Addendum to

Comments on the EPA Document, "Draft Toxicological Review of Libby Amphibole Asbestos" (EPA/635/r/002a)

As Requested by SAB Members

Calculations that Define Risk Driver: Proposed Cancer Risk Using Proposed IUR, Compared to Noncancer Risk Using Proposed RfC

Calculations that Define the Sensitivity of Sampling and Analysis Required to Evaluate the Unprecedented Low Levels Necessary to Evaluate Risk at the Proposed RfC Level

Comparison of these Required Sensitivity Levels to Analytical Sensitivity Associated with Prior EPA Sampling at Libby

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This addendum provides technical support for, and clarification of, the following statements found on page 6 of my comments submitted January 27, 2012:

"If the proposed RfC were to be adopted, large amounts of current and historical sampling data from Libby would not meet the required sensitivity level for noncancer hazard evaluation. For example, the current analytical sensitivity for EPA ambient air sampling at Libby exceeds the proposed RfC. Similarly, analytical sensitivities for EPA's activity-based sampling program for Libby, which has been ongoing for several years, are 10 to 100 times above the levels needed to evaluate a hazard quotient of 1 using the proposed RfC. Furthermore, the cost of analyzing samples down to this unprecedented low level would be several thousand to tens of thousands of dollars per sample. The RfC would have significant implications for risk assessment and, in many cases, may drive a risk assessment, especially for exposure durations shorter than about 20 years, for which a hazard quotient of 1 would be reached before a 10^{-6} cancer risk"

1) Risk Driver

The draft RfC will likely drive future risk assessments. The graph on Figure 1 shows concentrations in air that, for continuous exposure (24/7), correspond to either a hazard quotient of 1 or one of three cancer risk levels: one in one million (1×10^{-6}), one in 100,000 (1×10^{-5}) and 1 in 10,000 (1×10^{-4}), which are traditionally used as limits of acceptability for regulatory risk assessments. The figure shows how, for cancer risks, these *risk-based* concentrations decrease with increasing duration of exposure (in years), meaning that if one is exposed for a long period of time, the same lower concentration will result in the same risk. For noncancer, the level stays the same, because noncancer risk is averaged on a daily (or yearly) basis. The line for noncancer is below those for 10^{-5} and 10^{-4} risks, meaning that noncancer hazard will exceed the acceptable level of 1 at a lower concentration (exposure) than it would take to exceed these risk levels. Similarly, with the exception of durations exceeding about 20 years, the non-cancer level lies below the cancer level of 10^{-6}. These relationships might change if age adjustment is made on the cancer unit risk but likely not significantly for the 10^{-6} relationship and likely not at all for the 10^{-5} or 10^{-4} risks. The implication of this is that risk assessors will need to design sampling programs around lower target concentrations to accommodate the draft RfC.

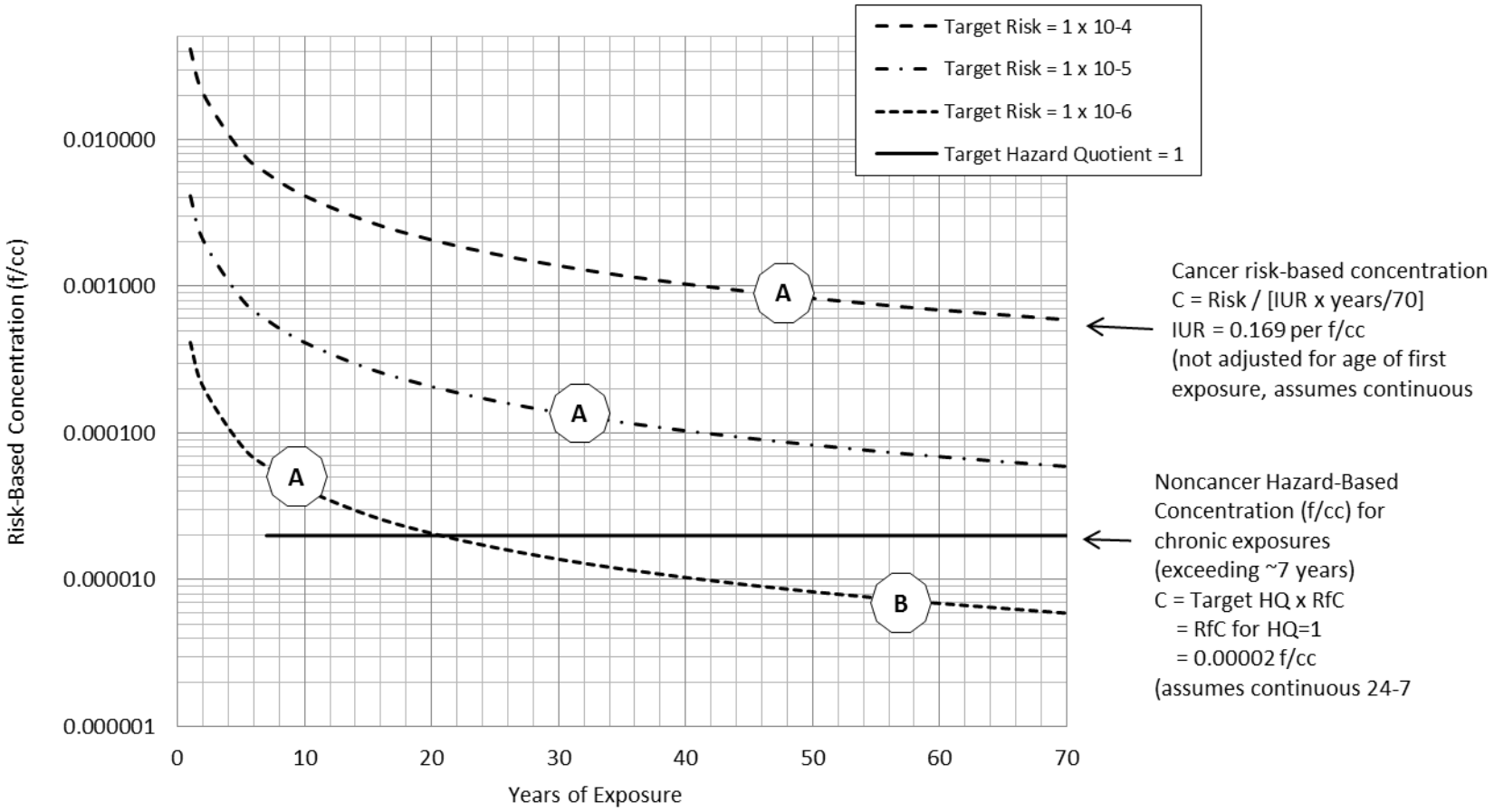
Figure 2 indicates where the noncancer hazard quotient (or index) would fall relative to the cancer risk range. This will in effect move the "action required" point to the lower end of the acceptable risk range.

2) Current analytical sensitivity for Libby ambient and activity-based sampling

EPA has developed sampling and analysis plans for its ongoing activity-based sampling efforts in Libby. Table 1-1 shows EPA's scenarios, exposure assumptions, and target sensitivities for activity-based sampling (ABS). On the basis of the draft RfC, and the scenario-specific exposure factors, new target sensitivities are calculated to meet with a hazard quotient of 1 for each scenario—these revised sensitivities range from about 12 to 16 times lower than the current targets. For ambient air, the revised target is about 6 times lower than the current target sensitivity. Because it is reasonable to assume that individuals may engage in more than one of the five activities, the target sensitivities could potentially be reduced by a factor of 5 (i.e., a target hazard quotient of 0.2 for each scenario) to ensure that, in combination, they do not exceed a hazard quotient of 1—this moves the disparity between current target sensitivities and those associated with the draft RfC to factors ranging from about 60 to over 80.

The time and societal cost associated with analyzing samples to these low target sensitivities would be significant. Laboratory capacity will be challenged to perform these duties without long delays. Using typically achievable sampling parameters to estimate volumes collected for each activity (assuming 2 to 4 hour sample times) and for ambient air (assuming a 5-day sample), and cost information provided by an analytical asbestos lab, Forensic Analytical Laboratories, the per-sample costs shown on Table 1-2 range from about $5,000 to about $16,000 for a hazard quotient of 1 for each scenario and are in the high tens of thousands of dollars for the sensitivities based on a hazard quotient of 0.2.

Figure 1. Risk Driver: Cancer versus Noncancer



A Cancer risk based exposure concentration *exceeds* concentration for a noncancer hazard of 1; the **noncancer health endpoint will drive risk assessment** and data quality objectives (analytical sensitivity)

B Cancer risk based exposure concentration is *lower than* concentration for a noncancer hazard of 1; the **cancer health endpoint will drive risk assessment** and data quality objectives (analytical sensitivity)

Figure 2. Risk Management Slide Showing Relative Placement of Hazard Index (purple arrows/outlines)

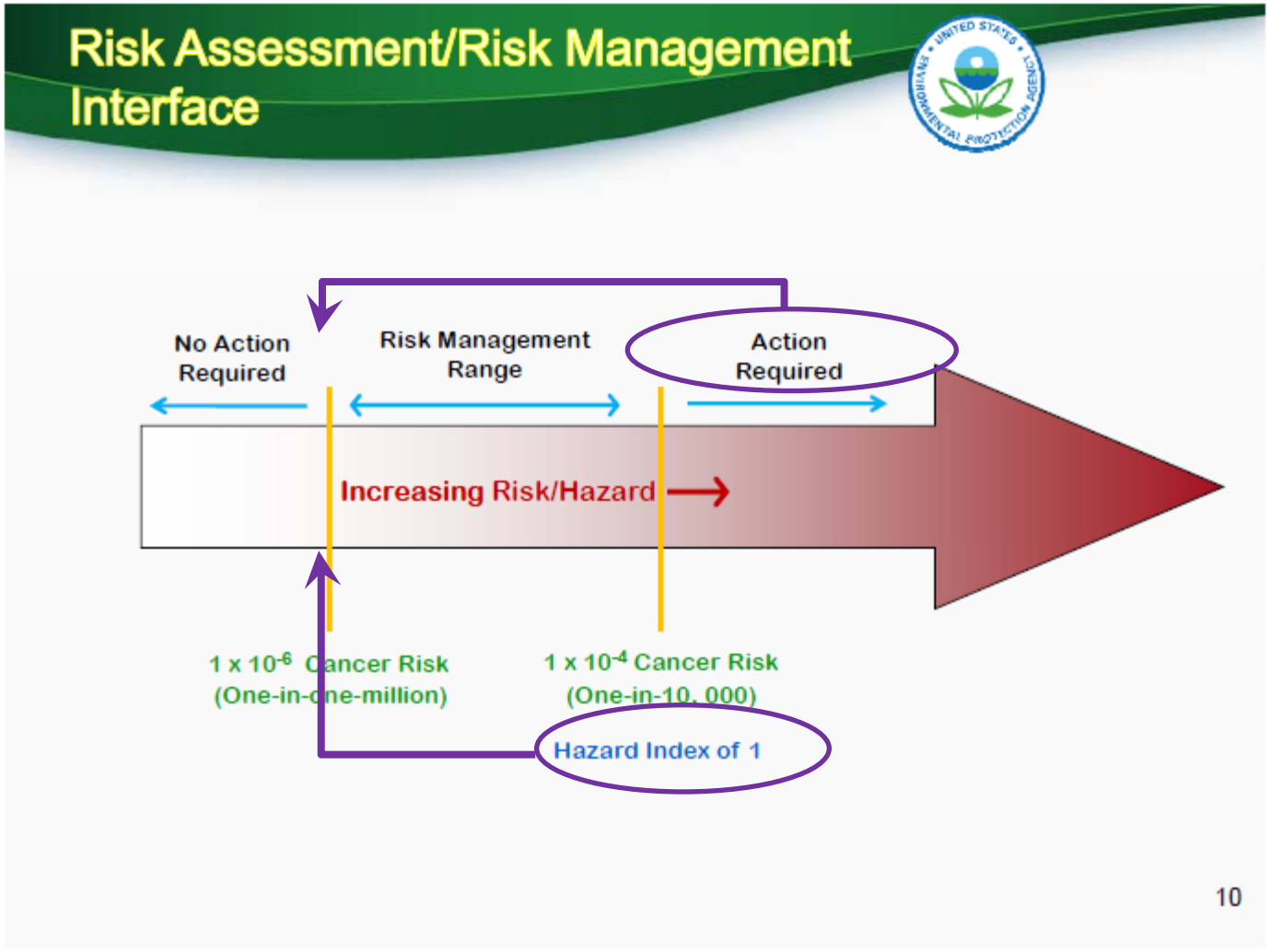


Table 1-1: Calculation of Required Analytical Sensitivity for Noncancer Health Endpoint Based on Draft RfC

From EPA Libby 2010 SAP (see note 1)						Calculated		
Scenario	**Exposure Time (hrs)**	**Exposure Frequency (days/year)**	**Target Analytical Sensitivity (f/cc)**	**note**	**Draft RfC (f/cc)**	**Time Weighting Factor, TWF** (3)	**Required target sensitivity for noncancer Hazard Quotient (HQ) = 1** (4)	**Required target sensitivity for noncancer target Hazard Quotient = 0.2 (1 of 5 scenarios)**
Residents in yards	8	60	0.002	(1)	2.0E-05	0.055	0.00012	0.000024
Residents in gardens	4	60	0.003	(1)	2.0E-05	0.027	0.00024	0.000049
Child playing on driveway	2	120	0.004	(1)	2.0E-05	0.027	0.00024	0.000049
Driving on Libby roads	4	180	0.001	(1)	2.0E-05	0.082	0.00008	0.000016
Biking in Libby (adult)	2	90	0.005	(1)	2.0E-05	0.021	0.00032	0.000065
Breathing ambient air			0.0000395	(2)	2.0E-05	1.0	0.00002	

Table 1-2: Calculation of Per Sample Costs of Laboratory Analysis to Meet Draft RfC-Required Analytical Sensitivities

Scenario	**Required Sensitivity for noncancer (Target Hazard Quotient = 1)** (4)	**Assumed Typical Sampling Duration (min)**	**Assumed flow rate of sampling pump (Liters/min)**	**Volume of Air Sampled (Liters)**	**Cost to Analyze Volume to Required Sensitivity for HQ=1** (5)	**Cost to Analyze for HQ=0.2 (1 of 5 scenarios)**
Residents in yards	1.22E-04	120	5	600	$ 15,500	$ 77,500
Residents in gardens	2.43E-04	120	5	600	$ 7,800	$ 39,000
Child playing on driveway	2.43E-04	120	5	600	$ 7,800	$ 39,000
Driving on Libby roads	8.11E-05	240	10	2400	$ 5,800	$ 29,000
Biking in Libby (adult)	3.24E-04	120	5	600	$ 5,800	$ 29,000
Breathing ambient air	2.00E-05	7200	2	14400	$ 3,900	

Notes:

1 Scenario, exposure and target sensitivity values taken from Table 3-3 of EPA *Sampling and Analysis Plan (EPA 2010) Supplemental Activity-based Sampling Libby Asbestos Site, Oper able Unit 4* , June 2010. http://www.epa.gov/region8/superfund/libby/OU4_SupplementalABS_SAP.pdf

2 Typical Sensitivity from EPA Libby sampling *"Ambient Air Sampling Results for Operable Unit 4, Libby asbestos Site, Libby, Montana 2010-2011" http://www.epa.gov/region8/superfund/libby/OU4_AmbientAirSamplingResults2010-2011.pdf*

3 Time Weighting Factor (fraction of time exposed) = exposure duration x exposure frequency / (24 x 365)

4 = RfC/TWF/3 for activity based scenarios (EPA 2010) and =RfC for ambient

5 Based on discussions with an analytical asbestos laboratory the cost for TEM analysis can be approximated by the following formula

Cost = (RfC/Required sensitivity) x (5.66×10^7/Volume sampled in Liters)