new or modified emission unit or units in excess of the maximum allowable emission rate based on the application of best available control technology for toxics (T-BACT), except as provided in subrule (2) of this rule.

(2) The requirement for T-BACT in subrule (1) of this rule shall not apply to any of the following:

(a) An emission unit or units for which standards have been promulgated under section 112(d) of the clean air act or for which a control technology determination has been made under section 112(g) or 112(j) of the clean air act for any of the following:

(i) The hazardous pollutants listed in section 112(b) of the clean air act.

(ii) Other toxic air contaminants that are volatile organic compounds, if the standard promulgated under section 112(d) of the clean air act or the determination made under section 112(g) or 112(j) of the clean air act controls similar compounds that are also volatile organic compounds.

(iii) Other toxic air contaminants that are particulate matter, if the standard promulgated under section 112(d) of the clean air act or the determination made under section 112(g) or 112(j) of the clean air act controls similar compounds that are also particulate matter.

(b) An emission unit or units that is in compliance with all of the following:

(i) The maximum allowable emissions of each toxic air contaminant from the proposed new or modified emission unit or units is 0.1 pound per hour or less for a carcinogen or 1.0 pound per hour or less for any other toxic air contaminant.

(ii) The applicable initial threshold screening level for the toxic air contaminant is more than 200 micrograms per cubic meter.

(iii) The applicable initial risk screening level is more than 0.1 micrograms per cubic meter.

(c) An emission unit or units which only emits toxic air contaminants that are particulates or VOCs and which is in compliance with BACT or LAER requirements for particulates and VOCs.

History: 1998 MR 10, Eff. Nov. 10, 1998.

R 336.1225 Health-based screening level requirement for new or modified sources of air toxics.

Rule 225. (1) A person who is responsible for any proposed new or modified emission unit or units for which an application for a permit to install is required by part 2 of these rules and which emits a toxic air contaminant (TAC) shall not cause or allow the emission of the

toxic air contaminant from the proposed new or modified emission unit or units in excess of the maximum allowable emission rate which results in a predicted maximum ambient impact that is more than the initial threshold screening level or the initial risk screening level, or both, except as provided in subrules (2) and (3) of this rule and in R 336.1226.

(2) As an alternative to complying with the initial risk screening level in subrule (1) of this rule, a person may instead demonstrate compliance with the secondary risk screening level. For the purpose of complying with the secondary risk screening level, the total allowable emissions of the carcinogen from the proposed new or modified emission unit or units and all existing emission units at the stationary source shall not result in a maximum ambient impact that is more than the secondary risk screening level.

(3) If the ambient impacts of a carcinogen occur on industrial property or public roadways, as an alternative to complying with the initial risk screening level or secondary risk screening level in subrule (1) or (2) of this rule, a person may instead demonstrate compliance with either of the following provisions:

(a) The maximum allowable emission rate of the carcinogen from the proposed new or modified emission unit or units results in ambient impacts that meet both of the following requirements:

(i) The maximum ambient impact on industrial property or public roadways is less than or equal to the initial risk screening level multiplied by a factor of 10.

(ii) The maximum ambient impact on all property that is not industrial or a public roadway is less than or equal to the initial risk screening level.

(b) The total allowable emissions of the carcinogen from the proposed new or modified emission unit or units and all existing emission units at the stationary source result in ambient impacts that meet both of the following requirements:

(i) The maximum ambient impact on industrial property or public roadways is less than or equal to the secondary risk screening level multiplied by a factor of 10.

(ii) The maximum ambient impact on all property that is not industrial or a public roadway is less than or equal to the secondary risk screening level.

(4) Any owner or operator who utilizes the alternative criteria provided in subrule (3) of this rule shall notify the department if a change in land use occurs for property determined to be industrial or a public roadway. The notification shall be submitted to the department within 30 days of the actual land use change. Within 60 days of the land use change, the owner or operator shall submit to the department a plan for complying with the requirements of subrule (1) of this rule. The plan shall require compliance with subrule (1) of this rule not later than 1 year after the due date of the plan submittal.

(5) For the purposes of this rule, industrial property includes only property where the activities are industrial in nature, for example, manufacturing, utilities, industrial research and development, or petroleum bulk storage. The term industrial property does not include farms or commercial establishments.

(6) For the purpose of subrules (1), (2), and (3) of this rule, both of the following provisions apply:

(a) All polychlorinated dibenzodioxins and dibenzofurans shall be considered as 1 toxic air contaminant, expressed as an equivalent concentration of 2,3,7,8-tetrachlorodibenzo-p-dioxin, based upon the relative potency of the isomers emitted from the emission unit or units.

(b) If 2 or more toxic air contaminants are present and known to result in toxicological interaction, then the interactive effects shall be considered in establishing initial threshold screening levels, initial risk screening levels, and secondary risk screening levels.

History: 1998 MR 10, Eff. Nov. 10, 1998.

R 336.1226 Exemptions from the health-based screening level requirement.

Rule 226. The health-based screening level requirement provided in R 336.1225(1) shall not apply to any of the following:

(a) Emissions of a toxic air contaminant that meet both of the following requirements:

(i) The emission rate is less than 10 pounds per month and 0.14 pound per hour.

(ii) The toxic air contaminant is not a carcinogen or a high concern toxic air contaminant listed in table 20.

Table 20. List of High Concern Toxic Air Contaminants

CHEMICAL NAME	CAS NUMBER
2,4,6-trinitrotoluene (TNT)	118-96-7
2-diethylaminoethanol	100-37-8
Acrolein	107-02-8
allyl chloride	107-05-1
alpha chloroacetophenone	532-27-4
alpha-amylase	9000-90-2
antimony compounds[1]	
Arsine	7784-42-1
barium compounds[1]	
Biphenyl	92-52-4
Bromine	7726-95-6
chlorine dioxide	10049-04-4
chlormadinone acetate	302-22-7
chlorpyrifos	2921-88-2
cobalt compounds[1]	
Colophony	8050-09-7
dibromochloropropane	96-12-8
dibutyltin oxide	818-08-6
Dichlorvos	62-73-7
diisocyanate compounds[1,2]	
dimethyl sulfate	77-78-1
glutaraldehyde	111-30-8
halogenated dimethylhydantoin compounds[3]	
isocyanate compounds[1,4]	

CHEMICAL NAME	CAS NUMBER
maleic anhydride	108-31-6
manganese compounds[1]	
melengesterol acetate	2919-66-6
mercury compounds[1]	
octachlorostyrene	29082-74-7
osmium tetroxide	20816-12-0
pentachlorobenzene	608-93-5
platinum soluble salt	7440-06-4
selenium compounds[1]	
Subtilisins (proteolytic enzymes)[5]	
sulfuric acid (including sulfur trioxide and oleum)	7664-93-9
tetrachlorobenzene compounds[6]	
thallium compounds[1]	
Vanadium pentaoxide	1314-62-1

[1] These listings include any unique chemical substance that contains the named chemical (for example, antimony, barium, cobalt, diisocyanate, isocyanate, manganese, mercury, selenium, and thallium) as part of the chemical structure.

[2] Diisocyanate compounds include compounds with 2 of the isocyanate functional groups (-CNCO).

[3] Halogenated dimethylhydantoin compounds includes those compounds with a hydantoin infrastructure (NHCONHCOCH2) substituted by 2 methyl groups at the 5 position on the ringed structure and halogens at the 1 or 3 position or the 1 and 3 position.

[4] Isocyanate compounds includes compounds with 1 or more of the isocyanate functional groups (-CNCO).

[5] Subtilisins (proteolytic enzymes) includes any members of the group of proteolytic enzymes derived from *Bacillus subtilis* or closely related organisms.

[6] Tetrachlorobenzenes includes compounds that consist of a benzene ring substituted with 4 chlorine atoms.

(b) An emission unit or units for which standards have been promulgated under section 112(f) of the clean air act for hazardous air pollutants listed under section 112(b) of the clean air act.

(c) Air contaminants and emission units that are regulated by the following national emission standards for hazardous air pollutants promulgated on or before November 14, 1990, under section 112 of the clean air act, as amended, 42 U.S.C. §7401 et seq:

(i) Subpart B - National emission standard for radon-222 emissions from underground uranium mines.

(ii) Subpart C - National emission standards for beryllium.

(iii) Subpart D - National emission standard for beryllium rocket motor firing.

(iv) Subpart E - National emission standard for mercury.

(v) Subpart F - National emission standard for vinyl chloride.

(vi) Subpart H - National emission standard for radionuclide emissions from department of energy facilities.

(vii) Subpart I - National emission standard for radionuclide emissions from facilities licensed by the nuclear regulatory commission and federal facilities not covered by subpart H.

(viii) Subpart J - National emission standard for equipment leaks (fugitive emission sources) of benzene.

(ix) Subpart K - National emission standard for radionuclide emissions from elemental phosphorus plants.

(x) Subpart L - National emission standard for benzene emissions from coke-by-product recovery plants.

(xi) Subpart M - National emission standard for asbestos.

(xii) Subpart N - National emission standard for inorganic arsenic emissions from glass manufacturing plants.

(xiii) Subpart O - National emission standard for inorganic arsenic emissions from primary copper smelters.

(xiv) Subpart P - National emission standard for inorganic arsenic emissions from arsenic trioxide and metallic arsenic production facilities.

(xv) Subpart V - National emission standard for equipment leaks (fugitive emission sources).

(xvi) Subpart W - National emission standard for radon-222 emissions from licensed uranium mill tailings.

(xvii) Subpart Y - National emission standard for benzene emissions from benzene storage vessels.

(xviii) Subpart BB - National emission standards for benzene emissions from benzene transfer operations.

(xix) Subpart FF - National emission standards for benzene waste operations.

(d) Emissions of a toxic air contaminant if it is demonstrated, on a case-by-case basis, to the satisfaction of the department, that the proposed new or modified emission unit or units will not cause or contribute to a violation of the provisions of R 336.1901. The demonstration shall include all relevant scientific information such as the following:

(i) All available information on the health effects of the toxic air contaminant.

(ii) The levels at which adverse health or environmental effects have occurred.

(iii) Net air quality benefits that would occur as a result of replacing an existing facility.

(iv) Actual exposure levels and duration of exposure.

(v) The uncertainty in data or analysis.

(vi) Other supporting information requested by the department.

History: 1998 MR 10, Eff. Nov. 10, 1998.

R 336.1227 Demonstration of compliance with health-based screening level.

Rule 227. (1) Compliance with the health-based screening level provisions of R 336.1225 shall be determined by any of the following:

(a) The emission rate of each toxic air contaminant is not greater than the rates determined from the algorithms in table 21. If table 21 provides 2 allowable emission rates for a screening level specific averaging time, then compliance with both emission rates is required.

Table 21. Algorithms for determining allowable emission rates (AER)

Screening Level (SL) Averaging Time	**Monthly Emission Rate (pounds per month)[1,2]**	**24 Hour Emission Rate (pounds per 24 hours)[1,3]**	**8 Hour Emission Rate (pounds per 8 hours)[1,4]**	**1 Hour Maximum Emission Rate (pounds per hour)[1,5]**
Annual	SL X 40 = AER			SL X 0.54 = AER
24 hours		SL X 0.12 = AER		SL X 0.05 = AER
8 hours			SL X 0.02 = AER	SL X 0.02 = AER
1 hour				SL X 0.001 = AER

[1] All screening levels (SL) are in units of $\mu g/m^3$.

[2] The constant value of 40 is in units of $\frac{lbs/month}{\mu g/m^3}$.

[3] The constant value of 0.12 is in units of $\frac{lbs/24hours}{\mu g/m^3}$.

[4] The constant value of 0.02 is in units of $\frac{lbs/8hours}{\mu g/m^3}$.

[5] The constant values of 0.54, 0.05, 0.02, and 0.001 are in units of $\frac{lbs/hour}{\mu g/m^3}$.

(b) The emission rate of each toxic air contaminant is not greater than the rate determined from the AIR matrix screening methodology in table 22 or determined by any other screening method approved by the department.

(c) The maximum ambient impact of each toxic air contaminant is less than the applicable screening level (initial threshold screening level, initial risk screening level, or secondary risk screening level) determined using the maximum hourly emission rate in accordance with the provisions of R 336.1240 or R 336.1241, or both.

(2) For intermittent emissions, the average emission rate may be used to determine the allowable emission rate in subrule(1)(b) of this rule or the maximum ambient impact in subrule (1)(c) of this rule, if the average rate is not less than 10% of the maximum hourly rate. An average rate that is less than 10% of the maximum rate may only be used if the applicant can demonstrate, to the satisfaction of the department, that the proposed new or

modified emission unit or units will not cause or contribute to peak exposures that may result in a violation of the provisions of R 336.1901. Intermittent emissions are emissions that are not allowed to be emitted continuously for the entire length of the time specified in the averaging time for the appropriate screening level.

(3) Table 22 reads as follows:

History: 1998 MR 10, Eff. Nov. 10, 1998.

Table 22
Ambient Impact Ratio (AIR) Matrix

Description

The ambient impact ratio (AIR) matrix enables the determination of an emission rate of a toxic air contaminant (TAC) that would cause a maximum predicted ambient air impact equal to a screening level. This emission rate is derived by multiplying the screening level by the appropriate AIR value. Emission rates which do not exceed that rate are determined to be in compliance with the health-based screening level under R 336.1225.

Use of the AIR matrix requires information pertinent to the dispersion characteristics of the emission source, namely, the distance to the nearest secured property line and the height of the stack and the influential building. The AIR matrix shall not be used if any of the following provisions apply:

(a) the stack height is less than 10 feet.

(b) if the influential building height is more than 100 feet.

(c) if there are terrain elevations that are more than 25% of the discharging stack height within a distance of 500 feet from the stack.

(d) for the analysis of elevated receptors, for example, hospital air intakes.

Instructions for the use of the AIR matrix are as follows:

Instructions

1. Determine the height of the discharging stack from ground level in feet (H_s).

2. Determine the height of the influential building in feet (H_b). This is done by first identifying all buildings, including buildings on-site and off-site, located within a distance of 5 times their height from the discharging stack. Then, determine which building is the highest. This is the influential building, with height (H_b) in feet. If the stack is not attached to a building, then a building height 2.5 times lower than the stack height must be assumed.

3. Determine the ratio of the stack height to the influential building height by dividing the stack height, in feet, by the influential building height, in feet, for example, H_s/H_b.

4. Determine the minimum distance, in feet, from the discharging stack to the secured property line. If there is no secured property line, then a distance of 25 feet is used.

5. Determine the appropriate value from the AIR matrix. This is done by selecting the column with the appropriate influential building height and H_s/H_b ratio, and selecting the row with the appropriate minimum distance to the secured property line. If the influential

building height is between values in the column headings, then use the lower value or interpolate between values in the column headings. If H_s is less than H_b, then set the influential building height equal to the stack height and use the 1.25 H_s/H_b column. If H_s/H_b is between 1 and 1.25, then select the 1.25 column. If H_s/H_b is between 1.25 and 1.75, then use the 1.25 column or interpolate between the 1.25 and 1.75 columns. If H_s/H_b is between 1.75 and 2.5, then use the 1.75 column or interpolate between the 1.75 and 2.5 columns. If H_s/H_b is greater than or equal to 2.5, then use the 2.5 column. If the minimum distance to the secured property line is between 2 distances in the row headings, then use the lower value, for example, if the distance is 250 feet, then use the 200 foot distance row in the matrix.

The value thus derived from the body of the matrix is the ratio of the annual averaged hourly emission rate divided by the maximum annual ambient impact, in units of (lbs/hr)/(ug/m^3). This value is referred to as the annual AIR.

6. The annual averaged hourly emission rate ratio (annual AIR) is adjusted as necessary for shorter averaging times, consistent with the averaging times for the screening levels. This adjustment is done as follows:

24-hr AIR (lbs/hr)/(ug/m^3) = annual AIR x 0.091.

8-hr AIR (lbs/hr)/(ug/m^3) = annual AIR x 0.046.

1-hr AIR (lbs/hr)/(ug/m^3) = annual AIR x 0.02.

7. Determine the maximum emission rate that would comply with the health-based screening level and averaging time. This is done by multiplying the screening level, in ug/m^3, by the AIR value for the appropriate averaging time. The result is the highest emission rate, averaged over the averaging time period, that would be in compliance with the screening level. If a source's maximum hourly emission rate does not exceed this, then the screening level would not be exceeded. If the emission is intermittent, then the emission rate can be averaged over the applicable averaging time as long as the averaged emission rate is not less than 10% of the maximum hourly emission rate, as specified in R 336.1227(2).

8. In the special case of TAC emissions from multiple stacks, determine the AIR value for each stack and select the lowest value among them. Then proceed as in step number 7.

Table 22. Ambient Impact Ratio (AIR) Matrix
Annual Averaged Hourly Emission Rate Ambient Impact Ratios (AIRs) in Units of (lbs/hr)/(μg/m^3)
for Toxic Air Contaminants (TACs) with Annual Averaged Screening Levels

	BLDG HT (ft)	**10**			**20**			**30**			**40**			**50**		
	H_s / H_b	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**
	Stack Height->	**12.5**	**17.5**	**25.0**	**25.0**	**35.0**	**50.0**	**37.5**	**52.5**	**75.0**	**50.0**	**70.0**	**100.0**	**62.5**	**87.5**	**125.0**
DISTANCE FT	25	0.0085	0.022	0.159	0.032	0.084	0.679	0.075	0.220	1.603	0.152	0.421	2.941	0.263	0.736	4.630
	50	0.0087	0.022	0.159	0.032	0.084	0.679	0.075	0.220	1.603	0.152	0.421	2.941	0.263	0.736	4.630
	75	0.0096	0.022	0.159	0.032	0.084	0.679	0.075	0.220	1.603	0.152	0.421	2.941	0.263	0.736	4.630
	100	0.011	0.023	0.159	0.033	0.084	0.679	0.075	0.220	1.603	0.152	0.421	2.941	0.263	0.736	4.630
	200	0.020	0.040	0.159	0.042	0.084	0.679	0.082	0.220	1.603	0.157	0.421	2.941	0.266	0.736	4.630
	300	0.030	0.053	0.178	0.059	0.113	0.679	0.099	0.221	1.603	0.174	0.421	2.941	0.282	0.736	4.630
	400	0.040	0.065	0.171	0.077	0.140	0.679	0.126	0.268	1.603	0.200	0.421	2.941	0.312	0.736	4.630
	500	0.051	0.077	0.189	0.094	0.164	0.679	0.153	0.318	1.603	0.243	0.505	2.941	0.351	0.743	4.630
	600	0.063	0.091	0.222	0.112	0.188	0.746	0.181	0.368	1.603	0.287	0.588	2.941	0.409	0.838	4.630
	700	0.075	0.104	0.241	0.130	0.211	0.812	0.208	0.413	1.603	0.328	0.664	2.941	0.468	0.951	4.717
	800	0.089	0.119	0.257	0.148	0.235	0.768	0.235	0.459	1.608	0.370	0.740	2.941	0.528	1.064	4.803
	900	0.103	0.134	0.264	0.167	0.258	0.770	0.261	0.502	1.672	0.411	0.812	2.941	0.585	1.168	4.854
	1000	0.119	0.151	0.272	0.187	0.282	0.800	0.289	0.545	1.786	0.452	0.883	2.959	0.644	1.276	4.950
	1500	0.209	0.245	0.318	0.290	0.406	1.080	0.428	0.756	1.953	0.654	1.214	3.521	0.924	1.761	5.376
	2000	0.311	0.350	0.383	0.408	0.539	1.256	0.573	0.965	2.304	0.861	1.534	3.731	1.205	2.222	5.882

	BLDG HT (ft)	**60**			**70**			**80**			**90**			**100**		
	H_s / H_b	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**	**1.25**	**1.75**	**2.50**
	Stack Height->	**75.0**	**105.0**	**150.0**	**87.5**	**122.5**	**175.0**	**100.0**	**140.0**	**200.0**	**112.5**	**157.5**	**225.0**	**125.0**	**175.0**	**250.0**
DISTANCE FT	25	0.412	1.114	6.098	0.606	1.656	8.621	0.839	2.242	8.333	1.126	3.049	13.514	1.458	3.876	14.286
	50	0.412	1.114	6.098	0.606	1.656	8.621	0.839	2.242	8.333	1.126	3.049	13.514	1.458	3.876	14.286
	75	0.412	1.114	6.098	0.606	1.656	8.621	0.839	2.242	8.333	1.126	3.049	13.514	1.458	3.876	14.286
	100	0.412	1.114	6.098	0.606	1.656	8.621	0.839	2.242	8.333	1.126	3.049	13.514	1.458	3.876	14.286
	200	0.413	1.114	6.098	0.606	1.656	8.621	0.839	2.242	8.333	1.126	3.049	13.514	1.458	3.876	14.286
	300	0.426	1.114	6.098	0.614	1.656	8.621	0.845	2.242	8.333	1.129	3.049	13.514	1.458	3.876	14.286
	400	0.455	1.114	6.098	0.641	1.656	8.621	0.868	2.242	8.333	1.147	3.049	13.514	1.475	3.876	14.286
	500	0.498	1.114	6.098	0.683	1.656	8.621	0.909	2.242	8.333	1.185	3.049	13.514	1.506	3.876	14.286
	600	0.545	1.114	6.098	0.741	1.656	8.621	0.967	2.242	8.333	1.244	3.049	13.514	1.563	3.876	14.286
	700	0.625	1.269	6.250	0.808	1.672	8.621	1.040	2.242	8.333	1.316	3.049	13.514	1.634	3.876	14.286
	800	0.705	1.429	6.410	0.901	1.825	8.621	1.111	2.242	8.333	1.404	3.049	13.514	1.730	3.876	14.286
	900	0.781	1.572	6.579	1.000	2.016	8.621	1.235	2.488	9.091	1.502	3.086	13.514	1.832	3.876	14.286
	1000	0.861	1.724	6.849	1.101	2.203	9.091	1.359	2.732	10.000	1.634	3.289	13.514	1.931	3.876	14.286
	1500	1.232	2.404	7.042	1.577	3.106	9.615	1.953	3.846	11.905	2.358	4.505	15.152	2.778	5.208	16.129
	2000	1.603	3.049	7.353	2.041	3.968	9.615	2.525	4.808	12.821	3.049	5.618	16.129	3.597	6.494	18.519

R 336.1228 Requirement for lower emission rate than required by T-BACT and health-based screening levels.

Rule 228. The department may determine, on a case-by-case basis, that the maximum allowable emission rate determined in R 36.1224(1), R 336.1225(1), R 336.1225(2), or R 336.1225(3) may not provide adequate protection of human health or the environment. In this case, the department shall establish a maximum allowable emission rate considering all relevant scientific information, such as exposure from routes of exposure other than direct inhalation, synergistic or additive effects from other toxic air contaminants, and effects on the environment.

History: 1998 MR 10, Eff. Nov. 10, 1998.

R 336.1229 Methodology for determining health-based screening levels.

Rule 229. (1) The initial and secondary risk screening levels for a carcinogen shall be determined by any of the following:

(a) The cancer risk assessment screening methodology contained in R 336.1231.

(b) The United States environmental protection agency guidelines for carcinogen risk assessment, United States environmental protection agency, 1986, as adopted by reference in R 336.1299.

(c) Any alternative cancer risk assessment methodology which can be demonstrated to the department to be more appropriate based on biological grounds and which is supported by the scientific data.

(2) The initial threshold screening level shall be determined by either of the following:

(a) The methodology for determining the initial threshold screening level contained in R 336.1232.

(b) Any alternative methodology to assess noncarcinogenic health effects that can be demonstrated to the department to be more appropriate based on toxicological grounds and that is supported by the scientific data.

History: 1998 MR 10, Eff. Nov. 10, 1998.

R 336.1230 Informational list for health-based screening levels and T-BACT determinations.

Rule 230. For information purposes, the department will maintain up-to-date lists of the following information and will provide the information upon request:

(a) Chemical abstract service numbers and the basis for determining each of the following screening levels:

(i) Initial threshold screening levels reviewed by the department.

(ii) Initial and secondary risk-based screening levels reviewed by the department.

(b) Ambient concentrations for toxic air contaminants reviewed by the department under R 336.1226(d) and R 336.1228, the applicable chemical abstract service number, and the basis for any alternative concentration approved under these rules.

(c) T-BACT determinations reviewed by the department.

History: 1992 MR 4, Eff. Apr. 17, 1992; 1994 MR 11, Eff. Dec. 31, 1994; 1998 MR 10, Eff. Nov. 10, 1998.

R 336.1231 Cancer risk assessment screening methodology.

Rule 231. (1) The initial risk screening level (IRSL) and the secondary risk screening level (SRSL) shall be determined as follows:

$$IRSL = \frac{1 x 10^{-6}}{unit\,risk}$$

$$SRSL = \frac{1 x 10^{-5}}{unit\,risk}$$

Where:

Unit risk = Additional lifetime cancer risk occurring in a population in which all individuals are exposed continuously for life to a concentration of 1 microgram per cubic meter of the chemical in the air they breathe. The unit risk value shall be determined according to the methodology in subrule (2) of this rule.

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

1×10^{-5} = An upper bound lifetime cancer risk of 1 in 100,000.

(2) Both of the following provisions apply to derivation of unit risk:

(a) The unit risk value determined by the United States environmental protection agency according to the guidelines for carcinogen risk assessment, United States environmental protection agency, 1986, shall be used to estimate risk. This standard is adopted by reference in R 336.1299.

(b) If a unit risk value has not been determined by the United States environmental protection agency, then the unit risk value shall be determined as follows:

Unit risk = q_1*

Where:

q_1* = Linear function or slope of the multistage model as derived in subrule (3) of this rule. This parameter is expressed in units of (microgram per cubic meter)$^{-1}$.

(3) All of the following provisions apply to the derivation of q_1*:

(a) This methodology, based upon animal bioassay data, shall be used when human epidemiology data are not available to estimate increased cancer risk.

(b) Carcinogenesis bioassay data are fit to the multistage model using a linearized multistage computer model. The upper 95% confidence limit on risk at the 1 in 1,000,000

risk level is divided by the maximum likelihood dose at the same level of risk that determines the slope, q_1*. This is taken as an upper bound of the potency of the chemical in inducing cancer at low doses. When the multistage model does not fit the data sufficiently, then data at the highest dose shall be deleted and the model refitted to the rest of the data. This procedure shall be continued until an acceptable fit to the data is obtained. To determine whether a fit is acceptable, the chi-square statistic:

$$X^2 = \sum_{i=1}^{h} \frac{(X_i - N_i P_i)^2}{N_i P_i (1 - P_i)}$$

is calculated, where N_i is the number of animals in the ith dose group, X_i is the number of animals in the ith dose group with a tumor response, P_i is the probability of a response in the ith dose group estimated by fitting the multistage model to the data, and h is the number of remaining groups. The fit is determined to be unacceptable when chi-square is larger than the cumulative 99% point of the chi-square distribution with f degrees of freedom, where f equals the number of dose groups minus the number of nonzero multistate coefficients. If a single study in which a chemical induces more than 1 type of tumor is available, then the response for the tumor type predicting the highest estimate of q_1* is used for the risk assessment. If 2 or more studies of equal quality are available, but vary in species, strain, sex, or tumor type, then the data set giving the highest estimate of q_1* is used for the risk assessment. If 2 or more studies exist which are identical regarding species, strain, sex, and tumor type and are of equal quality, then the geometric mean of the q_1* values from these data sets is used. However, where 2 or more significantly elevated tumor sites or types are observed in the same study, extrapolations may be conducted on selected sites or types. These selections shall be made on biological grounds. To obtain a total estimate of carcinogenic risk, animals with 1 or more tumor sites or types that show significantly elevated tumor incidence may be pooled and used for extrapolation. The pooled estimates shall generally be used in preference to risk estimates based on single sites or types. Quantitative risk extrapolations shall generally not be done on the basis of totals that include tumor sites without statistically significant elevations.

(c) To determine the equivalent human dose from animal data, it is assumed that milligram/surface area/day is an equivalent dose between species. To make this adjustment, the parameter q_1*, in units of $(\text{milligram/kilogram/day})^{-1}$, is multiplied by factor (T), where:

$$T = (W_H / W_A)^{1/3}$$

W_H = Average weight of an adult human and assumed to be 70 kilogram.

W_A = Body weight of the animal test species in kilogram.

(d) All dose levels input to the model are adjusted to give a lifetime average daily dose. If dosing was only for a fraction of a lifetime, then the total dose is averaged over the entire lifespan.

(e) If the duration of the experiment (Le) is less than the natural lifespan of the test animal (L), then the parameter q_1*, is multiplied by the factor $(L/Le)^3$.

(f) If the experimental route of exposure was by oral administration and inadequate pharmacokinetic and metabolism data are available to determine equivalent exposure levels via inhalation, then the following methodology is used:

(i) Oral bioassay data are used to estimate q_1* as in subdivisions (a) to (e) of this subrule. The parameter q_1* will be in units of (milligram/kilogram/day)$^{-1}$.

(ii) To convert the parameter q_1* based upon oral exposure in units of (milligram/kilogram/day)$^{-1}$ to q_1* based upon inhalation exposure in units of (micrograms per cubic meter)$^{-1}$, it is assumed that a 70-kilogram person inhales 20 cubic meters of air per day. Thus:

$$q_1^* \ (ug / m^3)^{-1} = q_1^* \ (milligram / kilogram / day)^{-1} \ \frac{20 \ m^3}{70 \ kg} \ x \ \frac{1 \ mg}{1000ug} \ x \ \frac{a}{b}$$

a = Absorption efficiency by the inhalation route of exposure.

b = Absorption efficiency by the oral route of exposure.

In the absence of data on absorption efficiencies it is assumed that a = b.

(g) If exposure was by inhalation and the carcinogenic agent is an aerosol, then it is assumed the aerosol is deposited proportionally to the volume of air inspired. In the absence of specific deposition data, the daily dose (d) to be used for modeling is determined as follows:

$$D = EEC \ x \ \frac{I_A}{W_A}$$

Where:

EEC = Experimental exposure concentration in milligrams per cubic meter (mg/m³).

I_A = Daily inhalation rate of the experimental animal in cubic meters per day (m³/day).

W_A = Body weight of the experimental animal in kilograms (kg).

(h) If exposure was by inhalation and the carcinogenic agent is a gas, then the available data shall be evaluated to determine dose equivalency between humans and experimental animals. In the absence of adequate data, if the carcinogenic agent is a poorly water soluble gas that reaches equilibrium between air breathed and body compartments, then it is assumed that a certain concentration in parts per million (ppm) or micrograms per cubic meter (ug/m³) in experimental animals is equivalent to the same concentration in humans.

(4) An annual average time period shall be used for the IRSL and SRSL.

History: 1992 MR 4, Eff. Apr. 17, 1992; 1998 MR 10, Eff. Nov. 10, 1998.

R 336.1232 Methodology for determining initial threshold screening level.

Rule 232. (1) The initial threshold screening level (ITSL) for each toxic air contaminant shall be determined as follows:

(a) If an inhalation reference concentration (RfC) can be determined from best available information sources, then the initial threshold screening level equals the inhalation RfC.

(b) If an initial threshold screening level cannot be determined under the provisions of subdivision (a) of this subrule and an oral reference dose (RfD) can be determined through best available information and data are not available to indicate that oral route to inhalation route extrapolation is inappropriate, then the initial threshold screening level is determined as follows:

$$ITSL = Oral\ RfD\ x \frac{70\ kg}{20\ m^3}$$

(c) If an initial threshold screening level cannot be determined under the provisions of subdivision (a) or (b) of this subrule and an occupational exposure level (OEL) exists for the toxic air contaminant, then the initial threshold screening level is determined as follows:

ITSL = OEL divided by 100

Where occupational exposure level is the lowest value of either the national institute of occupational safety and health (NIOSH) recommended exposure level listed in the NIOSH pocket guide to chemical hazards (June 1994) or the time-weighted average or ceiling TLV listed in the 1996 American conference of governmental and industrial hygienists threshold limit value (TLV) booklet. These standards are adopted by reference in R 336.1299.

(d) If an initial threshold screening level cannot be determined under the provisions of subdivision (a), (b), or (c) of this subrule, then the initial threshold screening level may be determined from a 7-day, inhalation, no observed adverse effect level (NOAEL) or lowest observable adverse effect level (LOAEL) as follows:

$$ITSL = \frac{NOAEL}{35\ x\ 100}\ x \frac{hours\ exposed\ per\ day}{24\ hours\ per\ day}$$

$$ITSL = \frac{LOAEL}{35\ x\ 100\ x\ UF}\ x \frac{hours\ exposed\ per\ day}{24\ hours\ per\ day}$$

Where:

UF = A value from 1 to 10 determined on a case-by-case basis, considering type and severity of effect.

The ITSL may be determined on a case-by-case basis using NOAELs or LOAELs from repeated dose studies other than 7-day studies.

(e) If an initial threshold screening level cannot be determined under the provisions of subdivision (a), (b), (c), or (d) of this subrule, then the initial threshold screening level may be determined from a 7-day, oral, no observed adverse effect level or lowest observable effect level (LOAEL) as follows:

$$ITSL = \frac{NOAEL\ (mg / kg / day)}{35 \times 100} \times \frac{W_A}{I_A} \times \frac{b}{a}$$

$$ITSL = \frac{LOAEL}{35 \times 100 \times UF} \times \frac{W_A}{I_A} \times \frac{b}{a}$$

Where:

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

I_A = Daily inhalation rate of experimental animal in cubic meters/day.

b = Absorption efficiency by the oral route of exposure.

a = Absorption efficiency by the inhalation route of exposure.

UF = A value from 1 to 10 determined on a case-by-case basis, considering type and severity of effect.

The ITSL may be determined on a case-by-case basis using NOAELs or LOAELs from repeated dose studies other than 7-day studies.

(f) If an initial threshold screening level cannot be determined under the provisions of subdivision (a), (b), (c), (d), or (e) of this subrule, then the initial threshold screening level may be determined from an inhalation LC50 that is 4 or more hours in duration as follows:

$$ITSL = \frac{LC50}{500 \times 100}$$

(g) If an initial threshold screening level cannot be determined under the provisions of subdivision (a), (b), (c), (d), (e), or (f) of this subrule, then the initial threshold screening level may be determined from a 1-hour inhalation LC50 as follows:

$$ITSL = \frac{LC50}{500 \times 100 \times 40}$$

(h) If an initial threshold screening level cannot be determined under the provisions of subdivision (a), (b), (c), (d), (e), (f), or (g) of this subrule, then the initial threshold screening level may be determined from an animal oral LD50 as follows:

$$ITSL = \frac{1}{500} \times \frac{1}{40} \times \frac{1}{100} \times \frac{LD50\ (mg / kg) \times W_A}{0.167 \times I_A}$$

Where:

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

I_A = Daily inhalation rate of experimental animal in cubic meters/day.

(i) If an initial threshold screening level cannot be determined under the provisions of subdivision (a), (b), (c), (d), (e), (f), (g), or (h) of this subrule, then the initial threshold screening level = 0.1 ug/m³.

(2) The averaging times to be used for initial threshold screening levels are as follows:

(a) If the initial threshold screening level is derived from an occupational exposure level as in subrule (1)(c) of this rule, then the averaging time is 8 hours for initial threshold screening levels based on time-weighted average threshold limit values or recommended exposure levels and 1 hour for initial threshold screening levels based on ceiling threshold limit values or recommended exposure levels.

(b) If the initial threshold screening level is derived as in subrule (1)(a) and (b) of this rule, then the averaging time is 24 hours.

(c) If the initial threshold screening level is derived as in subrule (1)(d), (e), (f), (g), (h), or (i) of this rule, then the averaging time is annual.

(d) The commission may require shorter averaging times if necessary to provide adequate protection from the acute effects of a toxic air contaminant.

History: 1992 MR 4, Eff. Apr. 17, 1992; 1998 MR 10, Eff. Nov. 10, 1998.