

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>IMA-NA believes that NIOSH made a significant mistake by inappropriately expanding the scope of the draft Roadmap from a proposed pathway for scientific research to a hybrid document incorporating broad statements of NIOSH policy. In the process NIOSH has injected its own perception of the state of the science and colored the proposed research agenda.</p> <p>The draft revised Roadmap now is cast as a Current Intelligence Bulletin. According to the NIOSH Web site, Current Intelligence Bulletins "review and evaluate new and emerging information about occupational hazards." IMA-NA finds this at odds with the stated goal of the Roadmap and revised Roadmap:</p> <p>The purpose of the Roadmap is to outline major areas of controversy and to recommend a research framework that can serve as a guide for the development of specific research programs within and across disciplines. The intended goals of the research to be undertaken are to provide answers to current scientific questions, reduce scientific</p>	<p>The purpose and scope of the <i>Roadmap</i> have not changed between the draft and the revised draft versions. The reason for incorporating NIOSH's existing policy in the revised draft <i>Roadmap</i> was to provide an understanding of the basis for the proposed research. The wording of the existing recommendation has been clarified to ensure unambiguous use of terminology acceptable to the mineralogical community, as several peer reviewers recommended. The intent and implementation of the existing policy is not changed in any way by the rewording. The proposed rewording of the existing policy should not be construed as a draft revised REL.</p> <p>The proposed rewording to clarify the existing recommendation does not change the potential impact of the legislation currently pending in Congress that would mandate MSHA to adopt NIOSH RELs as PELs.</p> <p>As the commenter has cited, the purpose of a Current Intelligence Bulletin is to "review and evaluate new and emerging information about occupational hazards", which, along with the proposed framework for future research presented in Part 2, is what is accomplished within the revised draft <i>Roadmap</i>.</p>	<p>The following has been added to the Roadmap in the Forward: "While this December 2008 version of the <i>Roadmap</i> includes a clarified rewording of the existing NIOSH REL, this is only included for the purpose of providing a better understanding of the basis for the proposed research. It is not intended to establish or revise existing NIOSH occupational health policy relating to asbestos, and no regulatory response by OSHA or MSHA is requested or expected."</p>

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>uncertainties, and provide a sound scientific foundation for future policy development so that optimal health protection can be assured.</p> <p>IMA-NA fully supports this statement of the Roadmaps' intended purpose, but objects to NIOSH putting the policy "cart" before the science "horse." For instance, NIOSH uses the draft revised Roadmap document as the vehicle to revise its recommended exposure limit (REL) for asbestos and expand its scope specifically to include elongated mineral particles (EMPs). Where the initial draft document was primarily a research roadmap, once finalized the revised draft document would assume regulatory consequence. OSHA and MSHA are statutorily required to propose NIOSH RELs, typically contained in criteria documents, as permissible exposure limits (PELs) or formally announce their reasons for not doing so. Moreover, legislation currently pending in Congress would mandate that MSHA adopt NIOSH RELs as PELs. Discussion of the NIOSH REL, as currently constituted or as revised, has no place in a scientific research roadmap.</p>		

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>The draft revised REL makes clear that even though EMPs included in the count are not necessarily asbestos fibers, they will be treated as if they are asbestos fibers. It was IMA-NA's impression that the purpose of the Roadmap and revised Roadmap documents is to provide answers to just these types of current scientific questions. Consequently, IMA-NA recommends a return to the original and proper purpose of the Roadmap document, namely providing a framework for scientific research. NIOSH should refrain from casting the revised Roadmap document as a Current Intelligence Bulletin and refrain from using it as a vehicle for rendering policy pronouncements, such as the proposed revision to the REL for asbestos fibers.</p>		
	<p>In its previous comments IMA-NA took exception to the term "fiber-like" cleavage fragments that NIOSH utilized throughout the Roadmap document. IMA-NA remarked that the term was a misnomer and was misleading, and that its continued inadvertent and improper use might lead to treating elongated amphibole cleavage fragments as asbestos fibers. Specifically, IMA-NA was concerned about the possible</p>	<p>As discussed in the revised draft <i>Roadmap</i> (p. 61), "NIOSH recognizes that its descriptions of the REL since 1990 have created confusion and caused many to infer that the additional covered minerals were included by NIOSH in its definition of "asbestos." For this reason, the revised draft <i>Roadmap</i> included a clarification of the existing REL, which makes clear that "EMPs included in the fiber counts are not necessarily asbestos fibers."</p>	

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>application of arbitrary fiber-counting criteria to “define” asbestos rather than to simply count asbestos fibers once identified. This unintended outcome would run counter to cleavage fragment health science. In light of the NIOSH proposed revision of the REL for asbestos fibers, that concern appears well founded.</p> <p>NIOSH did drop use of the “fiber-like” descriptor in the revised Roadmap, but instead of recognizing a distinct difference between asbestos fibers and cleavage fragments NIOSH coined an entirely new descriptor: “elongated mineral particles” (EMPs). The bright-line distinction IMA-NA believes the draft Roadmap and revised Roadmap should convey regrettably continues to be obscured because EMPs include both asbestos fibers and cleavage fragments. Although NIOSH dropped its “unified theory” from the revised Roadmap, it continues to link asbestos fibers and cleavage fragments. NIOSH should refrain from linking the two by conjoining “asbestos fibers” and “elongated mineral particles” with the phrase “and other.” IMA-NA recommends that NIOSH address asbestos fibers and cleavage fragments separately. We once again refer NIOSH</p>	<p>However, as it was not the intent of the <i>Roadmap</i> to revise existing NIOSH policy, the nonasbestiform analogs remain covered minerals under the clarified NIOSH REL (for asbestos fibers and related elongated mineral particles). Also, while it was not the intent of the <i>Roadmap</i> to defend the current REL, the basis for NIOSH’s 1990 change in policy to include the nonasbestiform analogs as covered minerals is summarized in Section 1.5 of the revised draft <i>Roadmap</i>. The purpose of incorporating a description of NIOSH’s existing policy is to provide an understanding of the basis for the proposed research.</p>	

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>to the comments on the "cleavage fragment issue" IMA-NA previously submitted on the draft Roadmap document (see pages 2-6 and accompanying attachments).</p> <p>What is needed is development of an analytical method, likely involving a series of analytical steps and clearer definitions, which can distinguish between asbestos fibers and cleavage fragments. The revised Roadmap recognizes this need and it should be made a top research priority. For instance, polarized light microscopy (PLM) always has been used to identify minerals, mineral types, and mineral habit characteristics prior to and during development of x-ray diffraction (XRD), scanning electron microscopy (SEM), and transmission electron microscopy (TEM) techniques. Its continued use should not be discounted. Similarly, more advanced techniques, such as SEM, may offer promise in differentiating asbestos fibers and cleavage fragments. NIOSH should investigate use of the full suite of analytical tools available to lend precision to the mineral identification process. NIOSH then could establish an REL specific to asbestos fibers. Importantly for the industrial minerals industry, development of such an</p>	<p>As discussed in detail in Section 2.4 of the revised draft <i>Roadmap</i>, development and validation of analytical methods is a stated priority.</p>	

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>analytical method would preclude nonasbestiform cleavage fragments from being improperly characterized as asbestos fibers.</p>		
	<p>IMA-NA disagrees with the conclusion in the draft revised Roadmap that the epidemiological studies previously conducted on worker populations exposed occupationally to nonasbestiform analogs of asbestos varieties are inconclusive. These studies generally can be considered negative for asbestos-related disease.</p>	<p>The NIOSH rationale for considering the findings from these studies as "inconclusive," rather than negative (or positive), are discussed in the revised draft <i>Roadmap</i>. The commenter considers the evidence to be convincingly negative. The review article by Gibbs and Gamble reaches a similar conclusion that "the weight of evidence fully supports a conclusion that non-asbestiform amphiboles do not increase the risk of lung cancer or mesothelioma." However, as discussed in the revised draft <i>Roadmap</i>, the available evidence provides far more ambiguous results.</p>	<p>No revision</p>
	<p>Several peer reviewers of the draft Roadmap document commented that new epidemiological studies of asbestos-exposed populations would be of limited value because exposure to asbestos fibers had decreased markedly over the years. In contrast, worker populations continue to be exposed to cleavage fragments, although these exposures likewise have decreased over the years. Rather than relying exclusively on <i>in vitro</i> and <i>in vivo</i> toxicological testing to determine conclusively whether cleavage fragments cause the same health effects as asbestos fibers, the revised Roadmap</p>	<p>The revised draft <i>Roadmap</i> clearly states in Section 2.3.3 that feasible and informative epidemiological studies should be performed.</p>	<p>No revision</p>

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>should express a strong preference for epidemiological studies of worker populations exposed occupationally to nonasbestiform analogs of asbestos varieties to make this determination. These studies should be rigorously designed to minimize confounding variables and resolve definitively, to the extent possible, the issue of whether exposures to nonasbestiform analogs of asbestos varieties produce the same health effects as asbestos fibers. Given diverse geology special care must be taken to properly characterize the mineral exposures involved in these epidemiological studies.</p>		
	<p><i>In vitro</i> and <i>in vivo</i> studies of the various nonasbestiform analogs can help determine whether additional epidemiological studies are even necessary. Properly designed toxicological studies, utilizing properly characterized materials (examining such characteristics as mineral composition, dimension, biopersistence, surface chemistry, etc.) could help inform issues of relative mineral particle toxicity. IMA-NA believes the existing <i>in vitro</i> and <i>in vivo</i> studies that address nonasbestiform elongated mineral particulate consistently demonstrate a difference in biologic effect when</p>	<p>The revised draft <i>Roadmap</i> does not propose the exclusive use of <i>in vitro</i> and <i>in vivo</i> tests to ascertain the toxicity of mineral particles. Rather, in Section 2.5 it states: "Because of the limited opportunities that exist for informative epidemiological studies, it will be necessary to complement them with toxicological testing, and an integrated approach to toxicological research will be needed to understand how these minerals might potentially induce disease. Where epidemiological studies are possible, or can be updated, attempts should be made to link their results with those of toxicological studies to assess the ability of various types of toxicological testing to predict health outcomes in humans."</p>	<p>No revision</p>

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>contrasted with asbestos fibers. However, in light of the existing negative epidemiological studies, IMA-NA takes exception to the exclusive use of <i>in vitro</i> and <i>in vivo</i> toxicological testing to definitively determine whether EMPs cause the same adverse health effects as asbestos fibers.</p>		
	<p>Finally, in its response to the peer reviewers of the initial draft Roadmap document, NIOSH indicated that it currently was exploring having the revised Roadmap document reviewed by the National Academies of Sciences (of which the Institute of Medicine is a component). IMA-NA endorses such a high-level scientific review to validate the scope and direction of the NIOSH research agenda relative to asbestos fibers and nonasbestiform cleavage fragments. IMA-NA encourages NIOSH to pursue this additional review and would be pleased to assist the National Research Council/Institute of Medicine committee in whatever way it can.</p>	<p>Plans for the review by the National Academies of Science are proceeding.</p>	<p>No revision</p>