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<p>Page 3 (Figures 1 & 2): An effort is made in these figures to provide a visual comparison between tremolite cleavage fragments and "Commercial Asbestos - Tremolite" from the NIST Standard Reference Material 1867a.</p>	<p>While pictures are worth a thousand words and were requested by several reviewers, this is a very poor pictorial comparison. The "asbestos" figure predominantly shows cleavage fragments and not the asbestiform crystal growth habit the picture text says it shows.</p> <p>In our prior Roadmap submission, File # 7 contained clear evidence that the NIST Standard Reference 1867a for tremolite used in figure #2 contains considerable nonasbestiform tremolite (cleavage fragments) -along with actual tremolite asbestos. NIOSH is encouraged to look to a purer tremolite asbestos standard for photomicrographs of actual tremolite asbestos so that the reader is provided a true photomicrograph comparison. Lapses of this sort serve only to further confuse and obscure the issues.</p> <p>RTV often recommends the work of the US Bureau of Mines as a viable reference source in terms of demonstrating the difference in crystal growth habit and clarification of mineral terms. Interestingly, it is believed that even the BOM counted and sized cleavage fragments in an asbestos standard material when attempting to size amphibole asbestos fibers by aspect ratio (IC 8751 BOM Circular 11977 -Select Silicate Minerals and Their Asbestiform Varieties: Mineralogical Definitions and Identification-Characterization - Figure 42 page 44). Even so, the work of the BOM provides a much improved comparison and discussion of the difference in crystal growth habit and various crystal shapes and patterns (single and aggregate) then does the present NIOSH draft. The drawings on page</p>	<p>As indicated by the commenter, pictures were included in the draft revised <i>Roadmap</i> in response to a peer reviewer's comments. Several pictures were chosen that would be generally informative. Based on these comments a much more detailed description of particles is needed. However, it is impossible to provide a complete and comprehensive atlas of all mineral types and forms that are discussed in the <i>Roadmap</i>. Also, mineralogists sometimes disagree on the nature of the mineral particles observed. Therefore, the value of including a few mineral particle pictures is minimal.</p>	<p>The pictures have been deleted from the <i>Roadmap</i>.</p>

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<p>Page 16-17: There is discussion on these pages regarding the regulation and control of asbestiform minerals (amphiboles in particular) that fall outside the six asbestos regulated minerals but known to pose the same pathogenic effect as asbestos.</p>	<p>24 (Figure 21) of this BOM document might be particularly helpful. A copy of this BOM Circular is appended.</p> <p>RTV would agree that enough flexibility in the regulatory system should exist to apply appropriate standards and controls when any significant risk is reasonably identified. As stressed in our cover correspondence, however, this should not be accomplished by abandoning the need to maintain accurate exposure characterization.</p> <p>Like NIOSH, RTV believes it is reasonable that the Libby asbestiform amphiboles winchite and richterite be included with the 5 listed asbestiform amphiboles and regulated under the generic term "asbestos". Health evidence and similarity in mineralogy support this. Other asbestiform or highly fibrous minerals outside the amphibole mineral group that reasonably show a "same as" asbestos risk (e.g. fibrous erionite -a zeolite), might also be regulated as stringently as asbestos (e.g. "apply asbestos std.") but should not lose their identity as a discrete mineral species or simply be referred to as asbestos due to a broader difference in the mineral species (not an amphibole or serpentine).</p> <p>Most importantly, care must be exercised not to "lump" nonasbestiform elongated mineral particulates of any kind under a single generic term that infers a single risk without adequate evidence for doing so (a debatable practice even then as the definition of "adequate" is likely to be different one researcher to the next). We believe to error on the side of safety is commendable, but also that prudence can be stretched too far - especially when it involves viewing major portions of the earth's crust as or "like" asbestos.</p>	<p>It is not the intent of the <i>Roadmap</i> to defend or revise existing NIOSH policy. NIOSH recognizes that the 1990 extension of its REL to explicitly include the nonasbestiform analogs as covered minerals lacked definitive scientific underpinning, and that some relevant subsequent research has been carried out since 1990. Thus, NIOSH was motivated to develop the <i>Roadmap</i>. It is anticipated that comprehensive and detailed review and assessment of available published scientific literature and other evidence, as well as new studies, will be undertaken in the research for which a framework is proposed in the <i>Roadmap</i>. In various places in the revised draft <i>Roadmap</i>, NIOSH stresses the need for careful characterization</p>	<p>No revision</p>

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<p>Epidemiological Studies (pages 18-27)</p> <p>NIOSH was responsive to commenter requests that the human cohort studies involving exposure to elongated amphibole cleavage fragments receive expanded discussion. Predictably, much of this discussion is devoted to RTV tremolitic talc mined in northern New York State. Though the discussion is generally balanced, there are a few misleading and speculative statements in addition to data omissions which should be addressed. On Page 18 this sections begins with the statement "Epidemiologic studies of populations with exposures reported to be nonasbestiform have been conducted in the talc mining region of upstate New York, the Homestake gold mine in South Dakota, and the taconite mining region of northeastern Minnesota." (emphasis added). At least in respect to RTV talc, previously submitted File #1 provides ample evidence that RTV talc workers are exposed to copious nonasbestiform amphibole particulate (mostly tremolite). Further, it was shown that many of these fragments satisfy the commonly applied description of an EMP particle as one with a 3 to 1 aspect ratio (a.r.) or greater that is also 5 micrometers or more in length. This elongated amphibole particulate easily exceeds the existing PEL and REL applied to asbestos fibers (0.5 -6.0 fibers/cc range recorded in the mine and mill).</p> <p>The nonasbestiform amphibole nature of this exposure has been repeatedly confirmed over a span of decades in analytical report after analytical report by highly regarded mineral scientists. Some 40-60% of this talc is clearly known to be nonasbestiform amphibole. We believe the phrase "have been reported to be nonasbestiform" is therefore disingenuous in respect to RTV talc and likely also in respect to the other mining exposures mentioned. The composition of RTV talc is very well defined and NIOSH should not suggest otherwise.</p>	<p>On Page 18 this sections begins with the statement "Epidemiologic studies of populations with exposures to EMP's that have been reported to be nonasbestiform have been conducted in the talc mining region of upstate New York, the Homestake gold mine in South Dakota, and the taconite mining region of northeastern Minnesota." (emphasis added). At least in respect to RTV talc, previously submitted File #1 provides ample evidence that RTV talc workers are exposed to copious nonasbestiform amphibole particulate (mostly tremolite). Further, it was shown that many of these fragments satisfy the commonly applied description of an EMP particle as one with a 3 to 1 aspect ratio (a.r.) or greater that is also 5 micrometers or more in length. This elongated amphibole particulate easily exceeds the existing PEL and REL applied to asbestos fibers (0.5 -6.0 fibers/cc range recorded in the mine and mill).</p> <p>The nonasbestiform amphibole nature of this exposure has been repeatedly confirmed over a span of decades in analytical report after analytical report by highly regarded mineral scientists. Some 40-60% of this talc is clearly known to be nonasbestiform amphibole. We believe the phrase "have been reported to be nonasbestiform" is therefore disingenuous in respect to RTV talc and likely also in respect to the other mining exposures mentioned. The composition of RTV talc is very well defined and NIOSH should not suggest otherwise.</p>	<p>of exposures (in both laboratory and epidemiological studies).</p> <p>In the revised draft <i>Roadmap</i> the following description of the mineralogy at RTV is provided "In contrast, a paper by Kelse [2005] reported the percentage by weight of talc from the RTV mine in upstate New York as 20-40% talc, 40-60% nonasbestiform tremolite, 15-30% nonasbestiform antigorite-lizardite, and 1-5% nonasbestiform anthophyllite. Up to 5.6% of the total product was comprised of talc and talc/amphibole fibers, and up to 1.8% of the minerals were reported to have an asbestiform habit (emphasis added) [Kelse 2005]".</p> <p>The revised draft <i>Roadmap</i> acknowledges the considerable variability in</p>	<p>No revision</p>

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<p>conducted in the talc mining region of upstate New York, the Homestake gold mine in South Dakota, and the talconite mining region of northeastern Minnesota." (emphasis added).</p>	<p>The nonasbestiform nature of amphiboles encountered at Homestake and in the talconite studies (cummingtonite-grunerite) are reasonably well documented and generally recognized as well. Further discussion on these nonasbestiform amphibole exposures, however, should be addressed by others.</p>	<p>mineral composition and morphology of the RTV geology. A research objective outlined in the <i>Roadmap</i> is the need for developing standardized mineral nomenclature that can be used for identifying discrete airborne EMPs in occupational epidemiology and experimental animal studies.</p>	
<p>On Page 19 and again on Page 23, NIOSH references early literature reports of elevated mesothelioma rates in certain NY counties in which talc mining is said to have occurred. NIOSH also correctly notes that this elevation no longer exists. NIOSH further notes, in regard to these past rates, that "Mesothelioma rates have been reported to be significantly elevated in Jefferson County, which is the site of much of the talc industry in New York." The suggestion is made in the references cited that these</p>	<p>Regional records indicate that at least 30 talc mining companies operated in the region with the earliest beginning sometime in the mid 1800's (we believe this to be the first talc mined in the United States). With the possible exception of one or two mines (though we know of none specifically), all of these mines are located in St Lawrence County -not Jefferson County.</p> <p>We also know this mining region presents a complex and varied geological deposit that is by no means one large homogenous rock north of Syracuse, New York. RTV does not know the exact mineral composition of other, now long defunct, talc mines in the region. As noted, however, the composition of RTV talc is well documented and since 1974, it is the only talc mined in the region. To make this point, the following excerpt from a geological description of the Balmat-Edwards talc mining district in St Lawrence county (location also of the RTV talc mine) can be cited:</p>	<p>The commenter's concern about the complexity of the geology and mineralogy of the talc mining region of Upstate NY seems valid.</p>	<p>The revised draft <i>Roadmap</i> has been revised by inserting the following caveat in Section 1.5.1.3.2: "Attributing these findings to employment in the RTV mine is difficult because there were</p>

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<p>talc mines may have posed (or contributed to) an environmental mesothelioma risk.</p>	<p><i>"The metamorphic alternation of the sedimentary Grenville limestones (over a billion years old) resulted in major deposits of tremolite, some of which was further altered to nearly pure talc, including many variations between. Plastic flow, faulting, and shearing added to the complexity of the ore-body. Efficiency mining required a great deal of prospect drilling and professional geological mapping in order to predict the highly complex deformation."</i> Fred Totten -Geologist</p> <p>We feel it is important that NIOSH make it clear when referencing observations involving an entire region (especially on a historical basis) to carefully note that the mining exposures addressed no longer exist and may not reflect those of current talc mining in the region (now limited only to RTV). Without this cautionary note, the reader is left with the impression that "a region" poses a single, homogenous mineral particulate exposure when we do not know that to be the case. Given the varied and complex geology of that region, a homogenous particulate exposure is, in fact, highly unlikely.</p>		<p>numerous mines operating in these counties and the mineralogic composition of the ores mined varied substantially [Peterson et al. 1993]. "</p>
<p>On Pane 19 NIOSH references the Hull paper in regard to lung tissue analysis findings.</p>	<p>John Addison performed a critical review of the analytical techniques used to perform the particulate identification in this paper in 2006. While the relevance of this case study to RTV talc remains uncertain (no work histories provided), Mr. Addison finds a number of methodological issues which he feels leaves some conclusions drawn by the authors as "unreliable". A copy of this review is appended and bears review in respect to reliance on this particular case study (published as a supplement paper) in respect to analytical</p>	<p>As a short summary of a presentation made at a scientific meeting, the Hull et al. [2002] report offers very limited detail on methods used, making an understanding of the report's findings difficult. More importantly, the Hull</p>	<p>The short paragraph on the lung fiber analyses by Hull et al. [2002] has been deleted from the <i>Roadmap</i>.</p>

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	<p>methods applied. Additional critical review on other aspects of the Hull paper has also been completed by researchers with varied disciplines (pathologists, statisticians, etc.). If desired, a copy of this extended critique can be provided upon request. Additional review may be found in previously provided File # 5 (Gibbs and Gamble overview of human studies involving nonasbestiform amphiboles).</p>	<p>et al. [2002] study included only 2 cases of mesothelioma, and it offers essentially no useful evidence for or against an association of that disease with occupational exposure in talc mines in Upstate New York. Moreover, the single paragraph in the revised draft <i>Roadmap</i> that summarizes the lung fiber analyses by Hull et al. [2002] tends to disrupt the more substantive content in that section on epidemiological studies of New York Talc Miners and Millers.</p>	
<p>On Page 20 in referring to the persistently elevated rate of lung cancer among RTV talc workers, NIOSH notes that the most "persuasive argument against a causal interpretation of these findings is that the lung cancer excess in this study population did not increase with duration and measures of exposure to talc dust."</p>	<p>Fortunately, RTV talc workers are among the most studied talc miners in the world so a reasonable amount of dust exposure data and work histories are available. This information appears sufficiently complete to provide at least a basic "plausibility" check of the alternative explanations provided by NIOSH.</p> <p>In respect to the issue of tenure and prior talc mining exposure, the following table shows the prior work histories of all lung cancer decedents reported in the most recent RTV talc mortality study (Honda, et al.) with less than 1 year of employment at the RTV talc mine and mill. This short</p>	<p>The data provided by the commenter do not appear to support the idea that workers may have had prior exposures in other mines. However, as the commenter notes, this information is not complete. First, the data only reflect 55% of the cases. It is possible that the other cases with longer employment at RTV also</p>	<p>No revision</p>

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<p>And that "the excess of lung cancer in this cohort has been reported to be limited to workers with short employment (< 1 years)".</p> <p>Toward the bottom of that page, however, NIOSH then offers "plausible" explanations for these inverse dose-response findings which it feels might still cast suspicion upon the dust as the causative factor. The two "plausible" concerns are expressed as follows: (a) short term RTV talc worker lung cancer cases may have been exposed to similar talc dust in other "neighboring" talc mines prior to RTV talc employment causing an unreported unrecognized long term exposure and (b), the respirable dust data used to gauge direct exposure-response relationships in the Honda et al study may not have adequately represented quantitative exposure to elongated mineral</p>	<p>tenure sub-group (17) represents 55% of the total 31 lung cancer decedents reported in this study. Histories were obtained from employment applications.</p> <table border="1" data-bbox="415 1003 1049 1587"> <thead> <tr> <th>Tenure at RTV</th> <th>All Prior Mining</th> <th>Prior Talc Mining</th> </tr> </thead> <tbody> <tr> <td>1 day</td> <td>Iron Mine 1 yr.</td> <td>0</td> </tr> <tr> <td>3 days</td> <td>0</td> <td>0</td> </tr> <tr> <td>6 days</td> <td>Zinc Mine 1 yr.</td> <td>0</td> </tr> <tr> <td>6 days</td> <td>0</td> <td>0</td> </tr> <tr> <td>8 days</td> <td>Iron Mine 1 yr.</td> <td>0</td> </tr> <tr> <td>16 days</td> <td>? (unclear record)</td> <td>?</td> </tr> <tr> <td>18 days</td> <td>0</td> <td>0</td> </tr> <tr> <td>27 days</td> <td>? (unclear record)</td> <td>?</td> </tr> <tr> <td>1 1/2 months</td> <td>0</td> <td>0</td> </tr> <tr> <td>2 months</td> <td>Zinc (1y), Iron (1y)</td> <td>0</td> </tr> <tr> <td>2 1/2 months</td> <td>0</td> <td>0</td> </tr> <tr> <td>2 3/4 months</td> <td>Zinc 16 yrs</td> <td>0</td> </tr> <tr> <td>4 months</td> <td>zinc, coal, talc 18 y total yes, but unspecified time</td> <td></td> </tr> <tr> <td>6 months</td> <td>zinc 1 1/2 y</td> <td>0</td> </tr> <tr> <td>8 months</td> <td>zinc 2 yrs, talc 1 yr</td> <td>1 yr</td> </tr> <tr> <td>10 1/2 months</td> <td>?(unclear record)</td> <td>?</td> </tr> </tbody> </table> <p>While there are some uncertainties due to incomplete records, there is little support for the argument that pre-RTV talc mining work histories (regional talc mining in particular) might explain elevated lung cancer among this short tenure sub-set. In the Gamble case control study (File # 2) this potential was also addressed, supports this observation and further lends no support to this NIOSH concern.</p>	Tenure at RTV	All Prior Mining	Prior Talc Mining	1 day	Iron Mine 1 yr.	0	3 days	0	0	6 days	Zinc Mine 1 yr.	0	6 days	0	0	8 days	Iron Mine 1 yr.	0	16 days	? (unclear record)	?	18 days	0	0	27 days	? (unclear record)	?	1 1/2 months	0	0	2 months	Zinc (1y), Iron (1y)	0	2 1/2 months	0	0	2 3/4 months	Zinc 16 yrs	0	4 months	zinc, coal, talc 18 y total yes, but unspecified time		6 months	zinc 1 1/2 y	0	8 months	zinc 2 yrs, talc 1 yr	1 yr	10 1/2 months	?(unclear record)	?	<p>had more history of employment in other talc mines. There are also a few cases in this group with missing information. It is also questionable whether employment records would provide reliable information on past employment.</p> <p>The commenter is correct that the issue of prior employment in talc mines was considered in the case-control study by Gamble. This is pointed out on page 21, line 18-21 of the revised draft <i>Roadmap</i>.</p>	
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<p>particulate. The latter concern was expressed on Page 22.</p> <p>NIOSH's second expressed concern, that the cumulative respirable dust exposure (33% lower for lung cancer decedents than all decedents) may not have been a reliable indicator of EMP exposure, can be tested as well.</p>	<p>This can be checked with available respirable dust to "fiber" count data (3:1 a.r. or more -5 um or greater lengths) through several sources. It is assumed EMP means particulate that satisfy this counting criteria.</p> <p>NIOSH (1980) Resp. Dust to Fibers/cc (Fibers >5 um 3: 1 or greater a.r.) For select mine and mill jobs with at least 2 data points -personal samples One sampling effort (over a period of several days in late 1970's)</p> <table border="1" data-bbox="779 882 1023 1596"> <thead> <tr> <th></th> <th>Resp. Dust</th> <th>Fibers/cc</th> <th>(Impinger)</th> <th>Mppcf</th> </tr> </thead> <tbody> <tr> <td>Mine: Scrapper/slusher</td> <td>1.29</td> <td>?</td> <td>11.8</td> <td></td> </tr> <tr> <td>Driller</td> <td>.98</td> <td>3.0</td> <td>11.7</td> <td></td> </tr> <tr> <td>Trammer</td> <td>.64</td> <td>5.6</td> <td>10.1</td> <td></td> </tr> <tr> <td>Mill: Wheeler Op.</td> <td>1.56</td> <td>8.4</td> <td>3.1</td> <td></td> </tr> <tr> <td>Hardinge Op. Packers</td> <td>1.09</td> <td>7.9</td> <td>3.4</td> <td></td> </tr> <tr> <td>Forklift Op</td> <td>.35</td> <td>4.0</td> <td>1.6</td> <td></td> </tr> </tbody> </table> <p>All Available Data: Resp. Dust to Fibers/cc (Fibers >5um 3: 1 or greater a.r.) For select mine and mill jobs with at last two data point comparisons - Personnel & fixed samples -all information sources -all avail. years</p> <p>() = number of samples used in average.</p>		Resp. Dust	Fibers/cc	(Impinger)	Mppcf	Mine: Scrapper/slusher	1.29	?	11.8		Driller	.98	3.0	11.7		Trammer	.64	5.6	10.1		Mill: Wheeler Op.	1.56	8.4	3.1		Hardinge Op. Packers	1.09	7.9	3.4		Forklift Op	.35	4.0	1.6		<p>As cited by the commenter, the NIOSH 1980 report "Occupational Exposure to Talc Containing Asbestos" concluded that dust concentrations (impinger and respirable dust) for operations in the mine and mill prior to 1970 were difficult to interpret due to the paucity of exposure data for some operations and the small number of samples taken in any given year. Fiber measurements had only been made in the mine and mill since the 1970s. Dust measurements (impinger) reported from several sources since 1954 for operations in the mine and mill indicated no consistent trends in dust concentrations when all mine operations were considered and a slight decrease in exposures for</p>	<p>The sentence on page 21: "Although the Honda study was based on reconstructed exposures to respirable dust, these exposure estimates may not be correlated with exposure to EMPs." And the sentence on page 26 "However, dust exposures are a very poor surrogate of exposure to nonasbestiform EMPs in these settings." have been replaced in the revised draft Roadmap to further explain the potential to attenuate the exposure-</p>
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	<p>Mppcf Mine: UG Crusher 17.2 (23) Scrapper/slusher 15.0(34) Drillers 14.1 (19) Trammer 7.9 (21) Mill: Wheeler Op. 10.1(32) Packers 16.0(69) Hardinge Op. 8.7(29) Forklift Op. 1.6 (2) Drier/crusher Op. 8.1 (31)</p> <p>Resp. Dust Fibers/cc - Total (Imp.) Dust</p> <p>1.2 (5) 1.5 (13) 6.9 (13) 1.1 (6) 0.3 (2) 3.2(4) 1.1 (8) 1.7 (12) 3.6 (4) .9 (5) 1.4 (18) 3.1 (4) .92 (24) 5.5(23) 3.8(32) .64(49) 1.7(7) 2.9(48) .57(25) 2.9(48) 1.7(28) .54 (8) 4.0 (2) 2.0 (12) .54(23) 0.8 (6) 3.2 (24) 8.1 (31)</p> <p>It is difficult to use these data with high confidence as respirable dust and fibers/cc data should represent the same sampled activity on the same day, same sample duration, either be personnel samples or fixed samples (not mixed) and be processed/analyzed by the same laboratory. The NIOSH data is closest to satisfying these features but the data is limited to a relatively short sampling period (several</p>	<p>some mill operations. However, the interpretation of these measurement results is difficult due to the limited number of samples collected in any calendar year. As noted by the commenter, it is difficult to determine with high confidence the relationship between respirable dust measurements and fiber exposure data unless simultaneous measurements are made at the same job or operation and sampled for the same duration. In addition, given the limited amount of historical dust measurement data, it's difficult to assess the variability of exposures that may have occurred at operations over time and how that variability in dust concentrations was related to fiber concentrations. In addition, relationships between health outcomes and exposure to an agent of interest can be attenuated when a nonspecific exposure indicator is used as a surrogate for exposure to the agent of interest [Blair et al. 2007; Friesen et al. 2007]. Thus, when the exposure index used to assess the effect of EMPs is based on a surrogate measure, such as respirable dust, rather than on specific measurement of EMP concentrations, the lack of an exposure-response</p>	<p>relationship by using surrogate data with the following: 'Relationships between health outcomes and exposure to an agent of interest can be attenuated when a nonspecific exposure indicator is used as a surrogate for exposure to the agent of interest [Blair et al. 2007; Friesen et al. 2007]. Thus, when the exposure index used to assess the effect of EMPs is based on a surrogate measure, such as respirable dust, rather than on specific measurement of EMP concentrations, the lack of an exposure-response</p>

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	<p>weeks).</p> <p>In preparing the "all available data" table, personnel samples were predominantly used for respirable dust and fibers/cc data points. Total dust tended to be fixed samples as did impinger samples. Indicators of data variability are not included in this table but could be produced (ranges, standard deviations, etc.). Data sources included NIOSH data, company sampling data, insurance company data, regulatory agency data, researcher data and NY State Health Dept. data (early impinger work). The earliest data points appeared in 1952 (RTV talc mining began in 1948) and continued through 2007.</p> <p>It would seem reasonable that as respirable dust levels increase, respirable elongated mineral fibers (EMPs) present in the airborne dust, would also increase. Available comparison data does not appear to contradict this. The data set indicates that higher respirable dust levels "generally" do tend to reflect higher EMP levels. Admittedly, the difference in respirable dust levels between various common job activities is not very significant (particularly in the mill) and there are several fiber count levels that seem to buck the correlation trend -but these involve only a few data points. In general, available dust data does not, in my opinion, support the unreliability of using respirable dust in the dose-response analysis referenced in the Honda, et al paper. Certainly no clear, significant disparity is seen between comparative levels of respirable dust versus EMP levels.</p>	<p>exposure indicator is used as a surrogate for exposure to the agent of interest [Blair et al. 2007; Friesen et al. 2007]. Thus, particularly where the composition of a mixed exposure may vary by work area, an exposure-response relationship developed to assess the effect of EMPs must be considered suspect if the exposure index used is based on measurements of dust concentrations and not specifically on measurements of EMP concentrations.</p> <p>It is anticipated that a comprehensive and detailed review and assessment of available published scientific literature and other evidence will be undertaken in the research for which a framework is proposed in the <i>Roadmap</i>. An important research objective is the identification of workplaces</p>	<p>relationship between the exposure index and the health outcome must be considered suspect particularly where the composition of a mixed exposure varies by work area."</p>

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	<p>Though the two explanations for the lack of exposure-response in RTV Talc worker lung cancer mortality studies offered by NIOSH are plausible considerations, available data does not support either one.</p> <p>Importantly, there is additional evidence of the absence of a "same as asbestos" risk among RTV talc previously provided in file #2 which was not addressed in the updated NIOSH draft pages 18-23. Given the importance of the Vanderbilt talc cohort in regard to elongated non-asbestiform amphibole exposure (EMP), each piece of evidence should be addressed in some form and recognized as part of a data base that either supports a dust causal link or does not. It is the totality of evidence in respect to RTV talc that we feel is most compelling -not one single study.</p> <p>Not mentioned in the draft are references to the fact that nonmalignant respiratory disease among Vanderbilt talc workers does follow the classic dose-response pattern (noted by NIOSH, Honda, et al and other researchers). RTV talc workers most exposed show the highest levels of nonmalignant respiratory disease said to be dust linked -or likely to be over the study period (1960-1989). Elevated exposure to any talc over time can cause "talcosis". NIOSH</p>	<p>where workers are exposed to EMPs so that appropriate studies can be initiated to determine the extent of exposure and the feasibility of conducting epidemiology studies.</p> <p>The commenter is correct in suggesting that it is important to note that an exposure-response relationship was observed for NMRD and pneumoconiosis in the RTV studies.</p>	<p>To address this concern, the following sentence has been inserted at the end of the paragraph describing the results from the recent Honda et al. study: "In contrast, exposure-response relationships were observed in this study between cumulative exposure to respirable dust and NMRD and pulmonary fibrosis."</p>

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	<p>should explain, if NIOSH still believes exposure to RTV talc dust caused the excess lung cancer, how these two contradictory exposure findings can exist in the same cohort.</p> <p>Also provided in File #2 but not mentioned, are more up-to-date non-malignant respiratory disease observations summarized by Brian Boehlecke, MD (a former NIOSH pulmonary specialist and Professor of Medicine at the University of North Carolina).</p> <p>These observations were derived from the results of RTV's semi-annual medical surveillance program. Observations of this nature covering a span of 15 years (1985 - 2000) for existing employees made by an occupational pulmonary specialist of some note would seem worthy of mention. Again, this is a cohort likely exposed to the highest concentration of elongated amphibole cleavage fragments in the world (in addition to talc fiber in several forms). It should be noted, in this regard, that RTV talc miners are a union work force with a seniority system. Upwards of 60% of Vanderbilt talc workers have worked 20 years or more at the Vanderbilt talc mine and mill (30% 30 years or more). As reflected in the status summary, Dr. Boehlecke does not find the pulmonary experience of these talc workers to be consistent with that of a workforce exposed to asbestos. This observation can not be dismissed due to an over abundance of short term workers who had not yet had time to manifest dust linked pulmonary abnormalities.</p> <p>Over 30 years have passed since the extremely elevated dust exposures recorded in other area talc operations ended (see data previously submitted). As a result, Vanderbilt talc</p>	<p>Dr. Boehlecke's reports do not appear to have much bearing on this issue. These reports are based on a series of cross-sectional examinations, which would be very unlikely to detect an excess of lung cancer or mesothelioma. He did identify individuals with pleural plaques and pulmonary fibrosis both of which are, in fact, consistent with findings in asbestos workers. The fact that his most recent studies have only one pneumoconiosis case would appear to be a testament to efforts at controlling dust exposures at RTV, but does not argue against there being an asbestos-like pattern of disease.</p>	<p>No revision of the revised draft <i>Roadmap</i> was made in reference to Dr. Boehlecke's reports.</p>

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	<p>workers now reflect the effects of much lower over-all dust levels experienced only at the Vanderbilt mine. In 2000 Dr. Boehlecke records only one case of irregular opacities consistent with a dust etiology at a 110 profusion level -with no change to 1994. The most recent medical surveillance findings (2008) continue to show only this one pneumoconiosis case which has now advanced to a 1/2 profusion level after 34 years of employment.</p> <p>Pleural plaques, found among both asbestos and talc workers (and perhaps linked to other mineral exposures), are also observed among approx. 10% of workers with an excess of 20 years of talc work (without decrements in lung function observed). We believe this is among the best pulmonary experience in the mining industry -not among the worst.</p> <p>Also not mentioned as yet another indicator of the absence of a "same as asbestos" effect is the comparison made by Lamm (1988) between RTV talc workers and Vermont talc workers in regard to lung cancer and non-malignant respiratory disease (see previously provided File # 2). Please note that this is not the same reference to Lamm (1988) which addresses short term workers. While cohort to cohort comparisons are admittedly difficult to make, this VT to NY comparison appears to be among the most defensible (i.e. same years of operation, similar cohort numbers, absence of quartz as a confounder, similar over-all dust levels, etc.). The key distinction between these two talc exposures is the absence of non-asbestiform amphiboles in Vermont talc versus the 40-60% prevalence in RTV NY talc.</p> <p>For workers with more than one year exposure in both</p>	<p>This is a very important observation. The fact that respiratory disease excesses are similar in RTV and Vermont talc workers might argue against the hypothesis that the excess is related to elongated particles, which are reportedly not present in the Vermont talc mines and mills.</p>	<p>The following sentence has been inserted at the end of the paragraph discussing the Vermont talc worker studies (line 7 on page 23 of the revised draft <i>Roadmap</i>): "It has been argued [Lamm and Starr 1988] that this provides evidence against the</p>

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<p>On Pane 21 there is a discussion of the Gamble (1993) nested case control study of RTV talc workers. As noted in this study, Dr. Gamble addresses several possible explanations for the persistent lung cancer rates among RTV talc workers such as smoking and prior</p>	<p>mining populations, the lung cancer rate is no different among Vermont talc workers than among Vanderbilt NY talc workers. Interestingly, the rate of non-malignant respiratory disease linked deaths is actually much higher among Vermont talc workers. When considering whether non- asbestiform amphiboles do or do not pose an asbestos like risk, this comparison would seem worthy of mention (even if only to debate the strength or significance of the comparison). This comparison study should be addressed when discussing Vermont talc worker studies on page 22.</p> <p>Lastly, also not mentioned but provided in File # 2, is the link between several of the animal and cell studies referenced in the NIOSH draft and the use of Vanderbilt talc in these studies. This will be addressed further in the animal and cell studies section as this is an important part of the science base in respect to RTV talc and should be addressed. These studies lend no support to RTV talc as a "same as" asbestos exposure.</p>		<p>hypothesis that the lung cancer excess among RTV miners is related to exposure to asbestos or nonasbestiform EMPs, since these were not known to be present in Vermont talc. A similar pattern has been observed in the studies of talc miners and millers at RTV."</p>
<p></p>	<p>NIOSH and others, however, have stated that while smoking prevalence is elevated, it can not account for the entire excess. In contrast, Dr. Gamble has stated that it could be because the prevalence recorded does fit within the confidence intervals of his study. Dr. Gamble notes that there is a 73% smoking prevalence among the non-case controls -not just the 100% prevalence found among the cases. This conflict of interpretation might also be linked to the selection of which smoking "mode!" is used to calculate cancer rates (apparently there are conservative models and</p>	<p>The paper by Gamble does note that the confidence intervals from his study includes the theoretical 1.60 odds ratio (OR) that Brown had suggested was the maximum possible OR that could be attributable to smoking. However, this theoretical OR of 1.6 is</p>	<p>No revision needed</p>

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<p>employment. The author concludes that smoking provides a more plausible explanation for the persistent excess lung cancer observed than does exposure to RTV talc dust (whatever its composition) or prior employment exposures.</p>	<p>less conservative models). Dr. Gamble does defend his position in his case control study (page 453) and RTV does not feel NIOSH has adequately addressed his assessment</p>	<p>based on an assumption that 100% of the cohort would be smokers. This clearly not likely to be the case—in the Gamble study 64% is the best estimate of the percentage of smokers in the population. The fact that 100% of the lung cancer cases smoked is not unusual and is similar to what is seen in other studies of occupational exposures, including asbestos. There are several simulation studies that have clearly demonstrated that relative risks (or ORs) of greater than 1.5 for lung cancer are unlikely to be due to smoking in occupational studies. It still seems to be highly improbable that the excess of lung cancer observed in these studies could be fully explained by smoking.</p>	
<p>On Page 22 -second paragraph NIOSH states "NIOSH (1980) reported that dust from these talc mines</p>	<p>In this NIOSH 1980 Technical Report, elongated amphibole particulate in RTV talc was not simply described as EMPs. On the Abstract page (iv) of this 28 year old report the industrial hygiene portion of the study flatly states: "Time-</p>	<p>The commenter points out an inaccuracy in the revised draft <i>Roadmap</i>.</p>	<p>This statement has been revised to read: "NIOSH [1980] reported that</p>

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<p>contains chrysotile, tremolite EMPs, and anthophyllite EMPs. However, the identification of these EMPs as asbestiform has been the subject of debate." This statement does not accurately reflect what NIOSH actually said in 1980.</p>	<p>weighted average (TWA) exposures to asbestiform amphiboles (anthophyllite and tremolite) were found to be in excess of present U.S. Occupational Safety and Health (OSHA) and Mine Safety and Health Administration (MSHA) occupational exposure standards -etc.-". There is no "debate" or confusion reflected in that statement. NIOSH clearly described the tremolite and anthophyllite found in RTV talc as "asbestos" -not EMPs. In roughly the same time period, NIOSH did exactly the same thing with nonasbestiform cummingtonite- grunerite exposures at the Homestake mine (which NIOSH referred to as "amosite"). RTV believes this occurred because NIOSH maintained this "policy" of viewing the elongated cleavage fragment analogs of asbestiform minerals as the "same as asbestos" based on perceived risk (the utilization of risk -real or imagined -to justify improper mineral characterization).</p> <p>In respect to the minor talc and transitional fiber found in RTV talc, confusion is understandable. In the mid 1970's analytical expertise and instrumentation was not as sophisticated as it is today in respect to the ability to properly identify these unusual particulates. However, the identification of nonasbestiform amphibole cleavage fragments in RTV talc (tremolite in particular) as asbestos should not have occurred. NIOSH is to be commended for withdrawing this dated Technical Report from its document library. It is unfortunate, however, that it continues to be referenced.</p>	<p>In the Kelse [2005] White Paper the following</p>	<p>dust from these talc mines contains chrysotile, tremolite, and anthophyllite asbestos. However, the identification of these minerals as asbestiform has been the subject of debate."</p>
<p>Also on page 22 in the same paragraph, NIOSH quotes</p>	<p>That is not what was reported in the White Paper. The statement in this document reads as follows: "The combined</p>	<p>In the Kelse [2005] White Paper the following</p>	<p>To accurately reflect Kelse's</p>

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<p>the mineral composition of RTV talc provided in an RTV document known as the "White Paper". In reporting this composition the NIOSH draft states: "Up to 5.6% of the total product was comprised of talc and talc/amphibole fibers, and up to 1.8% (typically about 0.5% by weight) of the total product was reported to be asbestiform amphibole fibers." (emphasis added).</p>	<p>weight of those fibers that do exhibit an asbestiform growth habit typically falls around 0.5%. These fibers are not cleavage fragments nor are they asbestos." Above this statement it is pointed out that the "fibers" referenced are talc and transitional fibers -not amphibole asbestos fibers. This misstatement in the NIOSH document should be corrected. We know of no "asbestiform" amphibole fibers that have ever been confirmed in RTV talc (only mischaracterizations of cleavage fragments or transitional fibers).</p> <p>Part of the transitional or mixed fiber is amphibole and part (typically the majority) is talc. The properties of these mixed fibers are not those of pure amphibole or pure talc. Again, it is important that proper mineral characterization always be applied. NIOSH did a reasonable job of describing transitional minerals in this draft document.</p>	<p>statement is made "The term <i>asbestiform</i> merely means <i>like asbestos</i>. Asbestiform fibers grow like asbestos, they look like asbestos, they exhibit parallel crystal growth, they are flexible, they appear as fiber bundles with splayed terminations, they are very long and thin. However, these characteristics do not make them asbestos merely because they exhibit morphological similarities."</p>	<p>report, this statement has been revised to read: "Up to 5.6% of the total product was comprised of talc fibers and talc/amphibole fibers. Up to 1.8% was reported to have an asbestiform habit, though the asbestiform component was reported not to be asbestos [Kelse 2005]."</p>
<p>On page 22 bottom paragraph, the NIOSH cohort study of Vermont talc miners and millers is discussed. As noted above, we believe the Lamm (1988) comparison study with RTV talc should be addressed in this section. Beyond that, however, NIOSH describes in this section its rationale for not linking the moderate excess lung cancer observed</p>	<p>NIOSH findings among RTV talc workers are very similar in respect to millers versus miners. Yet, despite this similar observation, NIOSH makes no mention of this for RTV talc and suggested in the late 1970's that the excess lung cancer noted among RTV talc workers was dust linked. RTV believes this occurred because NIOSH incorrectly believed there was asbestos in RTV talc. Bearing that possible bias in mind, the observations of Lamm (1988) comparing NY talc workers with Vermont talc workers should be of particular interest.</p>	<p>The commenter correctly points out that a similar pattern in the results for miners versus millers was observed in the of RTV talc studies as in the Vermont talc studies. In both cases NMRD was observed to be elevated in both miners and millers, but lung cancer mortality was only observed to be in excess among miners. This is an</p>	<p>The following sentence has been added to the text at the end of the first paragraph on page 23 line 7 of the revised draft <i>Roadmap</i>: "A similar pattern has been observed in the studies of talc miners and millers at RTV. In the</p>

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<p>among Vermont talc workers to the talc dust. In part, this was due to the contradiction seen between the non-malignant respiratory disease (NMRD) experience versus the lung cancer experience. Higher dust levels in the mills produced higher NMRD but not lung cancer. Instead, excess lung cancer was observed among the miners who experienced lower dust exposure than the millers</p>		<p>important observation.</p>	<p>most recent update of this cohort [Honda et al. 2002], NMRD mortality was found to be significantly increased among both miners and millers. However, the excess of lung cancer mortality was predominantly among miners.”</p>
<p>On page 23 under summary comments, we believe this summary would not read as it does if the above omissions had been addressed.</p>	<p>We believe studies of RTV talc (which include the results of animal and cell experimentation -see below) more convincingly point away from this talc as a "same as" asbestos exposure. NIOSH discussion of RTV talc studies is, however, better balanced than it has been in the past. RTV believes NIOSH continues to maintain a bias when it comes to studies of RTV talc.</p>	<p>To address apparent remaining "imbalance" in the revised draft <i>Roadmap</i>, all comments have been carefully reviewed, resulting in additional revisions.</p>	<p>See descriptions of specific additional revisions made in response to other comments.</p>
<p>On Page 28 NIOSH again outlines the position it has historically held in regard to elongated non-asbestiform amphiboles and serpentines articulated at the OSHA hearings in 1990 (i.e. treat as asbestos). NIOSH first points to animal studies as the basis</p>	<p>In effect, the "dimensional" argument presented by NIOSH was applied to non- asbestiform particles in a broad-brush way. The animal studies cited did not, in actual fact, support the position NIOSH took because the "dimensions" most implicated belong to those most commonly found among asbestos fibers -not elongated nonasbestiform amphibole cleavage fragments. Differences in biologic effect and particle dimension between asbestos fibers and elongated cleavage fragments in animal and cell studies have been</p>	<p>In the revised draft <i>Roadmap</i>, two <i>in vivo</i> studies are discussed on page 28. The first (Smith et al. 1979) was negative for nonasbestiform EMP-induced tumors, while the second (Davis et al., 1991) was positive. It was noted</p>	<p>No revision</p>

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<p>of this position or "policy". The animal studies cited by NIOSH, however, do not actually show a "same as asbestos" risk for elongated non-asbestiform particles but rather merely support the importance of mineral fiber length, width and bio-persistence.</p>	<p>reviewed by several authors (see previously provided examples in File # 5) and in papers cited by NIOSH such as Wylie et al (1993).</p> <p>As discussed at some length in our prior submission, discussion of "similarly sized" or "appropriately sized" asbestos fibers and elongated cleavage fragments are believed to be greatly exaggerated in terms of what is commonly found. The expanded discussion with references in previously provided File # 6 in our prior submission should be reviewed in this regard. RTV has come to believe that much of this "similarly sized" argument originates from sizing elongated cleavage fragments found in asbestos standard samples and/or excessive grinding in sample preparations. The prevalence of "similarly sized" is grossly exaggerated -especially when the fibrillar bundling structure of asbestiform fibers is ignored.</p> <p>NIOSH cites Stanton Page 28 and again on Daze 40 as one of the supporting animal studies for its earlier position. In doing so, however, NIOSH fails to mention that talc samples #6 and #7 are RTV tremolitic talc samples which contain upwards of 50% nonasbestiform amphibole (tremolite in abundance). These samples produced 0% tumors in the experimental animals. Interestingly, sample #6 also recorded a log number of Stanton critical dimension fibers (longer than 8 micrometers and thinner than 0.25 micrometers). This sample should have produced upwards of a 60% tumor response based upon the Stanton hypothesis -yet no tumors were observed.</p> <p>Contradictions of this type to the "Stanton hypothesis"</p>	<p>that for both there was an issue of contamination with asbestiform structures. This appears to be a balanced discussion of the need for better data.</p> <p>The comment later cites Wylie et al. (1997) as supporting an assertion that nonasbestiform structures have low biological activity <i>in vitro</i>. However, the comment includes a quotation from the paper "indicating an important role of mineralogical composition rather than size of fibers." This is the critical point. Looking at the body of several publications from the Mossman group, the importance of particle-induced generation of reactive oxidant species in activation of cell signaling pathways <i>in vitro</i> is noted. Generation of reactive species is a property of composition, not dimension. Therefore, one</p>	

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	<p>suggest to other researchers that mineral type is also plays a role -as NIOSH does point out. These "critical dimension" fibers were not cleavage fragments but rather the talc and transitional fiber found in RTV talc. File #2previously provided contains documentation confirming the identity of those two talc samples. When discussing RTV talc, NIOSH failed to point this out as additional evidence for or against RTV talc as posing a "same as" asbestos risk.</p> <p>Although on Page 40 NIOSH references an In Vitro study by Wylie, Mossman, et al (1997). This study is discussed in regard to the importance of experimental design and exposure metrics such as fiber mass, fiber number, or fiber surface area. NIOSH does not mention, however, that this cell study is yet another study that specifically involved a comparison between RTV talc and asbestos. In this instance the purpose of the study was to contrast a concentrate of RTV talc fiber (with transitional fibers) against an equivalent (or as close to equivalent) concentrate of asbestos fiber (crocidolite and chrysotile in this case). FD-14 (RTV talc used in the Smith animal study -see below) was used in the experiment as well as a whole product comparison.</p> <p>In this study, all elongated particulate in each sample were carefully sized. The researchers noted a difference in cell proliferative effects (in Hamster Tracheal Epithelial cells) that "could not be explained by differences in fiber dimensions or surface areas, indicating an important role of mineralogical composition rather than size of fibers." Cytotoxicity for all fibers > 5 um and similar surface area was similar but cytotoxicity is not generally viewed as a measure of carcinogenicity and can be produced with many</p>	<p>would expect both asbestiform and nonasbestiform structures of the same elemental composition to generate oxidants. This is a reason why the <i>Roadmap</i> calls for further research in this area.</p>	

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	<p>non-asbestos materials with no demonstrated carcinogenic effect (as we understand it).</p> <p>NIOSH also references Smith (1979) (Page 28 and again on page 47) and points out some possible limitations in this study. This IP injection study contrasted tremolite asbestos to nonasbestiform tremolite. Whatever the limitations, this study did show tumor production above background for the asbestos samples and 0% tumors for the nonasbestiform tremolite tested in the same way. One of the nonasbestiform samples (FD-14) was an off-the-shelf sample of RTV talc and the other a concentrate of nonasbestiform tremolite of respirable size that originated from the RTV talc ore body. The presence of these two RTV samples in this study was not mentioned. File #2 (previously provided) contains documentation confirming the identity and origin of these samples. NIOSH does point out that the FD-14 (RTV talc) sample did contain tremolite with a 13% fiber content as defined by a 3:1 aspect ratio.</p> <p>These are two early animal studies (pre 1990) that directly involved RTV talc and independently produced the same result -no tumors. In contrast, tremolite asbestos and other forms of asbestos tested under the same test conditions produced tumors. While there may or may not be protocol lapses in these studies (to few animals, not enough dose variations, experiment too short, etc.) neither provide a shred of "same as" asbestos evidence for elongated nonasbestiform amphiboles or the talc and transitional fiber found in RTV talc. Failure to point out that these animal studies produced negative results for RTV talc in contrast to tremolite asbestos does not inform the reader in respect to</p>		

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<p>On Page 29 (and again on Page 48) NIOSH discusses the study by Davis et al. 1991. This study contrasted three tremolite asbestos samples to three tremolite samples described as nonasbestiform but of differing morphologies (granular to highly elongated or acicular). Early into this IP injection study numerous animal deaths and tumors were observed for the asbestos exposed animals while none was observed for the non-asbestos tremolite exposed group</p>	<p>additional evidence that RTV talc may or may not pose a "same as" asbestos exposure (a "weight of evidence" consideration possibly more important than the strengths or weaknesses of a single study).</p> <p>As NIOSH notes, however, at the very end of the study one non-asbestos tremolite sample (Italian Sample) produced a significant 67% pleural tumor rate. The authors found and reported an asbestos subpopulation in this sample and attributed the late hour tumors to this low dose asbestos exposure. A second non-asbestos sample (also containing unusually high aspect ratio material) produced a 12% late hour tumor prevalence when the authors consider fewer than 10% to be background at a 10 mg dose. It was noted (page 48) that this sample also contained some long, thin asbestiform tremolite fibers though fewer than observed in the Italian sample. The authors concluded this sample (uncharacteristic of typical cleavage fragment populations) "is unlikely to show evidence of carcinogenicity following administration by the more natural route of inhalation" and that this material "is probably to be considered harmless to human beings." The third non-asbestos tremolite sample (more granular/prismatic) produced below background tumors.</p> <p>Though these observations are mentioned by NIOSH, there is a note of reservation made in this presentation suggesting that the asbestos subpopulation might not simply explain the tumors observed in the predominantly nonasbestiform tremolite samples. There is the suggestion that the high acicular nonasbestiform tremolite in these samples may be</p>	<p>The revised draft <i>Roadmap</i>'s description of the Davis et al. [1991] results was not intended to imply that nonasbestiform EMPs are the only reasonable cause of the tumors resulting from exposure to the Italian tremolite. While the description largely succeeds in this, as evidenced in the comment, some additional minor revision where the description referred to "the Italian nonasbestiform tremolite" could help address this comment.</p>	<p>The statement that appeared on page 40, lines 29-32, has been revised by deleting the word "nonasbestiform" as follows: "It has been suggested that the response reported for the Italian nonasbestiform tremolite is of a pattern expected for a low dose of highly carcinogenic asbestos tremolite [Addison 2007]."</p>

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	<p>fully responsible or have acted in a contributory manner. It is not possible to "prove" this one way or the other without sample purification and retesting of these high acicular tremolite samples. As the authors point out, however, relatively minor amphibole asbestos subpopulations in otherwise nonasbestiform exposures is likely the more plausible explanation in an animal study in which materials are deposited directly on or into the highly sensitive pleura.</p>		
	<p>NIOSH's discussion of health studies continue to promote fiber size over crystal growth distinctions and other particulate characteristics as most key to asbestos and other EMP risk. This orientation, however, appears significantly less pronounced than that seen in the first NIOSH draft.</p> <p>As earlier noted, RTV does not dispute the key role particle dimension plays in particulate risk but does believe crystal growth habit, mineral type and linked physio-chemical properties also play a key role. RTV agrees with NIOSH that these variables (section 1.6.3 pp 34-38) deserve additional investigation.</p> <p>In regard to nonasbestiform elongated minerals NIOSH does note the conclusions of researchers on Page 48, 49, 51 and 52 who have both reviewed the literature and directly studied the distinction between elongated particulate and asbestos fiber. These researchers conclude that a distinct difference in biologic effect is consistently demonstrated in the human, animal and cell work completed to date (Addison, McConnell, Mossman, Berman, Gibbs, Gamble and others). The health link to fiber dimensions most</p>	<p>The revised draft <i>Roadmap</i> clearly states that it is a general overview of the available literature with the intent to identify the key areas of uncertainty that may impact worker health. The <i>Roadmap</i> is not intended as a comprehensive review of the literature nor is it intended to produce a comprehensive analysis of all issues. NIOSH recognizes and states in the revised draft <i>Roadmap</i> that the available studies indicate differences between toxicity of the asbestiform and nonasbestiform particles. However, it is an integral</p>	<p>No revision</p>

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	<p>characteristic of asbestos fibers is further cited by NIOSH through the work of other researchers (Lippmann, Stanton, Dement, etc.).</p> <p>RTV believes that while improved, NIOSH continues to subtly "imply" an asbestos fiber risk for elongated cleavage fragments throughout the draft document. This occurs each time a study showing a difference between asbestos fiber and non-asbestos particulate is critiqued by NIOSH as potentially faulty -or worse, when pertinent studies are not addressed at all. The strengths and weaknesses of studies should be recognized but care should be taken to avoid implying results may not be meaningful -especially if consistent with other studies and in the absence of evidence to the contrary.</p> <p>Another example, is the advancement of general fiber risk theories that can be interpreted as suggesting non-asbestos EMPs might pose an asbestos risk "if of appropriate size or "if in sufficient concentration, etc. Pointing out the fact that the vast majority of asbestos fibers are typically shorter than 5 micrometers and that this is consistently observed in lung tissue (Dodson et al.) is an example of an implied risk. Such an observation (as NIOSH did recognize) does not necessarily mean these short fibers "cause" all or some asbestos disease end points. The health literature generally does not support this short fiber association however prevalent short asbestos fiber may be. NIOSH recognizes this as well.</p> <p>Extrapolations from asbestos fiber mechanism studies to elongated particulate can be viewed as speculative as well.</p>	<p>part of the scientific process to point out the strengths and weaknesses of the arguments in favor of any hypothesis. In keeping with the purpose of the <i>Roadmap</i>, an overview of the strengths and weaknesses of the available health-related information on nonasbestiform analogs are provided in the revised draft <i>Roadmap</i>. These studies are critiqued in the same manner as the studies on short asbestos fibers mentioned by the commenter.</p> <p>It is not the intent of the <i>Roadmap</i> to defend or revise existing NIOSH policy. It is anticipated that</p>	

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	<p>To the extent nonasbestiform elongated particulate may share some compositional similarities to tested asbestos fibers, these similarities should be recognized and not presumed to be risk linked characteristics until proven to be.</p> <p>RTV would not argue against any insufficiently explored hypothesis being tested, or against the value of identifying a universal EMP risk linked characteristic (if one exists).</p> <p>RTV believes, however, that theoretical constructs should not overshadow direct study results or the "trend" direction of these results. Since no study is without fault, the significance of the totality of evidence (human, animal and cell) takes on extra importance in our view. RTV does not believe NIOSH would argue with this general concept, but the tenor of the draft document indicates that the Institute is not yet ready to fully embrace it when it comes to EMP or when addressing RTV talc specifically -even though the objectivity of NIOSH in both areas shows improvement in our view. RTV believes the objectivity of NIOSH in this area does, however, show improvement.</p>	<p>comprehensive and detailed review and assessment of available published scientific literature and other evidence, as well as new studies, will be undertaken in the research for which a framework is proposed in the <i>Roadmap</i>.</p>	