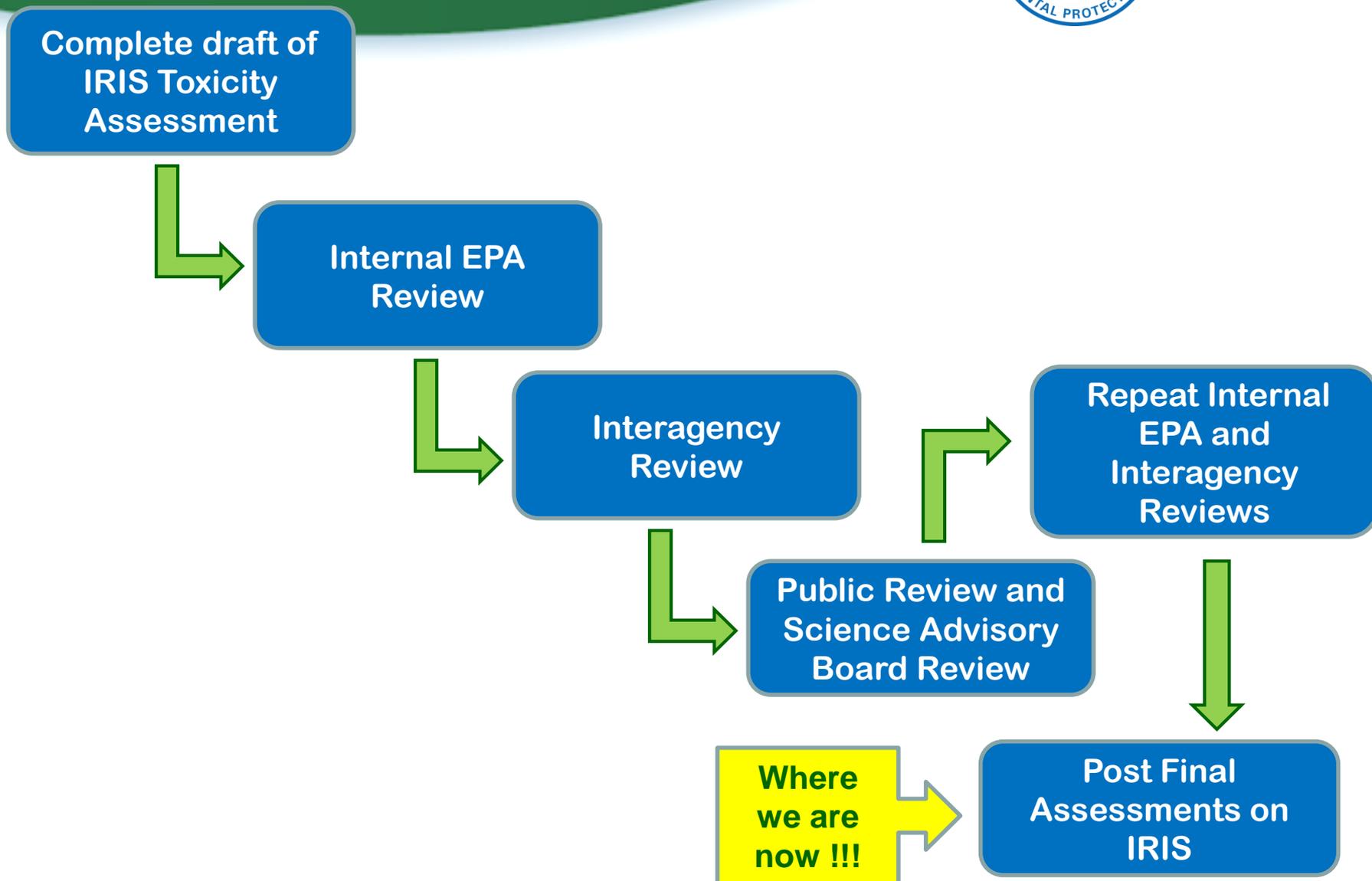


Toxicological Review of Libby Amphibole Asbestos



IRIS Development and Review Process





EPA Timeline for LAA Toxicity Review

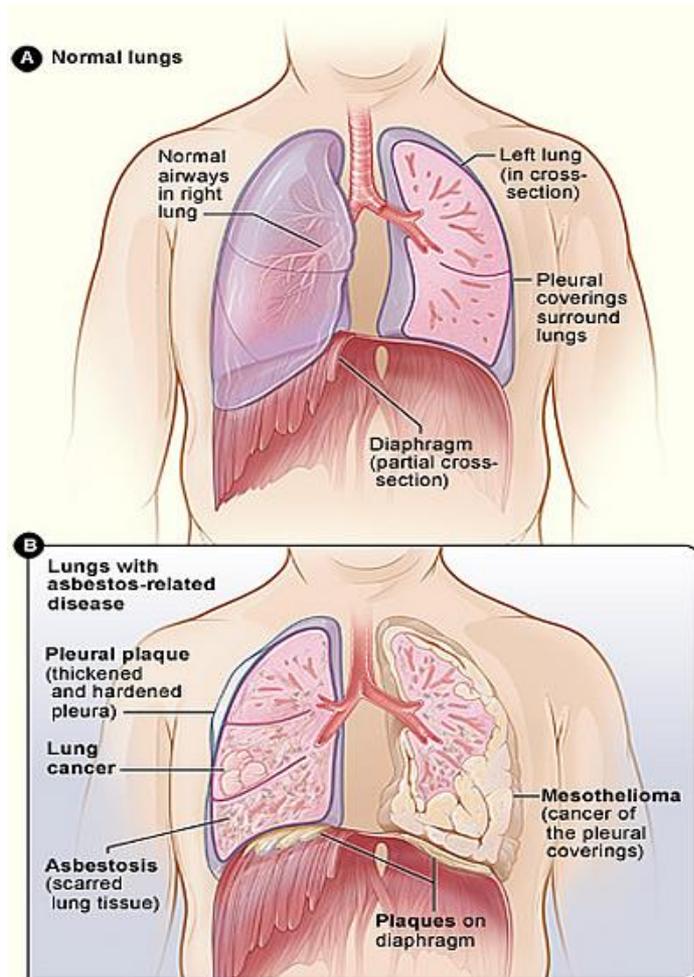
- 2006 Region 8 begins development on reference concentration (RfC)
 - (Non-cancer Toxicity value based on localized pleural thickening)
- 2007 EPA/NCEA begins development of inhalation unit risk (IUR)
 - (Cancer Toxicity value based on lung cancer and mesothelioma)
- 2011 Draft LAA Toxicity Review made available to the public and to the Science Advisory Board (SAB); Public listening sessions held
- 2012 SAB meetings in February, May, July, and September;
public comments made to EPA and to SAB
- 2013 EPA receives SAB final report in January and begins revision
- 2014 EPA completes revised draft LAA Toxicity Review; Completes Final Agency Review and Interagency Science Discussion
- 2014 EPA completes LAA Toxicity Review in December



Basis for Libby Amphibole Asbestos Toxicity Values

- Review and analysis of experimental animal and human epidemiological data
- Toxicity value for cancer (IUR) based on EPA analysis of workers at the Libby operations
- Toxicity value for non-cancer (RfC) based on EPA analysis of workers exposed to Libby vermiculite at O. M. Scott facility in Marysville, OH

Asbestos-Related Diseases

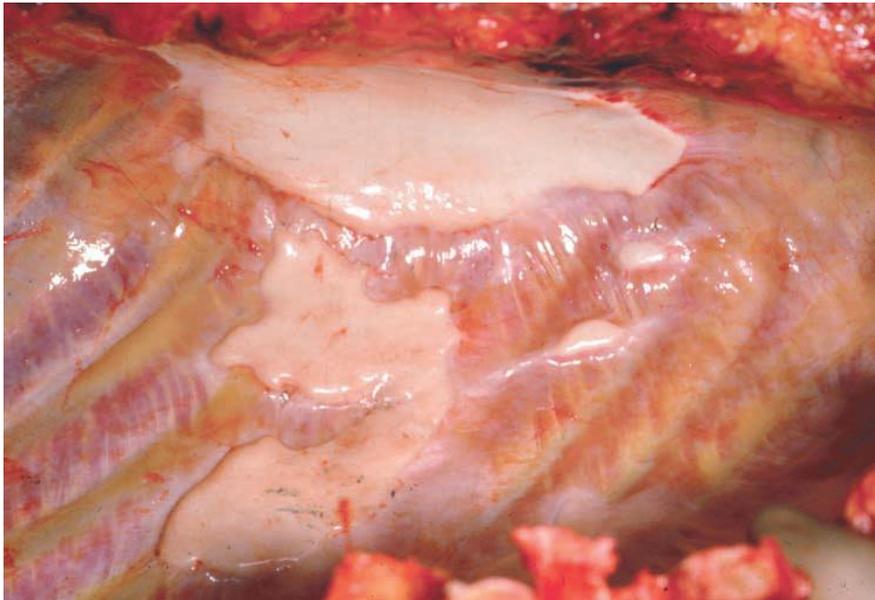




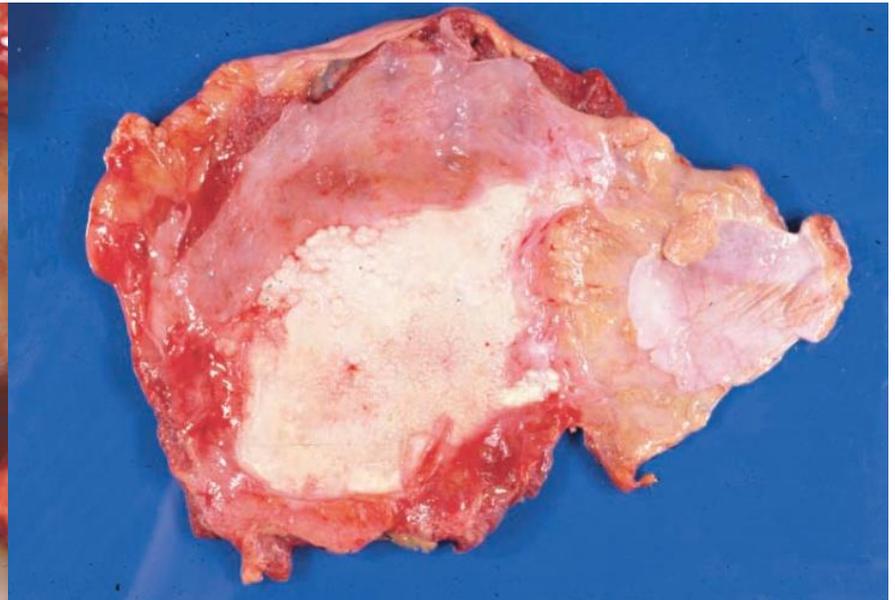
EPA Concludes LPT is endpoint for RfC

- Localized pleural thickening (LPT) is the critical effect for deriving an RfC.
- LPT (pleural plaques) are well-recognized as a marker of exposure to asbestos, meaning they rarely occur except following exposure to asbestos (i.e., they are “specific” to asbestos).
- Although pleural plaques have long been considered inconsequential markers of asbestos exposure, studies of large cohorts have shown a significant reduction in pulmonary function attributable to the plaques, averaging about 5% of FVC, even when interstitial fibrosis (asbestosis) is absent radiographically.
- Thus, LPT is a pathological change associated with decreased pulmonary function, and thus is considered an appropriate adverse effect for deriving the RfC.

What is localized pleural thickening (LPT)?



Gross appearance at autopsy of asbestos-associated pleural plaques overlying the lateral thoracic wall.



Gross appearance of large asbestos-related pleural plaque over the dome of the diaphragm.

Toxicity Values



	1988 General	2011	2014
	Asbestos	Draft	Final
IUR (Cancer)	0.23 (f/cc) ⁻¹	0.17 (f/cc) ⁻¹	0.17 (f/cc)⁻¹
RfC (Noncancer)*	No value	0.00002 fiber/cc = 20 fibers/m ³	0.00009 fiber/cc = 90 fibers/m³

Cubic centimeter (cc):



Cubic meter (m³):



*Following expert peer-review advice from the SAB, EPA implemented recommended changes in the exposure-response modeling resulting in a change in the RfC.



Summary

- EPA has conducted an extensive review and analysis of the cancer and non-cancer literature and data
- Based on human epidemiological data from the Libby miner population and the Marysville, OH worker population, EPA has developed toxicity factors for both cancer and non-cancer endpoints
- The cancer toxicity value [IUR] is 0.17 (f/cc)^{-1}
- The non-cancer toxicity value [RfC] is 0.00009 f/cc (or 90 fibers/m^3)
 - This is the first non-cancer toxicity value for a mineral fiber
- These values will be used in the risk assessment for the Libby Asbestos Superfund Site



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EPA Libby Action Plan Workgroup

EPA Agency Review: *Office of Solid Waste and
Emergency Response , Office of Water, Office
of Children's Health Protection and Regions
2,7,8, and 10*

Interagency Science Consultation & Discussion:

Department of Defense
NASA

Department of Health and Human Services
(ATSDR, NIEHS and NIOSH)

Office of Management and Budget & OSTP
Council on Environmental Quality

Science Advisory Board