

Roadmap Reference	Comment Received	Response	Change to Roadmap
	<p>I. The roadmap should state that the definition of asbestos is being clarified not changed.</p> <p>The revised draft states that there has been confusion as to whether the “additional covered minerals” covered by NIOSH’s REL since 1990 have been included in the definition of asbestos. It goes on to say that “NIOSH wishes to make it clear that such nonasbestiform minerals are not ‘asbestos’ or ‘asbestos minerals.’” The revised draft should state explicitly that this clarifies existing policy.</p> <p>Since at least 1990 NIOSH has made a distinction between asbestos minerals and other materials that are covered by the REL. For example, NIOSH’s testimony in the 1990 OSHA rulemaking hearing was that “the asbestos minerals are defined as chrysotile, crocidolite, amosite (cummingtonite-grunerite), anthophyllite, tremolite, and actinolite. In addition, airborne cleavage fragments from the nonasbestiform habits of the serpentine minerals antigorite and lizardite, and the amphibole minerals contained in the series cummingtonite-grunerite, tremolite-ferroactinolite, and glaucophane-riebeckite shall also be counted as fibers provided they meet the criteria for a fiber when viewed microscopically.” This is also the current description of the REL in the NIOSH Pocket Guide.</p> <p>Some individuals and organizations may have become confused, because in some places NIOSH has referred to the nonasbestiform materials covered by the REL as “asbestos fibers.” But NIOSH has never referred to them as “asbestos” or “asbestos minerals” and a careful reading of NIOSH documents shows that NIOSH has consistently stated that the REL covers</p>	<p>The Executive Summary has been revised to more explicitly indicate that NIOSH’s asbestos policy is not changed with the clarification presented in the <i>Roadmap</i>.</p>	<p>The Executive Summary now states: “The clarified wording of the existing NIOSH REL is included in this document only 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>

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	<p>the limited list of "asbestos minerals" noted above along with other non-asbestos materials.</p> <p>The revised draft sharpens the way this distinction is described, but it does not make any substantive change. Asbestos is now defined as "A generic term for silicate minerals occurring in the asbestiform habit, usually used to refer to those minerals that have been commercially exploited as asbestos, including chrysotile in the serpentine mineral group and tremolite asbestos, actinolite asbestos, anthophyllite asbestos, cummingtonite-grunerite asbestos (amosite), and riebeckite asbestos (crocidolite) in the amphibole mineral group." The revised draft also defines the materials covered by the REL as these six commercial forms of asbestos plus a list of other materials that are not covered by the asbestos definition, including "their nonasbestiform analogs (the serpentine minerals antigorite and lizardite, and the amphibole minerals contained in the cummingtonite-grunerite mineral series, the tremolite-ferroactinolite mineral series, and the glaucophane-riebeckite mineral series)."</p> <p>The definitions of asbestos and REL-covered materials from the 1990 documents and the new revised Roadmap draft are identical in substance although different in wording. Therefore, the Roadmap should not that this clarification, rather than a change to the definition of asbestos.</p>		

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	<p>II. The roadmap should state that the listed concerns with NIOSH's 1990 recommendations are concerns held by some stakeholders and are not necessarily concerns of NIOSH itself.</p> <p>The revised draft lists six "concerns" that have been raised through the years. The document should state which individuals and/or organizations have raised these concerns and make it clear that this is not an official list of NIOSH's "concerns."</p>	<p>The various listed concerns have come from multiple sources including various stakeholders and, in some cases, NIOSH's researchers. It would not be possible to specify single stakeholders who are wholly responsible for each of the listed concerns. The listed concerns are issues which NIOSH believes should be addressed through additional research to provide better evidence-based recommendations to protect workers.</p>	<p>No revision</p>
	<p>III. The roadmap should qualify the potential use of short-term tests.</p> <p>The revised draft states that the ideal outcome of a strategic research program would be to use the research results to develop recommendations for worker protection and that it would be "particularly advantageous" if this could be "based primarily on results from validated <i>in vitro</i> or short term <i>in vivo</i> assays."</p> <p>AAJ urges NIOSH set this statement in proper context by stating clearly that there are no such tests that currently have sufficient sensitivity, specificity and predictive value to be used for such a purpose.</p>	<p>The strengths and limitations of model systems used to study EMPs are discussed in Sections 1.6.4.1 and 2.2 of the revised draft <i>Roadmap</i>. In section 2.2 it is stated that "(2) no single assay and battery of short-term assays could predict the outcome of a chronic inhalation bioassay for carcinogenicity; and (3) several short-term <i>in vitro</i> and <i>in vivo</i> studies may be useful to assess the relative potential of various EMPs to cause lung toxicity or carcinogenicity [Vu et al. 1996]."</p> <p>It is not the intent of the <i>Roadmap</i> to suggest that the currently available <i>in vitro</i> and short-term <i>in vivo</i> assays are</p>	<p>The statement in the Path Forward has been revised to read: "It would be particularly advantageous if a battery of validated <i>in vitro</i> or short-term <i>in vivo</i> assays could be developed that have sufficient predictive value to identify EMPs that should be included in the recommendations."</p>

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	<p>IV. The roadmap should state that NIOSH's position with regard to precautionary action in the face of uncertainty has been clarified but not changed.</p> <p>The executive summary of the revised draft states on p. vii: "Due to various study limitations, NIOSH has viewed findings from relevant epidemiological studies as providing inconclusive, as opposed to either positive or negative, evidence regarding health hazards associated with exposures to EMPs from nonasbestiform amphiboles." Later in the document (p. 17) it is made clear that "based on inconclusive epidemiological evidence for lung cancer risk associated with exposure to cleavage fragments... NIOSH took the precautionary approach..." and included these materials among those covered by the REL.</p> <p>NIOSH should state clearly in the executive summary that its view on this matter has not changed, that it still believes that precautionary action is often appropriate when the evidence is inconclusive, and that the existence of the Roadmap is not a retraction of past policy statements or documents. The executive summary should also state that while the scientific basis for public policy evolves over time, NIOSH's past statements and documents regarding asbestos have always been based on the best available evidence and continue to reflect the Agency's sound scientific judgment. Without such statements it will be difficult to understand the implications on pp. 27-28 and p. 62.</p>	<p>sufficient to predict health outcomes from chronic exposure in humans.</p> <p>The revised draft <i>Roadmap</i> is not intended to establish or change any NIOSH policy or recommendation. Thus, there is no need for the <i>Roadmap</i> to point out that the precautionary approach is still appropriate. Likewise, additional statements indicating that NIOSH has used and continues to use the best available evidence to develop policy statements or documents are not needed in the <i>Roadmap</i>. In response to Comment I (see above), the Executive Summary has been revised to more explicitly indicate that NIOSH's asbestos policy is not substantively changed with the clarification presented in the <i>Roadmap</i>.</p>	<p>No revision beyond that described in response to Comment I (above).</p>

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	<p>V. The roadmap should state more clearly that new analytic tools such as transmission electron microscopy (TEM) should not be used by regulatory agencies without first changing the exposure standards to which they are applied.</p> <p>The revised draft on p. 54 states: "Care should be taken in developing or applying new analytical methods to the analysis of asbestos for standardized and compliance assessments. The use of new or different analytical methods to assess exposures must be carefully evaluated and validated to ensure that they measure exposures covered by the health protection standard." This is not a sufficient caution.</p> <p>The Roadmap document should address the possibility that a new method applied to an older, existing health protection standard may inadvertently reduce worker protections. For example, the existing OSHA asbestos standard is based on PCM analysis, recognizing that this method is relatively insensitive and will measure fibers not covered by the standard. The standard, therefore, was set at a higher level than if the analytic technique had been more specific. For example, consider a workplace where the airborne fibers were 50% asbestos and 50% nonasbestiform. PCM sampling might show that workers were exposed to total fiber levels just exceeding the standard of 0.1 f/cc. If TEM sampling were done in the same workplace and distinguished clearly between asbestos and nonasbestiform fibers and reported the exposure level just in terms of the covered asbestos, the result would be just more than half the PEL. The NIOSH roadmap document needs to state that if sampling and analytic methods for risk assessment become more sensitive and specific, the allowable standards for asbestos exposure will need to be revised downward.</p>	<p>The revised draft <i>Roadmap</i> already addresses the need to develop new risk assessments when changes are made to the analytical methods used to assess exposure. In addition to the citation from the commenter, this point is addressed several times in the revised draft <i>Roadmap</i>, including the Executive Summary ("In addition, any substantive change in analytical techniques used to evaluate samples and/or the criteria for determining exposure concentrations will necessitate a reassessment of current risk estimates, which are based on PCM-derived fiber concentrations." - and in Section 2.4 ("Modifications of current analytical methods and development of new analytical methods will require an assessment of worker health implications (e.g., how do the results using improved or new methods relate to human risk estimates based on counts of EMPs made by PCM?). To ensure that relevant toxicological parameters (e.g., dimension, durability, and physicochemical parameters) are incorporated in the analysis and measurement, changes in analytical methods should be made in concert with changes in how asbestos fibers</p>	<p>No revision</p>

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		<p>or other EMPs are defined.”) NIOSH believes these adequately address the need to redo risk assessments if analytical techniques are applied that measure exposures differently than the method used to develop existing risk assessments.</p>	
	<p>VI. The suggestion to convene an expert panel to consider whether there is an adequate database to conduct a quantitative risk assessment for nonasbestiform amphibole EMPs should be deleted.</p> <p>The revised draft states (p. 77) “If nonasbestiform amphibole EMPs are in fact associated with some risk, a quantitative risk assessment would be needed to understand whether the risks are similar to the risk associated with exposures to asbestos fibers. An expert panel could be assembled and charged with ascertaining if the existing epidemiological evidence could support development of a likely maximum risk estimate associated with exposure to nonasbestiform amphibole EMPs.” While it would be useful to know the relative potency of various nonasbestiform vs asbestos fibers, the expert asbestos panel recently assembled by the Science Advisory Board of the EPA has already considered this question and concluded that the existing epidemiological evidence is not sufficient to support quantitative risk assessment. AAJ therefore asks that this suggestion be deleted from the final Roadmap.</p>	<p>NIOSH agrees that available evidence on nonasbestiform amphibole EMPs is likely insufficient at this time to conduct a quantitative risk assessment, and that this point warrants clarification.</p>	<p>The statement has been revised to: “A risk assessment of nonasbestiform amphibole EMPs should be performed if new epidemiological and other evidence is sufficient to support such a risk estimate that could, in turn, lead to development of a risk management policy for nonasbestiform amphibole EMPs that is distinct from asbestos fiber policy.”</p>