NIOSH CIB 68: NIOSH Chemical Carcinogen Policy
NIOSH Responses to Public Review Comments
August 16, 2016

Public comments are available in full as submitted at www.regulations.gov, CDC-2013-0023.

Commenter/Topic	**Public Comment**	***NIOSH Response***
Federal Register Questions:		
	Question #1: Are the proposed carcinogen policies consistent with the current scientific knowledge of toxicology, risk assessment, industrial hygiene, and occupational cancer?	
IARC	The proposed carcinogen policy is reasonable and consistent with current scientific knowledge. Given the large number of agents used in commerce and the rapid pace at which new ones are introduced, a robust, yet efficient method of identifying agents that represent a cancer hazard to workers is an important step toward cancer prevention. The proposed policy would accomplish this goal for many agents by drawing on existing evaluations by other agencies, including the IARC Monographs. It is also appropriate for NIOSH to make a determination of occupational relevance, since some of the agents that have been evaluated by other agencies may not involve significant exposure to workers in the United States. The process proposed by NIOSH would normally assign agents to the highest category of hazard assigned by NTP, EPA, or IARC. This is appropriate because differences in the level hazard recognised by various agencies often reflect evolution of the state of knowledge over time; thus more recent evaluations incorporating new studies tend to lead to upgrading the level of hazard. Moreover, reconciling potential differences among hazard evaluations in favour of providing greater protection to workers is prudent and consistent with best practice for cancer prevention.	*NIOSH appreciates IARC support for its chemical carcinogen classification policy.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Diane Brown, (AFSCME)	AFSCME supports updating NIOSH's carcinogen policy. NIOSH's views and policy are an important resource in our efforts to protect workers from exposure to harmful agents. An updated policy must reflect current scientific evidence and technologies as necessary to protect workers from carcinogens at the same level as the general public. AFSCME agrees that relying on carcinogen classifications of National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC) is consistent with current scientific knowledge. However, in accordance with occupational safety and health principles, the policy should place more emphasis on substitution. In addition, choosing 1/1000 or any other risk level is a policy decision, not a scientific one.	*As stated in the document, "Because there is no safe level of exposure to occupational carcinogens, NIOSH will continue to recommend reduction of exposure to an occupational carcinogen according to the hierarchy of controls through elimination or substitution and implementation of engineering controls, if practical, and the use of administrative controls before use of personal protective equipment (PPE). When exposures to carcinogens cannot be eliminated, NIOSH will also (1) calculate a range of risk estimates, from 1 excess cancer case in 100 workers to 1 excess cancer case in 1 million workers over a 45-year working lifetime when the data permit, and (2) set a risk management limit for carcinogens (RML-CA). When data permit NIOSH to complete a quantitative risk assessment (QRA), NIOSH will use the results of the QRA to perform both tasks." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure."*

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Anna Fendley, (USW)	For the most part, the proposed policy update is consistent with current scientific knowledge. However, as noted above, USW disagrees that NIOSH should be setting RELs using a target risk level of 1 in 1000. It is widely recognized in the occupational safety and health community that there is no safe level of exposure to carcinogens, and 1 in 1000 leaves workers at a high level of excess risk.	*NIOSH appreciates USW's support for its chemical carcinogen policy. As stated in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

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Darius Sivin, PhD, UAW	The UAW agrees that relying on carcinogen classifications of National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC) is consistent with current scientific knowledge. However, as elaborated below, the policy should place more emphasis on substitution. In addition, choosing 1/1000 or any other risk level is a policy decision, not a scientific one. As explained in the answer to question 6, it would be best for NIOSH not to choose a particular risk level.	*NIOSH appreciates UAW's support of its chemical carcinogen classification policy. As stated in the document, "NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical.* *Finally, several public commenters urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave*

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		such a policy decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk; however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."

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Deborah Proctor of ToxStrategies, Inc. and Marc Kolanz, CIH, Materion Brush Inc.	The proposed carcinogen policies are not consistent with the state of the science of risk assessment. There are several areas that require further consideration and discussion. Specifically, NIOSH should incorporate current scientific knowledge and practices regarding the use of Mode of Action (MOA) in risk assessment. Although MOA assessment is mentioned in the document, its use is not adequately described or consistent with the state-of the-science. The Draft Cancer Policy does not contain adequate details regarding the use of MOA information for low dose extrapolation, and it does not appear that NIOSH will use the current state of the science in its risk assessments to set RELs. It is unclear whether (1) NIOSH will conduct formal weight-of-evidence reviews and human relevance evaluations to reach MOA determinations or (2) NIOSH will rely upon assessments that have been conducted by other regulatory agencies. As noted in the policies, MOA is important for determining the most scientifically valid method for low-dose extrapolation. NIOSH should describe how it will conduct MOA evaluations in the Cancer Policy. The United States Environmental Protection Agency (EPA) has formally described MOA analysis in the context of cancer risk assessment in an MOA framework in the "Guidelines for Carcinogen Risk Assessment" (EPA, 2005). Although cited by NIOSH in the Draft Cancer Policy, it is not clear if NIOSH plans to follow EPA guidelines for Cancer Risk Assessment, or other approaches such as those published in the scientific literature. EPA suggests using linear extrapolations when the MOA is "mutagenic", known to be linear, or unknown, and non-linear extrapolation methods for dose-response modeling when the MOA is expected to be non-mutagenic and non-linear (U.S. EPA, 2005). Thus, the current state of the science supports the use of weight of evidence regarding chemical-specific MOAs in risk assessments.	*As stated in the document, "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical evaluation of chemical carcinogenicity should be made explicit [Weed 2005]." With regard to the steps in a risk assessment, as stated in the document, "The discussion below*

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		summarizes key elements of the NIOSH approach to QRA. NIOSH expects to publish more comprehensive guidance describing its approach to risk assessment in the future. Until then, NIOSH will continue to use the risk assessment methods as more fully described in the NIOSH Criteria Document on Hexavalent Chromium [NIOSH 2013] and Current Intelligence Bulletin on Titanium Dioxide [NIOSH 2011a]."

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Deborah Proctor of ToxStrategies, Inc. and Marc Kolanz, CIH, Materion Brush Inc.	Further, it should be recognized that Crump (2011)—cited in the NIOSH policies as the basis for stating that "it is highly unlikely that one can demonstrate empirically that a threshold exists"— does not argue that thresholds do not exist; rather, that it is problematic to quantify a threshold. The author, then, proceeds to suggest an alternative approach to risk assessment that does not require the quantification of a specific threshold. It does not appear that NIOSH is embracing this recommendation or following current state of the science for MOA evaluation or use of the Human Relevance Framework (Meek et al. 2003). If NIOSH intends to use the recommendations of Crump (2011), the Cancer Policy needs to explain how NIOSH intends to do so. The Draft Cancer Policy cites the recent cancer risk assessment for titanium dioxide of an example when non-linear exposure response was used (NIOSH 2011). This is a document that contains no formal MOA evaluation wherein key events are evaluated or formal human relevance review. In fact, the mechanistic discussion simply argues why lung tumors in rats are a relevant basis for risk assessment even though all six epidemiological studies of titanium dioxide exposed workers showed no dose-response (NIOSH 2011). Thus, NIOSH should explain how it intends to use MOA analysis in cancer risk assessment. The state of the science supports use of a formal MOA analysis as described by the EPA (2005) guidance and multiple peer-review published papers (Meek et al. 2003; 2013; Seed et al. 2005; Boobis et al. 2008; 2009; Julian et al. 2009). Furthermore, the NIOSH policy does not clearly distinguish between "genotoxic" and "mutagenic" MOAs. As discussed in greater detail below, some genotoxic compounds may act by indirect mechanisms that are only occur at high doses (e.g., Thompson et al. 2013 assessment for ingestion cancer risk of hexavalent chromium). In addition to U.S. EPA's MOA	*Addressing the specific MOA issues raised by the commenter is beyond the scope of this document. As stated in the document, "The discussion below summarizes key elements of the NIOSH approach to QRA. NIOSH expects to publish more comprehensive guidance describing its approach to risk assessment in the future. Until then, NIOSH will continue to use the risk assessment methods as more fully described in the NIOSH Criteria Document on Hexavalent Chromium [NIOSH 2013] and Current Intelligence Bulletin on Titanium Dioxide [NIOSH 2011a]."*

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	framework, there are several review articles describing MOA and human relevance frameworks for informing risk assessment (Seed et al., 2005, Julien et al., 2009; Boobis et al., 2008, 2009; Meek, 2013) that should be included in the guidance. Additional language is needed that describes how NIOSH will use or evaluate MOA information in risk assessment in establishing RELs.	

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Cindy Sage, MA, BioInitiative	While my comment primarily addresses Question (2), I endorse the comments filed by Dana Loomis, IARC posted on February 10, 2014 that address the classification of carcinogens to better sync with the IARC guidelines. In particular, "*The assignment of IARC Group 2B agents with less than sufficient evidence in animals requires additional considerations. NIOSH has proposed assigning agents in IARC Group 2B with limited animal evidence to GHS Category 2. While this assignment is reasonable, the proposal neglects the remaining Group 2B agents with less than limited evidence in animals. In the IARC system, agents with limited or inadequate evidence in animals but limited evidence in humans can be assigned to Group 2B. It is recommended that NIOSH adopt a similar approach and assign these IARC 2B agents with limited evidence in humans to GHS Category 2 on the principle that the evidence in humans merits a higher classification than that which would be assigned based on animal data alone. "* [Comment of Dana Loomis, IARC]	*The NIOSH process for developing GHS classifications has been removed from this policy for further analysis and development.*
	Question #2: Is there additional scientific information related to the issues of the proposed NIOSH carcinogen policies that should be considered for inclusion? Is there any discussion in the document that should be omitted?	
IARC	The document has neither significant omissions nor information that should be deleted.	*No response required.*

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Diane Brown, (AFSCME)	It is AFSCME's position that information on elimination, substitution and closed systems should be added to the document. The substitution of safer materials or the use of completely enclosed systems is preferable to compliance with exposure limits. There are no "safe" levels of exposure to any carcinogen. AFSCME recommends that NIOSH include in every criteria document and every NIOSH Pocket Guide an entry for a carcinogen that reads: "This substance is a carcinogen. It is recommended that a safer substitute be used instead. If a safer substitute is not feasible, it is recommended that the substance be present in the workplace only in a closed system. The recommended exposure limits (REL) for this substance is to be used as a guideline to manage risk only in cases in which elimination, substitution and closed systems are not feasible."	*As stated in the document, "NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical." Adding specific information on elimination, substitution and closed systems is beyond the scope of this document. However, NIOSH is conducting additional analysis and development of these issues to inform future guidance.*
Anna Fendley, (USW)	USW does not have additional scientific information to include.	*No response required.*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	The UAW believes that information on elimination, substitution and closed systems should be added to the document. Substitution of safer materials or complete enclosure of systems are preferable to compliance with exposure limits. This is because no safe level of exposure to any carcinogen has been adequately demonstrated. Inclusion of this information would be consistent with the following statement on p. 30 of the draft policy: NIOSH strongly advocates using safer alternatives to toxic chemicals, including substituting non-carcinogenic chemicals for carcinogens whenever feasible. It would also be consistent with the following statements included in NIOSH's presentation at the public meeting on December 16, 2013: NIOSH affirms scientific knowledge that the only way to eliminate excess risk from carcinogens is to prevent exposure NIOSH advocates using safer alternatives and to substitute non-carcinogen chemicals whenever feasible Removing all carcinogens in commerce is impractical so guidance on reducing carcinogen exposures to workers is needed.	*As stated in the document, "NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical." Adding specific information on elimination, substitution and closed systems is beyond the scope of this document. However, NIOSH is conducting additional analysis and development of these issues to inform future guidance.*

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Darius Sivin, PhD, UAW	The UAW recommends that NIOSH adopt a policy for all carcinogens similar to the European Directive 2004137/EC- carcinogens or mutagens at work. This directive indicates that occupational exposure limits are a line of defense to be used only if substitution, elimination and entirely closed systems are infeasible. Article 5 of that directive states the following: Article 5: Prevention and Reduction of Exposure 1. Where the results of the assessment referred to in Article 3(2) reveal a risk to workers' health or safety, workers' exposure must be prevented. 2. Where it is not technically possible to replace the carcinogen or mutagen by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system. 3. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible. 4. Exposure shall not exceed the limit value of a carcinogen... To this end, the UAW recommends the following: That section 5.0 of the carcinogen policy be retitled 6.0 and that a new section 5 be created entitled, "Elimination, Substitution and Closed Systems." The UAW recommends that the content of that section be a set of recommendations similar to the European Directive above. We recommend that the section refer the reader to the OSHA web page "Transitioning to Safer	*As stated in the document, "NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical." Adding specific information on elimination, substitution and closed systems is beyond the scope of this document. However, NIOSH is conducting additional analysis and development of these issues to inform future guidance.*

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	Chemicals: A Toolkit for Employers and Workers" (https:l/www.osha.gov/dsqlsafer chemicals/basics.html) That every criteria document and every NIOSH Pocket Guide entry for a carcinogen contain the following: "This substance is a carcinogen. It is recommended that a safer substitute be used instead. If a safer substitute is not feasible, it is recommended that the substance be present in the workplace only in a closed system. The recommended exposure limit (REL) for this substance is to be used as a guideline to manage risk only in cases in which elimination, substitution and closed systems are not feasible."	

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Deborah Proctor of ToxStrategies, Inc. and Marc Kolanz, CIH, Materion Brush Inc.	In addition to MOA evaluation, NIOSH should clearly address the differences between genotoxic and mutagenic MOAs. NIOSH indicates that "Genotoxic (DNA-damaging) carcinogens are presumed to act via nonthreshold mechanisms, and occupational exposure limits (OELs) for these chemicals are typically based on low-dose linear models" (NIOSH, 2013, p. 31, line 8-10). This statement is misleading. Genotoxic compounds can act directly or indirectly to cause cancer. Certain substances deemed to be genotoxic may not act by a mutagenic MOA. Furthermore, it is not the case that only chemicals that induce inflammation or oxidative stress can damage DNA through mechanisms that have a threshold. It is well accepted that some compounds, e.g. spindle poisons, induce genotoxicity through mechanisms that have a threshold. NIOSH should clarify terminology regarding 'genotoxicity.' Furthermore, NIOSH should recognize and develop a policy regarding the use of toxicity data occurring as a result of "lung overload" which is known to occur in rats exposed to poorly soluble particles. The MOA and human relevance of such data have been examined in detail and questioned based on recent scientific data by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) in Technical Report No. 122, Poorly Soluble Particles/Lung Overload (December 2013). This technical report concludes that carcinogenicity induced by lung overload has a threshold, which can be estimated based on the dose-response for non-neoplastic effects (oxidative stress and inflammation). Consistent with the comment for adoption of formal MOA evaluations in development of RELs, NIOSH should review and incorporate the scientific findings of this report in its Draft Cancer Policy.	*The examples used in this document were for illustration purposes and not intended to provide an exhaustive list of mechanisms of action that are associated with non-linear dose response. As stated in the document, "The discussion below summarizes key elements of the NIOSH approach to QRA. NIOSH expects to publish more comprehensive guidance describing its approach to risk assessment in the future. Until then, NIOSH will continue to use the risk assessment methods as more fully described in the NIOSH Criteria Document on Hexavalent Chromium [NIOSH 2013] and Current Intelligence Bulletin on Titanium Dioxide [NIOSH 2011a]."*

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Cindy Sage, MA, BioInitiative	Substantial evidence exists that existing workplace exposure limits for EMF and RFR are outdated, and likely place the health and well-being of workers, and possibly of their offspring, at considerable risk. In support of the recommendation that NIOSH direct funding toward EMF and RFR research in it's NORA program, this letter documents evidence based on the 2012 BioInitiative Report. The 2012 Report has updated five years of published science, public health, public policy and global response since the original BioInitiative Report of 2007. Both Reports are incorporated by reference and are available for download at www.bioinitiative.org. The two Reports provide significant scientific and public health information of a growing risk from chronic exposure to electromagnetic fields and radiofrequency radiation that NIOSH is urged to incorporate in this proceeding. This evidence indicates that current occupational cancer risk assessment is not sufficient in light of the large body of published scientific study of EMF and RFR cancer risks, nor are current safety limits adequate. This letter specifically points to key evidence not apparently included yet that NIOSH should consider for inclusion with respect to carcinogen policies. This letter also urges that NIOSH consider the non-linear dose response aspect of EMF/RFR exposures - in that the traditional linear dose-response applied to chemical toxins is likely inappropriate and will lead to under-estimated risk of carcinogenicity for EMF/RFR. Further, exposure of the growing fetus is a concern for both cancers and neurological development, so exposures of both the working mother and father may contribute to adverse health outcomes in the offspring. Thus workplace exposures to EMF/RFR that may affect the health and development of the fetus, and eventually of the life-long health of that individual should require NIOSH attention in NORA-047 research efforts.	*This policy focuses on chemical carcinogens in the workplace. Consideration of EMF and RFR is beyond the scope of this document, however we will share your concerns with management and researchers at NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
	Question #3: Is the proposed carcinogen classification policy explained in a clear and transparent manner? Is the basis for the proposed policy adequately explained?	
IARC	The proposed policy and its basis are adequately explained. However, the use of equivocal language in several paragraphs leaves room for questions about how the assignments would be made. For example, page 26 line 27 says that NIOSH "will consider" assigning agents to GHS category 1B under certain conditions. However, the wording implies that after consideration the agents might not be assigned to 1B. If this is the intended meaning, the procedure would be more transparent if circumstances under which agents would not be assigned to 1B and the category (or categories) to which those agents would be assigned were specified. A similar statement about Category 2 on page 27 line 1 is also subject to question.	*The NIOSH GHS walk-across process has been removed from the final document. This topic is undergoing further analysis and development. NIOSH will use the GHS criteria for carcinogenicity for new classifications.*
Diane Brown, (AFSCME)	AFSCME agrees that the proposed carcinogen classification policy and its basis are adequately explained in a clear and transparent manner. AFSCME also supports NIOSH's proposal to rely on the carcinogen classifications of the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC).	*NIOSH appreciates this positive feedback.*
Anna Fendley, (USW)	The proposed policy and its basis are clearly and adequately explained.	*NIOSH appreciates this positive feedback.*
Darius Sivin, PhD, UAW	The UAW agrees that the proposed carcinogen classification policy and its basis are adequately explained in a clear and transparent manner. The UAW strongly supports NIOSH's proposal to rely on the carcinogen classifications of the National Toxicology Program (NTP}, the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC).	*NIOSH appreciates this positive feedback.*

Commenter/Topic	Public Comment	*NIOSH Response*
	Question #4: Are there issues relevant to the classification of occupational carcinogens that have not been adequately addressed in this proposed policy? If so, provide information and specify references for consideration?	
IARC	In the description of carcinogen evaluations for the IARC Monographs (pages 17-18), it should be noted that overall evaluations by IARC are based on the weight of the evidence from research on cancer in humans and animals and other relevant data. Although the Preamble to the IARC Monographs refers to evaluating the "strength of evidence," it is noted in the text that this wording is employed for historical continuity (IARC, 2006). IARC is aware that the terminology used to describe various evaluation approaches has evolved over time and believes that "weight of the evidence," as currently understood, best describes the approach taken in the Monographs. Reference IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Preamble. Lyon, France, 2006.	*NIOSH agrees and has clarified the language describing the IARC process with quotes from the IARC monograph preambles.*
Diane Brown, (AFSCME)	AFSCME believes that NIOSH has adequately addressed issues relevant to the classification of occupational carcinogens in its proposed policy. We believe that most chemicals designated as carcinogens by NTP, IARC and EPA will also impact on the workplace. We agree with NIOSH's proposal to implement its efforts based on the assumption that all chemicals listed by these agencies will also need to be listed as occupational carcinogens by NIOSH.	*NIOSH appreciates the positive comments. As stated in the document, "NIOSH will evaluate whether the chemical is likely to pose a risk in the occupational environment and whether the data underlying the cancer classification is applicable to the occupational setting. NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation. This is because there are likely only very rare instances in which a chemical classified as a*

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		carcinogen by NTP, EPA, or IARC would not also be potentially carcinogenic to exposed workers. NIOSH will consider the issues described below in deciding whether a chemical is relevant to the occupational environment."
Anna Fendley, (USW)	The proposed update neglects to adequately address promoting the adoption of safer alternatives. Currently the policy moves from a discussion of classifying and determining the occupational relevance of a carcinogen to determining the risk levels. There is a missing step. NIOSH needs to include a separate section in the policy to elevate assessments and adoption of safer alternatives to carcinogens as the most effective industrial hygiene strategy to protect workers. The proposed update also neglects to adequately address mixtures of chemicals in workplaces. This is a complicated and potentially never-ending body of work, but NIOSH should address the issue of mixtures, possibly by identify common mixtures and exposures. As we suggested in our 2011 comments, NIOSH may want to look at the American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) mixture formula, as it attempts to identify risk for a mixture of similar substances that have common target organs or systems.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer." With regard to the issue of mixtures, NIOSH is conducting further analysis and development of this topic to inform future guidance. In addition, NIOSH currently has an active project on cumulative risk assessment, which deals with the issue of exposure to mixtures, among other things.*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	The UAW agrees that NIOSH has adequately addressed issues relevant to the classification of occupational carcinogens in its proposed policy. The UAW believes that most chemicals designated as carcinogens by these agencies will likely have occupational relevance. We agree with NIOSH's proposal to implement its efforts based on the assumption that all chemicals listed by these agencies will also need to be listed as occupational carcinogens by NIOSH.	*NIOSH appreciates the positive comments. As stated in the document, "NIOSH will evaluate whether the chemical is likely to pose a risk in the occupational environment and whether the data underlying the cancer classification is applicable to the occupational setting. NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation. This is because there are likely only very rare instances in which a chemical classified as a carcinogen by NTP, EPA, or IARC would not also be potentially carcinogenic to exposed workers. NIOSH will consider the issues described below in deciding whether a chemical is relevant to the occupational environment."*

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Janet Newton, EMRadiation Policy Institute	**III. DISCUSSION** 7. It is in this context that EMRPI submits written Comment in CDC–2013–0023; Docket Number NIOSH 240–A. We address the Overall Questions in an order that most logically coincides the content of our Comment. 8. Workplace exposures to electromagnetic fields (EMFs) from ELFs (Extremely Low Frequency) up through the RF/MW (radiofrequency/microwave) radiation frequencies continue to increase and are becoming a ubiquitous environmental factor across all occupational sectors. Wireless internet networks in offices, schools, restaurants, public transit, and transportation terminals, i.e., airport terminal "hot spots", are commonplace and continue to expand. The job requirement that employees use Smart phones, I-Pads, wireless tablets and other wireless devices so that they can be in constant contact with their employers has become the norm. Many other hi-tech jobs now require employees to operate electronic equipment and machinery that emit electromagnetic fields from the ELF range up through the RF/MW frequencies. 9. US federal public health policy for long-term, low-intensity EMF exposure is inadequate. Principally, the Federal Communications Commission (FCC), an engineering and licensing agency, is responsible for assuring the safety of the public's exposure to environmental levels of RF/MW radiation. 10. To document EMRPI's history that tracks the FCC's failure to enforce its RF safety policies responsible for protecting American workers, we provide here the complete text of our November 18, 2013 Reply in FCC 13-39, ET Docket No. 03-137 Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields. **(To see their November 18, 2013 Reply to FCC 13-39, ET Docket No. 03-137, please view the word file**	*This policy focuses on chemical carcinogens in the workplace. Consideration of EMF and RFR is beyond the scope of this document, however we will share your concerns with management and researchers at NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
	EMR (Newton)-PC21)	

Commenter/Topic	Public Comment	*NIOSH Response*
	Question #5: NIOSH adapted the OSHA Hazard Communication Table Relating Approximate Equivalences among IARC, NTP RoC, and GHS Carcinogenicity Classifications (Appendix F, Part D, OSHA Globally Harmonized System for Hazard Communication) to provide a simple, systematic method of determining GHS cancer hazard categories. However, NIOSH has further considered the GHS carcinogen categories 1B and 2 because NTP classification reasonably anticipated to be a human carcinogen and IARC classification 2B have criteria that overlap the two GHS categories. NIOSH has reviewed the criteria for GHS classification and has determined that chemicals classified by NTP as reasonably anticipated and chemicals classified as IARC 2B ''that have sufficient evidence from animal data'' meet the criteria for GHS Carcinogen Category 1B. Chemicals classified by NTP as reasonably anticipated and chemicals classified by IARC as 2B ''that have limited evidence from animal data'' meet the criteria for GHS Carcinogen Category 2. **NIOSH is requesting comments on the validity of the NIOSH Correspondence table (Table 2) and its usefulness as a guide to determine GHS hazard categories.**	
IARC	The general approach to classification laid out in the NIOSH Correspondence Table is reasonable. IARC agrees that it is appropriate to assign agents in IARC Groups 1 and 2A to GHS categories 1A and 1B, respectively, and that agents in IARC Group 2B with sufficient animal evidence can also be assigned to GHS Category 1B.	*NIOSH appreciates this response but notes that the NIOSH Correspondence Table has been removed from the document for further analysis and development.*

Commenter/Topic	Public Comment	*NIOSH Response*
IARC	The assignment of IARC Group 2B agents with less than sufficient evidence in animals requires additional considerations. NIOSH has proposed assigning agents in IARC Group 2B with limited animal evidence to GHS Category 2. While this assignment is reasonable, the proposal neglects the remaining Group 2B agents with less than limited evidence in animals. In the IARC system, agents with limited or inadequate evidence in animals but limited evidence in humans can be assigned to Group 2B. It is recommended that NIOSH adopt a similar approach and assign these IARC 2B agents with limited evidence in humans to GHS Category 2 on the principle that the evidence in humans merits a higher classification than that which would be assigned based on animal data alone. The degree of mechanistic support could also be considered in decisions about how to classify IARC Group 2B agents. The IARC system allows agents with inadequate evidence in humans and less than sufficient evidence in animals to be assigned to Group 2B if there is strong mechanistic support from other relevant data (for example, Benzo[c]phenanthrene, Benz[j]aceanthrylene, IARC Monographs vol 92; Dibenz[c,h]acridine, vol 103). Assigning agents in this category to GHS Category 2 on the basis of strong mechanistic data would give workers a higher level of protection in the absence of adequate epidemiological or animal bioassay data.	*NIOSH appreciates this response but notes that the NIOSH Correspondence Table has been removed from the document for further analysis and development.*

Commenter/Topic	Public Comment	*NIOSH Response*
Diane Brown, (AFSCME)	In general, we support the criteria proposed by NIOSH for the equivalences among the IARC, NTP, and GHS carcinogenicity classifications. However, as NIOSH itself has noted, there are instances where there is overlap or inconsistency within the classifications. We agree that it is appropriate to further scrutinize the NTP classification "reasonably anticipated" and the IARC 2B category because those classifications include substances that should belong in GHS Category 1B. Many substances that have been reviewed by NTP and IARC and found to have sufficient animal evidence of carcinogenicity should be classified in GHS Category 1B rather than Category 2. NIOSH will need to further scrutinize individual substances where there is not agreement or where in the NTP and IARC reviews are dated.	*NIOSH appreciates this response but notes that the NIOSH Correspondence Table has been removed from the document for further analysis and development.*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	The UAW supports the criteria proposed by NIOSH for the equivalences among the IARC, NTP, and GHS carcinogenicity classifications. We agree that it is appropriate to further scrutinize the NTP classification "reasonably anticipated" and the IARC 28 category because those classifications include substances that should belong in GHS Category 1B. Many substances that have been reviewed by NTP and IARC and found to have sufficient animal evidence of carcinogenicity should be classified in GHS Category 1B rather than Category 2. This is appropriate given the nature of the IARC and/or NTP classifications and the GHS criteria. This also underlines the need for individual review of these substances by NIOSH when making these classifications. In some cases, the NTP and IARC reviews may be outdated, and important new information is now available that would indicate that this substance should be classified at a higher level. The use of mechanistic data in these evaluations is increasing, and the criteria for using these data in cancer classification systems are evolving. NIOSH should provide some level of individual review of the basis for the most recent classification by IARC or NTP and of more recent scientific studies on that substance when developing any classification decision.	*NIOSH appreciates this response but notes that the NIOSH Correspondence Table has been removed from the document for further analysis and development.*

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, (ACC)	ARASP supports an approach to utilize GHS carcinogen classifications when relevant and applicable to identify occupational hazards, as it will allow a means of developing common positions and consistency in the evaluation of chemical risks. The Revised Policy plans to assign a GHS carcinogen category of 1A (known to have carcinogenic potential for humans) whenever the NTP, EPA or IARC have made a corresponding classification. However, for other categories, assigning classifications is not as straightforward. For example, NIOSH's approach allows the possibility of a GHS classification of 1B (presumed to have carcinogenic potential for humans) for substances that have been classified by NTP as "reasonably anticipated." It is possible that a substance classified by NTP as "reasonably anticipated" could have been classified based on less than sufficient evidence of carcinogenicity in humans or laboratory animals and as such this type of substance would be more ac curately assigned a GHS classification of Category 2 (suspected carcinogen) based on evidence which is not sufficiently convincing. While this is partially addressed in the text on page 27, it is not accurately captured in Table 1 or 2 which appear to imply that all NTP RoC classifications of "reasonably anticipated" are equivalent to a GHS classification of 1B. It is unclear in the Revised Policy whether NIOSH will utilize a default approach of assigning a GHS classification of 1B to chemicals classified by NTP as "reasonably anticipated." Using the NTP classification without sufficient review of the underlying data could lead to misleading or inaccurate NIOSH classifications. It is also important to note that an NTP classification does not necessarily consider important mechanistic and mode of action information that may impact a final classification reached by NIOSH. **Recommendation – In order to ensure the consideration of current scientific knowledge, NIOSH should evaluate each cancer classification on a substance by substance basis. The evaluation should explicitly review all available data, including information that may not have been considered or available during**	*NIOSH appreciates this response but notes that the NIOSH Correspondence Table has been removed from the document for further analysis and development.*

Commenter/Topic	Public Comment	*NIOSH Response*
	the time NTP, EPA or IARC derived its classifications. A thorough systematic review of the available data will be necessary to ensure that the appropriate classification is scientifically supported and assigned by NIOSH.	

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Fendley, (USW)	In general, USW supports the criteria proposed by NIOSH for the equivalences among the IARC, NTP, and GHS carcinogenicity classifications. It is certainly appropriate for NIOSH to determine the applicable Globally Harmonized System of Classification and Labeling (GHS) carcinogen category for all listed chemicals due to OSHA's adopting of GHS under the hazard communication standard and growing familiarity with the GHS system among workers in the United States.	*NIOSH appreciates this response but notes that the NIOSH Correspondence Table has been removed from the document for further analysis and development.*
	Question #6: Is the proposed target risk level policy explained in a clear and transparent manner? Is the basis for the proposed policy adequately explained? If not, specify (section, page, and line number) where clarification is needed.	

Commenter/Topic	**Public Comment**	***NIOSH Response***
Diane Brown, (AFSCME)	The proposed target risk level policy and its basis are adequately explained. AFSCME does not agree with a 1 in 1,000 working lifetime risk. We understand the history of NIOSH's basis for the proposed policy. The 1 in a 1,000 lifetime risk represents an interpretation by the Solicitor of Labor's (SOL) office of a non-binding footnote to the Benzene case.1 While OSHA must respond to the SOL, NIOSH is under no such obligation. NIOSH is a scientific organization, does not issue binding regulations, and is not covered by the Benzene case. The mission of NIOSH is to generate new knowledge in the field of occupational safety and health and to transfer that knowledge into practice for the betterment of workers. To adopt 1 in 1,000 working lifetime risk as the target level for a recommended exposure limit (REL) would be contrary to NIOSH's mission. If followed, the recommendation could result in 1000 fatal cancer cases per million workers exposed. People have the same right to protection at work that they do in other activities. There can be no justification for setting exposure limits for workers that provide less protection than for the general population, for which de minimis risk is considered to be 1 in 1 million lifetime risk. If NIOSH determines that it is necessary to establish a target risk level, AFSCME would encourage NIOSH to use EPA's de minimis risk level of 10-6 . In principle, workers have the same human right to protection from carcinogenic exposures as other members of our society.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. As explained in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible." Also, "An excess lifetime risk level*

Commenter/Topic	Public Comment	*NIOSH Response*
		of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical.*

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Fendley, (USW)	The proposed target risk level policy is clearly explained, although as noted above, USW disagrees with the target risk level.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. As explained in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible." Also, "An excess lifetime risk level*

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		of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical.*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	The proposed target risk level policy and its basis are adequately explained. However, the UAW believes that 1/1000 lifetime risk is not adequate protection for workers. NIOSH is a scientific organization in the U.S. Public Health Service. It does not issue binding regulations and it is not covered by the Benzene case 1. Moreover the 1 in 1,000 working lifetime risk represents an interpretation by the Solicitor of Labor's (SOL) office of a non-binding footnote to the Benzene case. While OSHA must respond to the SOL, NIOSH is under no such obligation. The mission of NIOSH is to generate new knowledge in the field of occupational safety and health and to transfer that knowledge into practice for the betterment of workers. To adopt 1 in 1,000 working lifetime risk as the target level for a recommended exposure limit (REL) would be contrary to NIOSH's mission. It would be outrageous for any entity within the U.S. Public Health Service to issue a recommendation which, if followed, would result in 1000 fatal cancer cases per million workers exposed. People have the same right to protection at work that they do in other activities. There can be no principled justification for setting exposure limits for workers that provide less protection than for the general population, for which de minimis risk is considered to be 1 in 1 million lifetime risk. If there are legal or administrative reasons for which NIOSH needs to provide information as to exposure levels associated with 1 in 1000 lifetime risk, the information provided should not be described as a recommended exposure limit. Scientifically, it is not necessary to have a particular target risk level. Due to uncertainty and inherent incompleteness of information, as described in Science and Decisions: Advancing Risk Assessmenf, any target risk level chosen may be associated with a wide range of exposure levels. Even the 95% lower confidence limit estimate of the dose producing a 1 in 1,000 lifetime excess	*As explained in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible." Also, "An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of*

Commenter/Topic	Public Comment	*NIOSH Response*
	risk can be sensitive to the assumptions used in the model from which it is derived. This sensitivity can mean the limit, itself, is really a range. NIOSH criteria documents for carcinogens should be explicit about the uncertainties and the variability involved in any estimate of risk and should provide details as to the uncertainties and variability involved in estimating the risk associated with a particular substance.	*exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures.* *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical.*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	More robust data sets have less uncertainty and, for any given data set, the further away one extrapolates from the range of observed data, the more uncertainty there is. This means that it might be the case that for one substance there is adequate evidenceto estimate an exposure level associated with a 10-4 risk while for another substance the evidence supports an estimate of a 10-5 risk. For each substance, it might be the case that uncertainties are such that meaningful estimates of exposure levels associated with lower risks are not possible. This would be an adequate reason to publish RELs associated with different risk levels as long as NIOSH clearly articulates the uncertainties involved and the reasons for its choices in its criteria documents. For this reason the UAW does not believe that NIOSH necessarily has to choose a target risk level. If NIOSH determines that it is necessary to establish a target risk level, the UAW would encourage NIOSH to use EPA's de minimis risk level of 10-6 . This is because in principle, workers have the same human rights to protection from carcinogenic exposures as other members of our society. If NIOSH were to find it necessary, for some reason, to choose a target risk level higher than 10-6 , the UAW would strongly encourage NIOSH to provide detailed reasons for which the choice is necessary and to issue a statement that NIOSH nevertheless believes that, in principle, workers have the same human rights to protection from carcinogenic exposures as other members of our society.	*As explained in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible." Also, "An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of*

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		exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical.*

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, (ACC)	Resolving Conflicts Between NTP, EPA and IARC Classifications In the Revised Policy it is unclear whether NIOSH will consider a hierarchy when utilizing the classifications derived from other agencies. Page 24 of the Revised Policy notes that when differences arise NIOSH will consider the totality of the data and the relevance of the data to the workplace and the review will be based on how recently the data were evaluated, how complete the data set was, and whether the routes of exposure, modes of action, and other considerations were relevant to workplace exposures. Recommendation – The Revised Policy should include greater discussion regarding if NIOSH will utilize a hierarchy when relying on other agencies classifications to reach conclusions. Recommendation – NIOSH should include information about the WOE framework it will plan to employ to ensure that all relevant information is considered. There are several approaches that NIOSH should consider related to the evaluation of risk from less-than-lifetime exposures,11 combining toxicological and epidemiological evidence to establish causal inference,12 utilization of mode of action information in evaluations13 and best practices for conducting systematic review14.	*NIOSH has clarified language regarding how it will utilize information from EPA, NTP and IARC for carcinogen classification. As stated in the document, "NIOSH will review information and scientific studies relied upon by NTP, EPA, or IARC in developing each chemical carcinogen hazard assessment to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment. Under such circumstances, NIOSH will either nominate the chemical to NTP for review or conduct a full review of the evidence and classify the chemical itself. This review will include consideration of route of exposure, tumor site, mode of action, and any other scientific information that may have bearing on the occupational relevance of the carcinogen classification."* *With regard to weight-of-evidence considerations, NIOSH states in the document, "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or*

Commenter/Topic	Public Comment	*NIOSH Response*
		stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical evaluation of chemical carcinogenicity should be made explicit [Weed 2005]."

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, (ACC)	Approach to Exposure-Response The Revised Policy states that NIOSH will treat exposure-response as low-dose linear unless a non-linear mode of action has been clearly established (page 30 of the Revised Policy). As the scientific understanding relating to mode of action is rarely, if ever, 'clearly established,' any default approach should consistently consider the current understanding of modes of action and dose response relationships relevant to the exposure levels of concern. Unfortunately, the NIOSH proposed approach does not appear to readily allow for the consideration of mode of action information. Consequently, the NIOSH default approach of low-dose linearity can potentially over estimate risk. As noted in the EPA's 2005 Guidelines for Carcinogen Risk Assessment15: "The linear approach is used when: (1) there is an absence of sufficient information on modes of action or (2) the mode of action information indicates that the dose-response curve at low dose is or is expected to be linear. Where alternative approaches have significant biological support, and no scientific consensus favors a single approach, an assessment may present results using alternative approaches. A nonlinear approach can be used to develop a reference dose or a reference concentration (see Section 3.3.4)." Recommendation – NIOSH should revise its current approach to allow for the use of mode of action information in determining whether low -dose linearity is warranted. In the event that the available data could support either a linear or non-linear dose- response, both approaches should be presented and utilized to develop RELs.	*A full description of NIOSH risk assessment methods, including consideration of mode of action, is beyond the scope of this document. As stated in the document, "The discussion below summarizes key elements of the NIOSH approach to QRA. NIOSH expects to publish more comprehensive guidance describing its approach to risk assessment in the future. Until then, NIOSH will continue to use the risk assessment methods as more fully described in the NIOSH Criteria Document on Hexavalent Chromium [NIOSH 2013] and Current Intelligence Bulletin on Titanium Dioxide [NIOSH 2011a]."*

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, (ACC)	Utilizing Best Available Chemical Assessment Practices In section 5.0 of the Revised Policy, NIOSH describes its process for the development of candidate RELs. It states that "NIOSH conducts quantitative risk assessment by using mathematical models to describe the exposure-response and to estimate low-dose risk." NIOSH in turn uses those estimates to set RELs. However, the Revised Policy does not describe the types of modeling that NIOSH intends to utilize when developing RELs. Additionally, the Revised Policy states that as NIOSH uses epidemiology data to develop RELs it "…will project both the central estimate and a 95% lower confidence limit, and the REL will typically be based on the 95% lower confidence limit. While we support the presentation of both the central estimate and the 95% lower confidence limit, NIOSH should not have a default approach to deriving RELs based on the 95% lower confidence limit. Recommendation – Some discussion should be added to the Revised Policy to reflect available modeling approaches that may be employed by NIOSH. Recommendation – When deriving a REL that is based primarily on animal data, NIOSH should develop a human equivalency concentration (HEC) to adequately incorporate available toxicokinetic information in the REL calculation. EPA's 2005 Guidelines on Carcinogenic Risk Assessment provides additional detail on the derivation and utility of HECs. Recommendation – An objective and transparent REL derivation process should rely on the best available dose-response data to determine the best estimate for calculating a REL. NIOSH should determine whether to use the central estimate or the 95% lower confidence limit based on the data available and not have a default policy of utilizing the 95% lower confidence limit.	*NIOSH notes that this document was not intended to provide detailed instructions on how RELs are derived. As stated in the document, "The discussion below summarizes key elements of the NIOSH approach to QRA. NIOSH expects to publish more comprehensive guidance describing its approach to risk assessment in the future. Until then, NIOSH will continue to use the risk assessment methods as more fully described in the NIOSH Criteria Document on Hexavalent Chromium [NIOSH 2013] and Current Intelligence Bulletin on Titanium Dioxide [NIOSH 2011a]."*

Commenter/Topic	Public Comment	*NIOSH Response*
Deborah Proctor of ToxStrategies, Inc. and Marc Kolanz, CIH, Materion Brush Inc.	The current language in the Draft Cancer Policy adequately explains the rationale for using the target risk level at 1 in 1,000 lifetime excess risk. However, NIOSH has not clearly described its basis for using the 95% lower confidence limit of the maximum likelihood estimate (MLE) for a 1 in 1,000 risk when modeling epidemiological data. This is a departure from NIOSH's, as well as OSHA's, previous approaches to risk assessment using human data and has been put forward without justification. This policy is objectionable for a number of reasons. First, if NIOSH wishes to describe uncertainty based on statistical variability, then both the upper and lower confidence limits should be presented. However, the REL should be based on the MLE because the MLE is the most scientifically and statistically supportable value. Second, as NIOSH is aware, the quality of epidemiological studies varies considerably as well as their utility for risk assessment. If multiple studies have similar MLE results, relying on the lower confidence limit, rather than the MLE, as the basis for the REL will result in a REL based on the study with the least statistical power and widest confidence intervals. Hence, use of the MLE as the basis of the REL, with an explanation of the variability around that value, including the upper and lower confidence limits, is preferable as opposed to using only the lower confidence interval. Use of the MLE will provide the best information to characterize cancer risk and as the basis for a REL. Use of the 95% lower confidence limit adds an additional layer of conservatism that is not necessary or warranted in most cases.	*NIOSH has revised the language regarding the 95% lower confidence limit in the document to further describe the reasoning. As stated in the document, "When practical, given the available data for QRA, NIOSH will project both a central estimate and a 95% lower confidence limit estimate of various exposure concentrations of interest. NIOSH will base its risk estimates on the 95% lower confidence limit, when it is feasible to do so. The central estimate of risk is analogous to a mean or average concentration corresponding to a specific risk level, which in this example is 1 in 10,000. The 95% lower confidence limit is a measure of the imprecision in the risk estimate, and by using the 95% lower confidence limit as the basis for NIOSH risk estimates, there is greater assurance that workers are protected to at least a risk level of 1 in 10,000 over a working lifetime." However, NIOSH recognizes that in some cases the data do not support use of the lower confidence limit. NIOSH will evaluate the information on a case by case basis, but in the absence of a reason not to use the lower confidence limit, NIOSH prefers that limit in the development of an RML-CA.*

Commenter/Topic	Public Comment	*NIOSH Response*
Deborah Proctor of ToxStrategies, Inc. and Marc Kolanz, CIH, Materion Brush Inc.	Finally, although not typically recognized, it is important to point out that RELs protective of cancer are developed for cumulative average exposures divided into daily exposures for a 45 year working lifetime and compared to exposure measures (industrial hygiene data) collected over the course of a work shift. Variability in workplace exposure and methods to evaluate compliance with OELs for airborne substances are discussed extensively in Ogden and Lavoue (2012) and Deubner (2013). Ogden and Lavoue (2012) state, "In practice, it is common to require that exposure is controlled so that <5% of exposures exceed the limit …" Thus, in practice, compliance with an OEL is met when the 95th percentile is <OEL. If the 95 th percentile of airborne exposures equals the REL, consistent with compliance, then the mean of exposure is expected to be far below the REL because exposures vary log-normally (Ogden and Lavoue 2012). As carcinogenic RELs are calculated from cumulative average exposure, compliance with the REL 95% of the time, results in average exposure that is associated with far less than 1 in a 1,000 increased risk. Further, carcinogenic RELs are protective of potential cumulative exposure occurring 5 days per week, 50 weeks per year, for 45 years, and actual individual exposure duration is typically of far less than 45 years. Thus, although RELs are traditionally set for 45 years of exposure, it is appropriate for NIOSH to recognize the risk at the REL is below 1 in 1,000 for exposure durations less than 45 years. Finally, NIOSH should recognize and describe that many chemicals demonstrate a dose- rate effect where higher exposures experienced over a shorter period of time (such as in some epidemiology studies or animal toxicology studies used as the basis for the REL) result in greater damage, e.g., oxidative stress and inflammation from high dose particle loading that would be repaired at lower exposures. These high dose effects promote, and in some cases, cause tumor formation and are not relevant at lower exposures. The	*This document does not address the practice of individual companies requiring compliance so that the 95th percentile of exposures are less than the REL (or in the case of carcinogens, the RML-CA). NIOSH will refer this comment to the exposure assessment team.* *With regard to the dose-rate effect, when data are available to substantiate and describe a dose-rate effect, NIOSH uses that information in setting RELs (or RML-CAs). For example, if there is concern that higher short term exposures may be hazardous, NIOSH may set a short-term exposure limit (STEL). These considerations are beyond the scope of this document.*

Commenter/Topic	Public Comment	*NIOSH Response*
	risk of cancer at lower exposure levels, which are insufficient to cause these high-dose effects, are overestimated when using a cumulative exposure metric, and dividing exposure over a working lifetime, as is done for calculation of the carcinogenic RELs. Thus, setting RELs at a 1 in 1,000 target risk level realistically achieves theoretical excess risks far below this target risk level. For several reasons described herein, in a work environment that consistently achieves the REL (95% of the time), actual average cumulative exposure will be lower than that associated with a theoretical or actual 1 in 1,000 increased risk.	

Commenter/Topic	Public Comment	*NIOSH Response*
	Question #7: An analytical feasibility (AF) notation will be used to identify those RELs that are established to reflect the limitations of the sampling and analytical method (i.e., AF) and not the target risk level of 1 in 1,000. Is this notation adequately explained?	

Commenter/Topic	Public Comment	*NIOSH Response*
Diane Brown, (AFSCME)	It is AFSCME's position that all RELs should be health-based. Workers read the term "Recommended Exposure Limit" and assume it to mean "safe". Since some currently published RELs are based on analytic feasibility, AFSCME supports labeling them as such in order to alert users that the REL is not health-based target risk level, but instead reflects the limitations of the sampling and analytical method. By definition, an analytic feasibility REL is set at a level at which NIOSH has determined there is still significant risk. AFSCME opposes the establishment of any new analytic feasibility RELs and urges NIOSH to replace all existing analytic feasibility RELs with health-based RELs. We do not believe that setting RELs according to analytic feasibility is consistent with NIOSH's mission. In addition, analytic feasibility RELs can become outdated quickly as technology improves.	*As stated in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level.* *In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. NIOSH defines an RML-CA as the maximum 8-hour*

Commenter/Topic	Public Comment	*NIOSH Response*
		time-weighted average concentration of an occupational carcinogen above which a worker should not be exposed. An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."*

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Fendley, (USW)	The proposed policy is clearly explained. As noted above, USW does not agree that NIOSH should be setting new RELs based on AF.	*As stated in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. NIOSH defines an RML-CA as the maximum 8-hour time-*

Commenter/Topic	Public Comment	*NIOSH Response*
		weighted average concentration of an occupational carcinogen above which a worker should not be exposed. An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	It is the position of the UAW that all RELs should be health based. Since there exist RELs based on analytic feasibility, the UAW strongly supports labeling them as such in order to alert users that the REL is not health-based target risk level, but instead it reflects the limitations of the sampling and analytical method. However, the UAW opposes the continued existence of analytic feasibility RELs. By definition, a RELAF is set at a level at which NIOSH has determined there is still a significant risk. For reasons similar to those articulated above in the answer to question 6, we do not believe that setting RELs according to analytic feasibility is consistent with NIOSH's public health mission. Moreover, analytic feasibility RELs can become outdated quickly as analytic technology improves. The UAW opposes the establishment of any new analytic feasibility RELs and urges NIOSH to replace all existing analytic feasibility RELs with health based RELs. The UAW strongly disagrees with NIOSH's statement that a sampling and analytical method must be available to accurately measure exposures at the REL. If there is no available method or if the limit of quantitation is higher than the health-based target risk level, the establishment of a health-based NIOSH REL, may spur the development of technology to measure exposures at the appropriate level. Since NIOSH RELs are not enforceable, the fact that appropriate measurement technology will not be available immediately does not create legal problems. A research and development recommendation in the absence of a REL is likely to fall on deaf ears.	*As stated in the document, "Several commenters criticized the NIOSH proposal to set the REL at the LOQ when the LOQ value is greater than the 1 in 1,000 cancer risk estimate presented in the public draft of this document. They urged that NIOSH should set the REL at the level necessary to protect worker health and not at some higher level. These commenters indicated that analytic methods change frequently, and a REL set at the LOQ will rapidly become out of date. Many of these commenters also suggested that NIOSH set two levels—the REL calculated to be health protective and the higher level suggested by the LOQ. The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When the LOQ is greater than the lower bound of the 1 in 10,000risk estimate, NIOSH will consider initiating research to improve the LOQ for the analytical method. In addition, NIOSH will revise the RML-CA when the LOQ for a NIOSH or OSHA validated or partially validated analytical method is reduced."*

Commenter/Topic	Public Comment	*NIOSH Response*
	Question #8: Is the proposed analytical feasibility and technical achievability policy explained in a clear and transparent manner? Is the basis for the proposed policy adequately explained? If not, specify (section, page, and line number) where clarification is needed.	
Diane Brown, (AFSCME)	AFSCME is pleased that NIOSH will no longer specifically consider engineering achievability for each chemical-specific REL. As stated above, we believe that RELs should be health based. A health based REL may drive new engineering solutions or substitution.	*NIOSH appreciates this support for this policy.*
Anna Fendley, (USW)	The proposed policy is clearly explained.	*No response required.*
Darius Sivin, PhD, UAW	The UAW is pleased that NIOSH will no longer specifically consider engineering achievability for each chemical-specific REL. We believe that NIOSH lacks the resources to evaluate this well. In addition, we believe that RELs should be health based. A health based REL may drive new engineering solutions or substitution.	*NIOSH appreciates this support for this policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
Anonymous	I must answer NO to question number ONE and YES to question number TWO.	*NIOSH has considered the existing science on the exposure-risk relation between chemical carcinogens and cancer in drafting its carcinogen policy. As stated in the document, "The mode of action for carcinogens can affect the mathematical modeling assumptions and change the way a QRA is conducted. Genotoxic ("DNA damaging") carcinogens are presumed to act via non-threshold mechanisms, and occupational exposure limits for these chemicals are typically based on low-dose linear models. It is often assumed that carcinogens that act through non-genotoxic mechanisms (such as hormonal imbalance) or through indirect mechanisms (such as genotoxicity secondary to inflammation) may have response thresholds below which the carcinogenic mechanism is inoperative and the excess risk is zero. However, it has been noted that any supposed threshold for a carcinogen can be adequately modeled by a sublinear, but non-threshold, mathematical model. Because of this, it is highly unlikely that one can demonstrate empirically that a threshold exists [Crump 2011]."* *In response to the commenter's second point, the current document is supported by an extensive review of the existing scientific*

Commenter/Topic	Public Comment	*NIOSH Response*
		information. NIOSH continues to assess the science as it evolves.

Commenter/Topic	Public Comment	*NIOSH Response*
Anonymous	In particular, whatever toxicological models and assumptions that are made and/or considered need to include non-linear "biphasic dose-response" models and mechanisms. The characteristic of these "... mechanisms involv[e] activation of adaptive cellular stress response pathways (ACSRPs)." These models are also known as hormetic models. The reason that biphasic dose-response toxicology models should be included is that they more accurately represent biological and biopsychosocial systems. Assuming a strict linear non-threshold model oversimplifies highly complex processes, overestimates the risks involved with exposure to many substances and processes, and creates undue regulatory burden in the economy. The notion (or "blind faith") that one alpha-particle, one molecule of benzene, or one asbestos fiber "causes cancer" does not match reality and should not be used for policy nor in the regulatory structure.	*In the absence of evidence of a nonlinear mode of action, NIOSH follows the widely accepted practice of treating the exposure-response relation for carcinogens as low-dose linear. However, when sufficient evidence of non-linearity is present, the present policy allows for estimating a non-linear exposure-response, as defined by the data. As stated in the document, "The mode of action for carcinogens can affect the mathematical modeling assumptions and change the way a QRA is conducted. Genotoxic ("DNA damaging") carcinogens are presumed to act via non-threshold mechanisms, and occupational exposure limits for these chemicals are typically based on low-dose linear models. It is often assumed that carcinogens that act through non-genotoxic mechanisms (such as hormonal imbalance) or through indirect mechanisms (such as genotoxicity secondary to inflammation) may have response thresholds below which the carcinogenic mechanism is inoperative and the excess risk is zero. However, it has been noted that any supposed threshold for a carcinogen can be adequately modeled by a sublinear, but non-threshold, mathematical model. Because of this, it is highly unlikely that one can demonstrate empirically that a threshold exists [Crump 2011]."*

Commenter/Topic	Public Comment	*NIOSH Response*
Anonymous	The reference citation that needs to be integrated with the "Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace" is the following: Mattson, M.P. and Calabrese, E.J. (2010). Hormesis: A Revolution in Biology, Toxicology and Medicine. New York, NY: Springer. ISBN 978-1-60761-494-4 DOI 10.1007/978-1-60761-495-1 http://dx.doi.org/10.1007/978-1-60761-495-1 The page of the "Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace" where this reference should be integrated is on page 31 and the paragraph starts with "The mode of action for carcinogens can affect the mathematical modeling assumptions..." It also needs to be integrated on page 33 in the section on " ... target risk level for setting RELs". Thank you for your time and efforts.	*The current policy allows for estimating a nonlinear exposure-response when sufficient evidence is present. NIOSH has extensively reviewed the scientific literature on nonlinear dose-risk relationships between chemical carcinogens and cancer. The existing evidence support nonlinear modeling approaches for non-genotoxic or indirectly genotoxic carcinogens that result in some residual risk for any exposure greater than zero. Sufficient evidence supporting hormesis as a superior exposure-response model for risk management is lacking at this time.*

Commenter/Topic	Public Comment	*NIOSH Response*
Deborah Proctor of ToxStrategies, Inc. and Marc Kolanz, CIH, Materion Brush Inc.	NIOSH Questions #3-5 As discussed in the Comments offered by Mr. Marc Kolanz of Materion, NIOSH should not automatically accept the carcinogen classification determination of other bodies as a basis for classifying a substance as an occupational carcinogen. Moreover, it is important to note that these classifications are qualitative and do not inform quantitative risk assessment processes. At a minimum, the existence of these different, and sometimes conflicting, classification schemes underscores the need for NIOSH to make an independent determination regarding the carcinogenicity of different substances for work-place exposures. However, the utility of considering the different carcinogen classifications has not been made clear in the Draft Cancer Policy. It is furthermore unclear how, "The NIOSH- assigned GHS carcinogen classification will improve risk communication for employers and workers by helping them identify hazards and target strategies to reduce exposure" (NIOSH 2013, p. 4, lines 12-14). As noted in the document, "In the 12th RoC, NTP states 'the listing of substances in the RoC only indicates a potential hazard and does not establish the exposure conditions that would pose cancer risks to individuals in their daily lives.'" (NIOSH 2013, p. 14, lines 15-17). NIOSH should add clarifying language that clearly indicates the purpose of using classifications, specifically as a tool for aiding risk communications to workers. If NIOSH believes that its determination should include different classifications than those offered by other entities, NIOSH should use the GHS classification system adopted by OSHA. Finally, the Draft Cancer Policy states: *"In most cases, if one agency classifies a chemical in its highest level for evidence of carcinogenicity and another agency classifies it at a lower level of concern (e.g., NTP: reasonably anticipated to be a human carcinogen and EPA: Group A: human carcinogen), NIOSH will assign the GHS category that has a classification that affords the most health protection (in the example, GHS*	*With regard to the carcinogen classifications by NTP, EPA and IARC, the document states, "NIOSH will review information and scientific studies relied upon by NTP, EPA, or IARC in developing each chemical carcinogen hazard assessment to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment. Under such circumstances, NIOSH will either nominate the chemical to NTP for review or conduct a full review of the evidence and classify the chemical itself. This review will include consideration of route of exposure, tumor site, mode of action, and any other scientific information that may have bearing on the occupational relevance of the carcinogen classification."* *With regard to the risk assessment, this document was not intended to provide a thorough review of NIOSH risk assessment methods. As stated in the document, "The discussion below summarizes key elements of the NIOSH approach to QRA. NIOSH expects to publish more comprehensive guidance describing its approach to risk assessment in the future. Until then, NIOSH will continue to use the risk assessment methods as more fully described in the NIOSH Criteria Document on Hexavalent Chromium [NIOSH*

Commenter/Topic	Public Comment	*NIOSH Response*
	carcinogen category 1A: known human carcinogen, corresponding to the EPA Group A: human carcinogen classification). Exceptions to this might occur if NIOSH determines the data supporting carcinogenicity considered by one agency is more occupationally relevant than data considered by another agency" (NIOSH, 2013, p. 26, lines 13-20). The above text implies that if the three agencies (NTP, EPA, IARC) categorize a carcinogen in such a way that results in different GHS categories, NIOSH will favor the categorization that "affords the most health protection." While NIOSH's exercise in forcing these various classifications into one of the GHS categories is of questionable value, it should be clear that NTP, EPA, and IARC categorizations are not updated annually, and that the dates that these agencies derive/publish their categorizations can reflect different states of the science at the time the decisions were made. NIOSH should not simply base their GHS categorization on the most health protective classification made by another agency, but rather on its independent analysis of the current state of the science.	*2013] and Current Intelligence Bulletin on Titanium Dioxide [NIOSH 2011a]."* *In addition, in the revision of the document, NIOSH has removed the GHS NIOSH Correspondence Table for additional analysis and development.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Kimberly Wise, (ACC)	Input on NIOSH Questions 1 – 4 As the topics covered in these four questions are related, ARASP is providing a combined response to them. The Revised Policy outlines NIOSH's process to assess potential chemical hazards in the workplace that may increase cancer risk. The approach plans to utilize carcinogen classifications from other organizations along with the information on associated workplace exposures. If NIOSH finds the scientific basis for the cancer classification relevant to occupational exposure then it will list that chemical as an occupational carcinogen. ARASP supports a process that utilizes up-to-date scientific knowledge about human health impacts and occupational exposure in an objective and systematic way to evaluate carcinogenic risk. Recommendation – NIOSH should ensure that its process allows for the utilization of all available scientific evidence when evaluating risk and relies on mode of action information to determine the relevance and biological plausibility for occupational exposure that could result in a cancer risk.	*As stated in the document, "NIOSH will review information and scientific studies relied upon by NTP, EPA, or IARC in developing each chemical carcinogen hazard assessment to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment. Under such circumstances, NIOSH will either nominate the chemical to NTP for review or conduct a full review of the evidence and classify the chemical itself. This review will include consideration of route of exposure, tumor site, mode of action, and any other scientific information that may have bearing on the occupational relevance of the carcinogen classification."*

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, (ACC)	As the topics covered in these two questions are related, ARASP is providing a combined response to them. The proposed feasibility policy and the analytical feasibility notation are adequately explained in the Revised Policy. Employers and employees benefit from health protective RELs which are based on the most relevant scientific information for evaluating occupation exposures and that can be measured using available analytical technologies. Recommendation – ARASP supports a policy that allows for the establishment of RELs at a level where exposure can be accurately measured and quantified.	*As stated in the document, "NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. NIOSH defines an RML-CA as the maximum 8-hour time weighted average concentration of an occupational carcinogen above which a worker should not be exposed.* *An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or*

Commenter/Topic	Public Comment	*NIOSH Response*
		substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."*

Commenter/Topic	Public Comment	*NIOSH Response*
Deborah Proctor of ToxStrategies, Inc. and Marc Kolanz, CIH, Materion Brush Inc.	It is appropriate for NIOSH to recognize the technical limits of analytical methods in quantifying exposures and to adopt the AF notation in setting RELs. It is important, however, that a quantitative risk assessment be conducted first to ensure that the limit of quantifications (LOQs) not become default RELs. Furthermore, it is unclear how NIOSH will address variability in achieving the stated LOQ and how the LOQ values will be changed over time as technical advances in analytical chemistry occur. Practically, the LOQ and minimum detection limit may vary based on the sample, e.g., presence of analytical interferences, sample collection type (e.g., total, inhalable or respirable), volume, etc, and work place conditions such as humidity. Thus, in some cases, it may be feasible to quantify the level of exposure below the specified LOQ and determine whether the risk-based REL has been achieved, and in other cases it may not be technically feasible to achieve the LOQ. These possibilities may introduce unnecessary confusion as to whether exposures are consistent with the REL. The Draft Cancer Policy needs to clarify that analytical feasibility should only use NIOSH-approved analytical methods as the benchmark for determining LOQs and the need to revise any AF-notated RELs.	*As stated in the document, "A sampling and analytical method that can accurately measure the exposure concentration over the recommended sampling period is necessary to assess occupational exposures below the RML-CA. NIOSH evaluates the method used to measure worker exposures to determine the LOQ, or how low a concentration can be reliably measured. It is important to identify a sampling and analytical method that can accurately measure the chemical at the health-based RML-CA (that is, the lower bound of the 1 in 10,000 excess cancer risk estimate), when it is available. After deriving the RML-CA, NIOSH will determine whether a NIOSH or OSHA analytical method can accurately measure the carcinogen at the RML-CA. If NIOSH determines that no partially or fully validated method is available, NIOSH will consider initiating research to develop a suitable method. When measurement of the occupational carcinogen is not analytically feasible at the lower bound of the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the LOQ of the analytical method for that occupational carcinogen." And further, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When the LOQ is greater than the lower*

Commenter/Topic	Public Comment	*NIOSH Response*
		bound of the 1 in 10,000 risk estimate, NIOSH will consider initiating research to improve the LOQ for the analytical method. In addition, NIOSH will revise the RML-CA when the LOQ for a NIOSH or OSHA validated or partially validated analytical method is reduced."

Commenter/Topic	Public Comment	*NIOSH Response*
Carcinogen Classification		
Christopher Lish and PSR	The NIOSH should maximize its resources and capacity by leveraging reviews and assessments of the carcinogenicity of chemicals conducted by other authoritative bodies.	*NIOSH appreciates this support for this NIOSH policy.*
Tony Stefani (SFFCPF)	We support using the other authoritative lists to identify carcinogens, which reduces duplication of effort and reserves NIOSH resources to look at the specific risks those chemicals pose to workers. We encourage NIOSH to assume all carcinogens are occupationally relevant, particularly since we may be exposed to them if there is a fire or other disaster at eh source of their production.	*NIOSH appreciates this support for this NIOSH policy.*
James L. McGraw, (IISRP)	The IISRP supports NIOSH's efforts to revise their carcinogen classification policy but we also believe that NIOSH should review each substance on a case by case basis to make sure that the most current scientific data is being utilized in drawing conclusion as to the appropriate classification.	*As stated in the document, "As part of its determination, NIOSH will review each chemical carcinogen hazard assessment, in conjunction with the information noted in the Chemical Carcinogen Policy's Industrial Usage and Hazard Assessment and Scientific Studies sections, to determine if the chemical meets the criteria of occupational relevance. Those chemicals that meet the relevance criteria will be designated "occupational carcinogens."*
Pamela Miller, (ACAT)	ACAT supports NIOSH's proposal to use the classifications issued by the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC). Under this new policy, NIOSH will be better able to focus its limited resources. NIOSH's mission will also be strengthened by implementing the proposal to use the	*NIOSH appreciates this support for this NIOSH policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
	classification from any of the three organizations that will provide the most health protection for impacted workers.	
Barbara Dawson, CIH, (AIHA)	The new classification policy proposed by NIOSH uses the assessment scheme currently used by the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC). AIHA supports this approach because it will enhance harmonization and will keep NIOSH from the additional cost of time and resources to find an alternate acceptable approach.	*NIOSH appreciates this support for this NIOSH policy.*
Dennis Shusterman, MD, MPH and Kashyap Thakore, PhD, (CDPH)	Relationship to authoritative bodies and Globally Harmonized System The proposal to integrate existing carcinogen classifications from NTP, EPA, and IARC is sensible and represents an efficient use of resources. The decision logic outlined in the draft is fairly straightforward and appears practical. NIOSH's proposal to classify carcinogens into multiple categories is a clear improvement over its current classification scheme utilizing the single category "potential occupational carcinogen." Finally, integrating NIOSH's classifications with the GHS will provide for more efficient hazard communication and control.	*NIOSH appreciates this support for this NIOSH policy.*
Dennis Shusterman, MD, MPH and Kashyap Thakore, PhD, (CDPH)	Occupational relevance One of the criteria for consideration of a chemical as an occupational carcinogen is the "applicability of evidence to occupational carcinogenicity." In section 4.1, the current draft document states: "NIOSH will first determine whether results from high-quality occupational epidemiology studies are available to assess worker cancer risks. When human evidence is not available	*NIOSH agrees that both occupational and non-occupational epidemiologic studies should be considered. This text has been clarified in the final policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
	[our emphasis], NIOSH will evaluate results from animal studies…" It is unclear why the results of human non-occupational epidemiologic studies would not also be considered here.	
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	Assessing occupational relevancy is an important step in the draft policy. One suggestion might be to provide examples of carcinogens that are not occupationally relevant and explain why.	*NIOSH has clarified the language in the document to indicate specific reasons why a chemical may not be considered occupationally relevant.*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	Some concerns and potential edits to the draft policy include: • NIOSH's assessment of occupational relevancy could be expanded for clarity. It would be helpful for NIOSH to assess some carcinogens currently identified by existing classifications as examples of chemicals that would not be considered as occupationally relevant and explain why.	*The assessment of occupational relevancy has been expanded in the final policy as suggested.*
Jeanne Rizzo, RN, (BCF)	Identification of Carcinogens and their Occupational Relevance The Breast Cancer Fund supports the proposal that NIOSH use the designation of carcinogens by the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC). These well-established research bodies expend significant resources to conduct extensive scientific reviews before designating a chemical as carcinogenic. There is no reason for NIOSH to duplicate these reviews thereby diverting scarce resources from other important responsibilities. NIOSH should also start with the presumption that any chemical identified as a carcinogen will have occupational relevance, only dismissing a chemical's impact in the workforce in the face of strong evidence to the contrary. In assigning the applicable carcinogen category under the Globally Harmonized System for	*NIOSH appreciates the Breast Cancer Fund support of this policy. The NIOSH process for developing GHS classifications has been removed from this policy for further analysis and development. NIOSH will use the GHS criteria for carcinogenicity when developing new chemical carcinogen classifications.*

Commenter/Topic	Public Comment	*NIOSH Response*
	Classification and Labelling of Chemicals (GHS) system, we urge NIOSH to perform individualized reviews to take into account different listing criteria and carefully consider more recent scientific evidence, particularly for older NTP, EPA or IARC determinations.	
Dorothy Wigmore, MS, Workforce, Inc.	We do support NIOSH's proposal to use the carcinogen classifications from the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC). We also support NIOSH using the classification decision from any of the organizations that provides the best protection for workers' health. NIOSH then can better focus its efforts on cancer prevention, rather than classification processes. As we have argued recently about right-to-know regulations, these lists allow the agency to use reliable sources rather than the amorphous "weight of evidence" that can be mis-used to cast doubt about the toxicity of various products. Authoritative lists are consistent with the approach used in California's innovative "green chemistry regulation" and are increasingly being used by other jurisdictions implementing the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS).	*NIOSH appreciates this support for this NIOSH policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
James Melius, MD, DRPH, NYS Laborers Health and Safety Trust Fund	However, there are a number of problems in the current draft that need to be addressed. Some statements in the draft policy need to be clarified, and some sections of the draft are confusing in their presentation of key elements of the proposed policy. The latter in particular provide a misleading emphasis to key elements of the policy. 1. The reliance on current carcinogen classification systems is appropriate. The NTP, IARC, EPA, and GHS classification systems are widely utilized and understood. In combination, the first three would, in general, provide classification information based on recent scientific literature, and their reviews utilize reputable scientific experts who utilize transparent and sound classification systems. This approach is preferable to NIOSH reviewing chemicals under its own classification system which could cause additional confusion and require considerable resources to put in place.	*NIOSH appreciates this support for the NIOSH occupational chemical carcinogen classification policy.*
James Melius, MD, DRPH, NYS Laborers Health and Safety Trust Fund	2. In general, I support the criteria proposed by NIOSH for the equivalences among the IARC, NTP, and GHS carcinogenicity classifications. I agree that it is appropriate to further scrutinize the NTP classification "reasonably anticipated" and the IARC 2B category because those classifications include substances that should belong in GHS Category 1B. Many substances that have been reviewed by NTP and IARC and found to have sufficient animal evidence of carcinogenicity should be classified in GHS Category 1B rather than Category 2. This is appropriate given the nature of the IARC and/or NTP classifications and the GHS criteria. However, other substances in those NTP and IARC categories should be classified as GHS Category 2. For example, a substance that was reviewed by IARC and was only raised from Category 3 to Category 2B based on mechanistic data might not have "sufficient evidence of carcinogenicity in animals" or other information needed to qualify for GHS Category 1B. This issue also underlines the need for individual review of these substances by NIOSH when making these classifications. In some cases, the NTP and IARC	*NIOSH has removed the section of the document on assignment of GHS categories for further analysis and development. With regard to review of evidence, NIOSH has revised the text in the document to say: "NIOSH will review information and scientific studies relied upon by NTP, EPA, or IARC in developing each chemical carcinogen hazard assessment to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment. Under such circumstances, NIOSH will either nominate the chemical to NTP for review or conduct a full review of the evidence and classify the chemical itself. This review will include consideration of route of*

Commenter/Topic	Public Comment	*NIOSH Response*
	reviews may be outdated, and more recent information is now available that would indicate that this substance should be classified at a higher level. The use of mechanistic data in these evaluations is increasing, and the criteria for using these data in cancer classification systems are evolving. Therefore, NIOSH should provide some level of individual review of the basis for the most recent classification by IARC or NTP and of more recent scientific studies on that substance when developing any classification decision.	*exposure, tumor site, mode of action, and any other scientific information that may have bearing on the occupational relevance of the carcinogen classification."*
James Melius, MD, DRPH, NYS Laborers Health and Safety Trust Fund	3. I support the NIOSH position that carcinogen determinations performed by these groups should be assumed to be occupationally relevant unless there is a strong evidence to the contrary. There should be no need for an exhaustive review in making this determination.	*NIOSH appreciates this support for this NIOSH policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
Ronald Loeppke, MD, MPH, (ACOEM)	We concur with the NIOSH plan to rely upon the classifications of agents put forward by authoritative bodies, specifically the U.S. National Toxicology Program (NTP) in their Report on Carcinogens (RoC), the U.S. Environmental Protection Agency (EPA) utilizing their Guidelines for Cancer Risk Assessment, and the International Agency for Research on Cancer (IARC). As NIOSH indicates, the use of existing evidence-based classifications of agents precludes the need for NIOSH to duplicate this effort, thus allowing them to focus on worker protection efforts, including setting of appropriate RELs. We endorse the NIOSH proposed approach to utilize the most health-protective classification from these authoritative bodies with the potential exceptions that have been noted. We concur with the approach that NIOSH suggests regarding agents that are likely relevant to workplace settings but that have not been evaluated by the authoritative bodies, such as IARC or EPA, i.e., to nominate them for NTP study or to conduct an internal NIOSH assessment. While we understand the resources involved for NIOSH if they are to develop their own science-based carcinogen classification of an agent in this setting, we feel it is important that NIOSH attempt to "fill the void" in knowledge for occupationally important chemicals/agents. Also, for the purposes of harmonizing classification, we are comfortable with the plan for NIOSH to include their determination of the appropriate GHS (Globally Harmonized System of Classification and Labeling of Chemicals) category, but the original risk categorizations of IARC, NTP and EPA should be retained when they are available for an agent. We do generally agree with the validity of the NIOSH correspondence table (Table 2) and its usefulness as a guide to determine GHS hazard categories.	*NIOSH appreciates this support of this NIOSH policy. The chemical-specific assessment that NIOSH will conduct is clarified and expanded on in the final policy. The assignment of GHS categories has been removed from this policy document for further analysis and development. When developing a new chemical carcinogen classification, NIOSH will use the criteria for carcinogenicity contained in the United Nations' Globally Harmonized System for Classification and Labelling of Chemicals (GHS) that have been incorporated into the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard 29 CFR §1910.1200 and any interpretation of the GHS criteria issued by OSHA. NIOSH will use the GHS criteria to assess carcinogenicity. If NIOSH determines that the evidence for a chemical corresponds to GHS class 1A, 1B, or 2, then NIOSH will designate the substance an "occupational carcinogen."*

Commenter/Topic	Public Comment	*NIOSH Response*
Ronald Loeppke, MD, MPH, (ACOEM)	The IARC and EPA classification systems provide categories that effectively correspond to designating an agent as a known, a probable, or a possible human carcinogen based upon available scientific evidence (NTP in the RoC does not include the latter designation). We agree with NIOSH that the term, "potential occupational carcinogen," does not accurately describe the state of knowledge regarding occupationally relevant known human carcinogens, such as benzene and asbestos. It would be appropriate to describe these agents, for which there is sufficient evidence of carcinogenicity in humans, as occupational carcinogens. However, in the approach proposed by NIOSH, an agent would be designated as an occupational carcinogen, if it were to fall into any of these three levels of evidence groups and if it were occupationally relevant. The decision by NIOSH to label all "occupationally relevant" agents that fall into any one of these categories as occupational carcinogens tends to blur the evidence-based distinctions indicated by these agency classification systems, even though NIOSH intends to list the authoritative body determinations after the occupational carcinogen label. While this appears to be a laudably health-conservative approach, it may "deflate" the perceived importance of the label and may result in misallocation of limited preventive resources by treating a known human carcinogen, such as benzene, in the same fashion as a possible human carcinogen, such as phenyl glycidyl ether or titanium dioxide. Furthermore, this "leveling" may impede the ability to place risks into proper perspective in risk communication efforts directed to workers. Intuitively, it seems reasonable to focus more energy on prevention of exposure for known human carcinogens than for probable or possible human carcinogens, particularly for agents in the latter group with only limited evidence for carcinogenicity in experimental animals or for which the mechanism of carcinogenicity in animals likely does not apply to humans.	*The assessment of occupational relevancy has been expanded in the final policy. In addition, NIOSH intends to communicate the reasons for the NIOSH classification (for example, based on NTP reasonably anticipated to be a carcinogen) when it makes its determination. As stated in the document, "After peer review and public comment, NIOSH will publish in the Federal Register a notice whether a chemical has been determined by NIOSH to be an occupational carcinogen, the reasons for the NIOSH classification, the RML-CA, and the range of risk estimates."*

Commenter/Topic	Public Comment	*NIOSH Response*
Ronald Loeppke, MD, MPH, (ACOEM)	For occupationally relevant agents which are known, probable, or possible carcinogens (as determined above) and for which there is reasonable scientific evidence for dermal absorption as a route of exposure (based upon animal or human evidence), we recommend that NIOSH indicate this potential risk when establishing an REL. The determined REL could then have a "skin" designation, akin to the approach used by the American Conference of Governmental Industrial Hygienists (ACGIH) in publishing threshold limit values (TLVs). For these agents with potential for dermal absorption, NIOSH would then recommend the use of appropriate personal protective equipment that would prevent skin exposure to workers.	*NIOSH has a separate process for assessing dermal hazards. Dermal hazards classifications are derived in Skin Notation Profiles. NIOSH is working on updating the information in the NIOSH Pocket Guide to include skin notation information, including chemicals that are absorbed through the skin that result in systemic toxicity.*
Anna Mazzucco, (NRCWF)	Areas of specific concern including the following: Policy should focus on effective use of resources rather than contributing to duplicated efforts between agencies. The intention of NIOSH to utilize existing NTP/EPA/IARC classifications in order to prevent redundant efforts across different agencies is clearly stated as follows: "Basing the NIOSH classification on the NTP, EPA, and IARC cancer classifications will prevent effort from being duplicated, which will allow NIOSH to focus its work and resources on evaluating the carcinogenic risk to workers and developing recommendations to manage workplace risk." This is indeed a worthy goal, as the President's Cancer Panel stated in their 2010 report, the federal regulatory effort is often stymied by "fragmented and overlapping authorities coupled with uneven and decentralized enforcement". However, for chemicals that have not been classified by NTP/EPA/IARC, NIOSH here maintains the option of developing their own classification system, despite infrastructure that is already in place to facilitate communication between these agencies, e.g. "As a founding member, NIOSH has a representative on the NTP Executive Committee, has input into prioritization of chemicals at NTP, and has a vote in all procedural matters". The intention to consider independent classification efforts raises concerns that the potential for efficient collaboration between federal agencies will not be fully realized, leading to waste of time and resources. Policies should be focused on making	*NIOSH appreciates the support of this policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
	existing systems more effective, not on furthering duplication of effort and lack of communication between agencies.	

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Mazzucco, (NRCWF)	Areas of specific concern including the following: When federal agencies disagree on a carcinogen classification, any "down- classification" must be supported by evidence. Discontinuation of the use of the term "potential occupational carcinogen", and replacement with an evidence-based carcinogen classification system where one has been absent is a positive step. However, while NIOSH plans to adopt NTP/EPA/IARC classifications, in cases where these agencies disagree, NIOSH will "adopt the classification determined to be most relevant to occupational exposures". As so described, this policy would allow for "down- classifying" of carcinogens based on workplace consideration. Given the technical difficulty in distinguishing between occupational and greater environmental exposures, more detailed information regarding this decision-making process is needed to ensure that any down-classifications are justified by scientific evidence.	*The discussion of this issue was expanded and clarified in the final document, as follows: "NIOSH will review information and scientific studies relied upon by NTP, EPA, or IARC in developing each chemical carcinogen hazard assessment to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment. Under such circumstances, NIOSH will either nominate the chemical to NTP for review or conduct a full review of the evidence and classify the chemical itself. This review will include consideration of route of exposure, tumor site, mode of action, and any other scientific information that may have bearing on the occupational relevance of the carcinogen classification.* *NIOSH review may take place years after another entity completed its cancer hazard assessment and carcinogen classification. New studies may become available during the interim. NIOSH will consider whether the new studies would potentially change the overall evaluation. Such information may increase the concern for a carcinogen (for example, supporting an upgrade of a classification to "known to be carcinogenic to humans"). More infrequently, it may decrease the concern (for example, owing to new*

Commenter/Topic	Public Comment	*NIOSH Response*
		information showing that studies supporting a classification of "reasonably anticipated to be carcinogenic to humans" were conducted using a substance containing a carcinogenic contaminant, casting doubt on the classification of the substance of interest). NIOSH will review evidence from any high quality, peer-reviewed, scientific study published after NTP, EPA, or IARC completed its hazard assessment (for example, an occupationally relevant scientific study published subsequent to the final record of studies contained in the underlying hazard assessment) to determine if the study suggests that the chemical no longer meets the criteria for the type of classification that NIOSH accepts for occupational relevance review. Under such circumstances, NIOSH will either nominate the chemical for NTP review or conduct a full evaluation of the information and classify the chemical itself."

Commenter/Topic	Public Comment	*NIOSH Response*
Alan Nye, PhD, (CTEH) and Daniel Saphire, (AAR)	AAR has several comments regarding the draft Policy: The draft Policy inadequately proposes a single descriptor to describe all carcinogenic substances. The draft Policy proposes to change the current terminology used by NIOSH to describe a carcinogenic substance, i.e., "potential occupational carcinogen" to "occupational carcinogen". Neither the current nor the proposed terminology is adequate to convey the range of the weight-of-evidence (WOE) for substances with carcinogenic potential. As stated on page 3, lines 19 through 25 of the draft Policy, the description "potential occupational carcinogen" does not adequately convey the state of scientific certainty regarding known human carcinogens such as asbestos and benzene. However, the proposed "occupational carcinogen" terminology ignores the uncertainties for a chemical such as naphthalene, on which there is only limited evidence of carcinogenicity in animals and no evidence of carcinogenicity in humans. In the case of naphthalene, a more appropriate and Globally Harmonized System (GHS) descriptor would be "suspected occupational carcinogen." Ultimately, the proposed terminology in the draft Policy may lead workers and employers wrongly to conclude that benzene, a known human carcinogen, and naphthalene, known to be carcinogenic only in animals, are considered by NIOSH to pose a similar risk of cancer to humans.	*As stated in the document, "NIOSH will continue to rely on a single cancer designation—that of occupational carcinogen. There are several reasons for this NIOSH decision. NIOSH has concluded that creating another cancer classification scheme, when several already exist, is unnecessary. NIOSH will rely on classifications and analyses done by other entities. It will display the classification each entity has assigned to the chemical. What is important is the systematic evaluation of the scientific evidence of carcinogenicity that each entity relies upon to justify its classification. For chemicals that have been classified with certain designations, NIOSH will use the hazard assessment that supported the classification and review it to determine that it is comprehensive and up to date. NIOSH has determined it is unnecessary for it to duplicate these preexisting scientific analyses. Once NIOSH determines that a chemical is an occupational carcinogen, the cancer classification tier to which it is assigned has little relevance for NIOSH risk management recommendations. Therefore, the agency sees little to be gained by developing another tiered classification system."*

Commenter/Topic	Public Comment	*NIOSH Response*
Alan Nye, PhD, (CTEH) and Daniel Saphire, (AAR)	AAR has several comments regarding the draft Policy: The draft Policy inadequately proposes a single descriptor to describe all carcinogenic substances. The draft Policy proposes to assign GHS carcinogen categories to carcinogens. In view of this, NIOSH should not use a single term to describe at least three GHS categories of carcinogens. The proposal to call any potentially carcinogenic substance an "occupational carcinogen" is in fact contrary to the GHS categorization scheme. Instead, it would be more appropriate for NIOSH to use the three categories in the GHS to describe carcinogenic substances. In the table below, A suggested alternative scheme is proposed that is compatible with the GHS carcinogen categories. Please see the AAR (Saphire) pdf file for the table. The current and draft NIOSH policy terminologies fail to provide the basis for communicating the importance of the differences in WOE for carcinogenicity. Without being overly complex, the alternative scheme proposed in the table above more accurately communicates the variations in WOE for potentially carcinogenic substances. Interestingly, the draft Policy itself states The GHS carcinogen classification will give employers useful information to more effectively communicate the chemical hazards to workers. (page 25, lines 8 and 9 of the draft Policy) In keeping with the desire of the draft Policy, it would be more technically appropriate and more easily understood by workers if the terminology for carcinogenic substances matched the appropriate GHS carcinogen classification, i.e., Category 1A, 1B, and 2 GHS carcinogens would be described as "known occupational carcinogens", "presumed occupational carcinogens", and "suspected occupational carcinogens", respectively.	*As stated in the document, "NIOSH will continue to rely on a single cancer designation—that of occupational carcinogen. There are several reasons for this NIOSH decision. NIOSH has concluded that creating another cancer classification scheme, when several already exist, is unnecessary. NIOSH will rely on classifications and analyses done by other entities. It will display the classification each entity has assigned to the chemical. What is important is the systematic evaluation of the scientific evidence of carcinogenicity that each entity relies upon to justify its classification. For chemicals that have been classified with certain designations, NIOSH will use the hazard assessment that supported the classification and review it to determine that it is comprehensive and up to date. NIOSH has determined it is unnecessary for it to duplicate these preexisting scientific analyses. Once NIOSH determines that a chemical is an occupational carcinogen, the cancer classification tier to which it is assigned has little relevance for NIOSH risk management recommendations. Therefore, the agency sees little to be gained by developing another tiered classification system."*

Commenter/Topic	Public Comment	*NIOSH Response*
Alan Nye, PhD, (CTEH) and Daniel Saphire, (AAR)	AAR has several comments regarding the draft Policy: Implementation of the draft Policy carcinogen classification policy will confuse users of the NIOSH Pocket Guide to Chemical Hazards. The draft Policy provides example entries for the carcinogen classifications for benzene and heptachlor on pages 28 and 29, respectively. These exemplify possible entries that would be included in the NIOSH Pocket Guide to Chemical Hazards ("Pocket Guide"). The draft Policy proposes to list classifications from NIOSH, GHS, NTP, EPA, and IARC together in the chemical listing. Such multiple entries for a chemical will likely confuse rather than inform Pocket Guide readers who attempt to discern whether there is a difference between the several classifications listed. Instead, the draft Policy should adopt the proposed terminology in the table above, i.e., "known occupational carcinogen", "presumed occupational carcinogen", and "suspected occupational carcinogen" that are described using the GHS terminology. In the first example, benzene is alternately described in the proposed listing as "occupational carcinogen", "known human carcinogen", "known to be carcinogenic to humans", "human carcinogen", and "carcinogenic to humans". While there are no significant differences in these descriptors, the carcinogenicity of benzene is described in five slightly different ways. The developers of the draft Policy should consider using a single NIOSH classification such as "known occupational carcinogen" The process by which NIOSH categorizes a carcinogen as "known occupational carcinogen", "presumed occupational carcinogen", or "suspected occupational carcinogen" could be provided in an appended section of the Pocket Guide and include a summary table showing the various carcinogen classifications from GHS, NTP, EPA, and IARC for each chemical evaluated. The example of heptachlor would likely cause even greater confusion in Pocket	*NIOSH will identify those chemicals that are carcinogenic in the workplace as an "occupational carcinogen". This is appropriate since risk management options for chemicals identified as occupational carcinogens are the same regardless of the classification nuances. In addition to that determination, NIOSH intends to provide the specific classifications for the chemical by NTP, EPA, and IARC to provide full risk communication. From the document, "After considering all comments it receives, NIOSH will publish in the Federal Register a notice whether a chemical has been determined by NIOSH to be an occupational carcinogen, the reasons for the NIOSH classification, the RML-CA, and the range of risk estimates."*

Commenter/Topic	Public Comment	*NIOSH Response*
	Guide readers. In the proposed listing, heptachlor is described as "occupational carcinogen", "presumed human carcinogen", "probable human carcinogen", and "possibly carcinogenic to humans." The Pocket Guide reader would be left to wonder about the differences, if any, between the descriptors "presumed", "probable", and "possibly" when describing the weight of evidence for the human carcinogenicity of heptachlor. As above, it would be less confusing to list heptachlor as a NIOSH "presumed occupational carcinogen" and append the weight of evidence classifications from GHS, NTP, EPA, and IARC in a summary table elsewhere in the Pocket Guide.	

Commenter/Topic	Public Comment	*NIOSH Response*
Alan Nye, PhD (CTEH) and Daniel Saphire (AAR)	AAR has several comments regarding the draft Policy: The draft Policy should consider alternate methods for setting RELs for GHS carcinogen category 2 chemicals. Regardless of GHS, NTP, EPA, or IARC classification, the draft Policy proposes to evaluate all potential carcinogens using a low-dose linear exposure-response as the default method for calculating an REL. The practical basis of assuming this type of exposure-response is that theoretical cancer risk is zero only when exposure is zero. The draft Policy indicates that a nonlinear mode of action may be used if such an exposure-response relationship is "clearly established." However, of the many potentially carcinogenic chemicals evaluated by EPA on its IRIS database, only orally administered chloroform has met the high burden of proof required to demonstrate a nonlinear mode of action. Particularly for GHS 2 cancer category chemicals, use of a low-dose linear mode for establishing cancer risk-based RELs may result in RELs that are tens to hundreds of times lower than the current RELs. Lowering RELs for chemicals in the GHS 2 category using the assumption of low-dose linear exposure-response is overly conservative in light of the limited WOE for the carcinogenicity of these chemicals to humans. For example, naphthalene is considered an IARC 2B group chemical ("possibly carcinogenic to humans") and an EPA Group C chemical ("possible human carcinogen"). As categorized using the guidance in Table 2 of the draft Policy, naphthalene would be classified as a GHS category 2 chemical ("suspected carcinogen"). If low-dose linear exposure-response methods such as those used by the State of California are used to develop an REL for naphthalene, an REL of approximately 0.04 parts per million (ppm) is calculated. This concentration is 250 times lower than the current REL of 10 ppm for naphthalene. This calculation is not intended to suggest that NIOSH adopt	*This policy was not intended to provide the entire risk assessment process for carcinogens. Instead, it was intended to address three particular issues: carcinogen classification, risk management level and analytical feasibility of the measurement method. NIOSH conducts appropriate statistical modeling of data, based on sound science. NIOSH has clarified the discussion of this point to prevent further misunderstanding. The statistical modeling strategy for a carcinogen is determined after careful consideration of the exposure-response information available, the mode of action and/or mechanism of action information available, and all other relevant factors. As stated in the document, "For carcinogen risk assessment, NIOSH generally treats exposure-response as low-dose linear unless a non-linear mode of action has been clearly established, in which case NIOSH will adopt a modeling approach defined by the data (including non-linear approaches when appropriate). In general, whether the model forms are linear or non-linear, any nonzero exposure to a carcinogen is expected to yield some excess risk of cancer."*

Commenter/Topic	Public Comment	*NIOSH Response*
	State of California methods. Rather, it illustrates the very large impact of using low-dose linear exposure-response assumptions when setting RELs for chemicals with only limited evidence of a potential cancer hazard to humans (GHS category 2). A more reasonable approach would be to reduce the existing REL by a factor to provide an additional margin of safety. The draft Policy should consider the use of safety factors rather than low-dose linear exposure-response modeling to derive RELs for GHS category 2 chemicals. Using a safety factor approach, a safety factor between 1 and 10 could be applied to existing RELs to provide an additional margin of safety. Such an approach has been used by the USEPA in determining Maximum Contaminant Level Goals (MCLGs) for chemicals in drinking water . In the case of EPA Group C chemicals, the EPA has established drinking water maximum contaminant level goals (MCLGs) by applying an additional risk management safety factor between 1 and 10 to a drinking water concentration based on protection of noncancer risk. In summary, use of a safety factor approach for GHS Category 2 chemicals would be a preferable option for determining RELs. Default use of low-dose linear exposure-response modeling may result in RELs hundreds of times lower than the current RELs for a class of chemicals with only limited evidence of carcinogenicity in animals.	

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Fendley, (USW)	In regards to Section 4 of the proposed update, USW strongly supports the proposal that NIOSH will base its classifications on the carcinogen hazard assessments from the U.S. National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC); and we thank NIOSH for incorporating this recommendation that USW and others made in our 2011 comments. As NIOSH indicated in its proposal, basing classifications on existing assessments will prevent duplication of effort and allow NIOSH to focus its resources on considerations of workplace conditions. At the December 2013 listening session, NIOSH officials stated that they anticipate the almost all chemicals will be determined to be occupationally relevant. Therefore, the policy should revised to consider the classifications by NTP, EPA, and IARC occupationally relevant unless NIOSH can demonstrate otherwise, rather than NIOSH needing to demonstrate occupational relevance.	*NIOSH appreciates the support for this policy. The occupational relevance section was clarified to better communicate NIOSH's understanding that chemicals deemed to be carcinogens by the NTP, IARC and EPA would in the vast majority of cases also be occupational carcinogens. Per the document, "NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation. This is because there are likely only very rare instances in which a chemical classified as a carcinogen by NTP, EPA, or IARC would not also be potentially carcinogenic to exposed workers." However, NIOSH will continue to demonstrate that by a consideration of occupational relevance issues.*

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Fendley, (USW)	USW also supports the designation change from the term "potential occupational carcinogen" to "occupational carcinogen." Although this shift did not address our 2011 comments that NIOSH should have a classification system that reflects varying degrees of strength of scientific evidence, it is a step away from the use of an inadequate and misleading term that did not adequately acknowledge the body of scientific knowledge that confirmed some substances are indeed human carcinogens.	*NIOSH appreciates this support for the change in terminology. As stated in the document, "NIOSH will continue to rely on a single cancer designation—that of occupational carcinogen. There are several reasons for this NIOSH decision. NIOSH has concluded that creating another cancer classification scheme, when several already exist, is unnecessary. NIOSH will rely on classifications and analyses done by other entities. It will display the classification each entity has assigned to the chemical. What is important is the systematic evaluation of the scientific evidence of carcinogenicity that each entity relies upon to justify its classification. For chemicals that have been classified with certain designations, NIOSH will use the hazard assessment that supported the classification and review it to determine that it is comprehensive and up to date. NIOSH has determined it is unnecessary for it to duplicate these preexisting scientific analyses. Once NIOSH determines that a chemical is an occupational carcinogen, the cancer classification tier to which it is assigned has little relevance for NIOSH risk management recommendations.* *Therefore, the agency sees little to be gained by developing another tiered classification system. The shift from a designation of*

Commenter/Topic	Public Comment	*NIOSH Response*
		"potential occupational carcinogen" to "occupational carcinogen" should not be interpreted as an effort by NIOSH to ignore the fact that the evidence of carcinogenicity for some chemicals is stronger than it is for other chemicals. For those chemicals that NIOSH is assessing, once sufficient evidence indicates that a chemical is reasonably expected to pose a cancer risk to workers, NIOSH will move forward to estimate the magnitude of that risk and make recommendations for reducing the risk and protecting workers from harm.

Commenter/Topic	Public Comment	*NIOSH Response*
Dave Foster, 42 Groups	The 42 groups listed below thank the National Institute for Occupational Safety and Health (NIOSH) for modernizing their carcinogens policy. We welcome this opportunity to comment on the draft document, "Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace." The world of work has changed dramatically since 1978 and NIOSH's updated policy should be designed to promote the most effective means of preventing cancer among workers. We support NIOSH's proposal to use the classifications issued by the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC) because it will allow the agency to more efficiently focus its efforts on cancer prevention rather than on the performance of separate classification processes. We also support NIOSH's decision to use the classification from any of the three organizations that will provide the most health protection for impacted workers.	*NIOSH appreciates the support for this NIOSH policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
Adam Finkel, ScD., CIH	1. In its carcinogen classification, NIOSH is wise to downplay the false distinction between "known" and "presumed" carcinogens; but it should not waste its time corroborating the common-sense default assumption that chemicals in commerce presumably create worker exposure. I commend NIOSH for downplaying the distinction between "known" and "potential" in favor of the simpler and more appropriate term "occupational carcinogen." For decades, many in industry and elsewhere have fetishized the known-vs.-potential dichotomy, while at the same time insisting on a system of evidence that blurs the same distinction. Simply put, it is clear that many "potential" carcinogens are simply human carcinogens for which the tool many insist upon—human epidemiology—is insufficiently powerful. In general terms, what we "know" is a strong function of how well we can discern: we now "know" that Jupiter has at least 67 moons orbiting it, but Galileo only knew of four of them, which in turn were four more than anyone before his telescope knew of. In cancer epidemiology, our "telescope" is designed to see rare tumors more clearly than common ones (the signal appears out of the background noise much more readily for the former)—but this is exactly the opposite of a system that would preferentially guide concern towards substances that cause more total harm to human health. For example, vinyl chloride is "known" because it caused a few dozen rare liver angiosarcomas each year; according to dose-response and exposure data, methylene chloride likely causes hundreds or more lung tumors annually, but it is merely a "potential" carcinogen because we can't do the epidemiology to find those tumors within the noise. I have urged NTP, EPA, and IARC to tweak their classification systems so that some substances with unequivocal animal evidence and plausible relevance to humans could be grouped as "known" without insisting on positive epidemiologic data to prove this, but until they do so, NIOSH is wise to report the full classifications of other agencies, but to treat Group A and B carcinogens as of comparable human-health importance.	*NIOSH appreciates the support for this policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
Adam Finkel, ScD., CIH	On the other hand, it is unfortunate that NIOSH has chosen what amounts to a default assumption (see Figure 1 on page 22 of the CIB) that a chemical might be presumed not to present occupational exposure unless the Institute can verify that this is the case. This is a weak default that runs counter to the common philosophy of defaults as articulated in numerous NAS reports and in the EPA Cancer Guidelines: defaults are health-protective presumptions that streamline risk assessment and that can be overturned if there exists compelling evidence to counter them. The onus is, and should be, on those seeking to show an exception to the rule. Here, it is hard to dispute the general proposition that if a substance is in commerce, it must be synthesized, refined, or extracted—and that these activities do not occur without workers and their labor. If there really is a generic issue of carcinogens that no workers are ever exposed to, NIOSH ought to be able to provide at least one real example of this. Instead, this is a classic case where the default should be "if there is something bizarre going on such that a carcinogen cannot ever be encountered by workers, let the evidence come to NIOSH; otherwise we will assume the obvious—that it can." One doesn't need to understand "job tasks known to use the chemical" (p 23, line 27) to presume that the chemical gets from the earth (or the laboratory) to the consumer thanks to the efforts of the nation's workers. I therefore suggest (as one example of verbiage that occurs elsewhere) that page 23, line 30 ("NIOSH will evaluate scientific studies to assess") should be replaced with "NIOSH will consider contrary evidence if provided to it, to assess…"	*From the document, "NIOSH will evaluate whether the chemical is likely to pose a risk in the occupational environment and whether the data underlying the cancer classification is applicable to the occupational setting. NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation. This is because there are likely only very rare instances in which a chemical classified as a carcinogen by NTP, EPA, or IARC would not also be potentially carcinogenic to exposed workers." However, NIOSH has maintained the language that it will evaluate the occupational relevance for each chemical carcinogen.*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, International Union, United Automobile, Aerospace & Agricultural Implement Workers of America-UAW	The International Union, UAW, representing more than one million active and retired members, welcomes this opportunity to comment on the draft document, "Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace." The following is a summary of the UAW's position on the draft policy: 1. The UAW strongly supports NIOSH's proposal to rely on the carcinogen classifications of the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC).	*NIOSH appreciates the support for this policy.*
Darius Sivin, PhD, UAW	2. The UAW agrees with NIOSH's presumption that most chemicals designated as carcinogens by these agencies will likely be occupational carcinogens.	*NIOSH appreciates the support for this policy.*
John Schweitzer, American Composites Manufacturers Association (ACMA)	Summary: The American Composites Manufacturers Association appreciates this opportunity to comment on the National Institute of Occupational Safety and Health's proposed revisions to its carcinogen policy. 1 We strongly support the goals of NIOSH in making substantial revisions to its policy. However, as explained in detail below, we are very concerned about the Institute's overconfidence in the utility of carcinogen classifications by other organizations. We also believe the Institute's apparent misunderstanding of the importance of robust weight--of-- evidence hazard assessment will likely lead to the mischaracterization of workplace health risks. Unless these flaws are remedied, NIOSH's proposed policy may fail in its goal to help employers and employees achieve safer and healthier workplaces.	*NIOSH has clarified the sections on consideration of weight of evidence in the final document, as follows: "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and*

Commenter/Topic	Public Comment	*NIOSH Response*
		interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical evaluation of chemical carcinogenicity should be made explicit [Weed 2005]."

Commenter/Topic	Public Comment	*NIOSH Response*
John Schweitzer, (ACMA)	We strongly support the goals of NIOSH in making substantial revisions to its policy. However, as explained in detail below, we are very concerned about the Institute's overconfidence in the utility of carcinogen classifications by other organizations. We also believe the Institute's apparent misunderstanding of the importance of robust weight--of-- evidence hazard assessment will likely lead to the mischaracterization of workplace health risks. Unless these flaws are remedied, NIOSH's proposed policy may fail in its goal to help employers and employees achieve safer and healthier workplaces.	*As stated in the document, "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical evaluation of chemical carcinogenicity should be made explicit [Weed 2005]. NTP, EPA, and IARC each describe their scientific approach as*

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		employing a thorough, systematic analysis of the body of evidence or evaluation of the strength of evidence using a transparent protocol and integration of evidence across studies. Each of these approaches for critically assessing and interpreting a body of scientific evidence satisfies NIOSH criteria. NIOSH views the assessments produced by NTP, IARC, and EPA to be of the highest scientific quality, subject to extensive peer review or prepared by acknowledged experts in the field in a consensus building process."

Commenter/Topic	Public Comment	*NIOSH Response*
John Schweitzer, (ACMA)	A reliable sign of a lack of proper weight-of-evidence assessment is that the classification procedures employed by NTP and IARC fail to give any meaningful consideration and weight to the degree of consistency among studies. A National Research Council (NRC) expert committee recently identified consistency (the "persistent association among different studies in different populations") as a critical criterion for postulating causality.7 The validity of our assertion that NTP fails to make proper use of weight--of--evidence assessment can be further tested by a quick review of NTP's styrene substance profile in the 12th Report on Carcinogens. The evidence sited by NTP in support of its styrene listing decision amounts to a disjointed list of inconsistent positive data taken completely out of context from the overall styrene toxicity database. Completely ad hoc justifications are employed in dismissing null or negative studies. No meaningful effort is made by NTP to weigh the informative value of each study when compared to other conflicting studies. NTP makes no attempt to assemble the limited positive data into a coherent account of how styrene might cause cancer in humans, and to consider the plausibility of this account in light of the many negative studies. The IARC assessment process similarly suffers from the characterization of substances as carcinogens when there is as few as one positive study, regardless of the overall available database for a substance. And while EPA's IRIS program is now responding to critical NRC reports,8 historically the assessments conducted for this program are of questionable validity. Further, many of the IRIS cancer classifications are old and do not account for recently available information.	*As stated in the document, "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical evaluation of chemical carcinogenicity should be made explicit [Weed 2005]. NTP, EPA, and IARC each describe their scientific approach as employing a thorough, systematic analysis*

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		of the body of evidence or evaluation of the strength of evidence using a transparent protocol and integration of evidence across studies. Each of these approaches for critically assessing and interpreting a body of scientific evidence satisfies NIOSH criteria. NIOSH views the assessments produced by NTP, IARC, and EPA to be of the highest scientific quality, subject to extensive peer review or prepared by acknowledged experts in the field in a consensus building process."

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John Schweitzer, (ACMA)	The importance of weight-of-evidence assessment: As we argue above, the cancer classifications issued by EPA, IARC and NTP are not suitable stand--ins for careful hazard assessments conducted by NIOSH. The Institute should perform such hazard assessment itself, after proposing and finalizing a detailed process for weight-- of--evidence review. NIOSH does propose a process for evaluating the applicability of evidence for occupational carcinogenicity. To conduct these evaluations, the Institute plans to,…evaluate scientific studies to assess how the described mode of action and the route of exposure used in the studies are relevant to workplace exposures. NIOSH will first determine whether results from high-quality occupational epidemiology studies are available to assess worker cancer risks. When human evidence is not available, NIOSH will evaluate results from animal studies to determine if they can apply to exposed workers. In general, inhalation and dermal studies conducted with animals are the most relevant because these are the typical exposures that workers encounter. However, oral or injection studies with animals may also be relevant to consider, especially for carcinogens that act systemically. For example, animal studies in which exposure to the chemical is administered via drinking water, food, or intraperitoneal injection, may provide relevant information about worker risks due to occupational exposure. On the other hand, there may be cases where a chemical acts locally and only at an injection site. NIOSH may determine these types of studies to be less relevant to occupational cancer risk. NIOSH will evaluate animal studies as to the relevance of the reported tumor type and site, mode of action, and metabolic processes for causing cancer in humans.9 The foregoing process may provide a useful list of the types of data NIOSH should consider. But this process, whether it is to be used for full hazard assessment or merely reviewing EPA, IARC and NTP classifications for relevance to occupational health, falls far short of a reasonably complete and sufficiently detailed weight--of--evidence assessment procedure. The NRC	*As stated in the document, "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical evaluation of chemical carcinogenicity should be made explicit [Weed 2005]. NTP, EPA, and IARC each describe their scientific approach as employing a thorough, systematic analysis*

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	expert committee suggested certain components to be included in a weight--of-- evidence assessment approach, none of which are addressed in the NIOSH proposal.10 In a paper submitted to a different NRC committee, Rhomberg helpfully observed that the intent of a weight--of--evidence approach is to "indicate that conclusions must be made based on objective scientific interpretations that integrate across sources of data and that evaluate how strongly one is justified in drawing conclusions (perhaps provisional conclusions) from less--than--definitive information," and emphasized that, …in judging the extent to which an array of data on a chemical should be interpreted as indicative of potential human risk, it is essential to articulate a hypothesis about the proposed basis for such an inference that is specific enough to expose the logic of the inference about human risk to testing against the available data. 11	*of the body of evidence or evaluation of the strength of evidence using a transparent protocol and integration of evidence across studies. Each of these approaches for critically assessing and interpreting a body of scientific evidence satisfies NIOSH criteria. NIOSH views the assessments produced by NTP, IARC, and EPA to be of the highest scientific quality, subject to extensive peer review or prepared by acknowledged experts in the field in a consensus building process."*

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John Schweitzer, (ACMA)	In contrast to NIOSH's proposed process for evaluating the applicability of evidence, in a true weight-of-evidence assessment data are not evaluated and discarded in turn. Instead, all possibly relevant data are synthesized and used together to test hypothetical exposure-to-illness pathways. An assessment process not centered on hypothesis testing is not a scientific process.12 In addition to the ECHA, Danish EPA and TCEQ styrene assessments mentioned above, recent reviews by Rhomberg and colleagues, and by the Styrene Information and Research Center, illustrate the necessity of using a careful and thorough weight-of-evidence approach to test competing theories of carcinogenicity.13 In contradiction to the conclusions of NTP and IARC, none of the several weight-of-evidence assessments of the styrene toxicity database concluded that styrene presents a cancer risk in humans.	*NIOSH notes that the National Academy of Science determined that the NTP assessment of styrene was scientifically sound. In addition, as stated in the document, "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical*

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		evaluation of chemical carcinogenicity should be made explicit [Weed 2005]. NTP, EPA, and IARC each describe their scientific approach as employing a thorough, systematic analysis of the body of evidence or evaluation of the strength of evidence using a transparent protocol and integration of evidence across studies. Each of these approaches for critically assessing and interpreting a body of scientific evidence satisfies NIOSH criteria. NIOSH views the assessments produced by NTP, IARC, and EPA to be of the highest scientific quality, subject to extensive peer review or prepared by acknowledged experts in the field in a consensus building process."

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John Schweitzer, (ACMA)	Conclusion: The small and medium companies using polymers and fiber reinforcement to manufacture composite products strongly support the scientifically valid assessment by NIOSH of workplace hazards and risks. However, the Institute must use weight--of--evidence analysis of relevant data to evaluate competing plausible hypotheses regarding the carcinogenic potential of substances, and the Institute's assessment process should comply with NRC guidelines. NIOSH should not take a shortcut by making improper use of cancer classifications by other agencies.	*NIOSH has clarified and strengthened the description of the robust and transparent processes used by NTP, EPA and IARC in their carcinogen classification processes. NIOSH disagrees that the NTP, IARC and EPA classification processes are not sufficient.*
Arlene Blum and 65 other Health Scientists and Medical Professionals	We strongly endorse NIOSH's proposal to use the hazard assessments for carcinogen classification issued by the National Toxicology Program (NTP), the Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC) rather than conducting a separate classification process (section 4). Our collective expertise suggests that most chemicals designated as carcinogens by these authoritative bodies will have occupational relevance. As such, we concur with NIOSH's proposal to implement its efforts based on the assumption that all chemicals listed by these agencies will also need to be listed by NIOSH. Deviations from this process should be based on demonstrating that a carcinogen is not occupationally relevant, rather than the other way around as it is extremely unlikely for any chemical that can be bought, sold or used to exist without first being extracted, manufactured, processed or otherwise used by workers (section 4.4). We urge NIOSH to establish a default in its policy to consider chemicals classified as carcinogens by NTP, IARC, or EPA to be occupationally relevant unless NIOSH is provided with compelling evidence to the contrary.	*NIOSH appreciates the support for this policy and has clarified and strengthened the discussion as follows, "NIOSH will evaluate whether the chemical is likely to pose a risk in the occupational environment and whether the data underlying the cancer classification is applicable to the occupational setting. NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation. This is because there are likely only very rare instances in which a chemical classified as a carcinogen by NTP, EPA, or IARC would not also be potentially carcinogenic to exposed workers."*

Commenter/Topic	Public Comment	*NIOSH Response*
Arlene Blum and 65 other Health Scientists and Medical Professionals	Under this new framework, we believe it is appropriate for NIOSH to determine the applicable Globally Harmonized System of Classification and Labeling (GHS) carcinogen category for all listed chemicals (section 4.2). We agree with NIOSH's criteria for determining the appropriate GHS carcinogen categories for specific IARC, NTP and EPA classifications. We also strongly support NIOSH's decision to use the classification from any of the three organizations that affords the most health protection. In our experience, differences in classifications among these organizations are often a matter of when the topic was last reviewed.	*The NIOSH GHS walk-across process has been removed from the final document. This topic is undergoing further analysis and development. NIOSH will use the GHS criteria for carcinogenicity for new classifications.*
Dean Venturin, (HTIW) Coalition	The "Potential Carcinogen" Classification Should be Retained Under this proposal, NIOSH would designate a single carcinogen classification of "occupational carcinogen," eliminating the previous classification, "potential occupational carcinogen." Classification would be based on the carcinogen hazard assessments from the U.S. National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC). However, the precise classifications of those organizations would not be repeated in the NIOSH designation. Such an approach would be a significant misrepresentation of the scientific information underlying the classifications made by the other organizations. Consider the case of RCF. With respect to potential workplace carcinogenicity, the RCF Criteria Document states: At this time, the available health data do not provide sufficient evidence for deriving a precise health based occupational exposure limit to protect against lung cancer. However, given what is known from the animal and epidemiological data, NIOSH supports the intent of the PSP and concurs that a recommended exposure limit (REL) of 0.5 f/cm3 as a TWA for up to a 10-hr	*The new label "occupational carcinogen" is not intended to suggest that every chemical so labeled would be a "known" carcinogen under other agencies' tiered classification schemes. NIOSH believes that the text of its' Cancer Policy makes clear that the term "occupational carcinogen" includes both "potential" and "known" carcinogens. As stated in the document, "NIOSH will continue to rely on a single cancer designation—that of occupational carcinogen. There are several reasons for this NIOSH decision. NIOSH has concluded that creating another cancer classification scheme, when several already exist, is unnecessary. NIOSH will rely on classifications and analyses done by other entities. It will display the classification each entity has assigned to the chemical. What is important is the systematic evaluation of the scientific evidence of carcinogenicity that each entity relies upon to justify its*

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	work shift during a 40-hr workweek will lower the risk for developing lung cancer (pp. v-vi).	*classification. For chemicals that have been classified with certain designations, NIOSH will use the hazard assessment that supported the classification and review it to determine that it is comprehensive and up to date. NIOSH has determined it is unnecessary for it to duplicate these preexisting scientific analyses. Once NIOSH determines that a chemical is an occupational carcinogen, the cancer classification tier to which it is assigned has little relevance for NIOSH risk management recommendations. Therefore, the agency sees little to be gained by developing another tiered classification system. The shift from a designation of "potential occupational carcinogen" to "occupational carcinogen" should not be interpreted as an effort by NIOSH to ignore the fact that the evidence of carcinogenicity for some chemicals is stronger than it is for other chemicals. For those chemicals that NIOSH is assessing, once sufficient evidence indicates that a chemical is reasonably expected to pose a cancer risk to workers, NIOSH will move forward to estimate the magnitude of that risk and make recommendations for reducing the risk and protecting workers from harm."*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	As this statement emphasizes, the potential carcinogenic risk to workers currently exposed to RCF, if any, is not known and cannot be quantified on the basis of existing data. For this reason alone, a risk-based REL for RCF would not be justified. Yet under this proposal, RCF would be designed as a workplace carcinogen and a risk-based REL would be developed. This is precisely the type of misinformation that the other carcinogen classification systems are designed to avoid. For example, as noted in the NIOSH document, the current EPA classification system includes the following categories: • Carcinogenic to humans. • Likely to be carcinogenic to humans. • Suggestive evidence of carcinogenic potential. • Inadequate information to assess carcinogenic potential. • Not likely to be carcinogenic to humans As noted on the website for EPA's carcinogen policy, these were meant to be dynamic, flexible classifications that evolve to reflect the current state of the science and risk assessment practices.1 They are intended as "summarizing the full range of available evidence and describing any conditions associated with conclusions about an agent's hazard potential using a weight-of-evidence narrative and accompanying descriptors." HTIW Coalition understands that the proposed NIOSH classification system would reference these underlying classifications. We also agree that it is appropriate in general for NIOSH to rely on them without performing a needless duplicative effort. However, we believe that the current system reasonably accomplishes these goals, differentiating clearly between known and potential workplace carcinogens. Elimination of this distinction would	*NIOSH did not previously distinguish between "known" and "potential" occupational carcinogens; the only designation was "potential occupational carcinogen." NIOSH has preserved the single designation (but dropped the word "potential") to be used in conjunction with the EPA, NTP and IARC classifications in order to provide more information to employers. Also, because the NIOSH risk management recommendations for known human carcinogens and chemicals with suggestive evidence of carcinogenic potential are identical, NIOSH is not adding a tiered system to its designation (the EPA, NTP, and IARC classifications serve that purpose). For example, a chemical may be noted as "occupational carcinogen, EPA likely to be carcinogenic to humans". This provides information on the source of the information, the level of uncertainty of the designation and that the chemical is occupationally relevant -- all important information for an employer. The NIOSH GHS Correspondence Table has been removed from the final policy. The intention is to include it in a future document on risk management issues for carcinogens. Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters*

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	fail to reflect the caveats in the underlying classifications and discriminate severely against materials, such as RCF, for which the current workplace risk, if any, cannot be quantified accurately. It also appears that the approach proposed by NIOSH would conflict with the GHS rules adopted by OSHA. The NIOSH document notes that under GHS, an authoritative body generally does not classify a carcinogen hazard. Instead, manufacturers have the ultimate responsibility for classifying all chemical hazards, including carcinogenicity. Yet under this proposal NIOSH would make a separate GHS classification, which could be different from the classification adopted by the manufacturer. Such a result increases the potential for scientific inaccuracy and would cause widespread confusion for RCF manufacturers, customers and workers. The current NIOSH system, which serves the agency's goals while avoiding these pitfalls, should be retained.	*suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments. NIOSH is not obligated to follow HCS. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently. NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.*

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, (ACC)	NIOSH has indicated that it plans to utilize the hazard assessments and classifications developed by the Environmental Protection Agency (EPA), National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC) and assess their relevance to the occupational setting. ARASP does not find this approach consistent with ensuring the consideration of all high quality scientific evidence. The NIOSH evaluation process must incorporate the best available and most relevant information utilizing a weight of evidence (WOE) approach that considers positive, negative and null study results when reaching conclusions. Many stakeholders and independent reviews have raised concerns about the approaches used by these programs. For instance, concerns have been raised by the National Research Council (NRC)7,8 and the Governmental Accountability Office9 regarding the EPA's Integrated Risk Information System (IRIS) including out of date information and significant concerns with the Agency's WOE evaluations. Additionally, the NRC10 is conducting a review of some NTP Report on Carcinogens (RoC) cancer classifications to ensure that the criteria used for classification is appropriate. Recommendation – NIOSH should fully evaluate the scientific basis and quality of the individual scientific assessments that underlie the classifications developed by EPA, NTP, and IARC prior to utilizing the classifications as a basis for the NIOSH classification. This will ensure that the scientific evidence is the most current and supports the assigned classification.	*As stated in the document, "As part of its determination, NIOSH will review each chemical carcinogen hazard assessment, in conjunction with the information noted in the Chemical Carcinogen Policy's Industrial Usage and Hazard Assessment and Scientific Studies sections, to determine if the chemical meets the criteria of occupational relevance. Those chemicals that meet the relevance criteria will be designated "occupational carcinogens."*

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	Instead of Rubberstamping Other Bodies' Determinations, NIOSH Should Continue to Conduct Its Own Assessments regarding the Carcinogenicity of Workplace Substances. Historically, NIOSH has embraced its statutory mission of being an investigative and research organization by conducting its own independent evaluation of the state of scientific knowledge in making a determination of whether a chemical substance is a potential occupational carcinogen. As stated in the Draft Cancer Policy, "[a] critical aspect of the NIOSH carcinogen policy is to maintain the ability to independently evaluate the quality and occupational relevance of the data." Draft Cancer Policy at 24. Notwithstanding this clearly stated goal, the Draft Cancer Policy reveals NIOSH's intention to abandon this important function and to become an uncritical endorser of other organization's work regardless of the currency of those determinations and any shortcomings in the processes rendering those determinations. As stated by Dr. Paul Schulte, NIOSH will accept carcinogenicity determinations by either NTP, IARC or EPA at "face value" and as "de facto the source of [NIOSH's] classification." See Transcript of Public Hearing regarding Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace held on December 16, 2013 at p. 36. The rationale for this approach, in Dr. Schulte's words, is "[t]o avoid duplication, and for more efficient use of government resources." Id. at p. 14. This shortcut approach is entirely at odds with NIOSH's stated goal in revising its Cancer Policy: "to provide a document that is scientifically sound, has relevance and utility, and is developed according to a rigorous, consistent, and transparent process." Id. at p. 8. By implication, NIOSH should develop a Cancer Policy that reflects these same attributes. However, for the following reasons, the Draft Cancer Policy falls woefully short of this goal:	*As stated in the document, "Under this new policy, authoritative documents produced by NIOSH addressing chemicals thought to cause cancer will rely on existing cancer hazard assessments completed by the U.S. National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC), whenever possible. These agencies are highly respected for their carcinogen classification systems and their transparent and systematic assessments of the scientific evidence concerning carcinogenicity. Reliance on these preexisting hazard assessments and cancer classifications will allow NIOSH to focus its limited resources on assessing occupational risks and recommending ways of reducing those risks. As part of its determination, NIOSH will review each chemical carcinogen hazard assessment, in conjunction with the information noted in the Chemical Carcinogen Policy's Industrial Usage and Hazard Assessment and Scientific Studies sections, to determine if the chemical meets the criteria of occupational relevance. Those chemicals that meet the relevance criteria will be designated "occupational carcinogens."*

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	1. There is no indication that NIOSH has performed any review of the processes used by NTP, IARC or EPA in making past carcinogenicity determinations to ensure that those processes were "scientifically sound." Indeed, there are numerous instances where those processes reasonably have been brought into question. In Materion's own experience, IARC's assessment of beryllium was fundamentally flawed. See Letter dated April 6, 2009 from Dr. David Deubner to Dr. Vincent Cogliano (attached). 2. By merely accepting at "face value" past determinations made by others, NIOSH rejects the added weight of any scientific studies and knowledge developed after those determinations were made. To the extent that any rote adoption of past classifications fails to consider more recent information, any NIOSH classifications lacks relevance and utility to workers and employers concerned about safety in the workplace. 3. While NIOSH's proposed process that automatically accepts the validity of determinations made by other specifically identified organizations may be consistent and transparent in its application, there is nothing rigorous about it. Moreover, by failing to critically examine those determinations, NIOSH fails to evaluate whether they were made in a consistent and transparent fashion. NIOSH should reconsider its intention to abandon the important role of independently evaluating the carcinogenicity of substances found in the workplace. Instead, NIOSH should work to develop a "rigorous, consistent and transparent" process for making its own assessment. As a next step, NIOSH should issue another Request for Information seeking input from stakeholders regarding the necessary components of such a process, including provisions for peer review and meaningful stakeholder participation.	*In the document, NIOSH states, "NIOSH will review information and scientific studies relied upon by NTP, EPA, or IARC in developing each chemical carcinogen hazard assessment to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment. Under such circumstances, NIOSH will either nominate the chemical to NTP for review or conduct a full review of the evidence and classify the chemical itself. This review will include consideration of route of exposure, tumor site, mode of action, and any other scientific information that may have bearing on the occupational relevance of the carcinogen classification." In addition, there is opportunity for public review and comment, where alternative scientific interpretations can be brought to NIOSH's attention. As stated in the document, "NIOSH will continue its policy of seeking public and stakeholder input on its comprehensive analyses and recommendations, submitting them to peer review, and then publishing an authoritative document containing the recommendations and all supporting analyses recommending practices to control worker exposures."*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	To clarify the policy and process, NIOSH should ensure the narrative sections of the Cancer Policy, particularly Section 4, conform to Figure 1. As proposed, the 2013 Draft Cancer Policy creates confusion as to NIOSH's classification process and implementation policies. The information presented in Figure 1 of the Draft 2013 Cancer Policy is not consistent with the narrative discussion under Section 4.0 of the policy. Based on the presentation and comments during the December 16, 2013, public hearing, we understand that the proposed NIOSH process generally would follow Figure 1. The Draft 2013 Cancer Policy needs to better clarify this process and suggestions for restructuring appear near the end of these comments.	*NIOSH has deleted Figure 1 in the final policy and has revised the policy to clarify and simplify the process.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	SIRC's primary concern is NIOSH's proposal to blindly rely on the carcinogenicity determinations made by the U.S. National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC). A closely related concern is NIOSH's proposal to develop informational Globally Harmonized System for Labeling and Classification of Chemicals (GHS) classifications based on those NTP/IARC/EPA determinations. NIOSH must first modify its approach to classification to conform to the GHS and the Hazard Communications Standard, as amended in 2012 (HCS 2012) framework for classification. Evidence-based science, responsible public policy and the applicable law preclude NIOSH from adopting the carcinogenicity determinations of those agencies, but rather require NIOSH to perform its own review of the science underlying those determinations as well as any subsequent scientific developments and then apply the weight of evidence (WOE) principles as established by HCS 2012. Science — NIOSH's process for carcinogen classification and the development of recommended exposure limits (RELs) must be based on the best available science and be consistent with the OSHA Hazard Communication Standard, as amended by HCS 2012, to align with GHS. Thus, the NIOSH carcinogen policy must be implemented in concordance with the WOE approach incorporated into both HCS 2012 and the GHS. In other words, NIOSH's proposal reflects a misunderstanding and inappropriate use of the read-across matrix created by OSHA in Appendix F of HCS 2012 and any similar table created by NIOSH. The read-across matrix created by OSHA was designed to provide a rough approximation of equivalency between the category descriptors used by IARC, NTP and the GHS where an unsophisticated classifier elects to simply assume the IARC and NTP carcinogenicity determinations are valid. NIOSH's role under the OSH Act, however, is not to proceed as an unsophisticated classifier of chemicals relying on the determinations of others. It therefore cannot adopt	*Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments. NIOSH is not obligated to follow HCS. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently. NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.*

Commenter/Topic	Public Comment	*NIOSH Response*
	an assumption that may conflict with the best available science on chemical classification, as established by the GHS and incorporated into HCS 2012, for expediency and administrative convenience. Policy — NIOSH supported HCS 2012 and should not now take a different approach to carcinogenicity classification for the sake of expedience. Rote reliance on the IARC, NTP and EPA IRIS classifications would be inappropriate and a disservice to those NIOSH is seeking to aid. Very few EPA and NTP classifications were developed in the last ten years, and even those classifications suffer from development under outdated risk assessment frameworks and reliance on antiquated literature reviews. Law — NIOSH will fail to meet its statutory obligations under the OSH Act if the approach to chemical classification underlying NIOSH's Cancer Policy and the development of RELs conflicts with the approach to chemical classification underlying OSHA's cancer policy and the development of permissible exposure levels (PELs). The OSH Act, operating through HCS 2012, requires NIOSH to classify chemicals based on HCS 2012 rather than another chemical classification scheme. It further precludes NIOSH from delegating its OSH Act responsibilities to other domestic and foreign agencies.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	II. NIOSH's Cancer Policy Must Support Application of the Best and Most Relevant Science As described in the Draft 2013 Cancer Policy, NIOSH proposes to rely, in two distinct ways, on the cancer hazard determinations made by NTP, EPA, and IARC. First, it appears that NIOSH would assume an existing NTP/EPA/IARC carcinogenicity determination is valid, absent a presentation of evidence undermining that determination. Under its proposal, NIOSH's role in the GHS cancer hazard determination would be limited to determining whether chemicals deemed to be carcinogens by those agencies are appropriately considered occupational chemicals– a task NIOSH refers to as determining "occupational relevance." NIOSH's stated objective in taking this approach is "classification efficiency" and finding ways to "lessen the time it takes to develop national recommended exposure limits" to allow "more chemicals to be assessed."5 Or, as stated more directly during the December 16, 2013, public hearing, NIOSH does not "intend to rethink" those (NTP/EPA/IARC) classifications and would limit its carcinogenicity determination to the narrow question of whether that "identified" cancer hazard would be manifested in the workplace, i.e., whether the chemical is an occupational carcinogen.6 In principle, SIRC supports efforts to reduce redundancy among chemical evaluation programs. However, the determination as to whether programs are redundant cannot be limited to whether the outcome of a particular program is to classify a chemical as a carcinogen, but must also ensure that the previous program made that determination on the basis of the criteria that must be applied by NIOSH under the OSH Act. SIRC has no objection to NIOSH using the work of other organizations to help inform its internal decision-making on whether to invest NIOSH resources in its own evaluation of the carcinogenic potential of substances that may be found in the workplace. However, evidence-based science, responsible public policy and the applicable law	*Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments.* *First, NIOSH is not obligated to follow HCS. The HCS applies to chemical manufacturers, importers, distributors and employers.29 C.F.R. 1910.1200 (b). It does not impose obligations on NIOSH. OSHA has no authority to issue regulations that bind NIOSH. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently.* *Second, even if NIOSH were bound by the HCS, that standard specifically permits reliance on NTP or IARC hazard analyses to establish that a substance is a carcinogen. Appendix A to the HCS provides:* *A.6.4 Classification of carcinogenicity* *A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing*

Commenter/Topic	Public Comment	*NIOSH Response*
	preclude NIOSH from simply adopting the carcinogenicity determinations of those agencies. The second role for NTP/EPA/IARC carcinogen classifications appears to be an over-simplified read-across approach to carcinogen classification as reflected in Table 2 of the Draft 2013 Cancer Policy. As noted above, NIOSH's proposal reflects a misunderstanding and inappropriate use of the read-across matrix created by OSHA in Appendix F of HCS 2012. The read-across matrix created by OSHA in Appendix F was designed to provide a rough approximation of equivalency between the category descriptors used by IARC, NTP and the GHS where the user of the table is authorized to simply assume the IARC and NTP carcinogenicity determinations are valid. In other words, it reflects an extension of the provisions in Sections 1910.1200(d)(1) and (d)(3)(ii) of HCS 2012, which allow an employer to rely of the hazard classifications provided by the chemical manufacturer or importer. While the carcinogen classification decisions and underlying analyses made by NTP, IARC, and EPA may be consulted by NIOSH for the information they provide, they cannot provide a basis for GHS classification.	*that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:* *A.6.4.1.1 National Toxicology Program (NTP), "Report on Carcinogens" (latest edition);* *A.6.4.1.2 International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest editions)* *A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.* *NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	A. EPA, NTP and IARC Cancer Classifications Fail to Meet NIOSH's Best Science Criteria NIOSH's objective of rigorous, high-quality science can only be met if it conducts a review of the current science at the time it seeks to assess a chemical under the Draft 2013 Cancer Policy. It is quite possible that the IARC/NTP/EPA assessment that NIOSH would accept at "face value" is out of date. Without a comprehensive literature review to ensure NIOSH is weighing the currently available science, NIOSH risks making an erroneous determination based on incomplete or outdated information. Consider, for example, that by EPA's own admission and as reported by the U.S. Government Accountability Office (GAO) in 2008, 287 of the assessments in the IRIS database may need to be updated, particularly where the IRIS toxicity values, such as oral reference doses or inhalation reference concentrations, are more than 10 years old.7 Furthermore, we note that, during the existence of NTP, nine NTP listings have been determined to be inappropriate and withdrawn.8 NIOSH should establish a policy of performing a literature search to capture everything published after the closing date for the literature search performed by NTP, IARC, and/or EPA, rather than the publication date of the agency's determination. This could be particularly important with regard to IARC because it often issues a Monograph years after the scientific analysis was performed. The literature search should include a public data call-in like EPA's IRIS program.9 Figure 1 of the Draft 2013 Cancer Policy and the narrative under section 4.0 should be amended to explicitly reflect that step. Additionally, many of the IARC/NTP/EPA assessments pre-date key scientific advances, and there appears to be a bias in the IARC and NTP processes	*The National Academy of Sciences has found the NTP process to be sound. NIOSH has clarified how it will review information as follows: "NIOSH will review information and scientific studies relied upon by NTP, EPA, or IARC in developing each chemical carcinogen hazard assessment to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment. Under such circumstances, NIOSH will either nominate the chemical to NTP for review or conduct a full review of the evidence and classify the chemical itself. This review will include consideration of route of exposure, tumor site, mode of action, and any other scientific information that may have bearing on the occupational relevance of the carcinogen classification."*

Commenter/Topic	Public Comment	*NIOSH Response*
	against recognizing those scientific advances. It is for these reasons that the National Academy of Sciences (NAS) is conducting a Congressionally-mandated scientific peer review of the determinations concerning formaldehyde and styrene in the NTP's 12th Report on Carcinogens (RoC) to ensure that both the classification criteria used by NTP, and the application of those criteria, reflect science best practices. 10 The final NAS report is expected by September 2014. At minimum, NIOSH should defer any policy incorporating NTP Report on Carcinogen classifications until the agency has had an opportunity to review the NAS report. Indeed, while the NAS report is focused on the RoC, the report's observations may help NIOSH refine its final policy.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	NAS is also assessing the scientific, technical, and process changes being implemented by the EPA for IRIS. Specifically, the committee will review the IRIS process and the changes being implemented or planned by EPA and will recommend modifications or additional changes as appropriate to improve the scientific and technical performance of the IRIS program. The committee will focus on the development of the IRIS assessments rather than the review process that follows draft development. Because several reviews of IRIS assessments have expressed concerns about EPA's weight-of-evidence analyses, the committee will review current methods for evidence-based reviews and recommend approaches for weighing scientific evidence for chemical hazard and dose-response assessments.11 SIRC is encouraged that NIOSH seeks to revise its Cancer Policy to reflect advances in scientific knowledge, and we support an evaluation process that utilizes a systematic approach for evaluating all relevant data in reaching conclusions. That systematic review should adhere to a rigorous standard of quality, which can only be met by allowing for early input and peer review.12	*NIOSH is confident that relying on the IARC, EPA and NTP classifications will provide scientifically defensible, transparent classifications. This policy does not propose to adopt dose-response assessments from other agencies. The NAS review focused on dose-response assessment.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	1. EPA IRIS Apart from the question of whether the current EPA IRIS chemical assessment program meets NIOSH's best-science criteria, an inventory of existing IRIS assessments demonstrates that they do not provide anything other than a point of departure for independent NIOSH evaluation. In an October 22, 2009, interview, Chon Shoaf, the manager of the IRIS Update Project, said that there were hundreds of IRIS assessments that were more than 10 years old and that EPA would "need to do 300 [each decade] to keep from falling farther behind." Needless to say, EPA has not set that pace for IRIS assessment since 2009. Rather, EPA has committed to increase the pace of IRIS assessment and to produce approximately 16 IRIS assessments during the latter part of 2013 and 2014.13 An examination of EPA's IRIS track shows that only half of the 16 assessments that EPA has now committed to complete by the end of 2014 are updates of previous assessments; the other eight are for chemicals to be added to the IRIS list.14 The current IRIS database has a total of 557 existing IRIS assessments that were performed since its origin in 1987. 15 More specifically, 501 of these assessments have not been significantly modified in the past ten years (since 2003), 424 of these assessments have not been significantly modified in the last 20 years (since 1993), and 220 of these assessments have not been significantly modified in the last 25 years (since 1989).16 No matter how well the IRIS assessments were performed at the time they were drafted, reliance by NIOSH on an existing IRIS assessment is not justified: (1) when new data have been developed on the health effects of the chemical; or (2) when new assessment methods, reflecting the best scientific methods, have been adopted since the original assessment.	*NIOSH is confident that relying on the IARC, EPA and NTP classifications will provide scientifically defensible, transparent classifications. This policy does not propose to adopt dose-response assessments from other agencies. The NAS review focused on dose-response assessment.*

Commenter/Topic	Public Comment	*NIOSH Response*
	For example, EPA adopted new cancer guidelines for performing cancer assessments in 2005 that substantially changed the way in which EPA assesses the cancer potential of chemicals.17 Only 53 of the 557 IRIS assessments have been produced or had any significant change made to them since 2004 and not all of those changes involved a review of the cancer classification for these chemicals. In summary, fewer than 10% of the IRIS cancer classifications reflect the application of modern cancer assessment methods adopted in 2005. Even without new data, NIOSH cannot assume that EPA would reach the same conclusions under the agency's 2005 Guidelines for Carcinogen Risk Assessment, as it did at the time that the IRIS assessment was performed. A 2011 NAS assessment of the EPA IRIS review of formaldehyde details a number of scientific best practices for assessments of chemicals in general and points out that ad hoc review processes cannot be relied on to produce scientifically valid assessments; indeed, weight of evidence to test plausible hypotheses of carcinogenicity are now being used by other institutions such as the Institute of Medicine.18,19	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	2. NTP Report on Carcinogens A similar analysis of the history of the NTP Report on Carcinogens (RoC) should be performed. As NTP states, "The 1st RoC was published in 1980 and contained 26 listings. Each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in the previous edition."20 To date, a total of 12 RoCs have been published; the most recent, the 12th RoC, was released in 2011 and includes 240 listings, but only added six substances to the 234 previously listed substances.21 The previous report (the 11th RoC) was published over nine years ago and added only 17. It is highly likely that additional, significant studies on many of these 240 substances have been published since these chemicals were first listed by NTP, many of them decades ago. NIOSH cannot confidently rely on these determinations made so many years ago without first thoroughly reviewing any new data produced since the listing as well as examining the analysis that led to the original listing in light of the steadily advancing science of hazard assessment since the initial listing. Similarly, risk assessment methodology and mode of action analysis have changed over time. Simply put, NIOSH's reputation as a scientific organization would risk being substantially compromised if it were to adopt the decades-old determinations of these other agencies without first thoroughly examining their current validity.	*The NAS has found the NTP process to be sound. NIOSH has clarified the policy to specifically state that "NIOSH will review . . . if new information casts doubt on the scientific credibility of the assessment." Therefore, for those cases in which additional data casts doubt on the original classification, NIOSH will be reviewing recent data.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	3. IARC While IARC Monographs also raise staleness issues, the Preamble to the Monograph series makes it quite clear that the IARC process is one of hazard determination without regard to a WOE framework.22 In describing the objective and scope of the IARC Monograph program, the Preamble states: "The Monographs represent the first step in carcinogen risk assessment, which involves examination of all relevant information in order to assess the strength of the available evidence that an agent could alter the age-specific incidence of cancer in humans."23 IARC describes the scientific basis for its evaluation as follows: "the strength of the evidence for carcinogenicity from human and experimental animal data is evaluated and classified into one of the following categories: sufficient evidence, limited evidence, inadequate evidence, or evidence suggesting lack of carcinogenicity."24 Accordingly, NIOSH cannot adopt an IARC carcinogenicity determination without performing its own review of the science underlying those determinations and applying the WOE principles as established by HCS 2012.	*NIOSH has clarified the policy to specifically state that "NIOSH will review . . . if new information casts doubt on the scientific credibility of the assessment." Therefore, for those cases in which additional data casts doubt on the original classification, NIOSH will be reviewing recent data. In addition, the IARC process has been described more thoroughly in the NIOSH Cancer Policy document. NIOSH is confident that the process is scientifically sound and transparent and appropriate as a source of carcinogen classifications.* *There is nothing in the HCS 2012 regulation that prevents or discourages NIOSH from adopting carcinogen classifications from reliable sources such as IARC.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	B. Pursuant to HCS 2012, NIOSH May Only Use NTP, EPA and IARC Classifications as a Reference NIOSH states that only "compelling evidence" can show that a substance listed by NTP, EPA or IARC "would not raise the risk of cancer to workers."25 As a threshold matter, we respectfully disagree. First, Congress did not authorize NIOSH to delegate its decision-making authority to any other domestic or foreign agency. Second, the agencies in question do not apply the criteria for making carcinogenicity determinations mandated by the OSH Act through operation of HCS 2012. Third, the criteria for making a determination under HCS 2012 is a weight of evidence determination based on "reliable and good quality evidence" rather than a presumption of "compelling evidence" based on antiquated or outdated assessments by other agencies. Beyond these threshold issues, SIRC is unclear whether NIOSH is suggesting that only "compelling evidence" would cause it to find that a chemical classified as a carcinogen by these agencies is not a carcinogen under the NIOSH Cancer Policy or whether NIOSH is suggesting that only "compelling evidence" could convince it that a NTP, EPA or IARC classified carcinogen does not have occupational relevance.26 In either case, NIOSH is creating an unauthorized high bar that also could have adverse ramifications for NIOSH. NIOSH may not be aware that "compelling evidence" is a term of art often used by EPA, and it has the implied meaning of "beyond a reasonable doubt," or that it would be virtually impossible for a chemical to be a carcinogen, a standard that would be impossible to meet. Working under the burden of such a standard, NIOSH may determine that a determination made by NTP, EPA or IARC is inappropriate, but cannot be avoided under the proposed policy because the NIOSH determination is not supported by "compelling evidence." Based on the foregoing, SIRC believes NIOSH must employ the same approach	*Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments. NIOSH is not obligated to follow HCS. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently. NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.* *NIOSH has clarified and simplified the language in the section describing when NIOSH would not adopt a carcinogen classification by IARC, NTP or EPA. NIOSH notes that in those cases in which NIOSH elects to conduct its own evaluation of carcinogenicity, GHS criteria would be used. This language is also clarified in the document.*

Commenter/Topic	Public Comment	*NIOSH Response*
	as OSHA's HCS 2012 and may only use the determinations of NTP, IARC and EPA as helpful information references under its Cancer Policy. As OSHA observed during deliberations on the 2012 amendments to the HCS, OSHA does not use IARC and NTP sources as "definitive in terms of a carcinogen determination" because it is not part of the GHS approach: OSHA did not propose to continue to require specific mention of IARC, NTP, and OSHA as sources of determinations regarding carcinogenicity. The requirement to consider these sources definitive in terms of a carcinogen determination was not included in the NPRM since it was not part of the GHS approach.27 As both a proponent and user of HCS 2012 to classify chemicals, NIOSH should base its updated Cancer Policy on the HCS 2012 framework.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	C. NIOSH Must Consider Mechanistic Data Section A.0.3.4 of HCS 2012 provides: "When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the chemical should not be classified." Several lines of research have investigated whether the types of lung tumors formed by a mode of action (MOA) that is specific to mice are relevant to tumor formation or other toxicity in humans. Neither IARC nor NTP has considered this issue. EPA, however, is studying the question. In fact, EPA just held a "State-of-the-Science Workshop on Chemically-induced Mouse Lung Tumors: Applications to Human Health Assessments" in order to discuss the available data and interpretation of results from studies of mouse bronchiolar-alveolar adenomas and carcinomas (lung tumors) following exposure to chemical agents, and the relevance of such tumors in mice to human cancer risk. Again, aside from the prohibition on delegation of authority, NIOSH may not rely on determinations that do not apply the mandatory HCS 2012 criteria.	*NIOSH has clarified the language in the policy to indicate how such information as mechanistic, mode-of-action and other data are used in its assessments. More detailed information about this can be seen in individual NIOSH chemical assessments.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	D. NIOSH's Determinations Must be Based on Weight of Evidence Through the evolution of workplace safety and health best practices, the world consensus is that all health hazard classifications, including carcinogenicity, must be based on WOE.28 Therefore, even if it were not required by the OSH Act, generally recognized scientific principles demand that the NIOSH evaluation process incorporate the best available and most relevant information utilizing a weight of evidence approach that considers positive, negative and null study results when reaching conclusions. For that reason, aside from the mandate of the OSH Act (operating through HCS 2012), NIOSH should fully evaluate the scientific basis and quality of the scientific assessments that underlie the classifications developed by EPA, IARC and NTP rather than simply accepting prior classifications as correct or directly translatable into GHS classification categories. As already mentioned, concerns have been raised by the National Research Council (NRC) and the GAO regarding EPA's IRIS, including reliance on dated information and problems with the agency's WOE evaluation.29,30,31 Although some may argue otherwise, NTP and IARC do not incorporate WOE in their processes and this, we believe, is a fatal shortcoming of NIOSH's plan to accept their determinations at "face value".32 With the NTP RoC, there is an inherent bias toward the presentation of study results showing adverse health effects (i.e., to support the existence of a carcinogenic effect) without any weighing of the results in light of their relevance to an assessment of the potential human carcinogenicity of a chemical. NTP's "Definition of Carcinogenicity Results" states: The National Toxicology Program describes the results of individual experiments on a chemical agent and notes the strength of the evidence for conclusions regarding each study. Negative results, in which the study animals	*NIOSH has included a discussion of the role of weight of evidence in its assessment to clarify its position. The NAS reviewed the NTP processes and found them sound.* *Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments. NIOSH is not obligated to follow HCS. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently. NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.*

Commenter/Topic	Public Comment	*NIOSH Response*
	do not have a greater incidence of neoplasia than control animals, do not necessarily mean that a chemical is not a carcinogen, inasmuch as the experiments are conducted under a limited set of conditions. Positive results demonstrate that a chemical is carcinogenic for laboratory animals under the conditions of the study and indicate that exposure to the chemical has the potential for hazard to humans. 33 NTP's approach is reflected quite clearly during the RoC process. For example, at the June 21, 2010, meeting of the NTP Board of Scientific Counselors (BSC) called to review several draft profiles for the RoC, Dr. Gloria Jahnke of NIEHS/NTP told one of the Counselors that she had not included a relevant study because "I'm not recording negative data here; I am recording data that supports our call. So that's why you didn't see it."34	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	The approaches of IARC and NTP are at odds with the WOE framework of the GHS, and, as noted above, IARC and NTP determinations are not conclusive for purposes of the GHS. In adopting HCS 2012 in cooperation with NIOSH, OSHA foreclosed the use of IARC and NTP determinations by OSHA or NIOSH for purposes of making a conclusive classification under the OSH Act. HCS 2012 permits their use only as significant references.35 Under HCS 2012, manufacturers and importers are required to "consider the full range of available scientific literature and other evidence concerning the potential hazards,"36 and then apply the applicable classification criteria in Appendix A to Section 1910.1200 under a weight of evidence analysis.37 According to OSHA, weight of evidence includes "the full range of available scientific literature and other evidence concerning the potential hazards" that serve as the basis for classification.38 OSHA's approach helps avoid the confusion and debate that the terms "strength of evidence" and "weight of evidence" have prompted in other contexts.39 It also avoids the inherent bias under the NTP toward the presentation of "positive studies".40 Under its Guidelines for Carcinogen Risk Assessment, EPA also emphasizes the importance of "weighing all of the evidence in reaching conclusions about the human carcinogenic potential of agents".41 EPA states that WOE—is accomplished in a single integrative step after assessing all of the individual lines of evidence, which is in contrast to the step-wise approach in the 1986 cancer guidelines. Evidence considered includes tumor findings, or lack thereof, in humans and laboratory animals; an agent's chemical and physical properties; its structure- activity relationships (SARs) as compared with other carcinogenic agents; and studies addressing potential carcinogenic processes and mode(s) of action, either in vivo or in vitro.42 A WOE evaluation also would resolve how NIOSH will resolve conflicts in the classifications derived by NTP, EPA and IARC. The 2013 Draft Cancer Policy is unclear as to whether NIOSH planned to consider a hierarchy when utilizing	*Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments. NIOSH is not obligated to follow HCS. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently. NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.*

Commenter/Topic	Public Comment	*NIOSH Response*
	the classifications derived from other agencies. Page 24 of the Draft 2013 Cancer Policy notes that, when differences arise, NIOSH will consider the totality of the data and the relevance of the data to the workplace, including how recently the data were evaluated, how complete the data set was, and whether the routes of exposure, modes of action, and other considerations were relevant to workplace exposures. We recommend that NIOSH incorporate HCS 2012 by reference into its Cancer Policy as the WOE framework it will employ to ensure that all relevant information is considered in accordance with the requirements of the OSH Act, operating through HCS 2012. For these reasons, NIOSH should conduct its own scientific review and evaluation of the available data prior to utilizing or deriving a classification to ensure that that the scientific evidence is the most current and supports the assigned classification under a WOE evaluation.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	III. NIOSH's Cancer Policy Must Be Consistent with HCS 2012 In its effort to improve worker safety and health, NIOSH must adopt a cancer policy aligned with HCS 2012 and not create conflict and disharmony. OSHA promulgated HCS 2012 in consultation with NIOSH and established the chemical classification system to be used by NIOSH in performing its responsibilities under the OSH Act. The HCS is no longer a hazard determination system, but rather a hazard classification system that establishes how chemicals will be classified for purposes of the OSH Act. NIOSH is bound by OSHA's determination and is not free to adopt a different system for chemical classification,43 particularly since it intends to publish GHS classifications for those chemicals that it finds to be occupationally relevant.	*Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments. NIOSH is not obligated to follow HCS. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently. NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.* *NIOSH also notes that the GHS assignment section has been removed from this policy for further analysis and development.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	A. NIOSH Supports GHS and Should Apply It NIOSH worked though the International Programme on Chemical Safety (IPCS) to create the GHS, and NIOSH explicitly supported the promulgation of the HCS amendments to align the HCS with GHS as reflected by its frequent and publically documented statements: • In 2006, NIOSH filed comments in response to OSHA's Advanced Notice of Proposed Rulemaking, supporting OSHA's revision of HCS 1994 to incorporate the GHS. • In 2009, NIOSH filed comments in response to OSHA's Notice of Proposed Rulemaking, supporting the proposed rule.44 In those comments, NIOSH concluded that that the detailed classification criteria of the GHS provided a "significant advantage" in that they:45 (1) "will improve accuracy and consistency in the information provided to employers and employees on chemical hazards and protective measures;" (2) "reduce the likelihood of differing interpretations of the same data;" and (3) "convey the severity of the effect, unlike the hazard classes in the current HCS," and unlike the outdated and generally ignored OSHA regulation commonly referred to as the OSHA Cancer Policy.46 • In March 2010, in written comments to OSHA in connection with its testimony on the OSHA GHS rulemaking, NIOSH reiterated its support for the proposed GHS Amendment to the HCS for the three reasons listed above, and further stated: NIOSH has consistently agreed with the discussed occupational safety and health benefits of the proposed HCS harmonization with the GHS [NIOSH 2006]. The GHS has the same general concept of an integrated, comprehensive process of identifying and communicating hazards but provides more extensive criteria to define the hazards in a consistent manner . . .	*The commenter provided a summary of NIOSH action regarding the HCS. No specific response needed.*

Commenter/Topic	Public Comment	*NIOSH Response*
	• On December 12, 2011, at the public meeting to discuss changes to NIOSH's policy on RELs and carcinogens, NIOSH staff reinforced its support and acknowledged that NIOSH had consistently supported OSHA's proposed GHS Amendment to the HCS. Furthermore, in the separate but related context of control banding, NIOSH has recognized the value of the GHS classification system. Specifically, NIOSH has indicated that there is a need for a "more efficient and quicker means of classifying chemicals" that would facilitate the use of "hazard banding approaches to control [exposures to] chemicals."47 In that regard, NIOSH promotes the IPSC control banding tools, which are based on the hazard classifications of chemicals identified through the GHS.48 NIOSH also describes the IPCS as having an established and internationally recognized leadership role in the preparation of risk assessments on specific chemicals, and for developing and harmonizing hazard and risk assessment methods. NIOSH notes that, in that role:49	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	B. Impact of the GHS Amendments to the HCS Until 2012, the HCS mandated that employers treat substances as carcinogens if the substances were: (1) identified as carcinogens in an OSHA substance-specific standard, or (2) classified as a carcinogen or potential carcinogen by the IARC Monograph or the NTP's RoC. The 2012 amendments to the HCS align the federal HCS (HCS 2012) with two critical aspects of the GHS. First, mandatory treatment as a carcinogen based on an IARC or RoC listing is no longer required. Second, HCS 2012 directs the domestic manufacturer or importer to self-classify each chemical based on a weight of evidence analysis. 1. HCS 2012 Requires Weight of Evidence A review of the completely overhauled approach to chemical health hazard classification found in Appendix A demonstrates that the HCS now operates under a WOE framework, and NTP and IARC determinations are no longer treated as conclusive findings of carcinogenicity under the HCS. Section 1910.1200(d)(2) of the HCS requires that entities making hazard classifications "identify and consider the full range of available scientific literature and other evidence concerning the potential hazards," and consult Appendix A of the HCS for classification of health hazards. Appendix A provides general classification considerations as well as specific guidance for determining whether to classify a chemical as a carcinogen. Section A.0.3.1 of HCS 2012 provides: "classification of a chemical shall be determined on the basis of the total weight of evidence using expert judgment." As provided in section A.6.2.1, the classification process for carcinogenicity is a weight of evidence evaluation that is based on strength of evidence and additional weight of evidence considerations. The nature of this inquiry is succinctly	*A discussion of how NIOSH views the evaluation of evidence to support carcinogen classification has been added to this document. As stated in the document, "NIOSH believes carcinogen classification should employ a systematic methodology for critically assessing and interpreting a body of scientific information. This methodology should include specific steps for the evaluation and integration of scientific information: defining a question or stating a problem of interest (causal question definition); creating a review protocol; identifying and selecting relevant information; evaluating individual studies (review of individual studies); assessing and integrating evidence across studies and providing an overall synthesis (data integration and evaluation); and interpretation of findings (drawing conclusions based on inferences) [Rhomberg et al, 2013]. These steps are important and are utilized by EPA, NTP, and IARC in their chemical carcinogen determinations. This type of review is critical for assessing and classifying chemical carcinogenicity. Whether this process is called "weight of evidence," "strength of evidence," "integration of evidence," or "systematic review," the important issue is that steps in the critical*

Commenter/Topic	Public Comment	*NIOSH Response*
	stated in section A.6.2.3: Carcinogen classification is a one-step, criterion-based process that involves two interrelated determinations: Evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories. OSHA describes strength of evidence as involving "the enumeration of tumors in human and animal studies and determination of their level of statistical significance."50 If statistically significant increases in tumors are observed, the strength of this evidence is further assessed depending on whether it involves human or animal studies and whether there is a clear, causal relationship. However, regardless of the preliminary strength of evidence determinations, it is only one component of the "two interrelated determinations" that comprise this one-step, criterion-based, weight of evidence process. Weight of evidence, according to OSHA, includes "the full range of available scientific literature and other evidence concerning the potential hazards" that serve as the basis for classification.51	*evaluation of chemical carcinogenicity should be made explicit [Weed 2005]. NTP, EPA, and IARC each describe their scientific approach as employing a thorough, systematic analysis of the body of evidence or evaluation of the strength of evidence using a transparent protocol and integration of evidence across studies. Each of these approaches for critically assessing and interpreting a body of scientific evidence satisfies NIOSH criteria. NIOSH views the assessments produced by NTP, IARC, and EPA to be of the highest scientific quality, subject to extensive peer review or prepared by acknowledged experts in the field in a consensus building process."*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	2. OSHA HCS 2012 Precludes Blind Deference to NTP and IARC In adopting HCS 2012, OSHA foreclosed automatic and determinative use of NTP and IARC. In other words, HCS 2012 preempts the processes used by NTP and IARC when it comes to workplace chemical assessments. Under HCS 2012, OSHA eliminated the requirement that manufacturers and importers treat substances as carcinogens based on a listing in the NTP RoC or an IARC Monograph. Rather, companies are now required to self-evaluate the hazards posed by a chemical based on a weight of evidence analysis.52 As OSHA stated: The hazard classification approach in the GHS is quite different from the performance-oriented approach in HCS 1994. The GHS has specific criteria for each health and physical hazard, along with detailed instructions for hazard evaluation and determinations as to whether mixtures of the substance are covered. OSHA has included the general provisions for hazard classification in paragraph (d) of the revised rule, and added extensive appendixes that address the criteria for each health or physical effect. Mandatory Appendices A and B provide classification guidance for Health Hazards and Physical Hazards, respectively.53 These requirements apply to industry and NIOSH alike. There are only two exceptions to this approach. First, a chemical that OSHA has determined to be a carcinogen in a substance-specific rulemaking must be classified as a carcinogen.54 Second, rather than making the determination as to whether a chemical is a carcinogen, HCS 2012 contains a provision designed to allow unsophisticated manufacturers and importers to rely on and adopt the NTP and IARC determinations. That exception reflects an extension of the provisions in Sections 1910.1200(d)(1) and (d)(3)(ii) of HCS 2012, which allow an employer to rely of the hazard classifications for a particular chemical	*Although OSHA "eliminated the requirement that manufacturers and importers treat substances as carcinogens based on a listing in the NTP RoC or an IARC Monograph", OSHA preserved the option of an employer adopting those classifications. An expanded discussion of the elements NIOSH looks for in evaluation of data to support a carcinogen classification is provided in this final document.*

Commenter/Topic	Public Comment	*NIOSH Response*
	provided by the chemical manufacturer or importer. It is an option available to individual manufacturers and importers and has no application to NIOSH. NIOSH is one of the two expert agencies identified under the OSH Act as having responsibility for developing and implementing chemical classification criteria.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	3. NIOSH's GHS Classifications, If Based on IARC and NTP Classifications, are Likely to Cause Conflicts and Confusion A primary concern is that NIOSH intends to rely on carcinogenicity determinations made by NTP/IARC/EPA and then pronounce the appropriate GHS classifications for those chemicals based on a simplistic translation of the NTP/IARC/EPA classifications, without regard to their validity, rather than applying the GHS weight of evidence framework. While we understand the Institute's desire to further workplace safety by providing employers with "useful information to more effectively communicate the chemical hazards to workers," we are concerned that NIOSH will create confusion through this practice.55 As already discussed, IARC and NTP cancer determinations are not dispositive of a cancer classification under HCS 2012. NIOSH's exclusive reliance on those assessments would conflict with the criteria that employers, manufacturers, and importers will use when self-classifying under HCS 2012, and with the criteria OSHA will use in bringing any enforcement action under HCS 2012. NIOSH's simple, read-across approach to GHS classification raises an additional issue. Presumably, NIOSH will be developing these informational GHS classifications as a service to employers who lack the resources to make GHS classifications. While our views of the GHS classification system may differ from that of the proposed policy, if GHS classification is really as simple as checking an IARC or NTP listing, is there really a resource issue for employers, or, more pointedly, for the chemical manufacturer preparing a Safety Data Sheet? NIOSH, albeit unintentionally, raises questions about the legal consequences where an employer's assessment differs from that of NIOSH and the employer relies acts on its own findings. Since NIOSH only intends for the GHS	*Several comments argued that NIOSH was obligated to follow OSHA's Hazard Communication standard and that its draft policy did not do so. These commenters suggested that the HCS requires an independent weight of evidence analysis and did not permit NIOSH to rely on hazard assessments completed by NTP, IARC, or EPA. NIOSH disagrees with these comments. NIOSH is not obligated to follow HCS. NIOSH is a scientific research agency independent of OSHA. While NIOSH strives to develop policies that complement OSHA's regulatory activities, it develops its scientific policies independently. NIOSH's reliance on hazard analyses completed by NTP, EPA, or IARC as the basis for its cancer assessment is entirely consistent with HCS.* *The NIOSH GHS assignment process has been removed from this policy for further analysis and development.*

Commenter/Topic	Public Comment	*NIOSH Response*
	classification to be informational, SIRC recommends it reconsider whether this exercise is of informational value.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	V. Align the Draft Policy Narrative and Figure 1 As noted previously, the 2013 Draft Cancer Policy creates confusion as to NIOSH's classification process. The information presented in Figure 1 of the Draft Cancer Policy ("NIOSH chemical carcinogen review process") is not consistent with the narrative discussion under Section 4.0 of the policy, which begins by saying there will be only one NIOSH classification	*NIOSH has revised the text and removed figure 1 to clarify and simplify the information.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	Consistent with our understanding of Figure 1 and informed by the narrative portion of the proposal as well as our prior comments, an outline of what Section 4.0 should provide follows. 1. A critical aspect of the NIOSH carcinogen policy is to independently evaluate the quality and occupational relevance of the data. Along with considering efficiency and clarity, NIOSH seeks to classify carcinogens using the GHS approach established in HCS 2012, which is globally recognized as the system that is appropriate and relevant to workplace exposures. 2. NIOSH begins its carcinogen assessment by evaluating occupational relevance to first determine whether workers are at risk of exposure to the chemical in the workplace. 3. If occupational exposure is not likely, NIOSH will not proceed with a carcinogen evaluation. 4. If occupational exposure is likely, NIOSH will evaluate whether the scientific evidence supports a determination of "occupational carcinogen." a. If the chemical under review has been classified by NTP, EPA or IARC, NIOSH will perform a de novo review to evaluate: (1) whether the scientific evidence supports a human cancer determination, including whether the described mode of action is relevant to humans; (2). and whether the scientific evidence supports an "occupational carcinogen" determination, including the potential for worker exposure, and whether the route(s) of exposure used in the studies is/are relevant to workplace exposures as reflected in human, animal and other high-quality studies. b. Based on this review, NIOSH will determine whether the substance is an	*NIOSH has revised the text to clarify the process NIOSH will use to evaluate carcinogens.*

Commenter/Topic	Public Comment	*NIOSH Response*
	occupational carcinogen. 5. Whenever data quality permits, NIOSH will use quantitative risk assessment, based on the best available data within a weight of evidence framework, to derive and communicate an array of exposure and corresponding risk levels. 6. If supported by NIOSH's evaluation, NIOSH may nominate a substance for review by NTP.	

Commenter/Topic	Public Comment	*NIOSH Response*
Risk Assessment Process		
Barbara Dawson, CIH, (AIHA)	Again addressing the target risk for carcinogen RELs, the document refers to mathematical models with varying assumptions. There are a number of these. Which ones will be employed for consistency purposes? Should they be listed or criteria defined?	*The mathematical models described in the document were for illustrative purposes only. This document was never intended to provide a complete roadmap to how NIOSH conducts quantitative risk assessment, but instead, to focus on three specific issues related to developing recommendations for carcinogens. The discussion of modeling has been clarified in the document. The commenter is also referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide for additional details on the NIOSH risk assessment process.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dennis Shusterman, MD, MPH and Kashyap Thakore, PhD, (CDPH)	Administrative process The proposal to have NIOSH staff evaluate the carcinogenic potency of substances ultimately classified as "occupational carcinogens" – and to derive RELs based upon target risk levels – poses a number of technical and procedural challenges. Firstly, NIOSH staff should consider designating a single technical reference document (e.g., from the US EPA 1 or the California Office of Environmental Health Hazard Assessment 2) as an authoritative procedural guide for risk estimation in order to both streamline the process and avoid confusion when communicating with stakeholders. In this latter regard, policies and procedures for drafting quantitative risk estimates – and the role of stakeholders in the review of draft recommendations – should be mapped out in advance. Based upon our experience with the standards-setting process in California, many high-volume chemicals have producers' groups or other interested parties whose participation can inject highly technical questions into the process. Addressing such issues as mechanism-of- action, physiologically based pharmacokinetic (PBPK) modeling, and choice of critical studies for derivation of potency slopes can demand considerable staff time and energy. Responsible NIOSH staff should be sufficient in both number and technical preparation for the proposed workload.	*The commenter is referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide for additional details on the NIOSH risk assessment process. With regard to stakeholder involvement, the NIOSH process has been to publish in the Federal Register a request for information on the substance under investigation, develop a draft document, conduct a public meeting, have peer and public review of the document, and, only after adequate review, to publish the final document. In some cases (for example, this Cancer Policy document), multiple public meetings and opportunities for comment and input have been held.*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	The use of low dose non-threshold linear modeling was proposed by NIOSH to establish the REL unless data clearly were present for a nonlinear model. NIOSH should not rule out the use of low dose modeling with thresholds for carcinogens, especially for those with non-genotoxic mechanisms.	*The modeling strategies presented were for illustration purposes only and not intended to limit NIOSH risk assessors to a single model. NIOSH typically uses the modeling strategy best suited to the data available, taking into consideration factors such as mode of action, pharmacokinetics, and other information, as appropriate. The commenter is referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide*

Commenter/Topic	Public Comment	*NIOSH Response*
		for additional details on the specifics of NIOSH risk assessments.
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	Recommend that within the REL documentation, NIOSH provides details that document more than one mathematical model to obtain the target risk level for carcinogens and explain which was chosen and why.	*The modeling strategies presented were for illustration purposes only and not intended to limit NIOSH risk assessors to a single model. NIOSH typically uses the modeling strategy best suited to the data available, taking into consideration factors such as mode of action, pharmacokinetics, and other information, as appropriate. The commenter is referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide for additional details on the specifics of NIOSH risk assessments.*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	NIOSH will use quantitative risk assessment (QRA) (page 4) when data quality permits to derive the risk based REL. A concern exists regarding the default approach employed when carcinogens are evaluated for which the QRA data are marginal.	*When data are marginal, NIOSH evaluates the available data and decides on the appropriate approach that both maximizes the utility of the data and makes sense in the context of the chemical of interest. The commenter is referred to the NIOSH document on occupational exposure to carbon nanotubes for additional insight.*

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Mazzucco, (NRCWF)	Areas of specific concern including the following: Safety determinations will only be as effective as the quality of the science they are based on. This report outlines the use of linear modeling to extrapolate low-dose effects of carcinogens. One key issue which was not discussed here is the issue of non-monotonic dose-response curves, with the low-dose effects of endocrine disruptors as an example which highlights inadequacy of classical toxicology models. Furthermore, other factors such as bioaccumulation and multigenerational effects must also be considered when determining recommended exposure limits.	*The modeling strategies presented were for illustration purposes only and not intended to limit NIOSH risk assessors to a single model. NIOSH typically uses the modeling strategy best suited to the data available, taking into consideration factors such as mode of action, pharmacokinetics, and other information, as appropriate. The commenter is referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide for additional details on the specifics of NIOSH risk assessments.*

Commenter/Topic	Public Comment	*NIOSH Response*
Alan Nye, PhD, (CTEH) and Daniel Saphire, (AAR)	AAR has several comments regarding the draft Policy: The Draft Policy does not clearly acknowledge the limitations of quantitative risk assessment. While the draft Policy acknowledges certain limitations associated with past NIOSH practices (for example, the limitation associated with calling all carcinogens "potential occupational carcinogens"), it does not adequately discuss limitations associated with quantitative risk assessment (QRA) procedures that will be used in the draft Policy. As determined in the draft Policy, the benchmark for REL development is the air concentration of a chemical associated with a theoretical 1 in 1,000 increase in lifetime cancer risk. The limitations of QRA in developing risk-based concentrations such as an REL are not well appreciated by workers or employers and so, must be clearly stated to provide a more complete understanding of the basis and limitations of the REL. In particular, the concept of "cancer risk" and its attendant hypothetical probability are prone to being misunderstood. Persons often mistake the cancer risk described in QRA as an actual or measurable risk. As stated by the Presidential/Congressional Commission on Risk Assessment and Risk Management : *It is misleading to express cancer risk in a manner that implies great precision, when cancer risk often is based on little or no more information than is available on noncancer effects. Risks from carcinogens are generally expressed in terms of upper-bound or worst-case predictions of incidence or numbers of deaths per unit of the population over 70 years. Although those predictions are not intended to be interpreted as actual or measurable cancer risks, they often are, even when the information base is restricted to observable dose-response data from rodent bioassays. In only a limited number of cases have additional*	*Specifying the details of the risk assessment process are beyond the scope of this document. However, the commenter is referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide as examples of the issues considered. With regard to the interpretation of cancer risk, NIOSH attempts to clearly characterize the strengths and weaknesses of the underlying data, acknowledge the uncertainties inherent in risk assessment and quantify those uncertainties to the extent possible in sensitivity analyses of alternate approaches to the risk assessment.*

Commenter/Topic	Public Comment	*NIOSH Response*
	mechanistic data aided in extrapolating between species and from high to low exposures.	

Commenter/Topic	Public Comment	*NIOSH Response*
Alan Nye, PhD, (CTEH) and Daniel Saphire, (AAR)	AAR has several comments regarding the draft Policy: The Draft Policy does not clearly acknowledge the limitations of quantitative risk assessment. Given that the prediction of cancer risk from exposure to chemical carcinogens is uncertain and thus cannot be described as being an "actual or measurable" risk, NIOSH should include language on the limitations of QRA in its draft Policy. Further, limitations on QRA should also be discussed in NIOSH criteria documents of specific chemicals such as hexavalent chromium. In describing the limitations on the use of its toxicity values from its Integrated Risk Information System (IRIS) database, the United States Environmental Protection Agency states the following, specifically noting that IRIS toxicity values cannot be used to accurately predict the incidence of human disease. *In general IRIS values cannot be validly used to accurately predict the incidence of human disease or the type of effects that chemical exposures have on humans. This is due to the numerous uncertainties involved in risk assessment, including those associated with extrapolations from animal data to humans and from high experimental doses to lower environmental exposures. The organs affected and the type of adverse effect resulting from chemical exposure may differ between study animals and humans. In addition, many factors besides exposure to a chemical influence the occurrence and extent of human disease.* Together with information concerning the magnitude of human exposure, the toxicity values in IRIS form the basis for determining theoretical cancer risks. Since the draft NIOSH Policy uses toxicity values derived using the same exposure-response assumptions as those used by USEPA, limitations described by the USEPA for its IRIS toxicity values also apply to the RELs derived using the QRA procedures described in the draft Policy. As such, exposures above or below the RELs cannot be said to accurately predict human lifetime cancer	*Specifying the details of the risk assessment process are beyond the scope of this document. However, the commenter is referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide as examples of the issues considered. With regard to the interpretation of cancer risk, in general, NIOSH attempts to clearly characterize the strengths and weaknesses of the underlying data, acknowledge the uncertainties inherent in risk assessment and quantify those uncertainties to the extent possible in sensitivity analyses of alternate approaches to the risk assessment.*

Commenter/Topic	Public Comment	*NIOSH Response*
	risks above or below 1 in 1,000. For the above reasons, the draft Policy and the NIOSH criteria documents should include discussion clearly explaining the limitations of QRA and the impact of these limitations on the RELs developed using the risk assessment procedures outlined in the draft Policy.	

Commenter/Topic	Public Comment	*NIOSH Response*
Alan Nye, PhD, (CTEH) and Daniel Saphire, (AAR)	AAR has several comments regarding the draft Policy: The draft Policy is silent on the need for periodic updates of RELs based on the availability of new scientific and medical evidence. While the draft Policy accounts for the possible lowering of RELs based on achieving a lower limit of quantitation for a chemical (page 33, lines 31 through 35), it does not include a provision for periodically updating RELs on the basis of receiving important new scientific information regarding dose-response, mode of action, or other relevant information. For example, the chemicals in the USEPA IRIS Program are periodically reviewed for new toxicity studies that may affect the derivation of toxicity factors developed under the program. Such a periodic review should also be considered by NIOSH. Thank you for the opportunity to provide these comments on behalf of the American Association of Railroads.	*Detailed procedures for updating the RELs are beyond the scope of this document. NIOSH prioritizes chemicals for risk assessment based on toxicity, exposure, new data on risk or exposure, and stakeholder interest. Although NIOSH does not maintain a specific schedule for review of chemicals, staff maintain currency on the literature and the Institute responds to requests for review.*
Adam Finkel, ScD., CIH	NIOSH has caught up with the risk assessment community as regards carcinogens, but should move expeditiously to catch up with respect to non-carcinogenic health effects as well, where solid risk-based methods also exist. I encourage NIOSH to adopt the established methods endorsed by the National Academy of Sciences (see Chapter 5 of Science and Decisions: Advancing Risk Assessment), and create a parallel science-policy document for conducting QRAs for non-cancer health endpoints. The NAS panel, and many other scientists, believe that the distinction between carcinogen and non-carcinogen risk assessment is artificial, and that dose-response modeling for populations exposed to the latter agents is appropriate and feasible, leading to risk-based exposure information and recommendations.	*Considering non-cancer risk assessment is beyond the scope of this document, but NIOSH will take the comment under advisement.*

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	NIOSH Should Avoid Policy Statements that Counteract the Relevance of Setting Realistic RELs In the Draft Cancer Policy, NIOSH explains the rationale for revising its policy in establishing RELs as follows: "Moving from a qualitative approach to a quantitative approach to risk assessment acknowledges excess risk, increases transparency for workers and employers, and it better relates to OSHA's work in developing occupational exposure limits." Draft Cancer Policy at 4 (emphasis added). As a governmental body that primarily serves in a research support role with no rulemaking authority, NIOSH should not make "official" statements in documents like its Cancer Policy that serve to undermine its primary role and confuse interested parties and that raise the possibility of unintended consequences with respect to economic growth, trade, scientific innovation and public safety. This is particularly the case when there is no indication that NIOSH has undertaken any systematic evaluation of the implications of such statements. For example, as part of the section explaining the rationale for deciding to set a target risk level, NIOSH states: Assuming there is no dose-response threshold for carcinogens, any exposure to a carcinogen involves some degree of excess risk. For this reason, the only way to completely eliminate the excess risk is to prevent exposure. NIOSH strongly advocates using safer alternative to toxic chemicals, including substituting noncarcinogenic chemicals for carcinogens whenever feasible. Id. at 30. This statement stands alone, unaccompanied by any discussion of how feasibility is to be assessed or what scientific, technical and economic criteria should be used in evaluating whether one substance is a preferable substitute for another. All chemicals demonstrate a dose- response, and with	*While NIOSH understands the importance of technical and economic feasibility in setting occupational standards, NIOSH is a public health institute whose primary role is to conduct research on protecting workers. The health implications of occupational exposure to carcinogens should be clearly understood by employers in order to best facilitate their choices in controlling exposures. With regard to the dose-response issue, NIOSH uses the best available science in conducting its quantitative risk assessments. The statement assuming no threshold is consistent with current scientific thinking on the genotoxic mode of action. For chemicals with a mode of action that would clearly not be expressed as a linear model, NIOSH considers non-linear mathematical models (see NIOSH document on occupational exposure to titanium dioxide).*

Commenter/Topic	Public Comment	*NIOSH Response*
	sufficient investigation of the mode of action (MOA) safe levels of exposure may be quantified. The assumption that a carcinogen has no "threshold" is a policy determination, not based in science. It has been established through genotoxicity testing that some carcinogenic substances have a threshold.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	NIOSH Will Fail to Meet its Statutory Obligations if NIOSH's Policy on RELs is not Consistent with OSHA's Policy on PELs According to the Draft 2013 Cancer Policy – NIOSH will no longer specifically consider engineering achievability for each chemical- specific REL. NIOSH will evaluate the capability for controlling airborne exposures with engineering controls in concert with the supporting documentation that accompanies a NIOSH REL policy document. If NIOSH lacks adequate exposure measurement/control data, the absence of such data will be explained when the REL is set and NIOSH will recommend that research be conducted to determine the efficacy of existing engineering controls. NIOSH will give recommendations that reflect the availability and efficacy of existing controls, including alternative risk management practices to reduce worker exposures.56 SIRC finds these statements to be quite confusing, if not unintelligible. It appears that NIOSH begins by stating that it will no longer address the technical feasibility of achieving a REL, but then indicates there would be two significant exceptions to that rule. First, this language appears to imply that NIOSH may conclude that a REL is technically feasible if that determination is supported by "adequate exposure measurement/control data," without making any effort to describe what is meant by "adequate exposure measurement/control data." As the court decisions have made clear, OSHA is required to demonstrate that a proposed PEL is technically and economically feasible for each covered industrial sector unless the agency is able to demonstrate that technical and economic feasibility can be properly established on a broad generic basis generally applicable to all industrial sectors. The same criteria would apply to NIOSH.	*Several comments criticized the draft cancer policy because NIOSH did not propose to evaluate the technological and economic feasibility of its RML-CA. These comments argued that NIOSH recommended risk management levels must be based on an evaluation of feasibility because OSHA standards must be feasible.* *NIOSH is a scientific research agency independent of OSHA. NIOSH recommendations are not binding, and are developed using the criteria set forth in section 20 of the OSH Act.* *Although NIOSH does not base its RML-CA on technological and economic feasibility findings, NIOSH makes information on technology to reduce exposures available to affected stakeholders who can use that information to implement appropriate exposure reductions. NIOSH does not consider economic feasibility in making health-based recommendations for RML-CAs.*

Commenter/Topic	Public Comment	*NIOSH Response*
	Second, even when NIOSH does not have adequate exposure measurement/control data to demonstrate that a REL is technically and economically feasible (either on a generic basis or for each industrial sector), NIOSH appears to suggest it can somehow demonstrate that a proposed REL is technically and economically feasible based on the availability and efficacy of existing controls despite the absence of adequate, supporting exposure measurement/control data. In other words, after acknowledging the lack of adequate exposure measurement/control data, NIOSH appears willing to make statements in an area it announced that it would not address based on unsupported opinion and possibly speculation.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	The 2013 Draft Cancer Policy requires clarification on these points. SIRC believes the NIOSH Cancer Policy should state that NIOSH will either support a finding of technical feasibility through the collection of reliable, representative and statistically significant sampling data or abandon any effort to address technical feasibility. In other words, NIOSH would proceed to address technical feasibility under one of the following alternatives: (1) obtain statistically significant field measurements of exposures for specific sites (in selected industries), specific processes or specific tasks demonstrating that the REL is currently being achieved approximately xx% of the time at the sampled site, for the sampled process or for the sampled task; (2) obtain statistically significant field measurements representative of specific industries, specific processes or specific tasks demonstrating that the REL is currently being achieved in xx% of the sampled industries, processes or tasks xx% of the time; and/or (3) state that NIOSH was unable to obtain sufficient data to determine whether the REL is currently being achieved and refrain from making any comment on technical feasibility.	*In seeking to determine and establish health-based RML-CAs, NIOSH does not emphasize technical feasibility as a factor for setting the RML-CA. However, NIOSH presents relevant and applicable data on engineering controls pertaining to technical achievability of given exposure levels when available and appropriate for additional guidance.*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	Section 3.0 is a helpful carcinogen classification review; however, this would be more effective as an appendix and not in the main body of the draft policy. Much of sections 5.2-5.3 would also be a good candidate for an appendix and not in the main body of the policy.	*NIOSH has substantially revised and shortened the document, but has not included any appendices.*

Commenter/Topic	Public Comment	*NIOSH Response*
Target Risk Level		
Christopher Lish and PSR	The NIOSH should publish exposure levels that correspond to a range of lifetime risks of cancer (e.g., 1 in a thousand, 1 in ten-thousand, 1 in a million, etc.) to better support OSHA's needs to set Permissible Exposure Limits (PELs).	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so.*
Christopher Lish and PSR	The NIOSH should not set Recommend Exposure Limits (RELs) at 1 in 1000--this "recommended" exposure level is not a "safe" exposure level. A range of exposures and the associated estimated range of risk can provide OSHA and others the information they need.	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central*

Commenter/Topic	Public Comment	*NIOSH Response*
		estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so.
Cheryl Osimo, (MBCC)	MBCC supports the previous comments submitted by Silent Spring Institute and would like to add the following comments. First, one extra cancer case per 1000 exposed workers is not an acceptable goal for NIOSH to set. It is way too high. For the general population EPA is concerned about one additional case per million exposed, and goals for carcinogens in drinking water are set (appropriately) to zero. NIOSH, as a research agency, should be articulating a goal of zero or the lowest possible exposure for carcinogens. OSHA, as a regulatory agency, is responsible for considering feasibility of exposure controls and availability of alternatives when they set standards. It is not appropriate for NIOSH to offer one per thousand as an acceptable workplace cancer risk.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended."*

Commenter/Topic	Public Comment	*NIOSH Response*
		NIOSH is analyzing and developing additional information on risk management, including substitution and elimination.
Pamela Miller, (ACAT)	While we applaud the many improvements in the NIOSH Update, ACAT strongly opposes NIOSH setting Recommended Exposure Limits or RELs for workers at 1 in 1000—a thousand times less protective than the levels considered safe for the general public. NIOSH can perform calculations for OSHA that set out a range of lifetime risks of cancer (e.g., one in 1,000, one in 10,000, and one in a million, etc.) without labeling this activity as setting RELs.	*NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and*

Commenter/Topic	Public Comment	*NIOSH Response*
		health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.

Commenter/Topic	Public Comment	*NIOSH Response*
Monica Smith, (BCAN)	The designation of Recommended Exposure Limit (REL) at a risk of 1 in 1000 is a troubling point in the update of Carcinogen Classification. The role of carcinogens in the development of cancer has been widely noted. The American Cancer Society directly notes workplace exposure as a risk factor for bladder cancer: "Certain industrial chemicals have been linked with bladder cancer. Chemicals called aromatic amines, such as benzidine and beta-naphthylamine, which are sometimes used in the dye industry, can cause bladder cancer. Other industries that use certain organic chemicals may also put workers at risk for bladder cancer if exposure is not limited by good workplace saftey practices. The industries carrying the highest risk include makers of rubber, leather, textiles, and paint products as well as printing companies. Other workers with an increased risk of developing bladder cancer include painters, machinists, printers, hairdresser (likely because of heavy exposure to hair dyes), and truck drivers (likely because of exposure to diesel fumes)." In the 2011 paper "Preventable Exposures Associated With Human Cancers" by lead author Vincent James Cogliano, there was sufficient evidence to link urinary bladder cancer to occupations that work with rubber production, painting, and radiation. Additionally, there was limited evidence to suggest a link between urinary bladder cancer and occupations including dry cleaning, the auto and trucking industry, hairdressers/barbers, printers and textile manufacturers. In April 2010, the President's Cancer Panel released a report titled "Reducing Environmental Cancer Risk: What We Can Do Now." It included the following statement to the president: "The Panel urges you most strongly to use the power of your office to remove carcinogens and other toxins from our food, water, and air that needlessly increase healthcare costs, cripple our Nation's productivity, and devastate American lives." The new standards regarding carcinogens in the workplace seem to directly contrast this position. In determining this "acceptable" carcinogen risk level, the health of workers does not appear to be a priority.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended." NIOSH is analyzing and developing additional information on risk management, including substitution and elimination.*

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J Burton LeBlanc, (AAJ)	AAJ, with members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, and protect access to the courts. AAJ applauds NIOSH's efforts to update its Cancer Policy so it is consistent with the policies of other organizations that evaluate the potential carcinogenicity of chemical substances, such as the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC). However, in response to NIOSH's 2011 Request for Information on its Cancer Policy, AAJ expressed concern that NIOSH was improperly basing its Cancer Policy on a flawed interpretation of the Benzene decision.1 NIOSH's currently proposed Cancer Policy continues to misconstrue the Benzene decision in two important ways.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision.*
J Burton LeBlanc, (AAJ)	First, the Benzene decision does not apply to recommended exposure limits established by NIOSH under section 20(a)(3) of the Occupational Safety & Health Act.2 Benzene applies to "occupational safety and health standards," as that term is defined in section 3(8) of the OSH Act.3 When OSHA establishes such a standard, it must be "reasonably necessary or appropriate" and technologically and economically feasible. NIOSH does not recommend "occupational safety and health standards" as defined by section 3(8). Instead, the Act directs NIOSH to "describe exposure levels that are safe for various periods of employment."4 There is no statutory basis for NIOSH to define its role under section 20 of the Act as identical to OSHA's role in setting standards.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision.*

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J Burton LeBlanc, (AAJ)	Second, Benzene does not require that OSHA set a standard at the 1 in 1 000 level and OSHA has never done so. OSHA relies on the 1 in 1000 level as a "policy norm" in defining risks that are clearly significant.5 Lesser risks may also be significant. There is simply no statutory or judicial reason for NIOSH to recommend continued exposure to significant risks, but that is what NIOSH policy would dictate if the current proposal were adopted. If NIOSH wants to identify the 1 in 1000 or 1 in 10,000 risk level, to provide information useful to OSHA during rulemaking, it should do so without suggesting that such an exposure is safe or recommended.	*NIOSH has revised the risk level at which its Risk Management Limit for Carcinogens (RML-CA) is set to 1 in 10,000 (or the limit of quantification of the analytical method, whichever is higher). As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended." NIOSH is analyzing and developing additional information on risk management, including substitution and elimination to be included in future recommendations. In addition, the*

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		document describes NIOSH thinking about only providing a range of risk estimates, but not a recommended exposure limit. As stated in the document, "Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave such a policy decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk; however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."

Commenter/Topic	Public Comment	*NIOSH Response*
J Burton LeBlanc, (AAJ)	In sum, AAJ urges NIOSH to revise its cancer policy. In doing so, NIOSH should ensure that it does not recommend continued exposure to cancer risks that are clearly significant. AAJ appreciates this opportunity to submit comments in response to the National Institute for Occupational Safety and Health's draft document regarding carcinogen risk level and chemical hazards in the world place. If you have any questions or comments, please contact Ivanna Yang, AAJ's Assistant Regulatory Counsel at (202) 944-2806	*The NIOSH cancer policy has been revised as described above.*
Patrick Morrison, (IAFF)	Compared to the general U.S. population, fire fighters have an increased risk for developing cancer. NIOSH's most recently published epidemiological study assessing the cancer risk of fire fighters found higher incidence rates of cancers of the respiratory, digestive, oral and urinary systems in a cohort of 30,000 professional U.S. fire fighters. These findings are consistent with previous studies assessing cancer risk in fire fighters. Therefore, the IAFF believes that NIOSH's use of 1 in 1000 target risk level to establish Recommended Exposure Limits (RELs) does not result in our members being afforded adequate protection from occupational carcinogens.	*As stated in the document, "Because there is no safe level of exposure to occupational carcinogens, NIOSH will continue to recommend reduction of exposure to an occupational carcinogen according to the hierarchy of controls through elimination or substitution and implementation of engineering controls, if practical, and the use of administrative controls before use of personal protective equipment (PPE). When exposures to carcinogens cannot be eliminated, NIOSH will also (1) calculate a range of risk estimates, from 1 excess cancer case in 100 workers to 1 excess cancer case in 1 million workers over a 45-year working lifetime when the data permit, and (2) set a risk management limit for carcinogens (RML-CA). When data permit NIOSH to complete a quantitative risk assessment (QRA), NIOSH will use the results of the QRA to perform both tasks.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Patrick Morrison, (IAFF)	The IAFF believes that our members should be afforded the same level of protection from exposure to carcinogens as the general public (e.g. one in one million). However, we recognize the nature of firefighting and the work environment does not always allow for this level of protection. Fire fighters are exposed to multiple known and possible carcinogens during a fire and in the fire station where they eat, sleep, train and work for extended periods of time.	*In response to this and other comments, NIOSH developed Risk Management Limits for Carcinogens (RML-CA) set at a level that should not exceed 1 in 10,000 excess risk or the limit of quantification of the analytical method, whichever is higher. Discussion of the rationale for these choices was expanded in the policy document.*

Commenter/Topic	Public Comment	*NIOSH Response*
Patrick Morrison, (IAFF)	The draft policy states that the main reason for selecting a targeted risk level of 1 in 1000 is to assist Occupational Safety and Health Administration (OSHA) in its interpretation of the U.S. Supreme Court's benzene decision. However, NIOSH can perform these calculations for OSHA by publishing exposure levels that correspond to a range of lifetime cancer risks (e.g. one in ten thousand, one in one hundred thousand, and one in one million). A range of exposure limits and associated estimated risk levels provides OSHA the information it needs to establish Permissible Exposure Limits that take into account both worker health and industry feasibility. Thus, NIOSH can modernize its carcinogen policy in a way that protects fire fighters and other workers to a relevant and achievable standard without resorting to an outdated 1 in 1000 target risk level for its RELs.	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control*

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		technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.

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Barbara Dawson, CIH, (AIHA)	AIHA supports the use of risk based exposure limits (RBOEL) for carcinogens. The chosen benchmark of 1-in-1000 risk over a 45-year working lifetime seems appropriate. Mention is made in the document that this risk is at least an order of magnitude higher than the cancer risk permitted in the United States for the general public. However, what is not mentioned in the document is that, according to the Bureau of Labor Statistics, the risk for accidental death occurring during employment in a working lifetime is slightly higher than 1-in-1000 over the entire U.S. worker population and very much higher for some classifications of workers (e.g., construction workers, commercial fishermen). What is even more interesting is that these accidental deaths of workers represent actuarial data; that is, this is the portion of workers who actually die as evidenced by historical records. The risk of cancer from exposure to a carcinogen on the other hand is putative and the result of low dose extrapolation of animal data. The extrapolation also assumes that there is a linear dose-response all the way down to exposures that are many orders of magnitude below those tested on animals. It also estimates the occurrence of cancer and not the rate of death from cancer. Given all of these factors, the criterion outlined by NIOSH for RBOELs for carcinogens seems perfectly reasonable.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended." NIOSH is analyzing and developing additional information on risk management, including substitution and elimination." In addition, the document describes NIOSH thinking about only providing a range of risk estimates, but not a recommended exposure limit. "Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave such a policy*

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		decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk; however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."

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Dennis Shusterman, MD, MPH and Kashyap Thakore, PhD, (CDPH)	Target risk level A target risk level of 1 per 1,000 workers over a 45-year working lifetime clearly meets the minimum risk criterion proposed by the Supreme Court in its "benzene decision." However, it is not clear that a lower target risk would not also meet the judicial threshold of regulatory concern. For the general public, chronic reference exposure levels (such as California's Safe Drinking Water and Toxic Enforcement Act or Proposition 65) require exposure notification if the cancer risk exceeds 1 / 100,000 over a lifetime of exposure. NIOSH might consider publishing RELs spanning a projected risk range (e.g., 1 / 1,000 ~ 1 / 10,000), and allowing the occupational rule-making agency, the Federal Occupational Safety and Health Administration (OSHA), to explore the legal feasibility of requiring more strict hazard control. Other issues dealing with lifetime risk include mixed exposures to multiple carcinogens, as well as potential inter-individual variability in susceptibility due to genetic, dietary, and other factors. In this regard, does NIOSH propose rules for combining risks from co-exposure to multiple carcinogens? In deriving risk estimates, will potential inter-individual variability be taken into account?	*In response to this and other comments, NIOSH developed Risk Management Limits for Carcinogens (RML-CAs) set at a level that should not exceed 1 in 10,000 excess risk or the limit of quantification of the analytical method, whichever is higher. Discussion of the rationale for these choices was expanded in the policy document. The reference to the Benzene decision was removed in the rationale and the document expands on the reasons for the RML-CA risk level. With regard to multiple exposures, NIOSH has an exploratory project on cumulative risk assessment separate from this effort.*

Commenter/Topic	Public Comment	*NIOSH Response*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	• Use of a target level of increased risk at 1/1000 for the occupational population - The use of risk-based RELs for carcinogens is a step directly into the 21st century for NIOSH. The chosen benchmark of 1 in 1000 risk at the 95th lower confidence limit for a 45 year working lifetime seems imminently appropriate and defendable. However, mention is made in the document that this risk is at least an order of magnitude higher than the cancer risk permitted in the US for the general public (1 in 100,000 or 1 in 1,000,000). It may be worth explaining the differences in risk magnitude for the two populations in the final document.	*In response to this and other comments, NIOSH developed Risk Management Limits for Carcinogens (RML-CAs) set at a level that should not exceed 1 in 10,000 excess risk or the limit of quantification of the analytical method, whichever is higher. Discussion of the rationale for these choices was expanded in the policy document to say, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended."*

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Edward J. Klinenberg, Ph.D., CIH , (CIHC)	• The draft policy does not mention that, according to the Bureau of Labor Statistics (BLS), the risk for accidental death occurring during employment in a working lifetime is slightly higher than 1 in 1000 over the entire US worker population and is significantly higher for some classifications of workers (e.g., construction workers, commercial fisherman). Even with this datum, the criterion outlined by NIOSH for risk-based RELs for carcinogens seems reasonable.	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control*

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		technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.

Commenter/Topic	Public Comment	*NIOSH Response*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	• Suggest NIOSH recommend use of 1/1000 target risk level for occupational carcinogens and not pose this as a question in the final version of the policy (page 30, line 31).	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control*

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		technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.

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Pete Stafford, (BCTD)	We oppose the proposed use by NIOSH of the lower 95% confidence limit for ONLY the 1/1000 increased risk in cancer, and reject any usage by NIOSH that might be misinterpreted as implying that 1/1000 is an acceptable residual risk. However this might be a valuable first step for allocating resources or setting priorities for updating RELs. While 1/1000 is certainly a significant risk, the institute may determine that for some agents there is a significant risk at well below 1/1000. NIOSH should define the factors considered in its use of the term "significant risk." Possible factors might include: a large occupationally exposed population; a significant fraction of the occupationally exposed population expected to be exposed continuously over their full 45 year work lifetime; brief cancer latency or observed onset at an earlier worker age; evidence of bioaccumulation; evidence of synergistic effects with other agents to which workers may be exposed; consumer or environmental exposures which may contribute significantly to total dose; available and effective substitute products with lower risk, or other factors. Neither the Supreme Court in the Benzene case, nor USDOL OSHA have determined the lower limit of risk that OSHA can regulate. NIOSH should play a role in evaluating the science behind the determination of what is a significant risk, in order to provide guidance for OSHA and OSHA state plans, who may establish lower PELs. Where adequate data is available, this might involve modeling to determine the lower 95% confidence limit for the 1/ ten thousand, and/or the 1/hundred thousand, in addition to the proposed 1/1000 risk level. NIOSH's carcinogen policy should be flexible enough to allow research (and RELs) to consider what level(s) of risk should appropriately be considered significant. If NIOSH adopts the 1/1000 target risk level as proposed, it should communicate this explicitly to users, perhaps with terms such as REL1,000 and REL1o.ooo. It seems likely that there will be quite a few years delay before existing RELs are revised. The use of REL1,ooo or REL1o,ooo would also be helpful in distinguishing new RELs developed or updated based	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control*

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	on this new process with existing RELs. It is also worth noting that section 3(8) of the OSH Act, as interpreted in the benzene case, instructs OSHA to set standards that are "reasonably necessary and appropriate." Statutory language in the Mine Safety Act and Construction Safety Act, might be interpreted differently, and NIOSH research should inform such policy debates in the future.	*technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

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Jeanne Rizzo, RN, (BCF)	While the Breast Cancer Fund supports some aspects of the proposed new policy, such as the use of carcinogen designations from well-established authorities, we are deeply concerned by and strongly oppose designating the Recommended Exposure Limit (REL) at a risk level of one in 1,000. Background Despite all of our advances in detection and treatment, we have not been able to stem the tide of breast cancer diagnoses. In fact, we are losing ground: today an astonishing 1 in 8 women will be diagnosed with breast cancer in her lifetime. This represents a 40 percent increase over the risk women faced 40 years ago. A strong and growing body of research is pointing to exposure to carcinogens, endocrine disrupting compounds and other toxic chemicals as an important factor in this increase in risk. Women make up nearly half the workforce in the United States, but very little research has explored work-related exposures and breast cancer. Despite these gaps, research does indicate higher risk of breast cancer among women in some occupations (Teitelbaum, 2003i; Brophy, 2012ii). These include women who work with toxic chemicals like organic solvents, including chemists, paper mill workers, textile workers, autoworkers, and microelectronics workers (Thompson, 2005iii; Shaham, 2006iv; Labrèche, 2010v); and women working with plastics or in food canning (Brophy, 2012ii). The 2012 Brophy study revealed some critical results. In this remarkable Canadian study, published in the peer-reviewed journal Environmental Health, the researchers meticulously eliminated other possible explanations (like smoking, physical activity, alcohol use and reproductive history) and were left with the conclusion that the chemicals the women were exposed to on the job were a decisive factor in increasing breast cancer risk. The results found that the women who work in plastics and food-canning have a staggering fivefold	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control*

Commenter/Topic	Public Comment	*NIOSH Response*
	increase in pre-menopausal breast cancer. Much more research on the connections between occupational exposures and breast cancer is needed. However, the evidence is clearly indicating that workers are in need of stronger protections from carcinogens and other toxic chemicals in the workplace.	*technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Jeanne Rizzo, RN, (BCF)	Proposed NIOSH Policy on Carcinogens As a general policy, workers should be afforded the same level of protection as the general public. The Breast Cancer Fund supports a return to NIOSH's previous hazard based standard of "no detectable exposure level to proven carcinogenic substances" and a precautionary approach to suspected or probable carcinogens. The first response to the identification of an occupationally relevant carcinogen should be for both government and industry to actively pursue identification of a safer alternative and we urge NISOH to include a stronger call for safer alternatives in this policy.	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control*

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Jeanne Rizzo, RN, (BCF)	Quantitative Risk Assessment The Breast Cancer Fund strongly opposes setting the Recommended Exposure Limit (REL) at a level "expected to produce one in 1,000 excess risk of cancer as a result of a 45-year working lifetime exposure." NIOSH is self-described as "the primary federal agency charged with conducting research and making recommendations for preventing occupational injuries, illnesses, and death…" (emphasis added). As a health organization, NIOSH has a responsibility to provide other federal agencies, industry and workers information about conditions that are truly protective of the health of workers. Ironically, in this policy NIOSH itself recommends keeping exposures below its "Recommended" Exposure Level! Rather, the policy refers to the one in 1,000 risk level as the "minimum" level of protection. If NIOSH is concerned with providing the Occupational Safety and Health Agency with the information needed to set Permissible Exposure Levels, then the agency should provide a range of risk levels running from one in 1,000 to one in 1,000,000. While NIOSH refers to one in 1,000 as minimum protection and "recommends" keeping risks below this level, in practice, regulatory policies are highly unlikely to go beyond the formal REL set by a health agency such as NIOSH, especially because regulatory agencies take into consideration other factors such as technical feasibility.	*As stated in the document, "Because there is no safe level of exposure to occupational carcinogens, NIOSH will continue to recommend reduction of exposure to an occupational carcinogen according to the hierarchy of controls through elimination or substitution and implementation of engineering controls, if practical, and the use of administrative controls before use of personal protective equipment (PPE). When exposures to carcinogens cannot be eliminated, NIOSH will also (1) calculate a range of risk estimates, from 1 excess cancer case in 100 workers to 1 excess cancer case in 1 million workers over a 45-year working lifetime when the data permit, and (2) set a risk management limit for carcinogens (RML-CA). When data permit NIOSH to complete a quantitative risk assessment (QRA), NIOSH will use the results of the QRA to perform both tasks.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jeanne Rizzo, RN, (BCF)	The Breast Cancer Fund strongly opposes a REL of one in 1,000 and urges NIOSH to be true to its mission by revising this policy to be truly protective of the health and lives of workers across the country. Workers, and the families and communities that depend on them, deserve nothing less.	*NIOSH publishes a range of working lifetime risks in its Criteria Documents and Current Intelligence Bulletins. This policy also includes provision for presenting an array of risk levels. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control*

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Dorothy Wigmore, MS, Workforce, Inc.	However we are flummoxed when it comes to NIOSH's other proposals that seem to undermine the agency's scientifically-valid and good public health intentions that are evident in the classification process. The NIOSH explanation about this latest version says that the agency: *foresees this revised policy as improving the relevance of the information on workplace exposures to carcinogens, which will help the occupational safety and health community achieve healthy and safe workplaces.* We share your goal of healthy and safe workplaces. However, we fear that the agency is going down a dangerous path with its misuse of the "significant risk" numbers in the "benzene decision", effectively replicating the bogus misinterpretation used by the Occupational Safety and Health Administration (OSHA). This is contrary to the scientific and precautionary approach the world has come to expect of NIOSH, and ignores the many comments made about why the agency should not take this path. NIOSH does acknowledge that keeping exposures within the "target risk level of 1 in 1,000 is the minimum level of protection" and that this is "one or more orders of magnitude higher than what the United States permits for the general public". Given that, how can you justify setting this "target risk level" that does not protect worker health and then going on to develop "Recommended Exposure Limits" (RELs) based on numbers you agree do not protect workers? It's astonishing "logic" that undermines NIOSH's reputation, mission and goals, and raises questions about the effectiveness of its programs such as prevention through design, green jobs and green chemistry, and occupational health disparities. Is the agency really trying to eliminate occupational hazards and prevent workers getting sick, hurt and dying before their time?	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically*

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Dorothy Wigmore, MS, Workforce, Inc.	Yes, the draft policy says that NIOSH chose the ineffective "targeted risk level" to help OSHA in its interpretation of the U.S. Supreme Court's benzene decision. NIOSH could do that by calculating a range of life-time risks of cancer (e.g., 1 in 1,000, 1 in 10,000, and 1 in a million, etc.) for particular chemicals or products. It does not have to, and should not, set RELs. This is an unethical sanctioning of worker exposure to carcinogens at levels that are orders of magnitude greater than what the US EPA says is "acceptable" for workers when they are part of the "general public". It also perpetuates a risk assessment approach that is not about primary prevention of hazards. Primary prevention requires substitution and elimination of hazards. NIOSH should promote and advocate this approach in all its activities, doing solution-focused and intervention research where necessary. NIOSH also should consistently point US employers and workers to information about how to stop using carcinogens and move to alternatives that are better for the health and safety of workers and their communities. It should promote large-scale use of the precautionary principle, informed substitution, toxics use reduction and green chemistry.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, NIOSH addressed comments that NIOSH should not set RELs: "Finally, several public commenters urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave such a policy decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is*

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		the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk; however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."

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James Melius, MD, DRPH, NYS Laborers Health and Safety Trust Fund	The target risk level section of the draft policy is the most problematic section of the draft policy. The interpretation (in this draft document) of the so-called Benzene and other court decisions regarding the setting of standards by OSHA is erroneous and misleading. The OSH Act mandate for NIOSH to set exposure levels (as quoted in Section 5.2) is the more relevant citation. Recommending "exposure levels at which no employee will suffer impaired health…." is not consistent with the setting a target level of 1 per 1000 excess cancer cases over a working lifetime. The discussion of perceptions of workplace risk as further justification for using the 1 per 1000 criterion utilizes a very selective set of references and misleading. I recommend that it be eliminated. NIOSH needs to restate a basic carcinogens policy in this document that is consistent with the mandate for NIOSH that is in the Act. That policy is never clearly integrated into the document but should be in order to be the basis for this new policy. That policy should be based on the scientific consensus that there is no threshold for exposure to a carcinogen (as discussed in the document). In principle, workers should be afforded the same protection as the general public, and in the workplace, the hierarchy of controls should be followed. Substitution of a carcinogen with a safer alternative should be recognized as the primary method of prevention. NIOSH should continue to recommend exposure limits based on risk assessment when needed. These risk assessments can be useful for supporting OSHA in the standard setting process or when recommending an exposure limit for a newly determined workplace health risk in the absence of other appropriate exposure limits. In most cases, a range of risk levels may be appropriate in these communications without focusing on a specific level. However, in some situations, a single risk level may need to be selected. For example, in NIOSH's Pocket Guide document, publishing a range of levels in the table in that document may be confusing and could lead an employer to assume that the least protective risk level was satisfactory.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, the document states, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be*

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	I do not believe that the 1 per 1000 level should be the default level. It is not appropriate given NIOSH's mandate and is not compatible with what we utilize to protect the general public from health hazards. A default level of 1 per million or one per one hundred thousand would be more appropriate. However, there may be situations where the scientific studies used as the basis for the risk assessment will not support a more stringent risk limit. The selection of a specific risk or exposure limit(s) needs to take into account the underlying science as well as the circumstances in which this limit will be published.	*analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}."*

Commenter/Topic	Public Comment	*NIOSH Response*
Diane Brown, (AFSCME)	In summary, AFSCME believes workers should be given the same level of protections from carcinogens as the general public, and that any NIOSH policy concerning carcinogens must reflect this policy. AFSCME also believes that the safest exposure to a carcinogen is no exposure, and that NIOSH's carcinogen policy should promote the use of safer alternatives. AFSCME appreciates the complexity and difficult nature of the questions. Thank you for the opportunity to comment on NIOSH's Draft Current Intelligence Bulletin "Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace".	*NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

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Ronald Loeppke, MD, MPH, (ACOEM)	While we understand the potential legal/regulatory and practical considerations that led NIOSH to recommend a target risk level of 1 in 1,000, we believe that that proposed level may be insufficiently protective, particularly in consideration of the likely presence of susceptible individuals and subgroups of individuals in the workplace. With this in mind, we respectfully suggest the following approach for setting the target risk levels. For at least those occupationally relevant carcinogens for which there is sufficient evidence to be categorized as known human carcinogens (based upon authoritative body or NIOSH determinations), we recommend using a target risk level of 1 in 10,000. For those agents that are categorized as probable or possible human carcinogens, i.e., those for which there is insufficient human evidence of carcinogenicity, we think it may be appropriate to use the proposed target risk level of 1 in 1,000. In general, based on both scientific concerns and ethical/philosophical grounds, we urge NIOSH to adopt a more protective posture in selecting the appropriate target risk level for carcinogens.	*NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

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Anna Mazzucco, (NRCWF)	Areas of specific concern including the following: Acceptable occupational risk assessments should be based on up-to-date, circumspect and truly representative information. NIOSH uses a lifetime cancer risk increase of 1 in 1,000 as the acceptable regulatory threshold, while stating that "controlling exposure to lower concentrations is always warranted, because an excess risk of 1 in 1,000 is one or more orders of magnitude higher than what the United States permits for the general public." This incongruous situation is justified in this document by two lines of reasoning. The first is the historic "benzene decision" made by the U.S. Supreme Court in 1980, where a 1 in 1,000 risk was described as part of a seemingly rhetorical example as follows, "if the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it". The second justification used is that workers are a very small subset of the general population, and thus higher exposures for small numbers of people may be considered acceptable if they are comparable to the overall risks of employment itself. This acceptable risk level of 1 in 1,000 for workers was based on a 1987 study based on 1984 data where it was "noted that both the wholesale and retail trade sector and the services sector had lifetime fatality rates between 1 and 2 per 1,000 employees", so therefore a 1 in 1,000 risk threshold would be consistent with the overall risks associated with these occupations. However, Bureau of Labor Statistics from near the same time period, 1979-1980, documented that some occupations had lower lifetime risks, such as in retail clothing (0.07 in 1,000) and electric equipment (0.45 in 1,000). Furthermore, this reasoning flies in the face of increasing evidence that the occupational use of carcinogens often spreads into the greater environment. Occupational use of such chemicals does not occur in an ecological vacuum, and containment and disposal techniques can be	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically*

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	inadequate. For example, trichloroethylene (TCE), an industrial solvent, is now present in approximately one-third of the U.S. water supply.3 As the President's Cancer Panel 2010 report observes "the line between occupational and environmental contaminants is fine and often difficult to demarcate".3 As mentioned above, the acceptable risk for the general public set by The Environmental Protection Agency is much lower, with an acceptable risk range of 1 in 10,000 to 1 in 1,000,00 for lifetime cancer risk. The maximum risk threshold for highly exposed individuals acceptable to the EPA, such as in the case of benzene, is still 10-fold less than the threshold set by NIOSH, and the EPA further considers the 1 in 1,000,000 threshold to be the target threshold for the greatest number of people possible, which is 1000 fold lower than the NIOSH threshold. There is no scientific basis for these different safety standards to coexist, and occupational and environmental exposures frequently become indistinguishable, allowing for higher public exposures to occur. Furthermore, considering the economic importance of a healthy workforce, and amidst growing health care costs, both fiscal and moral arguments can be made that the workforce should be afforded the same level of protection granted to the general public, otherwise the safety of both groups may be threatened.	*measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}."*

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Anna Fendley, (USW)	As USW stated in our 2011 comments, NIOSH should continue to have a carcinogen policy that is consistently updated and maintained to reflect the current research. Occupational cancers are an important concern to workers in a variety of workplaces across industries. In principle, workers should be afforded the same level of protection from exposure to carcinogens as the general public.	*NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

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Anna Fendley, (USW)	In regards to Section 5 of the proposed update, USW strongly disagrees with the proposed target level of 1 in 1000 working lifetime risk. As we stated in our 2011 comments, NIOSH should be performing risk assessment based upon the best science available, and it should not limit risk level to 1 in 1000. We disagree with the NIOSH interpretation of the "benzene" decision. NIOSH has the responsibility to work without this constraint and other considerations of feasibility to develop RELs to adequately protect workers. The safest level of exposure to a carcinogen is no exposure. In practice, recommended exposure levels (RELs) are considered a safe level of exposure. A recommended exposure level set with a proposed target level of 1 in 1000 is not a safe exposure level and does not result in workers receiving adequate protection. NIOSH cites OSHA's permissible exposure level (PEL) process as one of the reasons for using a target risk level of 1 in 1000. However, OSHA's PEL process does not need a single level. OSHA's process will be better served with a exposure levels that correspond to a range of working lifetime risk (e.g., 1 in a thousand, 1 in ten-thousand, and 1 in a million, etc).	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically*

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Dave Foster, 42 Groups	But we cannot support a NIOSH “Recommended Exposure Limit" (REL) for workers of 1 in 1000—a thousand times less protective than the levels considered safe for the general public. We believe that “recommending” levels of exposure that are not based on providing the highest level of protection for workers’ health undermines NIOSH’s mission and goals. To provide the Occupational Safety and Health Agency (OSHA) with the information needed to set Permissible Exposure Levels, NIOSH can perform calculations that set out a range of lifetime risks of cancer (e.g., one in 1,000, one in 10,000, and one in a million, etc.) without labeling this activity as setting RELs.	*NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, NIOSH addressed comments that NIOSH should not set RELs: "Finally, several public commenters urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. Many of these commenters objected that NIOSH should not “recommend” one specific exposure level and should leave such a policy decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk;*

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		however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."

Commenter/Topic	Public Comment	*NIOSH Response*
Adam Finkel, ScD., CIH	In setting risk-based exposure limits for the workplace, NIOSH is filling a crucial vacuum where the OSHA PELs and the ACGIH TLVs have failed; but it must rethink the misguided decision to "recommend" the unacceptably high risk level of 10-3. The CIB outlines a scientifically sound protocol for conducting QRA. If anything, NIOSH might emphasize how the procedures it recommends are based on sound science, not on administrative convenience. For example, the default on page 30, line 25 (low-dose linearity unless strong evidence exists to the contrary) is eminently sensible. This is especially so in the occupational setting, where "low-dose linear" in practice means a small decrement of exposure below the frank effect level seen in the laboratory or the epidemiologic study, and nothing like the "one molecule" criticism that has little place in environmental risk assessment but no relevance to the workplace. In a world in which OSHA can set final standards via interpolation (e.g., the new chromium (VI) PEL), ones that are above exposure levels associated with significant excesses of cancer in human studies or animal bioassays, the sarcasm about "orders of magnitude extrapolation" is quite inappropriate. Using this document's template, NIOSH risk assessments can do what the PELs and TLVs cannot or will not: they can give workers, employers, and society information about the probabilities of harm (risks) and the comparative risks of different substances. Unfortunately, the TLVs, while based on sound science, are not based on risk, and the PELs, while replete with risk information, ultimately are set based on a (highly timid, in my view) judgment about what levels are economically feasible. Thus, a statement such as "this PEL is higher than that one" offers zero information about relative harm—in the same way a report that "this life preserver is more orange than that one" tells one nothing about which one floats and which one sinks.	*NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, NIOSH addressed comments that NIOSH should not set RELs: "Finally, several public commenters urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave such a policy decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk;*

Commenter/Topic	Public Comment	*NIOSH Response*
	It is therefore unfortunate that NIOSH undermines the value of the risk information it will generate by insisting on "recommending" a single target level of risk. The whole point of conducting QRA is to allow policy-makers and individuals to see the entire relationship between exposure and risk. For this reason, EPA has developed "unit risk factors" for carcinogens and used them for decades—armed with them, the user can take the scientific evidence and find the risk level associated with any amount of exposure, or the amount of exposure associated with any level of risk.	*however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."*

Commenter/Topic	Public Comment	*NIOSH Response*
Adam Finkel, ScD., CIH	In my opinion, NIOSH is misinterpreting ¶20(a)(3) of the OSH Act, which merely says that HHS shall develop "exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." This language was written before scientists fully understood the relationship between very low levels of exposure and very low levels of excess risk, and therefore should not be read to require NIOSH to designate a single "magic number." The activity of "reading along the dose-response curve" to find a risk-specific dose (or a dose-specific risk) is quintessentially a policy/value exercise—values dictate the stopping point, and science informs as to what exposure is necessary to achieve the risk goal. NIOSH does not need to engage in the value-laden part of the process, but should instead provide more information rather than less. It should publish the "unit risk factor" relating occupational exposure to response (if it believes that relationship is linear over the relevant range), or an equation (such as a multistage polynomial) allowing anyone to relate exposure to response (if it believes the relationship is not linear). But if NIOSH insists on setting a target risk level, I urge it to look carefully at what value judgments it is thereby endorsing. An excess risk of 1/1000 is NOT "low compared to other fatality hazards" (the Rodricks et al reference cited on p. 32 is outdated), and in any event, "smaller than an enormous risk" is not the same as "acceptable." The Travis and Hattemer-Frey paper cited on p. 32, and any of the subsequent papers in the literature, can only demonstrate that in some situations, risks higher than 10-4 are "tolerated" (because of economic or other constraints)—it does not provide evidence of moral acceptability. Better evidence of our common shared values comes from the only instance in which Congress has enshrined a quantitative risk target in law—the 1990 Clean Air Act Amendments, where it required EPA to strive towards a risk level of 10-6. This is indeed (p. 4, line 35) "at least an order of magnitude" lower than	*NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, NIOSH addressed comments that NIOSH should not set RELs: "Finally, several public commenters urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave such a policy decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk;*

Commenter/Topic	Public Comment	*NIOSH Response*
	1/1000—it is exactly three orders of magnitude lower. NIOSH should not "recommend" a high risk level such as 10-3. Again, I urge NIOSH to avoid fixating on a single target, but any such target should be no higher than 10-4.	*however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."*

Commenter/Topic	Public Comment	*NIOSH Response*
Adam Finkel, ScD., CIH	In the alternative, NIOSH could simply change the terminology from "recommended" to something else, such as "Minimally Appropriate Risk-Based Limit." This would be fully in keeping with the longer statement on p. 33 (line 17): "keeping exposures within the target risk level of 1 in 1,000 is the minimum level of protection… controlling exposure to lower concentrations is always warranted." (emphasis in original). As an important matter of judicial interpretation on this topic, NIOSH has misinterpreted the Benzene decision. NIOSH should follow OSHA's official interpretation, as expressed inter alia in the 1997 Methylene Chloride final rule (62 FR No 7, Jan 10, 1997, p. 1560): OSHA's position is that 10-3 is "the uppermost end of a million-fold range suggested by the Court, somewhere below which the boundary of acceptable versus unacceptable risk must fall." Whatever OSHA chooses to make of that million-fold range, constrained as it is by considerations of economic feasibility, should not hamstring NIOSH. The Supreme Court was clear—when risk alone is the criterion, "acceptable risk" is somewhere between 10-3 and 10-9. It is unseemly, and unnecessary, for NIOSH to accept the very uppermost end of this wide range as its "Mission Accomplished" moment.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. As explained in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible." Also, "An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining*

Commenter/Topic	Public Comment	*NIOSH Response*
		risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	The UAW strongly disagrees with NIOSH's choice to base the recommended exposure limit on 1/1000 lifetime risk. The UAW believes that 1/1000 lifetime risk is not adequate protection for workers. In principle, workers have the same human rights to protection from carcinogenic exposures as other members of our society.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically*

Commenter/Topic	Public Comment	*NIOSH Response*
		measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}."

Commenter/Topic	Public Comment	*NIOSH Response*
Arlene Blum and 65 other Health Scientists and Medical Professionals	We strongly object to the proposal that an excess risk of 1 in 1,000 workers exposed to a specific carcinogen over a working life time is an acceptable "target" risk level for carcinogen RELs (section 6). We believe that a "recommended" exposure limit for workers that NIOSH admits is "orders of magnitude" less protective than the levels considered safe for the general public contradicts and undermines NIOSH's mission and goals as a Federal health agency. NIOSH's recommendations should always support the highest level of protection for worker safety and health. NIOSH can better inform individuals and policy makers, and support the Occupational Safety and Health Administration's need to set Permissible Exposure Limits (PELs) by calculating exposure levels that correspond to a range of lifetime risks of cancer (e.g., one in 1,000, one in 10,000, and one in a million, etc.). NIOSH can serve this function without labeling this activity as setting recommended exposure limits (RELs).	*NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, NIOSH addressed comments that NIOSH should not set RELs: "Finally, several public commenters urged NIOSH to provide only the exposure limits that correspond to various risk levels, such as 1 in 1,000, 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. Many of these commenters objected that NIOSH should not "recommend" one specific exposure level and should leave such a policy decision to OSHA. These commenters observed that NIOSH is a scientific research agency and that OSHA is the agency that is charged with making decisions about acceptable risks and feasibility. NIOSH agrees that it should provide information on the exposure levels that correspond to various levels of risk;*

Commenter/Topic	Public Comment	*NIOSH Response*
		however, NIOSH will continue to provide a health-based RML-CA to guide employers who seek to reduce exposures to occupational carcinogens to better protect their workers."

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	The 1/1,000 Benchmark For Significant Risk Must be Retained The Occupational Safety and Health (OSH) Act directs NIOSH to "develop such criteria as will effectuate the purposes of this chapter" (29 U.S.C. §669(a)(2)). The general purpose is "to assure so far as possible every working man and woman in the nation safe and healthful working conditions" (29 U.S.C. §651(b), emphasis added). With respect to NIOSH criteria,, this purpose is to be fulfilled "by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity or life expectancy as a result of his work experience" (29 U.S.C. §651(b)(7), emphasis added). The courts have noted that "the statute directs NIOSH to develop criteria documents that describe safe levels of exposure, and [OSHA] is to promulgate standards that ensure that employees are protected. The language employed by Congress in these two mandates is essentially identical . . . " Industrial Union Dept., AFL-CIO v. Hodgson, 499 F.2d 467, 476 (D.C. Cir. 1974)(emphasis added).2 With respect to the identical language governing OSHA standards, the Supreme Court has held: Relying on §6(b)(5)'s direction to set a standard "which most adequately assures . . . that no employee will suffer material impairment of health or functional capacity," the Government contends that the Secretary is required to impose standards that either guarantee workplaces that are free from any risk of material health impairment, however small, or that come as close as possible to doing so without ruining entire industries. If the purpose of the statute were to eliminate completely and with absolute certainty any risk of serious harm, we would agree that it would be proper for	*NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

Commenter/Topic	Public Comment	*NIOSH Response*
	[OSHA] to interpret §§ 3(8) and 6(b)(5) in this fashion. But we think it is clear that the statute was not designed to require employers to provide absolutely risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great enough to destroy an entire industry. Rather, both the language and the structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of significant risks of harm. Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 641 (1980)(emphasis added)("Benzene").	

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	Since the Benzene decision, courts of appeals have considered this plurality opinion to have been adopted by a majority of the Court in American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981). See AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir. 1992)("PELs"). Following the PELs decision, OSHA must not only establish that a substance poses a significant risk at some level, it must show that existing workplace exposures present a significant risk of material health impairment or that the new standards eliminate or substantially lessen the risk (PELs at 980). While the courts will generally not determine what level of risk is "significant," they have vacated regulations when OSHA merely issued findings that new limits will protect workers from a significant risk of some material health impairment without citing any specific studies. Mere conclusory statements have been found inadequate to support a finding of significant risk of material health impairment (PELs at 976). In the PELs case, the Eleventh Circuit states: The lesson of Benzene is clearly that OSHA may use assumptions, but only to the extent that those assumptions have some basis in reputable scientific evidence. If the agency is concerned that the standard should be more stringent than even a conservative interpretation of existing evidence supports, monitoring and medical testing may be done to accumulate the additional evidence needed to support that more protective limit. Benzene does not provide support for setting standards below the level substantiated by the evidence. Nor may OSHA base a finding of significant risk at lower levels of exposure on unsupported assumptions using evidence of health impairments at significantly higher levels of exposure (PELs at 979).	*Several commenters suggested that NIOSH should not rely on NTP, IARC, or EPA hazard assessments because these other agencies did not rely on the Benzene decision in developing their analyses. NIOSH disagrees with these comments. Nothing in NIOSH's cancer policy is inconsistent with the Benzene decision. NIOSH believes that NTP, EPA, and IARC each represent reputable bodies of scientific thought, fully consistent with the Benzene decision. NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	The courts have also given some indication of the boundaries of what they consider to be "significant risk." For example, in Benzene, the Supreme Court stated: "if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it (Benzene at 655). In American Dental Ass'n. v. Martin, 984 F.2d 823 (7th Cir. 1993), OSHA was chastised by the Court for not segregating dental employees whose risks of contracting HIV and hepatitis could be distinguished from other medical professionals. The risk of contracting HIV from dentistry is less than 1 in 100,000, which "falls far short of establishing a significant risk," according to the court (id at 835). It appears that OSHA consistently considers risk in the 1 in 1000 range to be "significant" and worthy of regulation. The following are risks that OSHA has found to be "significant": 8 - 160 deaths per 1000 workers (Benzene final rule, 52 FR 34460, 34463 Sept. 11, 1987); 186.2 - 266 deaths per 1000 workers (Cadmium proposed rule, 55 FR 4052, Feb. 6, 1990); 148 - 425 deaths per 1000 workers (Inorganic arsenic rule, 48 FR 1864, 1896, Jan. 14, 1983); 634 -1093 deaths per 10,000 workers (Ethylene oxide rule, 48 FR 17284, 17295, April 21, 1983; 49 FR 25,764); 6 - 30 deaths per 1000 (MDA proposed rule, 54 FR 20672, 20683, May 12, 1989);	*Several commenters suggested that NIOSH should not rely on NTP, IARC, or EPA hazard assessments because these other agencies did not rely on the Benzene decision in developing their analyses. NIOSH disagrees with these comments. Nothing in NIOSH's cancer policy is inconsistent with the Benzene decision. The Supreme Court, in the Benzene decision, made clear that OSHA can rely on a "body of reputable scientific thought." 448 US 607, 656 (1980). NIOSH believes that NTP, EPA, and IARC each represent reputable bodies of scientific thought, fully consistent with the Benzene decision. NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision.*

Commenter/Topic	Public Comment	*NIOSH Response*
	164 deaths per 1000 (asbestos rule).	

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	In spite of the apparent consensus regarding the "significance" of risks in the 1 in 1000 range, OSHA has allowed PELs to be set at levels leaving a residual risk in this range. For example, in the PELs case, the court notes that carbon tetrachloride was regulated to the 3.7 deaths in 1000 level, and that OSHA admitted that the residual risk "continues to be significant." Similarly, the vinyl bromide standard allowed a residual risk of 40 excess deaths per 1000: "clearly significant" according to OSHA (PELs at 976). Similarly, OSHA's ethylene oxide standards allow a "significant" risk of 12 -23 deaths per 10,000 workers, but were set at this level due to feasibility concerns. Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1502-03 (D.C. Cir. 1986). As discussed above, the courts have found that the statutory schemes for OSHA and NIOSH are identical in this respect, and the Supreme Court's holding in Benzene therefore applies to both agencies with equal force. To date, NIOSH apparently has agreed, adopting the 1/1,000 risk level as the target level for RELs. HTIW Coalition supports the NIOSH proposal to retain this approach, which we believe is required by current law.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 ($10^{-4)}$ risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically*

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		measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}."

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	P.4 Line 35. A risk near I in 1,000 is at least in order of magnitude higher than the cancer risk permitted in the United States for the general public. What Entity, other than the God of your beliefs or other higher power has the right to permit cancer?	*NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	P.30 TARGET RISK LEVEL FOR CARCINOGEN REL. Lines 12 to 14. Therefore, although they did not explicitly set a level of "significant" risk, it did imply that a 1 in a 1,000 lifetime excess risk is significant, while 1 in a billion risk is not, indicating that the threshold for a "significant" risk must lie within this interval. If one in a thousand is considered a "significant" risk, what would two in a thousand be classified as? Lines 16 & 17. For this reason, the only way to completely eliminate the excess risk is to prevent exposure. I agree strongly with the above statement Lines 24 to 28. HISTORY OF THE NIOSH TARGET RISK LEVEL FOR CARCINOGENS They note that " past regulatory decisions "indicate that in many circumstances risks greater than 1 in 10,000 are in fact tolerated" and consider a population based risk level of 1 in 10,000, ranging to 1 in 1,000 to indicate a de manifestis risk level (i.e. " a ceiling above which events are inherently unsafe and should be regulated without regard for cost). This is a systematic wrongdoing that ensures cancer levels are consistently i) going to exist, ii) increase, and iii) exist and continue in everyday human existence - cancer will never be a disease of the past.	*NIOSH has removed reference to the Benzene decision in its rationale for the appropriate risk level for its recommendations because it is not directly contributory to NIOSH decisions. NIOSH has expanded the text describing the rationale for its decisions without reference to the Benzene decision. Specifically, it states, "NIOSH will utilize the QRA to determine a range of risk estimates including 1 excess cancer case in 100 workers, 1 excess cancer case in 1,000 workers, 1 excess cancer case in 10,000 workers, 1 excess cancer case in 100,000 workers, and 1 excess cancer case in 1 million workers. NIOSH will project both a central estimate and a 95% lower confidence limit estimate of the dose producing excess cancer risk, when the data are scientifically suitable for doing so." In addition, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically*

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		measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}."

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	P. 33 Lines 28 to 35. NIOSH will evaluate carcinogens using risk-based exposure limits, and the NIOSH recommendations will be based on a quantitative risk assessment (QRA) based on the best available data. > The principle of 'No data means no harm' is in fact an improper formula to apply. > There is no scientific data on many chemicals because if I, as part of an experiment were to subject YOU to a carcinogen, I would probably be killing YOU. Morally, that is wrong. Another systematic wrongdoing. Based on the QRA, NIOSH will communicate in an array of risk levels, from excess cancer cases in 100 workers, to 1 excess cancer case in 1 million workers. For carcinogens where there is a 1 in 1,000 risk level, is below the limit of quantitation (LOQ) of the current NIOSH analytical method [NIOSH1994] (or other validated analytical equivalent), the LOQ will be the default REL. This REL can be revised to a lower LOQ when more analytical methods are developed. Why are mathematics being used as the CANCER ANSWER? This problem is not a NUMERICAL ISSUE. CANCER KILLS. Prevent exposure, prevent harm. Ensure exposure, ensure harm.	*NIOSH understands the commenter's concerns about exposure to carcinogens and encourages elimination and substitution of hazardous chemicals as the first step in the hierarchy of controls. However, in those cases where workers are exposed to carcinogens, it is useful to understand the risks. Therefore, NIOSH has developed Risk Management Limits for Carcinogens (RML-CA) set at a level that should not exceed 1 in 10,000 excess risk or the limit of quantification of the analytical method, whichever is higher. NIOSH views this limit as a starting place for implementing engineering controls and encourages employers to control carcinogens to lower levels of exposure.*

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	Furthermore, non-carcinogenic chemicals are not necessarily safer than carcinogenic chemicals. Is cyanide less of a hazard than titanium dioxide? Are the toxicities of "alternatives" adequately established? The substitution of non-carcinogenic chemicals for those that have been shown to cause cancer is a precautionary and flawed policy that does not appropriately consider the science of actual risks or economic consequences. As Materion cautioned NIOSH in responding to the 2011 RFI: The assignment of nomenclature and categorizations has served a useful purpose in the past to give people an understanding of risk potential. The nomenclature/classification process, however, has become so inclusive of any type of possible risk that organizations are now generating lists of thousands of substances as posing very severe health risks. These broad classification scenarios are now commonly being used as a means to ban, restrict or require mandatory substitution of materials, including those applications where the actual risk during use can be very low or non-existent. Such classification lists often ignore the scientific evidence and are too often being generated based on political agendas or to drive competitive advantage of one product over another in the marketplace. Also, in such scenarios, the importance tends to be placed on a highly generalized hazard classification rather than a risk assessment of the benefits versus harms of using a material in any particular application. For example, the substitution of a nickel beryllium alloy in the design of fire protection sprinkler heads resulted in sprinkler head failures and a massive recall and reinstallation of over 35 million sprinkler heads. Such use of a strict toxicity classification approach when selecting materials, without regard to societal benefits, could have resulted in the selection of a much less reliable material than the copper beryllium metal seal that was used as the final cap on the Macondo well-head in the Gulf of Mexico.	*NIOSH agrees that in order to be effective, the toxicity of alternatives must be well-studied. NIOSH does not advocate choosing chemical alternatives that have little or no toxicity data. In addition, NIOSH has not stated that noncarcinogenic chemicals are "safer" than carcinogens, but encourages employers to understand all of the toxicity and safety implications of using chemicals in their workplaces. NIOSH explained its reasoning, as follows, "An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment*

Commenter/Topic	Public Comment	*NIOSH Response*
	Comments of Materion Brush Inc. submitted in Docket No. NIOSH-240 at 1-2. Moreover, without supporting quantitative risk assessments, it is arbitrary and unscientific to take the position that all noncarcinogenic chemicals are "safer" than carcinogenic substances. Later, after stating that "NIOSH will recommend that exposures be kept below a target risk level of 1 in 1,000 cancer cases in a working lifetime," the Draft Cancer Policy says that "[c]ontrolling exposure to lower concentrations is always warranted." Id. at 33. In just eight words, NIOSH completely undercuts whatever value or relevance it intends to place on any of its RELs and thus fails in its role of providing useful information to assist OSHA in setting workplace exposure standards consistent with its statutory mandate and places an unfair burden on employers confronted with such a broad pronouncement from a governmental body.	*is the last line of defense, used when other methods do not adequately reduce exposures.* *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."*

Commenter/Topic	Public Comment	*NIOSH Response*
Basis of REL		
Christopher Lish and PSR	All published NIOSH's RELs should be health-based.	*NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Ronald Loeppke, MD, MPH, (ACOEM)	We agree with the proposed use by NIOSH of quantitative risk assessments to determine the cancer risk from working lifetime exposures to low concentrations (doses) of occupationally relevant agents, including the central and 95% lower confidence limit estimates of risk. NIOSH may want to consider relying upon other well-supported cancer risk assessments, e.g., from EPA, for this purpose rather than developing their own assessment. We agree that primacy should be given to selecting data stemming from high-quality epidemiologic studies or animal studies using relevant exposure routes (for use in developing these risk estimates). These estimates can then be used in developing cancer RELs for these agents. Because the resulting estimates from quantitative risk assessments will vary based upon the selected study data source and assumptions used in mathematical modeling, NIOSH should attempt to select the most appropriate study data and risk assessment approach to utilize in setting the REL. Doing so will result in RELs which will be health-protective but not necessarily the most health-conservative (if the latter would be less relevant to the occupational setting). We suggest that NIOSH specify in this document how they will make this selection between alternative risk assessment approaches or studies. Similarly, NIOSH should specify, in the material supporting the REL for a specific agent, the basis for the selection of the risk assessment approach utilized.	*Specifying the details of the risk assessment process are beyond the scope of this document. However, the commenter is referred to NIOSH documents on occupational exposure to hexavalent chromium and titanium dioxide as examples of the issues considered.*

Commenter/Topic	Public Comment	*NIOSH Response*
Darius Sivin, PhD, UAW	6. It is the position of the UAW that all RELs should be based on health alone and not on analytic feasibility or engineering achievability.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended."* *NIOSH is analyzing and developing additional information on risk management, including substitution and elimination.*

Commenter/Topic	Public Comment	*NIOSH Response*
Analytical and Technical Feasibility		
Barbara Dawson, CIH (AIHA)	AIHA believes the document is incorrect in one area of the proposal; namely, the treatment of RELs set when the reliable quantification limit is higher than an REL set using the criteria previously cited. Here NIOSH is proposing using a higher REL with an AF notation for Analytical Feasibility. This policy implicitly ignores the ability of modern exposure science to estimate exposures in essentially any scenario by physical- chemical modeling. AIHA suggests having two RELs in this instance. The first would be the standard REL using the criteria previously cited and the second an REL-AF to reflect the analytic realities.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available."*

Commenter/Topic	Public Comment	*NIOSH Response*
Dennis Shusterman, MD, MPH and Kashyap Thakore, PhD (CDPH)	The current document proposes setting RELs at the limit of quantification ("LOQ"), along with an "AF" ("analytical feasibility") notation, if the LOQ is greater than the target risk level. NIOSH might consider publishing both the calculated REL based on the target risk level [REL (Calc.)] and the REL (AF) taking into consideration current analytical limits.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available. This provides the risk communication information requested in the comment."*

Commenter/Topic	Public Comment	*NIOSH Response*
Pete Stafford, (BCTD)	We encourage NIOSH to separate the carcinogenicity (health effects) and analytical feasibility concepts and to define both. An REL with an AF notation is potentially confusing and the AF notation and associated analytical technology is likely to change more rapidly than the toxicological basis for an REL based entirely on health effects. Both should be provided. It is important to recognize that NIOSH RELs are used not only by OSHA in rulemaking, but also by owners and employers as a guide for risk management including design and implementation of controls. "Analytical feasibility" is not a barrier to the latter use, since the performance or capture efficiency of controls can be estimated using air flow measurements, tracer gases or test aerosols that do not require the measurement or analysis of a specific contaminant. This is well accepted industrial hygiene practice (for example, see Burgess, W.A. et al. Ventilation for Control of the Work Environment. Wiley New York; Chapter 13 Quantification of Hood Performance. Pp. 353-370. ©1989). NIOSH RELs based only on health effects should be used for selection or design of exposure controls. This is of great value even if field sampling and analytical methods may make it difficult for OSHA to directly implement it as a PEL. If industrial hygienists or engineers inadvertently use the RELAF for design of controls, then the resulting exposure control measures would be inadequate to prevent health effects. Similarly, the use of the REL to guide selection of Jess hazardous alternatives may be undermined by use of an REL that considers factors other than health effects.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available. This provides the risk communication information requested in the comment."*

Commenter/Topic	Public Comment	*NIOSH Response*
Jeanne Rizzo, RN, (BCF)	We support the proposed policy's provision making clear that the RELs issued will be "health- based" and no long consider factors such as technical feasibility. We also support making clear when a REL has been set by analytical feasibility rather than at a truly safe level. Moving forward, we urge the agency to set RELs at the level that is truly health protective regardless of analytical feasibility. Technologies change and setting a REL below the limit of quantitation will help workers understand their true risk and spur industry and academia to develop better techniques to assess exposures and resulting health risks.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available. This provides the risk communication information requested in the comment."*
Jeanne Rizzo, RN, (BCF)	In conclusion, we commend the agency for its work on this policy and support the use of carcinogen designations from NTP, EPA and IARC. We also support making RELs health based and labeling previous RELs that were set at analytical feasibility (AF). We also urge the agency to update those AF RELs to health protective RELs as soon as possible.	*NIOSH appreciates this support for these aspects of the policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
James Melius, MD, DRPH, NYS Laborers Health and Safety Trust Fund	I support NIOSH's decision to not include a comprehensive control feasibility evaluation is recommending exposure limits. This beyond the scope of the information routinely available to NIOSH and is better left to the standard setting process. I also disagree with the use of analytic feasibility as the basis for recommending limits. This is a vestige of the efforts of NIOSH (and others) to develop better industrial hygiene methods and was integrated into NIOSH' criteria document process where the lowest feasible measurement level became NIOSH's recommended exposure limit for many chemicals. Our analytical capabilities are much better now, and the analytical feasibility for measuring a substance may be more a function of cost (e.g., electron versus phase contrast microscopy for asbestos) or of the workplace setting (measuring asbestos in an office setting versus a factory making asbestos insulation). In addition, these analytic limits are constantly changing over time as new laboratory and sampling techniques are developed. I am concerned that a recommended limit based on analytical feasibility may relatively quickly become outdated or be inappropriate for many workplaces. It would be better to footnote the exposure limit in a table or document pointing out that there may be a problem with analytic feasibility rather than modifying the recommended limit. Older NIOSH exposure limits based on analytical feasibility should also be labeled as such.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available. This provides the risk communication information requested in the comment."*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Ronald Loeppke, MD, MPH, (ACOEM)	We understand and agree in principle with the proposed approach by NIOSH to set the REL at the limit of quantitation (LOQ) of the sampling and analytical method, the "REL-AF" (the analytically feasible REL), in those cases in which it is not analytically feasible to measure the concentration of the agent at the level of the health-based REL. However, in some cases, it may not be technically feasible to measure the concentration of the agent with adequate precision at levels as low as the LOQ (i.e., within ±25% of the true value 95% of the time). Accordingly, we recommend that NIOSH set (and publish) the "REL-AF" at the lowest level above the health-based REL at which measurements can be made with adequate precision. We recommend this approach because we believe that the "REL-AF" should be feasible and implementable. We recommend that NIOSH also publish the health-based REL in these situations. This approach would provide the greatest amount of useful information: a target goal to which NIOSH and organizations can aspire (should technical methodology improve), while also providing a practical and implementable REL for current use.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. The LOQ is the level at which the concentration can be reliably measured (as opposed to the limit of detection). When the LOQ is higher than the concentration at 1 in 10,000 risk level, the RML-CA will be set at the LOQ. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available. This provides the risk communication information requested in the comment."*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Anna Mazzucco, (NRCWF)	Areas of specific concern including the following: A safe exposure level based on technical feasibility rather than safety places workers at risk. A challenging situation arises when a chemical is carcinogenic at a certain dose, but the existing method to detect it is sensitive enough to only detect a higher amount. In the policy stated here, NIOSH will set the recommended exposure limit (REL) to the higher, detectable dose (the reliable quantitation limit). Adoption of this policy would directly place workers in potentially unsafe conditions, and also renders them powerless to detect or remove the agent to ensure safe levels. The only approach which guarantees safety is to ban chemicals falling into this situation until more sensitive detection methods are developed. Such a policy would accomplish a dual benefit of protecting workers while creating an incentive for industry to develop more sensitive diagnostic capabilities or safer alternatives to such chemicals.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available. This provides the risk communication information requested in the comment."*

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Fendley, (USW)	In regards to Section 6 of the proposed update, USW does not support the proposal to set new RELs using analytical feasibility, even if they are distinguished from health-based RELs. All published NIOSH RELs should be health-based. Due to limited resources at NIOSH, RELs based on analytic feasibility will become outdated as the ability to measure to lower levels improves more quickly than NIOSH can re-evaluate chemical substances under this proposed policy. As we stated in our 2011 comments, NIOSH is an agency that provides research, information and training in the field. It is not a regulatory agency, and its RELs are not legally enforceable. Therefore, NIOSH should not consider feasibility but should use the scientific evidence to identify the actual cancer risk to workers. However USW does support the proposal to label existing RELs that were based on analytic feasibility as such. NIOSH should update those existing RELs to be health-based as soon as possible.	*As stated in the document, "The ability to measure chemicals in the workplace is an important consideration for both evaluating and controlling worker exposures. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method for that occupational carcinogen. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs. In addition, NIOSH intends to communicate the risks at the LOQ and the concentration corresponding to a 1 in 10,000 risk level, when that information is available. This provides the risk communication information requested in the comment."*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Dean Venturin, (HTIW) Coalition	RELs Must be Based on Feasibility Considerations Current and longstanding NIOSH policy requires consideration of technological feasibility in establishment of RELs. This is in accordance with the statutory language, also discussed above, that requires criteria documents to "assure insofar as practicable that no employee will suffer diminished health, functional capacity or life expectancy as a result of his work experience." The courts have held that congressional use of the term practicable "imposes a clear duty on the agency to fulfill the statutory command to the extent that it is feasible or possible." Biodiversity Legal Foundation v. Babbitt, 146 F.3d 1249, 1254 (D.C. Cir. 1998), quoting Fund for Animals v. Babbitt, 903 F. Supp. 96, 107 (D.D.C. 1995). Thus, as with the determinations of "significant risk" and "material impairment," the statute effectively requires NIOSH to engage in the same feasibility determination that is required for OSHA standards. This requires determination of both technological and economic feasibility.	*Several comments criticized the draft cancer policy because NIOSH did not propose to evaluate the technological and economic feasibility of its RML-CA. These comments argued that NIOSH recommended risk management levels must be based on an evaluation of feasibility because OSHA standards must be feasible. NIOSH disagrees with these comments. NIOSH recommendations are not binding, and are developed using the criteria set forth in section 20 of the OSH Act. Although NIOSH does not base its RML-CA on technological and economic feasibility findings, NIOSH will make information on technology to reduce exposures available to affected stakeholders who can use that information to implement appropriate exposure reductions. NIOSH does not consider economic feasibility in making health-based recommendations for RML-CAs.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	In determining technological feasibility, the courts have required OSHA to demonstrate, for each affected industry segment, that a typical firm will be able to install engineering and work practice controls that can meet the PEL in most of its operations. For example, in the PEL case the 11th Circuit held that feasibility must be determined on an industry-by industry basis, and concluded that OSHA's feasibility showing based on two-digit SIC Codes was invalid: [T]he undisputed principle that feasibility is to be tested industry by industry demands that OSHA examine the technological feasibility of each industry individually . . . OSHA primarily relied on the more general two-digit codes in its feasibility analysis. For most of the SIC Codes discussed, OSHA provided only a general description of how generic engineering controls might be used in a given sector . . . However, OSHA made no attempt to show the ability of technology to meet specific exposure standards in specific industries. Except for an occasional specific conclusion as to whether a particular process control could meet a particular PEL, OSHA merely presented general conclusions as to the availability of these controls in a particular industry . . . OSHA correctly notes that all it need demonstrate is "a general presumption of feasibility for an industry." However, as this quote indicates, "a general presumption of feasibility" refers to a specific industry-by-industry determination that "a typical firm will be able to install engineering and work practice controls that can meet the PEL in most of its operations." OSHA can prove this "by pointing to technology that is either already in use or has been conceived and is reasonably capable of experimental refinement and distribution within the standard's deadlines." Only when OSHA has provided such proof for a given industry does there arise "presumption that industry can meet the PEL without relying on respirators . . .	*Several comments criticized the draft cancer policy because NIOSH did not propose to evaluate the technological and economic feasibility of its RML-CA. These comments argued that NIOSH recommended risk management levels must be based on an evaluation of feasibility because OSHA standards must be feasible.* *NIOSH disagrees with these comments.* *NIOSH recommendations are not binding, and are developed using the criteria set forth in section 20 of the OSH Act. Although NIOSH does not base its RML-CA on technological and economic feasibility findings, NIOSH will make information on technology to reduce exposures available to affected stakeholders who can use that information to implement appropriate exposure reductions. NIOSH does not consider economic feasibility in making health-based recommendations for RML-CAs.*

Commenter/Topic	Public Comment	*NIOSH Response*
	[I]t is clear that the concept of "a general presumption of feasibility" does not grant OSHA a license to make overbroad generalities as to feasibility or to group large categories of industries together without some explanation of why findings for the group adequately represent the different industries in that group (965 F.2d at 981-82, citations and footnotes omitted).	

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	In a later decision, the court found similar problems with OSHA's cadmium standard: Technological feasibility exists when the PEL can be met with engineering and work practice controls . . . Here, OSHA failed to meet this test from the start. In determining the technological feasibility of meeting the PEL in the dry color formulator industry, OSHA first determined the existing airborne levels of cadmium in the industry. However, the method OSHA employed in doing so was inadequate. Rather than analyzing the exposure levels in the dry color formulator industry, OSHA analyzed such exposures generically. In this case, OSHA lacks substantial evidence to demonstrate the accuracy of the pre-standard exposure levels it asserts. OSHA's analysis here relies on its determination of the starting exposure level. Its conclusion as to the feasibility of reducing these levels below the PEL is by method of a percentage reduction from the initial levels. For this reason, the initial levels are vital. In this case, the method of determining these initial levels was unreliable and insufficient, since the workers and plants to which the dry color industry was analogized were not shown to be sufficiently similar to justify such a comparison. OSHA employed the flawed and prohibited method of analyzing these pre-standard exposure levels generally, rather than specifically to the industry in question here. Color Pigments Mfrs. Assn. v. OSHA, 16 F.3d 1157, 1161-63 (11th Cir. 1994)(citations and footnotes omitted). In accordance with these opinions, current NIOSH policy requires that RELs be supported by findings of technological feasibility. This policy is required by current law and must be retained.	*Several comments criticized the draft cancer policy because NIOSH did not propose to evaluate the technological and economic feasibility of its RML-CA. These comments argued that NIOSH recommended risk management levels must be based on an evaluation of feasibility because OSHA standards must be feasible.* *NIOSH disagrees with these comments.* *NIOSH recommendations are not binding, and are developed using the criteria set forth in section 20 of the OSH Act. Although NIOSH does not base its RML-CA on technological and economic feasibility findings, NIOSH does make information on technology to reduce exposures available to affected stakeholders who can use that information to implement appropriate exposure reductions. NIOSH does not consider economic feasibility in making health-based recommendations for RML-CAs.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	Economic feasibility. Under the current policy NIOSH generally has considered only technological feasibility in the establishment of RELs. However, as discussed above, the courts have held that the requirements for OSHA PELs and NIOSH RELs are virtually identical, and have made it clear that in adopting PELs OSHA must examine economic as well as technological feasibility. PELs at 980. Accordingly, the same requirement applies to NIOSH. The analysis must "provide a reasonable assessment of the likely range of costs of its standard, and the likely affects of those costs on the industry . . . so as to demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry . . ." PELs at 982. In the PELs case, the court reiterated that economic feasibility must be determined on an industry-by industry basis, criticizing OSHA for using industry "sectors" that were based on two-digit SIC Codes and in many cases were defined too broadly to suit the court: In this rulemaking, although OSHA ostensibly recognized its responsibility "to demonstrate economic feasibility for an industry, the agency nevertheless determined feasibility for each industry "sector" (i.e., two-digit SIC Code), without explaining why such a broad grouping was appropriate . . . Indeed, it would seem particularly important not to aggregate disparate industries when making a showing of economic feasibility. OSHA admits that its economic feasibility conclusions only "have a high degree of validity on a sector basis," as opposed to a sub-sector or more industry- specific basis . . . OSHA then stated that "[t]he costs are sufficiently low per sector to demonstrate feasibility not only for each sector but also for each subsector." However, reliance on such tools as average estimates of cost can be extremely misleading in assessing the impact of particular standards on individual industries. Analyzing the economic impact for an entire sector could conceal particular industries laboring under special disabilities and likely to fail as a	*Several comments criticized the draft cancer policy because NIOSH did not propose to evaluate the technological and economic feasibility of its RML-CA. These comments argued that NIOSH recommended risk management levels must be based on an evaluation of feasibility because OSHA standards must be feasible.* *NIOSH disagrees with these comments.* *NIOSH recommendations are not binding, and are developed using the criteria set forth in section 20 of the OSH Act. Although NIOSH does not base its RML-CA on technological and economic feasibility findings, NIOSH will make information on technology to reduce exposures available to affected stakeholders who can use that information to implement appropriate exposure reductions. NIOSH does not consider economic feasibility in making health-based recommendations for RML-CAs.*

Commenter/Topic	Public Comment	*NIOSH Response*
	result of enforcement. Moreover, for some substances, OSHA failed even to analyze all the affected industry sectors. We find that OSHA has not met its burden of establishing that its 428 new PELs are either economically or technologically feasible (965 F.2d at 982, emphasis in original, citations and footnotes omitted). The court went on to note that while it was "not foreclosing the possibility" of analyses based on industry segments, OSHA would be required to show "that there are no disproportionately affected industries within the group" (id. n. 28).	

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	Two years later, the Eleventh Circuit reiterated and expanded upon this approach in invalidating the cadmium standard OSHA adopted for the dry color formulator industry. See Color Pigments Manufacturers Ass'n v. OSHA, 16 F.3d 1157 (11th Cir. 1994). In the cadmium case, OSHA had adopted "Separate Engineering Control Air Limits" (SECALs) for many industry sectors based on its determinations of feasible engineering controls for those sectors. The dry color formulators challenged OSHA's decision to subject their industry to the full effect of the 5 ug/m3 standard without a SECAL. Again, the court found that OSHA's "grouping of the dry color formulator industry with other users of cadmium pigments and its failure to study any particular dry color formulators whatsoever show that OSHA proceeded generically rather than making the requisite specific findings for this identifiable industry segment" (16 F.3d at 1161). First, the court rejected OSHA's conclusions with respect to technological feasibility because the agency had not accurately determined pre-existing airborne exposure levels for the industry. The court then went on to detail related defects in the economic feasibility findings:	*Several comments criticized the draft cancer policy because NIOSH did not propose to evaluate the technological and economic feasibility of its RML-CA. These comments argued that NIOSH recommended risk management levels must be based on an evaluation of feasibility because OSHA standards must be feasible.* *NIOSH disagrees with these comments.* *NIOSH recommendations are not binding, and are developed using the criteria set forth in section 20 of the OSH Act. Although NIOSH does not base its RML-CA on technological and economic feasibility findings, NIOSH makes information on technology to reduce exposures available to affected stakeholders who can use that information to implement appropriate exposure reductions. NIOSH does not consider economic feasibility in making health-based recommendations for RML-CAs.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	Essentially, OSHA's economic feasibility findings here suffer from the same deficiencies as its findings of technological feasibility. If it is incorrect in its determination of the pre-standard exposure levels for the dry color formulator industry, then it will undoubtedly cost more for each firm to reduce exposures to the PEL, absent a SECAL. Any increase in cost not anticipated by OSHA must be absorbed somewhere in the industry. The data before this court shows the industry to be comprised of many small concerns, with minimum ability to absorb significant capital outlays, and with even less ability to spread such expenditures among its customers in the form of price increases. Of primary concern is the current existence of more cheaply priced imported colors from foreign dry color formulators. OSHA asserts, without support in either research or common sense, that customers of dry color formulators would prefer to pay more for their supply of colors from local, domestic formulators than pay less for imported products. Even if this is currently true as it relates to the relatively small price difference between domestic and imported colors, there is no reason to assume that these customers will be willing, or even fiscally able, to absorb the more substantial increase which may be necessitated by a large outlay in meeting the PEL. Additionally, there is evidence that the overall market for these cadmium pigment based colors has decreased by as much as 35% over the past several years, for both domestic and imported products. The lag in the market for these products will make the distribution of any capital outlays through cost increases significantly less feasible. Moreover, OSHA asserted in its own findings that "the targeted level of 5 ug/m3 will be difficult to achieve for many plants in [the dry color formulator] sector." Although OSHA found it feasible on balance, this estimate of difficulty will be exacerbated if it is shown that the pre-standard exposure levels employed by OSHA were inaccurate.	*Several comments criticized the draft cancer policy because NIOSH did not propose to evaluate the technological and economic feasibility of its RML-CA. These comments argued that NIOSH recommended risk management levels must be based on an evaluation of feasibility because OSHA standards must be feasible.* *NIOSH disagrees with these comments.* *NIOSH recommendations are not binding, and are developed using the criteria set forth in section 20 of the OSH Act. Although NIOSH does not base its RML-CA on technological and economic feasibility findings, NIOSH makes information on technology to reduce exposures available to affected stakeholders who can use that information to implement appropriate exposure reductions. NIOSH does not consider economic feasibility in making health-based recommendations for RML-CAs.*

Commenter/Topic	Public Comment	*NIOSH Response*
	Therefore, we hold that OSHA's analysis of the economic feasibility of the PEL in the dry color formulator industry is not supported by substantial evidence because it is predicated upon faulty assumptions and flawed methodology (16 F.3d at 1163, citations and footnotes omitted). In the wake of these decisions OSHA has been increasingly careful to base its determinations of economic feasibility on precise definitions of the affected industry segments and detailed economic data for each segment. As discussed above, a similar analysis of economic feasibility for the affected industry segments is required to support the NIOSH RELs.	

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	SECTION 6.2 HISTORY P.34 Lines 9 - 23. In 1988, NIOSH used the phrases, "lowest feasible limit", "lowest feasible level", and fullest extent possible" interchangeably in NIOSH testimony to OSHA for rulemaking on air contaminants. NIOSH stated ... that work practices and engineering controls such as substitution, isolation, and ventilation should be used to control occupational exposures to the fullest extent feasible. Feasible: Adjective 1. Capable of being accomplished or brought about; possible; a feasible plan. 2. Used or dealt with successfully; suitable; feasible new sources of energy 3. Logical; likely; a feasible explanation. Noun Possibility, viability, usefulness, expediency, practicability, workability (www.thefreedictiunarv. com, 2014). Lines 16 and 17. Under the 1988 policy for potential occupational carcinogens, RELs for most carcinogens were non-quantitative values labeled "lowest feasible concentration" . > This ideology misses the mark, especially when the chemicals become intertwined and interact to possible become HYPER carcinogens. Lines 26, and 27. RELs developed under this policy are syntheses of quantitative risk assessment (when data permit) analytical measurement limits, and analysis of the achievability of the REL in the workplace. When data permit, in fact should be ' where data supports that problems exist'	*Past practices with regard to NIOSH RELs and policy for potential chemical carcinogens created some confusion and inconsistent application or interpretation of terminology and concepts. The revised carcinogen policy is designed to provide transparent and consistent application of well-defined criteria for assessing and classifying occupational carcinogens, and for clearly communicating the basis for health-based recommendations.*

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	P. 35 Lines 6 to 8. For example, the existing policy has resulted in some RELs being based on the limit of quantitation, limit of detection, or reliable quantification limit of the sampling and analytical method. This is a CANCER FORMULA that ensures harm. The only control there is to an exposure, is to ELIMINATE IT !! Lines 24 and 25.When NIOSH sets the REL at the limit of quantitation, or reliable quantitation limit, NIOSH will publish the REL with an "AF" notation (for Analytical Feasibility). AF should stand for Another Failure, or Another Fatality. Lines 29 and 30. A long-used framework to control exposures in the occupational environment consists of substitution, isolation, and ventilation, followed by administrative programs (NIOSH 1973). PREVENTION IS NOT PART OF THIS LONG-USED FRAMEWORK. THAT IS A HUGE PROBLEM.	*As stated in the document, "NIOSH will no longer use the term recommended exposure limit (REL) for chemical carcinogens. NIOSH will recommend an initial starting point for control, the Risk Management Level for Carcinogens (RML-CA), which corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. When measurement of the occupational carcinogen at the RML-CA is not analytically feasible at the 1 in 10,000 risk estimate, NIOSH will set the RML-CA at the limit of quantification (LOQ) of the analytical method. In addition, NIOSH will continue to evaluate available information on existing engineering controls and make that information available when publishing RML-CAs."* *Prevention has been and will continue to be a very important component of NIOSH chemical assessments.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Leo Petrilli	P. 36 Lines 2, 3, 5, 6 and 7. NIOSH, however, will no longer specifically consider engineering achievability for each chemical specific REL. If NIOSH lacks adequate exposure measurement/control data, the absence of such data will be explained when the REL is set and NIOSH will recommend that research be conducted to determine the efficiency of existing engineering controls. ENGINEERING CONTROLS? To CONTROL CANCERS? I doubt that ..this is the wrong answer - ensuring exposures means that harms are also ensured. The correct answer is to prevent exposures, thereby preventing harms. The University of Arizona published a Risk Management System document, specifically addressing chemical safety information. Available at the link below; http://risk.arizon.edu/healthandsafety/chemicalsafetyinfo/sectiontwo.shtml# principles.	*NIOSH promotes use of the hierarchy of controls for eliminating or minimizing exposures to chemical carcinogen hazards in the workplace. Accordingly, NIOSH recognizes that substitution of safer chemical alternatives is most effective, followed by use of effective engineering controls. For this concept, NIOSH will provide guidance where research and data are available to indicate technological achievability for reducing exposures below a given level (i.e., REL). These engineering controls can be used to prevent exposures and thereby prevent occupational cancer.*

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	NIOSH's Cancer Policy Should Be Consistent with NIOSH's and OSHA's Statutory Mission. As a creation of Congress, NIOSH needs to be mindful of its statutory mission when it adopts policies outlining how it intends to perform what it believes are important functions. In this regard, NIOSH should revisit the thorough legal analysis presented by Keller and Heckman LLP ("K&H") in its comments in response to NIOSH's initial request for information and public comment about possible revisions to its Cancer Policy. See Letter dated December 28, 2011 from Lawrence P. Halprin submitted to Docket No. NIOSH-240. After reviewing the statutory interplay between NIOSH and OSHA, K&H identified several shortcomings in NIOSH's past approach in developing RELs. In closing, K&H urged NIOSH to revise its Cancer Policy in a way that gives due consideration to technical and economic feasibility: In short, we believe, at a minimum, NIOSH must address technical feasibility in a meaningful way that advances the cooperative development of occupational safety and health standards rather than suggesting theoretical approaches that create false expectations as to what is feasible. We also believe it is critical for NIOSH, in cooperation with OSHA and all stakeholders, to effectively address economic feasibility. The examination of technical feasibility independent of economic feasibility tends to become an academic exercise that generates impractical if not misleading conclusions. Assessing economic feasibility is often the most difficult and most contentious part of setting occupational safety and health standards. Affordability is both difficult to determine with precision and a matter of the highest importance as the viability of businesses and the jobs they provide are at stake. For these reasons, we encourage NIOSH to consider allocating more if its research budget in consideration of economic feasibility. Id. at 9-10.	*The NIOSH Cancer Policy follows from the NIOSH Mission, as described in the OSH Act of 1970. Assessing chemical hazards is a crucial part of the NIOSH mission. This policy will help to clarify the health basis of exposures by linking that health basis more directly to the RML-CA. This has the advantage of making the RML-CAs more comparable and more easily understandable. Additionally, when the analytical limit of quantitation is greater than the health based 1/10,000 risk, NIOSH will set the RML-CA at the analytical limit of quantitation, but will provide information on the risks, as well. This combination of information on the health risks and the analytical limit of quantitation put the employers in the best position to determine appropriate engineering controls for their worksite. In addition, NIOSH intends to continue providing information on the effectiveness of engineering controls and risk management practices to further aid employers in reducing worker exposures.*

Commenter/Topic	Public Comment	*NIOSH Response*
	In Section 6.4.2 of the Draft Cancer Policy, NIOSH essentially disregards the admonition to stay true to its statutory directive to support OSHA in developing and adopting workplace standards that are technically, analytically and economically feasible. According to the draft, "NIOSH, however, will no longer specifically consider engineering achievability for each chemical-specific REL." Instead, NIOSH will "recommend that research be conducted to determine the efficacy of existing engineering controls" and "will give recommendations that reflect the availability and efficacy of existing controls, including risk management practices to reduce worker exposures." NIOSH further states, "[i]f the REL is at the LOQ then NIOSH and others will be recommending substitution." The adoption of such aspirational recommendations should be secondary to, and not in lieu of, NIOSH's role in developing feasible exposure limits.	

Commenter/Topic	Public Comment	*NIOSH Response*
Substitution		
Tony Stefani (SFFCPF)	Having lost so many of our, we are strongly opposed to NIOSH, an agency tasked with protecting the health of workers, recommending an exposure level that will result in one additional cancer in every thousand workers during their working lifetime, particularly when the general public is protected at a much higher level, usually 1 in a million. We urge the agency to provide a range of risk levels, but to set a recommendation exposure level that is truly safe for workers and in line with protection of the general public. While it is almost impossible to control all chemicals we are exposed to, reducing exposure to the broader workforce, by substituting safer alternatives at the source, can only help reduce the danger of exposures on our job.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended."*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Tony Stefani (SFFCPF)	The safest way to protect all workers, including firefighters is to assume no "safe" level of exposure to carcinogens and actively seek safer alternatives to replace them.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended."*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Christopher Lish and PSR	The safest level of exposure to carcinogens is no exposure. The NIOSH's carcinogen policy should promote the substitution of safer alternatives for carcinogens as the most effective means of preventing cancer among workers.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended."*

Commenter/Topic	Public Comment	*NIOSH Response*
Heather Buren, United Fire Service Women (UFSW), Nancy Barsotti	First, the target goal for workplace cancer risk is too high. One extra cancer per 1000 exposed workers is not an acceptable risk for developing cancer from toxic exposures in the workplace. I expect my government health agency to be proactive in trying to reduce exposure to carcinogens and eliminate carcinogens from our economy. As a goal, worker exposure to carcinogens should be zero, or as low as achievable.	*As explained in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible." Also, "An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of*

Commenter/Topic	Public Comment	*NIOSH Response*
		exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical.*

Commenter/Topic	Public Comment	*NIOSH Response*
Heather Buren, (UFSW), Nancy Barsotti	By making clear public health-protective guidelines for carcinogens, NIOSH can encourage innovation and introduction of safer alternatives. Thank you for taking the time to consider my thoughts on this important matter.	*As explained in the document, "Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 in a working lifetime, while still acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level. In keeping with these advances, NIOSH will set a "risk management limit for a carcinogen" or an "RML-CA," at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible." Also, "An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of*

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		exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical.

Commenter/Topic	**Public Comment**	***NIOSH Response***
Pamela Miller, (ACAT)	In addition to these calculations in lieu of RELs, ACAT proposes that all new NIOSH reviews of occupational carcinogens include a section on how to eliminate the use of known carcinogens and move to safer alternatives. Thank you for this opportunity to comment.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended." NIOSH is analyzing and developing additional information on risk management, including substitution and elimination.*

Commenter/Topic	Public Comment	*NIOSH Response*
Patrick Morrison, (IAFF)	During a fire, our members are forced to rely on their personal protective equipment (PPE) to keep them safe. Although PPE is the least effective exposure control measure, it is only one available to fire fighters on the fire ground. In the fire station, higher level controls such as engineering and administrative are needed to reduce exposure. Thus, the IAFF believes that NIOSH's occupational carcinogen policy should promote the utilization of the industrial hygiene hierarchy of controls. Substitution of an occupational carcinogen with a safer alternative should be recognized as the most effective way of reducing exposures to our members.	*Because there is no safe level of exposure to occupational carcinogens, NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures.*
Pete Stafford, (BCTD)	We support the proposed default assumption that the exposure response is linear at low doses; except where NIOSH determines that there is adequate data to support a different model. However, NIOSH should clearly state that for carcinogens the safest level of exposure is no exposure, and should identify and promote alternative or substitute products and engineering controls as the preferred actions in the hierarchy of controls. An important example for construction is asbestos, where use of alternative materials containing no asbestos should be promoted rather than exposure controls that reduce exposures below a NIOSH REL.	*Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Dave Foster, 42 Groups	Lastly, we believe that NIOSH's new reviews of occupational carcinogens should provide information on how to eliminate the use of known carcinogens and move to safer alternatives. Information on how to move up the hierarchy of controls deserves more attention in NIOSH's carcinogen policy because it is a more effective means of preventing cancer among workers. Again, thank you for this policy reform and for the opportunity to comment. And thank you for the work you do every day to protect the health and safety of workers across the United States.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer."*
Darius Sivin, PhD, UAW	The UAW recommends that NIOSH adopt a policy for all carcinogens indicating that occupational exposure limits, such as RELS, are a line of defense to be used only if substitution, elimination and entirely closed systems are infeasible.	*Because there is no safe level of exposure to occupational carcinogens, NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures.*

Commenter/Topic	Public Comment	*NIOSH Response*
Arlene Blum and 65 other Health Scientists and Medical Professionals	We believe that the new NIOSH reviews of occupational carcinogens should include information on and the promotion of safer alternatives. While NIOSH supports eliminating the use of known hazards as the most effective industrial hygiene control strategy, the discussion of alternatives in the proposed policy is minimally addressed in two sentences throughout the entire document (one in the introduction, one in section 5.1). We urge NIOSH to give more weight to the importance of this prevention strategy in the policy by including a stand-alone section on the issue. Thank you for the opportunity to offer input into this important policy to better prevent cancer among workers.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended." NIOSH is analyzing and developing additional information on risk management, including substitution and elimination.*

Commenter/Topic	Public Comment	*NIOSH Response*
General Comments		
Heather Buren, (UFSW), Nancy Barsotti	Second, I support NIOSH using all available information to develop a list of workplace carcinogens. The agency should also try to specify potential tumor sites for carcinogens, with more attention paid to chemicals linked to breast cancer. With current national breast cancer rates showing 1 in 8 women will be diagnosed in her lifetime, workers deserve to know whether the chemicals they are exposed to on a daily basis are linked with increased breast cancer risk.	*NIOSH appreciates this comment and the concern for carcinogens associated with breast cancer. For those workplace carcinogens that NIOSH evaluates, tumor sites are identified based on the available evidence, including breast cancer.*
James L. McGraw, (IISRP)	We have seen and fully support the comments provided by ARASP and urge NIOSH to carefully consider their input on each of the questions posed. Sound policy decisions require input from a number of sources including the regulated community and we appreciate the opportunity to provide our comments in support of ARASP.	*NIOSH has considered the ARASP comments and has provided responses are to their comments. NIOSH appreciates the participation in this process of as many different perspectives as possible, including from those impacted by the policy.*
Cheryl Osimo, (MBCC)	We support NIOSH using all available information to develop a list of carcinogens in the workplace and we especially recommend they include a comprehensive list of potential tumor sites, with greater attention to potential breast carcinogens. It is important for workers and occupational safety professionals to know if chemicals are potential breast carcinogens. Silent Spring Institute has published lists and evaluations of chemicals of concern for breast cancer, and these findings should be reflected in NIOSH cancer listings.	*NIOSH appreciates this comment and the concern for carcinogens associated with breast cancer. For those workplace carcinogens that NIOSH evaluates, tumor sites are identified based on the available evidence, including breast cancer.*
Monica Smith, (BCAN)	In addition to a staggering number of diagnoses and deaths, bladder cancer also greatly impacts the quality of life for patients. Invasive testing and treatments create practical concerns for patients, negatively effecting urinary function and sexual health. For more advanced cases of the disease, radical cystectomy is often the only option, resulting in an extreme modification of	*NIOSH appreciates this comment and the concern for carcinogens associated with breast cancer. For those workplace carcinogens that NIOSH evaluates, tumor sites are identified based on the available evidence, including bladder cancer.*

Commenter/Topic	Public Comment	*NIOSH Response*
	daily activities and painful recovery. These factors cannot be quantified, but should be considered when assessing the risk of bladder cancer.	
Monica Smith, (BCAN)	It is BCAN's position that exposure to all carcinogens in the workplace is unacceptable. As a community, it is our duty to protect the health of those in the workplace and beyond. We must limit exposure risk and prevent cancer diagnosis and death to improve the quality of life and build healthier communities. We respectfullly request that NIOSH rethink this provision and set a truly health protective REL for the workplace health of all Americans. Thank you for your coosideration.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended." NIOSH is analyzing and developing additional*

Commenter/Topic	Public Comment	*NIOSH Response*
		information on risk management, including substitution and elimination.
Robyn Robbins, United Food and Commercial Workers (UFCW) International Union	The UFCW represents 1.3 million workers in the US and Canada, who primarily work in retail grocery stores and food manufacturing plants. Nearly 800,000 work in retail grocery stores in the US. We represent over 158,000 workers in poultry and meat processing establishments in the US. The UFCW is concerned that this review of the NIOSH cancer policy does not address biological carcinogens or likely-to-be biological carcinogens. For over 20 years, data has been accumulating that workers in meatpacking and poultry plants are dying at higher rates of cancer than expected. In 2001, NIOSH's Dr. Elizabeth Ward conducted a literature review of research in both the US and abroad, finding that, "there is considerable evidence that people exposed to meat and meat products as part of their jobs experience excess rates of lymphoid neoplasms and lung cancers ..."	*This policy focuses on chemical carcinogens in the workplace. Consideration of biological carcinogens is beyond the scope of this document, however we will share your concerns with management and researchers at NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
Robyn Robbins, (UFCW) International Union	Food animal oncogenic viruses show potential for causing cancer in humans. Over many years, NIOSH and the NIH have funded numerous mortality and cancer incidence studies by Dr. Eric S. Johnson in US meatpacking and poultry cohorts. Dr. Johnson hypothesizes that oncogenic viruses present in animals may contribute to the excess occurrence of at least some of these cancers in workers. We urge NIOSH to continue to fund research in this area.	*This policy focuses on chemical carcinogens in the workplace. Consideration of biological carcinogens is beyond the scope of this document, however we will share your concerns with management and researchers at NIOSH.*
Robyn Robbins, (UFCW) International Union	The UFCW is particularly concerned about Aflatoxin (AFB1), an IARC Group 1human carcinogen. One line of research conducted by Dr. Susan Viegas in Portugal investigated the presence of aflatoxin in poultry litter, swine waste impoundments and in the air of poultry and swine houses. Another study in North Carolina measured high levels of AFB1in the airborne dust of swine houses. Biomarkers have also been found in the blood in poultry and swine house workers. Evidence of this biomarker in workers' blood indicates that they are being exposed to this known carcinogen in the course of their employment. We are deeply concerned about the potential risks to swine and poultry house workers, and encourage NIOSH to develop a research track in this issue.	*NIOSH understands the UCFW concern about aflatoxin exposure. This comment will be shared with management and researchers in NIOSH. Information about NIOSH research efforts are available on the NIOSH National Occupational Research Agenda sector webpages, available at http://www.cdc.gov/niosh/nora/*
Robyn Robbins, (UFCW) International Union	NIOSH is the only research agency in the US solely tasked with developing and conducting research on workplace hazards. The UFCW, on behalf of its 1.3 million members, urges NIOSH to take this cancer threat to meat and poultry workers seriously. NIOSH must develop research to broaden our knowledge of the causes of these cancers, and add them to the Agency's carcinogen policy as they are identified. We appreciate the opportunity to submit comments on this important issue.	*This policy focuses on chemical carcinogens in the workplace. Consideration of biological carcinogens is beyond the scope of this document, however we will share your concerns with management and researchers at NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
Barbara Dawson, CIH, (AIHA)	AIHA supports the decision to make the RELs risk-based; that is, NIOSH will no longer consider the technical achievability (i.e., ability to control exposure) in establishing these limits. In addition, NIOSH efforts to ensure that the carcinogen and related REL policies reflect current scientific and risk management practices are very good. This policy: Eliminates the term "potential occupational carcinogen" as it relates to known carcinogens (asbestos, benzene and cadmium); Addresses "to the extent feasible", projecting not only a no-effect exposure, but also exposure levels at which there may be no residual risks; Addresses how to establish an appropriate level of risk, 1-in-1000; Is now health-based alone vs integrating technical achievability as it did in some previous cases; Provides a note as to whether existing controls are effective or available, including risk management practices to reduce worker exposure. One question relating to this – Does NIOSH have the internal capability to answer this question? Aligns classifications which existed under various umbrellas, advancing a unitary approach – NTP, EPA, IARC and GHS.	*NIOSH appreciates AIHA support of this policy. In regards to the question of whether NIOSH has the internal capability to provide information about existing controls, this will vary depending on the specific carcinogen being studied. If NIOSH does not have the internal capability to answer this question it will request external input and information in this area. In addition, any internal information will be made available for peer and public review through the best practices followed for guidance development. In the document, NIOSH states: "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible,*

Commenter/Topic	Public Comment	*NIOSH Response*
		in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}."
Barbara Dawson, CIH, (AIHA)	While mention is made of hazard banding, AIHA does not believe the document goes far enough. The concept of a hierarchy of Occupational Exposure Limits (OELs), a suite of tools, needs to be incorporated into this document. The landscape has changed in terms of tools being used – this document should reflect this change.	*This information about a hierarchy of occupational exposure limits is beyond the scope of this policy on chemical carcinogens. NIOSH has a separate effort in development on occupational exposure banding that will provide additional information and guidance in this area.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dennis Shusterman, MD, MPH and Kashyap Thakore, PhD, California Department of Public Health (CDPH)	Beginning with the Occupational Safety and Health Act of 1970, NIOSH has been charged with producing Recommended Exposure Limits (RELs) for workplace chemicals based upon both their inherent toxicity and potential for occupational exposure. In the case of carcinogens, NIOSH has historically used the term "potential occupational carcinogen" to denote workplace chemicals with carcinogenic potential. However, the agency has generally avoided terminology denoting either carcinogenic potency or strength-of-evidence underlying a chemical's designation as a human carcinogen. This Current Intelligence Bulletin outlines a plan to: a) Integrate data from existing authoritative bodies (the National Toxicology Program [NTP], the US Environmental Protection Agency [EPA], and the International Agency for Research on Cancer [IARC]); b) Classify human carcinogens using relative strength-of-evidence terminology that is compatible with the Globally Harmonized System (GHS); c) Derive occupational RELs based upon a target [maximum] risk level.	*As stated in the document, "The 1995 NIOSH classification scheme did not distinguish between chemicals that are classified as carcinogens on the basis of multiple, occupational epidemiology studies, such as asbestos, benzene and cadmium, and those classifications that are based on extrapolations from animal bioassay data or other scientific information, such as titanium dioxide. NIOSH has been criticized because the 1995 policy does not allow for classifying chemicals on the basis of the magnitude and sufficiency of the scientific evidence. Despite this criticism, NIOSH will continue to rely on a single cancer designation—that of occupational carcinogen. There are several reasons for this NIOSH decision. NIOSH has concluded that creating another cancer classification scheme, when several already exist, is unnecessary. NIOSH will rely on classifications and analyses done by other entities. It will display the classification each entity has assigned to the chemical.*

Commenter/Topic	Public Comment	*NIOSH Response*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	Recent statements and actions by Fed OSHA appear to place an increased relevance on recommended RELs for potential regulatory enforcement under the General Duty Clause. Suggest NIOSH include a statement in the final version that RELs for identified occupational carcinogens are recommendations alone and not intended to supercede existing compliance regulations.	*NIOSH is not commenting on the actions of other agencies as part of this response to comments. The rationale for the risk management limit is as follows, "NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures.* *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	It would be helpful for NIOSH to clarify how the use of a qualitative approach and banding would be applied for the evaluation of RELs for occupational carcinogens.	*NIOSH has a separate effort in development on occupational exposure banding that will provide additional information and guidance in this area.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dorothy Wigmore, MS, Workforce, Inc.	OSHA itself recently moved in this direction with the very useful "toolkit" (Transitioning to safer chemicals, available at https://www.osha.gov/dsg/safer_chemicals/). Surely NIOSH can promote the toolkit's and similar resources, and investigate ways to improve them, especially so they are easier to use in particular sectors at the workplace level. The recent studies by Brophy, Keith and others, about high levels of women's breast cancer linked to specific occupations, point to sectors and chemicals that would be a good place to start. As the BlueGreen Alliance campaign slogan says, "It's time to put breast cancer out of work".	*NIOSH agrees that OSHA has provided useful tools in this area. NIOSH hopes to develop a risk management document that will describe relevant related tools and issues and provide resources that will be helpful to users.*
Dorothy Wigmore, MS, Workforce, Inc.	We also recommend NIOSH re-review the comments that Worksafe -- and many others who took similar public health positions -- made in December, 2011, that are not reflected in this current proposal. The historic, scientific and international perspectives provided could greatly improve this proposed policy. An improved policy will benefit workers and employers in the US and elsewhere, and support NIOSH's reputation as a key player in achieving healthy and safe workplaces.	*NIOSH appreciates this recommendation to reconsider previous public comments. The 2011 public draft document had a broader scope and included more information about different specific topics relevant to occupational carcinogens. This policy is focused on specific aspects of the 2011 document. As stated in the document, "To better clarify how it will address reducing exposures to occupational chemical carcinogens, NIOSH developed a new Chemical Carcinogen Policy. The new Chemical Carcinogen Policy governs how NIOSH classifies chemicals as occupational carcinogens, sets risk management limits for workers exposed to carcinogens, and incorporates information on the analytical limit of quantification (LOQ)." Public and peer input, national and international, were considered in the final version.*

Commenter/Topic	Public Comment	*NIOSH Response*
Ronald Loeppke, MD, MPH, (ACOEM)	ACOEM applauds the efforts of the National Institute for Occupational Safety and Health in developing this document. We do believe that the proposed carcinogen policies are consistent with the current scientific knowledge of toxicology, risk assessment, industrial hygiene, occupational cancer, and principles of carcinogenicity. Application of the proposed approach to classification and following the resulting recommended exposure limits (RELs) will lead to reduced risks to workers in settings in which they are potentially exposed to carcinogens. While the revised RELs will not be regulatory limits, they should provide an impetus for appropriate changes to the Occupational Safety and Health Administration's permissible exposure limits (PELs) and for organizations to better control exposures to carcinogens.	*NIOSH appreciates ACOEM support of this policy.*
Ronald Loeppke, MD, MPH, (ACOEM)	In terms of setting a REL, NIOSH should also consider how they would address certain types of "agents," such as shift work involving night work and occupations that are known, suspected, or possible risk factors for occupational cancer (even though the specific agent responsible for the increased risk may not have been identified). In these cases, it does not seem that one could set a recommended exposure limit, at least not in a fashion similar to that for specific chemical carcinogens.	*This policy focuses on chemical carcinogens in the workplace. Consideration of other carcinogenic agents is beyond the scope of this document, however we will share your concerns with management and researchers at NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Mazzucco, (NRCWF)	NIOSH is the federal agency responsible for driving research and informing policy on environmental carcinogens in the workplace. This draft intelligence bulletin represents the opportunity to protect Americans in the places where they spend significant amounts of time as they endeavor to earn a livelihood. In our estimation, this report represents a continuation of the status quo, reinforcing a reactionary rather than proactive approach to regulation, maintaining historical policy positions which are no longer appropriate, placing burdens on workers rather than on industry, and overlooking several glaring gaps in regulation. Furthermore, this report also does not provide sufficient information on the enactment of new policy initiatives which could lead to redundancy between agencies, the elimination of which is one of the stated goals of this very effort. Even more disconcerting, these new policies could allow a more permissive stance towards carcinogens in the workplace despite more stringent regulation of the very same agents by other federal agencies. Areas of specific concern including the following: o Safe exposure limits must be based on actual, not theoretical, workplace exposures. Real-life workplace chemical use involves multiple agents and complex exposures. This report does not give any concrete statements on efforts to address the true chemical milieu to which workers are exposed. The combinatorial effects of chemical agents is a basic pharmacological principle which has been relied upon in medical drug design for years. The scientific understanding of cancer as a multi-step, multi-factorial process has been well-documented for more than two decades. There is no scientific reason to limit our safety analyses to single agents. If the goal is to prevent chemical hazard exposure in the workplace, then we must start with the workplace, and not a theoretical framework which likely applies to very few real-life situations. Assessment of work procedures, logistics, storage conditions and other such factors must be considered in the development of safe exposure criteria in	*NIOSH considered the peer and public input in the final version of this policy. This policy describes how the use by NIOSH of carcinogen classification information from other agencies will reduce redundancy between agencies.* *Where available, NIOSH considers actual workplace data in its evaluation of workplace exposures. The RML-CA is intended to be based on an exposure-response relationship based on the best available health effects data. While NIOSH assesses some workplace chemical mixtures and has pilot efforts to better understand exposure to chemical mixtures, currently NIOSH assesses many chemicals individually. NIOSH agrees that the assessment of actual workplace exposure mixtures would be beneficial. NIOSH and other agencies are also considering how to use rapid, high throughput screening technologies.*

Commenter/Topic	Public Comment	*NIOSH Response*
	order for workers to be protected. Rapid, high-throughput and combinatorial screening technologies are also needed to adequately meet this challenge. As the President's Cancer Panel 2010 noted, "incentives to encourage development of this research are nearly non-existent",3 and this must be changed.	

Commenter/Topic	**Public Comment**	***NIOSH Response***
Anna Mazzucco, (NRCWF)	Areas of specific concern including the following: Sensitive subpopulations must be afforded the same protections as other groups. Birth defects and both childhood and adult cancers are known to be caused by in utero exposures. The rapid cell proliferation and delicate hormone balance required during this critical developmental window have been well-known for decades. The importance of protecting sensitive subpopulations, such as pregnant women, is an essential public health obligation already in practice by other federal agencies who regulate chemical substances. No details were given in this report regarding how considerations for sensitive subpopulations will be determined and communicated. As NIOSH sets risk thresholds for all workers, it must have regulations which sufficiently protect everyone in that group.	*This policy focuses only on specific aspects of the NIOSH chemical carcinogen policy. As stated in the document, "To better clarify how it will address reducing exposures to occupational chemical carcinogens, NIOSH developed a new Chemical Carcinogen Policy. The new Chemical Carcinogen Policy governs how NIOSH classifies chemicals as occupational carcinogens, sets risk management limits for workers exposed to carcinogens, and incorporates information on the analytical limit of quantification (LOQ)." Additional details on NIOSH risk assessment procedures can be found in the individual NIOSH risk assessments contained in the Criteria Document on Hexavalent Chromium and the Current Intelligence Bulletin on Titanium Dioxide.*
Adam Finkel, ScD., CIH	Finally, let me point out one typographical error that might be of some consequence: on page 9, line 11, OSHA's classification system dates from 1977, not "1997" as your document states.	*Revised as suggested.*

Commenter/Topic	Public Comment	*NIOSH Response*
John Schweitzer, (ACMA)	NIOSH requested comments on a proposed revision of its policy on workplace carcinogens ("carcinogen policy").3 The Institute's mission is to conduct research and make recommendations for preventing occupational injuries and illnesses. NIOSH employs its carcinogen policy to assess workplace hazards posed by chemicals that may increase the risk of cancer. NIOSH is proposing to revise its carcinogen policy to: • Use carcinogen classifications from other research organizations; • Model the relationship between exposure to toxic and carcinogenic chemicals in the workplace and the adverse health effects associated with those exposures; • Evaluate the capacity of current technology to measure the level of exposure in a workplace; and, • Recommend exposure limits to reduce the excess cancer risk associated with workplace exposures.4 According to the proposed policy, NIOSH will evaluate the potential workplace carcinogenic effect of chemicals classified as carcinogens by EPA, IARC and NTP. For each substance reviewed under its revised carcinogen policy, the Institute proposes to evaluate the occupational relevance of the EPA, IARC and NTP classifications using information on the potential for workplace exposures, and on the applicability for occupational carcinogenicity of evidence considered by these other organizations as they made their classification decisions.	*As stated in the document, "To better clarify how it will address reducing exposures to occupational chemical carcinogens, NIOSH developed a new Chemical Carcinogen Policy. The new Chemical Carcinogen Policy governs how NIOSH classifies chemicals as occupational carcinogens, sets risk management limits for workers exposed to carcinogens, and incorporates information on the analytical limit of quantification (LOQ)."*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	Under the proposal to update the Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace, NIOSH would no longer recognize "potential" workplace carcinogens. Substances would be considered to be workplace carcinogens according to designations made by EPA, IARC or NTP. For those substances, NIOSH would set RELs that are solely risk-based. Feasibility would no longer be a consideration. NIOSH would review risk and exposure data to determine whether a significant workplace risk may exist. The agency then would establish the REL at a level determined to eliminate such risk. Feasible control options would be discussed but not considered in establishing the limit. With respect to the level of significant risk, NIOSH is proposing to retain the current level of 1/1,000. However, comment is solicited on a more stringent limit. As a threshold question, the necessity of revising the current NIOSH system is not clear to HTIW Coalition. The agency has provided little justification for this substantial reversal of policy. A more specific discussion of the need to revise the current policy is essential if the agency's action is to pass legal and scientific muster.	*As stated in the document, "NIOSH developed this Chemical Carcinogen Policy because clear policies on how to classify chemicals as occupational carcinogens, set risk management limits for workers exposed to carcinogens, and incorporate information on the analytical limit of quantification (LOQ) leads to further progress in reducing the risk and occurrence of occupational cancer." And, "The goal is to simplify the process of assessing cancer risks so that the documents NIOSH produces are more useful for its stakeholders, timelier, and more consistent with those of other agencies that assess cancer risks."* *NIOSH considers this to represent updating and documentation of a current policy, rather than a substantial reversal of policy, in order to increase transparency and public understanding of the NIOSH assessment process.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	Further, as a significant stakeholder in the current policy, HTIW Coalition sees little need for change, and believes that the changes NIOSH is proposing are likely to cause considerable harm. Elimination of the classification for "potential" carcinogens would not accurately reflect the underlying classifications and would cause widespread confusion and misinformation in the workplace. Elimination of the feasibility element would do the same, and is not permitted by the Occupational Safety and Health Act. The combination of these two proposals would lead to development of a risk-based REL for REF, even though the RCF Criteria Document finds that development of a scientifically sound risk-based REL is not possible on the basis of the current information. Retention of the 1/1000 risk level is likewise required by current law and consistent with current federal policy for determining significant workplace risk. A change in any of these current policies would cast doubt on the continuing validity of the current RELs and cloud the significance of RELs in the workplace for many years to come. For these reasons, discussed in detail below, HTIW Coalition urges OSHA to abandon the current proposal. We also urge expansion of current policy to include consideration of economic feasibility in the establishment of RELs.	*NIOSH intends to clearly document the basis of its carcinogen determinations which should lead to increased transparency and understanding. The current policy is consistent with the Occupational Safety and Health Act and the NIOSH mission. As stated in the document, "NIOSH developed this Chemical Carcinogen Policy because clear policies on how to classify chemicals as occupational carcinogens, set risk management limits for workers exposed to carcinogens, and incorporate information on the analytical limit of quantification (LOQ) leads to further progress in reducing the risk and occurrence of occupational cancer." And, "The goal is to simplify the process of assessing cancer risks so that the documents NIOSH produces are more useful for its stakeholders, timelier, and more consistent with those of other agencies that assess cancer risks."* *NIOSH considers this to represent updating and documentation of a current policy in order to increase transparency and public understanding of the NIOSH assessment process.*

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	NIOSH HAS NOT DEMONSTRATED A NEED TO CHANGE THE CURRENT CARCINOGEN POLICY AS PROPOSED An agency that revises a current policy on which many have relied has an increased obligation to justify the change. This was explained by the Supreme Court in Motor Vehicle Manufacturers Ass'n of the United States v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29 (1983). In that case, the National Highway Traffic Safety Administration had issued a regulation requiring phase-in of "passive restraints" such as airbags and automatic seatbelts. Four years later, the Administration reversed course, beginning a process that led eventually to rescission of the passive-restraint requirement. The Supreme Court invalidated the agency's reversal. The Court framed its analysis by explaining that an agency "changing its course" must "supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance" (463 U.S. at 42). While acknowledging that agencies "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances,'" the Court instructed that "[i]f Congress established a presumption from which judicial review should start, that presumption . . . [is] against changes in current policy that are not justified by the rulemaking record" (emphasis in original). This principle requires substantial evidence in the record justifying the need for a change in policy. As the court held in Home Box Office v. FCC, 567 F.2d 9, 36 (D.C. Cir. 1977), a change in policy must be vacated absent such evidence, because "regulation perfectly reasonable and appropriate in the face of a given problem (is) highly capricious if that problem does not exist." In justifying the need to revise the current carcinogen policy, the Executive Summary of the NIOSH document simply states:	*NIOSH is updating and revising its chemical carcinogen policy to be consistent with current scientific practice and knowledge. As stated in the document, "NIOSH developed this Chemical Carcinogen Policy because clear policies on how to classify chemicals as occupational carcinogens, set risk management limits for workers exposed to carcinogens, and incorporate information on the analytical limit of quantification (LOQ) leads to further progress in reducing the risk and occurrence of occupational cancer." And, "The goal is to simplify the process of assessing cancer risks so that the documents NIOSH produces are more useful for its stakeholders, timelier, and more consistent with those of other agencies that assess cancer risks." NIOSH considers this to represent updating and documentation of a current policy, rather than a substantial reversal of policy, in order to increase transparency and public understanding of the NIOSH assessment process.*

Commenter/Topic	Public Comment	*NIOSH Response*
	Scientific knowledge has advanced in recent years, and NIOSH stakeholders (those people, businesses, and organizations concerned with achieving healthy and safe workplaces) have offered suggestions about how to improve NIOSH policy that relates to workplace carcinogens. As a result, NIOSH is revising its policy for classifying chemical carcinogens and is making these changes to enhance the efficiency of assessing risk across the federal government, and to increase the relevance of information on workplace exposures to carcinogens. The ensuing discussions offer little additional detail as to the need for the comprehensive changes that are proposed. At a minimum, NIOSH must provide such a justification prior to changing its policy.	

Commenter/Topic	Public Comment	*NIOSH Response*
Dean Venturin, (HTIW) Coalition	THE CURRENT PROPOSAL SHOULD BE ABANDONED As discussed above, HTIW Coalition is a significant stakeholder in the current NIOSH carcinogen policy. The industry has worked closely with NIOSH over the years to ensure a fair and accurate evaluation of RCF products, culminating in publication of the current RCF Criteria Document and PEL. We believe that NIOSH staff would agree that the RCF Criteria Document and PEL have been a very useful tool for reducing workplace exposure to RCF. Beyond RCF, NIOSH has adopted dozens of PELs for potential workplace carcinogens over the years. The entire current framework would be jeopardized by the changes NIOSH is proposing here, which are likely to cause considerable harm. Elimination of the classification for "potential" carcinogens would not accurately reflect the underlying classifications and would cause widespread confusion and misinformation in the workplace. Elimination of the feasibility element would do the same, and is not permitted by the Occupational Safety and Health Act. The combination of these two proposals would lead to development of a risk-based REL for REF, even though the RCF Criteria Document finds that development of a scientifically sound risk-based REL is not possible on the basis of the current information. Retention of the 1/1000 risk level is likewise required by current law and consistent with current federal policy for determining significant workplace risk. A change in any of these current policies would cast doubt on the continuing validity of the current RELs and cloud the significance of RELs in the workplace for many years to come. For these reasons, discussed in detail below, HTIW Coalition urges OSHA to abandon the recent proposal and retain the current carcinogen policy.	*NIOSH appreciates its continued partnership with the HTIW coalition and its collaboration with NIOSH and OSHA over the years. This collaboration has been useful in addressing occupational exposure to refractory ceramic fibers. With regard to the "potential occupational carcinogen" designation, as stated in the document, "NIOSH will continue to rely on a single cancer designation—that of occupational carcinogen. There are several reasons for this NIOSH decision. NIOSH has concluded that creating another cancer classification scheme, when several already exist, is unnecessary. NIOSH will rely on classifications and analyses done by other entities. It will display the classification each entity has assigned to the chemical. What is important is the systematic evaluation of the scientific evidence of carcinogenicity that each entity relies upon to justify its classification. For chemicals that have been classified with certain designations, NIOSH will use the hazard assessment that supported the classification and review it to determine that it is comprehensive and up to date. NIOSH has determined it is unnecessary for it to duplicate these preexisting scientific analyses. Once NIOSH determines that a chemical is an occupational carcinogen, the cancer classification tier to which it is*

Commenter/Topic	Public Comment	*NIOSH Response*
		assigned has little relevance for NIOSH risk management recommendations. Therefore, the agency sees little to be gained by developing another tiered classification system." With regard to the feasibility issue, NIOSH states, "NIOSH will set the RML-CA for an occupational carcinogen at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 (10^{-4}) risk estimate when analytically possible to measure. Historically, NIOSH issued recommended exposure limits (RELs) for carcinogens based on an excess risk level of 1 in 1,000 (10^{-3}), while acknowledging that there is no safe level of exposure to a carcinogen. This level of risk was recommended because it could be analytically measured and achieved in many workplaces. However, in the last 25 years, advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible, in many cases, to control occupational chemical carcinogens to a lower exposure level. Therefore, in order to incrementally move toward a level of exposure to occupational chemical carcinogens that is closer to background, NIOSH will begin issuing recommendations for RML-CAs that

Commenter/Topic	Public Comment	*NIOSH Response*
		would advise employers to take additional action to control chemical carcinogens when workplace exposures result in excess risks greater than 10^{-4}."

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	THE WRITER'S AREAS OF CONCERN INCLUDE: P.2 Line 7. Members of the Carcinogen and REL; Policy Update Committee. REL - Recommended Exposure limits? To Carcinogens? These are chemicals that are known to foster cancer growth. However, exactly how does the body achieve the following: I.Deal with a carcinogen- nullifying the harms? 2. Eliminate the carcinogen?	*The NIOSH terminology has been revised from Recommended Exposure Limit to Risk Management Limit for Carcinogens. As explained in the document, "NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens. NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not adequately reduce exposures.* *Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."*
Leo Petrilli	P.8 ACRONYMS. Another acronym needs to be included; CsA. Signifying - CANCERS ALLOWED	*The acronyms used in the final document are included and explained.*

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	P.9 Lines 28-33 INTRODUCTION. Once chemical carcinogens have been classified, quantitative risk assessments are typically conducted to characterize the risks of occupational exposure. Quantitative risk assessments are typically conducted to characterize the risks of occupational exposure. Quantitative risk assessment serves as the health basis of Recommended Exposure Limits (RELs). Because it can take large amounts of time and resources to assess risk and develop RELs, NIOSH is also investigating qualitative and semi quantitative approaches, such as hazard banding, to address the vast number of unregulated chemicals. Comment: Where do I begin? The Precautionary Principle is not here. In fact it has been replaced by buzz words that will cause cancers. Specifically, NIOSH is also investigating qualitative and semi-quantitative measures, such as hazard banding. How about this question? Do these chemicals intermix and intertwine to become HYPER-CARCINOGENS? What are the RELs for Hyper-Carcinogens? PREVENT EXPOSURE, PREVENT HARM. ENSURE EXPOSURE, ENSURE HARM.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended." NIOSH is analyzing and developing additional information on risk management, including substitution and elimination. While NIOSH does assess some chemical mixtures, in many cases it assesses individual chemicals. Employers, occupational safety and health professionals, and workers should be made aware that assessing individual chemicals*

Commenter/Topic	Public Comment	*NIOSH Response*
		may not adequately assess the risk of the mixture of chemicals.
Leo Petrilli	Section 2. PRINCIPLES FOR CONTROLLING HAZARDS. ADMINISTRATIVE HAZARD CONTROLS All of the aforementioned engineering hazard control methods, in order to exist or be effective, require the application of "administrative hazard controls". These consist of managerial efforts to reduce hazards through planning, information and training (e.g. the Laboratory Chemical Safety Manual, Hazard Communication Program), safe work practices, and environmental and medical surveillance (e.g. work place inspections, equipment preventative maintenance, and exposure monitoring).	*As stated in the document, "NIOSH will continue to recommend that employers reduce worker exposure to occupational carcinogens as much as possible through the hierarchy of controls, most importantly elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls. Administrative controls, such as work practice controls, are also an important way to minimize workers' exposures but are lower in the hierarchy. Personal protective equipment is the last line of defense, used when other methods do not*

Commenter/Topic	Public Comment	*NIOSH Response*
		adequately reduce exposures. Therefore, exposures should be kept below a risk level of 1 in 10,000, if practical."
Leo Petrilli	An Act Public Law 91-596 84 STKl'. 1590 91" Congress, s.2193 December 29, 1970 as amended through January l, 2004. Section 1. To assure safe and healthy working conditions for working men and women; by authorizing enforcement of the standards developed under the ACT; by assisting and encouraging the States in their efforts to assure safe and healthy working conditions; by providing research, information, education, and training in the field of occupational safety and health; and for other purposes. [See original submission at regulations.org for the entire text of the Occupational Safety and Health Act.]	*Since 1970 NIOSH has reviewed evidence on chemical carcinogenicity to support recommended exposure limits (RELs). Under the Occupational Safety and health Act of 1970 and the Federal Mine Safety and health Act of 1977, NIOSH is mandated to develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience. [29 United States Code 669 (a)(3) and for mining, 30 USC 8aa (a)(1) and 30 USC 811 (a)(6)(B).]* *The commenter provided the text of sections 1 through 13 of the Occupational Safety and Health Act.*

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	As per OCCUPATIONAL SAFEY AND HEALTH ACT, (1970). SECTION 13. www.osha.gov/as/opa/worker/danger.html REQUIREMENTS: The following conditions must be met before a hazard becomes an imminent danger: There must be a threat of death or serious physical harm. "Serious physical harm" means that a part of the body is damaged so severely that it cannot be used or cannot be used very well. - For a health hazard there must be a reasonable expectation that toxic substances or other health hazards are present, and exposure to them will shorten life or cause substantial reduction in physical or mental efficiency. » This harm caused by the health hazard [RELs] does not have to happen immediately. » The threat must be immediate or imminent. This means that one must believe that death or serious physical harm could occur in very soon. This is much more a military mentality as opposed to a LABOR PROCESS. For example, before OSHA could investigate the problem, or an OSHA inspector believes that imminent danger exists, the inspector must inform the affected employees and the employer that he/she is recommending that OSHA take steps to stop the imminent danger. Danger; Noun 1. Exposure or vulnerability to harm or risk 2. A source or an instance of risk or peril; menace 3. Obsolete Power, especially to harm.	*OSHA is a regulatory agency that conducts workplace inspections. NIOSH is a research agency that conducts research and makes recommendations.*

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	The American Heritage Dictionary of the English Language Note - Obsolete Power, NOT Absolute Power A chemical does not have to be ABSOL UTE to harm. Exposure limits can/will assure that the dangers will succeed. People will be injured, and most assuredly perish. Danger; Noun - the condition of being susceptible to harm or injury. "You are in no danger" or "there was a widespread danger of disease". Clear and present danger - a standard for judging when freedom of speech can be abridged 'no one has the right to shout "fire" in a crowded theater because such an action would pose a clear and present danger to public safety. Hazardousness, perilousness - the state of being dangerous. Insecurity- the state of being subject to danger or injury. Riskiness, peril - a state of danger involving risk. Vulnerability, exposure - the state of being vulnerable or exposed. Safety - the state of being certain that adverse effects will not be caused by some agent under defined conditions. Danger; a cause of pain, injury or loss; Causal agency, causal agent, cause - any entity that produces an effect or 1s responsible for events or results.	*As stated in the document, "An excess lifetime risk level of 1 in 10,000 is considered to be a starting point for continually reducing exposures in order to reduce the remaining risk. NIOSH has established the terminology RML-CA instead of REL to bring the language used for NIOSH recommendations into conformity with the recognition that there is no safe level of exposure to carcinogens."*

Commenter/Topic	Public Comment	*NIOSH Response*
	Endangerment, hazard, jeopardy, peril, risk - a source of danger; a possibility of incurring loss or misfortune. 1. Jeopardy, risk, peril, vulnerability, insecurity, precariousness, endangerment, hazard, threat, menace, pitfall, possibility, chance, prospect, liability, likelihood, probability. The American Heritage Dictionary of the English Language Thesaurus, 2014 RELs - Recommended Exposure limits - These are DEFINED CONDITIONS.	

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	ADMINISTRATIVE PROCEDURE ACT -JUNE 11th, 1946 PUBLIC LAW 404. 79th CONGRESS, CHAPTER 324, 2nd Session SECTION 2. As used in this Act. (a) AGENCY. "Agency" means authority (whether or not within or subject to review by another agency) of the Government of the United States other than Congress, the courts, or the governments of the possessions, Territories, or the District of Columbia. Nothing in the ACT shall be construed to repeal delegations of authority as provided by law. EXCEPT as to the requirements of Section 3. AGENCIES ALLOWING FOR SECRECY IN THE PUBLIC INTEREST. ADMINISTRATIVE PROCEDURE. ADJUDICATION. Section 5 (d) DECLATORY ORDERS - The Agency EACH AUTHORITY, INCLUDING FOR EXAMPLE OSHA OR NIOSH I WOULD INCLUDE IS AUTHORIZED IN IT'S SOUND DISCRETION, with like effect as in the case, of other orders, to issue a declatory order to terminate a controversy or remove uncertainty. Section 10. Except so far as (1) statues preclude judicial review or (2) agency action is by law committed to agency discretion, (a) RIGHT OF REVIEW - Any person suffering legal wrong because of any Agency action, or adversely Section 12. CONSTITUTION AND EFFECT. Nothing in this ACT shall be held to diminish the constitutional rights of any	*The text of the Administrative Procedure Act of 1946 was provided by the commenter. For occupational chemical carcinogens, NIOSH conducts research and makes recommendations. NIOSH provides public information and recommendations that may be used by OSHA and other agencies in their rule-making processes.*

Commenter/Topic	Public Comment	*NIOSH Response*
	person, or to limit or repeal additional requirements or privileges relating to evidence or procedure shall apply equally to agencies and persons.	

Commenter/Topic	**Public Comment**	***NIOSH Response***
Leo Petrilli	WORKERS FAMILY PROTECTION ACT Congress finds that; (A) Hazardous chemicals and substances that can threaten the health and safety of workers are being transported out of industries on worker's clothing and persons;	*The transport of hazardous chemicals outside of the workplace and into workers' homes is an important issue that NIOSH considers for each chemical being assessed.*

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, American Chemistry Council (ACC)	The American Chemistry Council's (ACC) Center for Advancing Risk Assessment Science and Policy (ARASP)2 welcomes the opportunity to provide comments in response to the National Institute for Occupational Safety and Health (NIOSH) notice indicating the availability of the draft document titled "Update to NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace" (herein referred to as Revised Policy)3. ARASP fosters activities to promote the adoption of policies and practices that assure the best available and most relevant science is used as the foundation for assessing potential risks from chemical exposures. ARASP submitted comments4 in December 2011 when NIOSH issued a request for public input on its approach to classifying carcinogens and establishing recommended exposure limits for occupational exposures to hazards associated with cancer (To view their previous comments, please see the word document [ACC(Wise)-PC10-Attachment]. We recognize the important role that NIOSH plays in evaluating potential workplace hazards and developing recommended exposure limits that are supported by the available scientific information. NIOSH considers the Revised Policy a "highly influential scientific assessment" and therefore it should adhere to a rigorous standard of quality and peer review as set forth in the Office of Management and Budget (OMB) "Final Information Quality Bulletin for Peer Review5." The OMB Bulletin notes that "In general, an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s)." While NIOSH has plans to conduct a peer review of the Revised Policy it is not clear if there will be a public peer review meeting where the peer review committee will discuss the Revised Policy. As well it is unclear if the peer review committee contains a balance of expertise and perspectives or if the public will be afforded an opportunity to recommend experts for	*NIOSH appreciates this recognition of the rigorous peer review process required of highly influential scientific assessments. NIOSH policy documents follow all relevant policies and practices, including the Office of Management and Budget Final Information Quality Bulletin for Peer Review. Peer reviewers were selected by NIOSH for their expertise, lack of conflict of interest, and contribution to a well-balanced peer review group.* *The NIOSH peer review process was conducted through individual letter reviews. Individual letter reviews allow peer reviewers to provide independent, unbiased, expert input on the draft document and the charge questions. The document development process, including peer and public reviews, was documented on the NIOSH website, in the NIOSH Docket Office, and on regulations.gov.* *NIOSH held two public meetings to discuss updating the NIOSH Carcinogen Policy,, one in 2011 and one in 2014. Peer reviewers were invited to attend the 2014 public meeting. The charge to the peer reviewers was provided to the peer reviewers and was made available to the public in a Federal Register*

Commenter/Topic	Public Comment	*NIOSH Response*
	inclusion on the peer review committee. Recommendation – NIOSH should ensure that its peer review includes: (1) the release of the names of the peer reviewers and their identified areas of expertise, (2) the conduct of a public peer review meeting that would allow discussion among the peer reviewers and afford the public an opportunity to interact with the peer reviewers and provide oral comments, (3) sufficient time for the peer review committee to review and consider public comments during their review of the Revised Policy, and (4) a NIOSH response to peer review comments prior to finalizing the Revised Policy. ARASP would also like the opportunity to present our comments orally to the peer review panel.	*notice and on the NIOSH website.* *NIOSH provided peer reviewers and the public access to the document development process, including peer and public reviews, through a dedicated web page, NIOSH Evaluation of its Cancer and REL Policies, available at http://www.cdc.gov/niosh/topics/cancer/policy.html. The process was also documented through traditional NIOSH webpages including the NIOSH Docket Office page and the NIOSH peer review agenda page.* *NIOSH made public on the NIOSH website the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' reports, and the NIOSH response to the peer reviewers' reports.*

Commenter/Topic	Public Comment	*NIOSH Response*
Kimberly Wise, (ACC)	ARASP supports NIOSH's efforts to revise its carcinogen classification and target risk level policy. We recommend that NIOSH subject the Revised Policy to a comprehensive peer review and adequately address peer review and public comments, including all the comments included above, prior to finalizing the policy. Additionally, each individual substance that is evaluated using this policy should be subject to peer review and a call for information to ensure that NIOSH has the most up to date scientific data to reach conclusions. ARASP would also like the opportunity to present our comments orally to the peer review panel.	*NIOSH conducted a rigorous peer and public review of the draft policy, including holding two public meetings. NIOSH considered and addressed the peer review and public comments received. The peer review was conducted through individual letter reviews. Peer reviewers were invited to attend the 2014 public meeting. The document development and review process is documented on the NIOSH website. Consistent with NIOSH's good guidance practices, each NIOSH assessment will undergo peer and public review and follow relevant policies and procedures. As stated in the document, "NIOSH will continue its policy of seeking public and stakeholder input on its comprehensive analyses and recommendations, submitting them to peer review, and then publishing an authoritative document containing the recommendations and all supporting analyses recommending practices to control worker exposures. These documents are usually Current Intelligence Bulletins or Criteria Documents. NIOSH will seek peer review and public comment, consistent with the Office of Management and Budget's Information Quality Guidelines about a determination regarding (1) chemical hazard assessment and occupational relevance reviews; (2) QRA for each*

Commenter/Topic	Public Comment	*NIOSH Response*
		occupational carcinogen, including but not limited to selection of data and mathematical models; (3) analytical methods for measuring the RML-CA; and (4) information regarding engineering controls."

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	If NIOSH issues the current draft of the document titled, “Current Intelligence Bulletin: Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace” (“Draft Cancer Policy”) without making significant changes, NIOSH would be stating its intention to abdicate its primary role as a research and investigative organization in support of OSHA’s mission to formulate safety and health standards within the statutory boundaries established by Congress. Instead, as it relates to identifying cancer threats in the workplace, NIOSH primarily would become a mere clearinghouse of determinations reached by other bodies without critically evaluating the scientific basis, transparency and currency of those determinations. Given the implications of its labeling a chemical substance as a workplace carcinogen, NIOSH needs to take, and its Cancer Policy needs to reflect, an active role in investigating and assessing the carcinogenic risks of chemical substances present in U.S. workplaces. Furthermore, rather than issuing aspirational goals for employers, NIOSH needs to focus its efforts in developing measurable risk-based recommended exposure limits (“RELs”) that are technologically and economically feasible in order to provide OSHA with practical guidance as it develops and promulgates appropriate occupational safety and health standards as Congress intended.	*As stated in the document, "NIOSH reviews each chemical carcinogen hazard assessment, in conjunction with the information noted in the Industrial Usage and Hazard Assessment and Scientific Studies sections, to determine if the chemical meets the criteria of occupational relevance. By relying upon the hazard assessment of NTP, IARC, or EPA, NIOSH will increase the number of cancer assessments it can complete without sacrificing the scientific quality of those assessments." In addition, "NIOSH will evaluate whether the chemical is likely to pose a risk in the occupational environment and whether the data underlying the cancer classification is applicable to the occupational setting. NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation. This is because there are likely only very rare instances in which a chemical classified as a carcinogen by NTP, EPA, or IARC would not also be potentially carcinogenic to exposed workers."*

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	In doing so, NIOSH needs to avoid past pitfalls. For example, past exposure limits have incorporated safety factors to account for uncertainty of risk. This generally has been done using an arbitrary process utilizing the opinion of a small select panel of scientists. Under this process, greater perceived uncertainty has led to the application of greater safety factors. The assigning of arbitrary uncertainty factors is simply not science, and risk assessors must use scientific data rather than automatic presumptions as they estimate the level of a chemical that is not likely to harm health. It is significant to remember that the word “extrapolation” means “beyond the evidence.” A scientific peer review panel convened by the United States Environmental Protective Agency (USEPA) to evaluate the draft, Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies Extrapolation, recommended that the USEPA continue its efforts to encourage risk assessors to use scientific data rather than automatic presumptions as they estimate the level of a chemical that is not likely to harm health. In establishing risk, all available data, both positive and negative, should be used with weight given to the data reflective of current exposure profiles. Risk assessment must move away from default assumptions and policy judgments that put constraints on risk assessments. Risk assessment needs to incorporate the total weight of evidence and not rely on single point values to ensure that variability is considered in any decision making process. It is important that NIOSH ensure stakeholders have ample opportunity to participate meaningfully in the process.	*As stated in the document, "After determining that a chemical is an occupational carcinogen, NIOSH will assess whether data are suitable for performing a quantitative risk assessment (QRA). If NIOSH determines that the data are suitable, NIOSH will perform a QRA based on the best available data." In addition, "NIOSH will continue to use the risk assessment methods as more fully described in the NIOSH Criteria Document on Hexavalent Chromium [NIOSH 2013] and Current Intelligence Bulletin on Titanium Dioxide [NIOSH 2011a]."*

Commenter/Topic	Public Comment	*NIOSH Response*
Marc Kolanz, CIH, Materion Brush Inc.	Materion recognizes NIOSH's proposed revisions to its cancer policy are founded on a continuing interest in advancing workplace protections. Workers and management personnel will be better informed when evidence of cancer is based on sound science and is communicated clearly to both. This is a common objective that Materion has supported for over more than half a century through customer letters, warning labels, training programs, the longest-running joint research program with NIOSH, and collaborations with others to advance science-based workplace safety and health. Undoubtedly, NIOSH recognizes its proposed revisions to its cancer policy will have significant economic ramifications in the marketplace for assessed substances. In administering its significant responsibilities under the law, the agency should apply its authority in the most scientifically thoughtful manner. There should be no shortcuts in establishing cancer determinations and in setting RELs. NIOSH should welcome a robust discussion on the science supporting or failing to support cancer findings regardless of prior decisions made by others or the agency previously. The best science should dictate conclusions. Following such a process will serve the public more effectively by raising the value of its assessments for purposes of controlling workplace exposures to carcinogens on solid scientific grounds. NIOSH's standing as a research agency will rise with a vigorous and transparent assessment, review and public debate process envisioned in the comments Materion offers.	*As stated in the document, "NIOSH will continue its policy of seeking public and stakeholder input on its comprehensive analyses and recommendations, submitting them to peer review, and then publishing an authoritative document containing the recommendations and all supporting analyses recommending practices to control worker exposures. These documents are usually Current Intelligence Bulletins or Criteria Documents. NIOSH will seek peer review and public comment, consistent with the Office of Management and Budget's Information Chemical Carcinogen Policy Quality Guidelines about a determination regarding (1) chemical hazard assessment and occupational relevance reviews; (2) QRA for each occupational carcinogen, including but not limited to selection of data and mathematical models; (3) analytical methods for measuring the RML-CA; and (4) information regarding engineering controls.*
Cindy Sage, MA, BioInitiative	Thank you for the opportunity to submit a public comment to NIOSH on it's current proceeding NIOSH-047 (CDC–2013–0023 and Docket Number NIOSH 240–A). This letter of comment is submitted to support the creation of a substantial research effort by NIOSH to study workplace exposures to electromagnetic fields (EMF) and radiofrequency radiation (RFR). It urges NIOSH to place the evaluation of electromagnetic fields and radiofrequency radiation as a high priority on the NORA research agenda for ten-year funding.	*This policy relates to chemical carcinogens only. Consideration of EMF is beyond the scope of this document. This comment will be shared with management and researchers in NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
Cindy Sage, MA, BioInitiative	NIOSH has targeted primarily chemical toxins in this assessment. However, the definition of carcinogens to be studied under the 10-year NORA program should include EMF and RFR as equal priorities to chemical toxins, given the extensive scientific evidence reporting carcinogenicity and neurotoxicity; and given the WHO IARC classification of both EMF and RFR as Possible Human Carcinogens (Group 2B). It is also important to underscore that the combined effects of chemical carcinogens and EMF have been shown to be synergistic – the combined effects are more damaging than either chemical or EMF exposures alone (Juutilainen J Kumlin T Naarala J. 2006 Do extremely low frequency magnetic fields enhance the effects of environmental carcinogens? A meta-analysis of experimental studies. Ing J Radiat Biol 82: 1-12.). Thus, the study of both chemical and EMF/RFR workplace exposures is of critical importance to a full picture of health risks. 1) NIOSH should take steps to evaluate workplace exposure to emissions from digital communications (cell phones and cordless phones - particularly those with DECT-radiating bases that are constant radiofrequency emitters, wireless computers, WI-FI and wireless networking devices and tablet devices that are often required in the workplace and have the potential to increase cancer and other health risks for workers, and possibly for their offspring. The Team Document (at NORA 10 Years, pages 49-50) suggests that NIOSH already recognizes the potential for EMF/RFR exposures to cause health harm at an unprecedented scale for workers. *"Today, almost everyone owns a cellular telephone. Cellular phones were "a science-based technology that created a new industry or radically transformed an existing one." This is the definition of an "emerging technology." The societal and industrial consequences of such technologies are often positive. However, since their development outpaces the understanding of their implications, they may pose new, unanticipated hazards. The cellular phone*	*The commenter provided conclusions from the BioInitiative 2007 and 2012 Reports on electromagnetic fields and radio frequency radiation. This policy relates to chemical carcinogens only. Consideration of EMF is beyond the scope of this document. This comment will be shared with management and researchers in NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
	was implicated as a causative agent in human brain cancers. As a result, millions of research dollars were expended pursuing an answer. While debate ensued, research was conducted, but individuals continued to be exposed. Should exposure to cellular phones prove to be linked to human brain cancer, costs will be incalculable." *"Formed in 1996, the NORA Emerging Technologies Team knew that a situation similar to the cellular phone story could unfold in occupational safety and health. Charged with protecting workers, the team faced the conundrum of designing prevention strategies for something that has not yet happened, is unanticipated, and absent of noticeable consequences. The team recognized that a new paradigm that moved from controlling identified hazards to anticipating, eliminating, or controlling the hazard before causing harm was imperative."*	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, Styrene Information and Research Center (SIRC)	The Styrene Information and Research Center (SIRC) appreciates the opportunity to submit comments on the National Institute for Occupational Safety and Health's (NIOSH) draft Current Intelligence Bulletin: Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace (Nov. 15, 2013) (Draft 2013 Cancer Policy). We support NIOSH's effort to update its 1978 and 1995 policies to reflect developments in cancer research and chemical classification. In the attached comments, we urge NIOSH to significantly modify the draft policy to more effectively advance the goals of the Occupational Safety and Health Act (OSH Act) by embracing the globally recognized state of the art in chemical classification. SIRC's primary concern is NIOSH's proposal to accept the carcinogenic determinations of the U.S. Environmental Protection Agency (EPA), the International Agency for Research on Cancer (IARC), and the U.S. National Toxicology Program (NTP) without question. This includes NIOSH's proposal to develop informational Globally Harmonized System for Labeling and Classification of Chemicals (GHS) classifications based on EPA, IARC, and NTP determinations even though these organizations do not apply the GHS framework for chemical classification. SIRC believes that NIOSH's commitment to the principles of evidence-based science, responsible public policy, and its obligations under the OSH Act will be significantly compromised if the Draft 2013 Cancer Policy is not revised to address these and the other concerns raised in our comments. In cooperation with NIOSH, in 2012, the Occupational Safety and Health Administration (OSHA) adopted the revised Hazard Communication Standard as the exclusive chemical classification regime for all actions taken by OSHA or NIOSH pursuant to the authority of the OSH Act. The OSH Act does not permit NIOSH to delegate its statutory responsibilities to other domestic or foreign	*NIOSH will use the determinations of other agencies as the starting point of its assessments to avoid redundancy and duplication of effort. For each chemical that NIOSH assesses, additional important occupational information, data, and recommendations will be collected and assessed as the basis of recommendations for the control of workplace exposures.*

Commenter/Topic	Public Comment	*NIOSH Response*
	government agencies. That is exactly what NIOSH would be doing if it were to adopt, without question, cancer classification determinations made by EPA, IARC or NTP. Furthermore, NIOSH would undermine its institutional importance by doing so. Congress assigned to NIOSH the responsibility for developing and implementing criteria to determine whether chemicals pose particular hazards, not merely to determine whether chemicals identified as posing a particular hazard by another agency have occupational relevance. OSHA is capable of concluding that a chemical has relevant occupational exposures, and if NIOSH's role were to be reduced to this task, as suggested in the Draft 2013 Cancer Policy, then the justification for the involvement of both NIOSH and OSHA in the development of occupational safety and health protections under the statute would be greatly diminished. SIRC urges that NIOSH reconsider the Draft 2013 Cancer Policy and amend the document consistent with our comments. The revised policy should then be republished for public comment and peer review.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	Guided by cutting-edge research and scientific analysis, protection of worker safety and health is a cornerstone of SIRC's mission. SIRC has, and will continue, to support advancements made by NIOSH and the U.S. Occupational Safety and Health Administration (OSHA) to prevent occupational injuries, illnesses, and death.3 We therefore support NIOSH's effort to update the Institute's 1978 and 1995 policies to reflect developments in cancer research and chemical classification.4 SIRC submitted comments to NIOSH in December 2011 when NIOSH requested public input on its approach to classifying carcinogens and establishing recommended exposure limits (REL) for occupational exposures to hazards associated with cancer. We are pleased to comment further on NIOSH's Draft 2013 Cancer Policy with the hope that it will be significantly modified to more effectively advance the goals of the Occupational Safety and Health Act (OSH Act).	*No response required.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	A. OSHA's Authority to Adopt an "Occupational Safety and Health Standard," such as a PEL, is Subject to OSHA Satisfying the Applicable Legal Criteria Established by Sections 3(8), 6(b)(5) and 6(f) of the OSH Act Section 3(8) of the Occupational Safety and Health Act (OSH Act) defines an occupational safety and health standard as: A standard which requires conditions, or the adoption or use of one or more means, methods, operations, or processes, reasonably necessary or appropriate to provide safe and healthful employment and places of employment. Section 6(b) of the OSH Act provides that: The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility [emphasis added] of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired. Further, Section 6(f) of the OSH Act provides that:	*No response required.*

Commenter/Topic	Public Comment	*NIOSH Response*
	The determinations of the Secretary shall be conclusive if supported by substantial evidence [emphasis added] in the record considered as a whole.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	Based on these statutory provisions, OSHA is authorized to adopt a health standard, pursuant to Sections 3(8) and 6(b) of the OSH Act, to address those identified workplace hazards that are shown to pose a significant risk of harm – sometimes referred to as a material impairment of health or functional capacity. Generally, to sustain a standard on judicial review as being reasonably necessary and appropriate, OSHA must demonstrate the following: a) Current workplace exposure levels to the identified hazards pose a significant risk of harm to the workers who would be covered by the standard;57 b) The proposed requirements would significantly or materially reduce the workplace risk to workers exposed to those identified hazards; c) The proposed requirements are technically and economically feasible and within the bounds of what are reasonable for each industrial sector; d) The proposed requirements are the most cost-effective approach for achieving the reduction in risk by those identified hazards; and e) For health standards dealing solely with harmful physical agents, the standard must, to the extent feasible and within reasonable bounds, reduce workplace exposures to a level below that which presents a significant risk of material impairment of health or functional capacity to employees. Based on the foregoing, OSHA's authority to adopt an Occupational Safety and Health Standard, such as a PEL, is subject to OSHA satisfying the legal criteria established by Sections 3(8), 6(b)(5) and 6(f) of the OSH Act.	*The commenter has provided information about OSHA regulatory requirements. NIOSH is a research agency and not subject to these same requirements.*

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	B. Section 20 of the OSH Act Directs NIOSH to Develop Criteria Enabling OSHA to Meet its Responsibilities, and Section 22 Authorizes NIOSH to Develop and Establish Recommended Occupational Safety and Health Standards Section 20(a) of the OSH Act directs NIOSH to develop and publish criteria identifying toxic substances, which will enable OSHA to meet its responsibility for the formulation of safety and health standards under the OSH Act. Specifically, Section 20(a) of the OSH Act directs the Secretary of Health and Human Services or NIOSH to perform the following research functions: (2) … consult with [OSHA] … to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling [OSHA] to meet [its] responsibility for the formulation of safety and health standards under this Act; and . . . on the basis of such research, demonstrations, and experiments and any other information available . . . develop and publish at least annually such criteria as will effectuate the purposes of this Act. (3) … on the basis of such research, demonstrations, and experiments, and any other information available … develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience. Furthermore, Section 22 of the OSH Act authorizes NIOSH to perform the following functions: (c)(1) develop and establish recommended occupational safety and health standards; (d)(1) conduct such research and experimental programs as … are necessary for the development of criteria for new and improved occupational safety and	*NIOSH will use the determinations of other agencies as the starting point of its assessments to avoid redundancy and duplication of effort. For each chemical that NIOSH assesses, additional important occupational information, data, and recommendations will be collected and assessed as the basis of recommendations for the control of workplace exposures. This policy is consistent with the NIOSH mandate of the Occupational Safety and Health Act.*

Commenter/Topic	Public Comment	*NIOSH Response*
	health standards, and (d)(2) after consideration of the results of such research and experimental programs make recommendations concerning new or improved occupational safety and health standards. NIOSH recently described its responsibilities for developing occupational safety and health standards under the OSH Act as follows:58 Through the Act, Congress charged NIOSH with [1] recommending occupational safety and health standards and [2] describing exposure levels that are safe for various periods of employment, including but not limited to the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy as a result of his or her work experience. Therefore, the OSH Act does not permit NIOSH to delegate those statutory responsibilities to other domestic government agencies (i.e., EPA and NTP) or any foreign government or international agency (i.e., IARC). The proposed policy erroneously implies that, other than validating potential worker exposure, NIOSH has no expertise or role to play in determining whether a substance is an occupational carcinogen. This is contrary to its statutory mandate.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	C. Current NIOSH Practice Makes Ineffective Use of its Authority and does not Provide OSHA with Criteria that Effectively Enable OSHA to Meet Its Responsibility As noted above, through the OSH Act, "Congress charged NIOSH with recommending occupational safety and health standards." That means Congress charged NIOSH with recommending "occupational safety and health standards" as that term is used in the OSH Act and interpreted by the decisions of the U.S. Supreme Court. The term cannot mean one thing for NIOSH and another for OSHA. For both NIOSH and OSHA, this term refers to mandatory control measures that are technically, analytically and economically feasible, whether the measure is a standalone PEL, or a PEL in a comprehensive substance-specific standard that includes a PEL, an action level and the traditional ancillary requirements. In those cases when NIOSH develops data of the type described above to support economic feasibility, the process of developing a health standard would be far more cost-effective if NIOSH recommendations were based on an integrated technical and economic feasibility analysis rather than providing a health effects analysis and risk assessment, and a technical feasibility analysis. The term "research" is not limited to reviewing toxicological studies and performing risk assessments.59 It also includes researching whether recommended control measures are technically and economically feasible. If NIOSH develops data to support economic feasibility, what is needed from NIOSH is an integrated technical and economic feasibility analysis based on the best available data. Under the current OSHA rulemaking process, OSHA, either directly or through a contractor, takes years to collect and analyze the minimum amount of data it believes is necessary to support a proposed rule. Industry then has only the relatively short time allowed by the rulemaking to	*NIOSH research and policy recommendations provide science-based recommendations for OSHA to consider in its rule-making process. NIOSH does not conduct full economic analyses as part of its criteria documents or current intelligence bulletins.*

Commenter/Topic	Public Comment	*NIOSH Response*
	organize and collect additional data. Agencies cannot expect industry to be continuously collecting and updating data from the time a NIOSH criteria document is issued.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	Rather than continuing the current inefficient division of labor, when NIOSH develops data of the type described above to support economic feasibility, NIOSH could facilitate and manage the operation of stakeholder groups working to prepare pre-rulemaking documents somewhat how the California Division of Occupational Safety and Health supports the development of health standards by the California Standards Board. The pre-rulemaking process and documents generated from it would provide OSHA a head start in promulgating a standard by: o Summarizing and incorporating stakeholder-provided data on hazards, exposures, risk assessment and the technical and economic feasibility of various compliance options (rather than theoretical control measures) into its recommendations; o Summarizing relevant NIOSH-sponsored research or analysis, conducted to fill in data gaps on hazards and exposures, identify and characterize compliance options (rather than theoretical control measures), and/or evaluate their technical and economic feasibility; o Identifying points of agreement among stakeholders; and o Identify points of disagreement that will need to be resolved by OSHA during formal rulemaking. Pre-rulemaking documents also could serve as a resource for employers during the time it takes OSHA to promulgate final rules. SIRC believes, at a minimum, NIOSH must address technical feasibility in a meaningful way that advances the cooperative development of occupational safety and health standards, or not at all, rather than suggesting theoretical approaches that create false expectations as to what is feasible. In those cases	*NIOSH will consider analytical feasibility when developing Risk Management Limits for carcinogenic chemicals. It will no longer consider engineering achievability but engineering control information will be provided.*

Commenter/Topic	Public Comment	*NIOSH Response*
	where NIOSH meaningfully addresses technical feasibility, we also believe it is critical for NIOSH, in cooperation with OSHA and all stakeholders, to effectively address economic feasibility. The examination of technical feasibility independent of economic feasibility tends to become an academic exercise that generates impractical if not misleading conclusions.	

Commenter/Topic	Public Comment	*NIOSH Response*
Jack Snyder, (SIRC)	Again, SIRC supports NIOSH's efforts to update its Cancer Policy. We understand that NIOSH is trying to identify ways that it can more efficiently evaluate chemicals for carcinogenicity and occupational relevance. That said, the OSH Act does not permit NIOSH to adopt, on face value, cancer classification determinations made by EPA, IARC or NTP. Doing so, NIOSH would undermine its institutional importance. Congress assigned to NIOSH the responsibility for developing and implementing criteria to determine whether chemicals pose particular hazards, not merely to determine whether chemicals identified as posing a particular hazard by another agency have occupational relevance. OSHA is capable of concluding that a chemical has relevant occupational exposures, and if NIOSH's role were to be reduced to this task, as suggested in the Draft 2013 Cancer Policy, then the justification for the involvement of both agencies in the development of occupational safety and health protections under the statute would be greatly diminished. Instead, NIOSH has statutory duties under Section 20 and 22 of the OSH Act because of the need for scientific depth and review. The Draft 2013 Cancer Policy would unlawfully relinquish and delegate much of that responsibility to other agencies and make NIOSH less relevant to the overall occupational protection process. SIRC recommends that NIOSH reconsider this Draft Cancer Policy and amend the document consistent with our comments, which are based on evidence-based science, sound public policy and the applicable law, and republish it for public comment and appropriate peer review.	*The NIOSH chemical carcinogen policy is consistent with the NIOSH mission and the OSHA Act. NIOSH will reduce duplication of effort within the U.S. Government by considering the chemical hazard identification information provided by other agencies. NIOSH will conduct its own, independent assessment of occupational relevance and make workplace recommendations.* *The NIOSH proposed recommendations for each specific chemical assessment will be available for peer and public review. NIOSH considered the SIRC comments, and all of the submitted comments, in the final version of the document. The NIOSH policy development process followed OMB, CDC, and NIOSH policies and procedures.*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	Include the number of chemicals listed as carcinogens by IARC as was done with the other two classification systems (page 17, line 6).	*The text was revised to focus on the procedures each agency uses rather than the number of chemicals listed as carcinogens.*

Commenter/Topic	Public Comment	*NIOSH Response*
Pete Stafford, (BCTD)	We support NIOSH's proposed use of IARC, EPA and NTP assessments of carcinogenicity, and believe that this will minimize duplication of effort. NIOSH guidance on specific risk phrases that are consistent with GHS as used in hazard communication is also critical for reducing conflicting messages on Safety Data Sheets and labels, and reducing the confusion associated with the current NIOSH policy which uses "potential human carcinogen" as the only category.	*As stated in the document, "NIOSH has decided to continue its approach of using one label for classifying all known and suspected chemical carcinogens. Although NIOSH recognizes the value of a tiered system in carcinogen classification for hazard communication, in practice, once a chemical has been designated a potential occupational carcinogen, the NIOSH risk management guidance has been the same. Therefore, NIOSH has decided not to adopt another tiered system as, without changing the NIOSH recommended risk management approach, it would complicate and confuse the process of carcinogen classification." In addition, "The NIOSH process for developing GHS classifications has been removed from this policy for further analysis and development. NIOSH will use the GHS criteria for carcinogenicity when developing new chemical carcinogen classifications.*
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	Section 3.0 is a helpful carcinogen classification review; however, this would be more effective as an appendix and not in the main body of the draft policy. Much of sections 5.2-5.3 would also be a good candidate for an appendix and not in the main body of the policy.	*The final version of this document has been simplified and reorganized.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
Christopher Lish and Physicians for Social Responsibility (PSR)	On a daily basis, workers can be exposed to cancer-causing substances in the workplace. They need a workplace policy that affords them the utmost protection from these hazardous substances. The National Institute for Occupational Safety and Health's (NIOSH) proposed update to its carcinogen policy should include the following core principles: The NIOSH's updated carcinogen policy should advance the prevention of cancer in all workplaces by employing the latest science and promoting the elimination of known carcinogens.	*As stated in the document, "Underlying this policy is the recognition that there is no safe level of exposure to a carcinogen, and therefore that reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer. Accordingly, this policy no longer uses the term recommended exposure limit (REL) for chemical carcinogens; rather NIOSH will only recommend an initial starting point for control, called the Risk Management Limit for Carcinogens (RMLCA). For each chemical identified as a carcinogen, this level corresponds to the 95% lower confidence limit of the risk estimate of one excess cancer case in 10,000 workers in a 45-year working lifetime. Keeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended."*
Tony Stefani, San Francisco Firefighters Cancer Prevention Foundation (SFFCPF)	Firefighters risk their lives everyday, not just from flames, smoke and building collapse. In fact the larger toll on our numbers comes from the various cancers that have taken so many from our ranks. Firefighters have a higher rate than the general public (2013 NIOSH FireFighter Cancer Study) and we firmly believe these cancers are the result of the toxic chemical environment we are exposed to at each and every working fire.	*When NIOSH assesses a chemical, it assesses the available information on its effects on all workers, including firefighters. More NIOSH information about cancer and firefighters, including the NIOSH research study, is available at http://www.cdc.gov/niosh/firefighters/cancer.html*

Commenter/Topic	Public Comment	*NIOSH Response*
		NIOSH also has a program dedicated to the investigation of firefighter line-of-duty deaths, the NIOSH Fire Fighter Fatality Investigation and Prevention Program.
Edward J. Klinenberg, Ph.D., CIH , (CIHC)	The CIHC believes the revised policy is positive for the following reasons: • Health based RELs - The decision to establish risk-based RELs based on health effects (vs. integrating a feasibility component at this stage) is the correct approach. • Use of the three existing US and international carcinogen classifications (NTP, EPA, and IARC) -The new classification policy proposes using the assessment schemes used by the NTP, EPA and IARC to enhance harmonization and keep NIOSH from reinventing the wheel. The use of existing qualified databases is scientifically appropriate and cost effective, as is the proposed methodology for determining RELs for carcinogens that are occupationally relevant. • Mechanism for setting a recommended exposure limit (REL), which can be no lower than a statistically valid limit of quantification (LOQ) for the analytical method. • Inclusion of a pathway for relating occupational carcinogen RELs to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). • Clarified flow charts • Decision to include “to the extent feasible”, projecting not only a no-effect exposure, but also exposure levels at which there may be no residual risks. This document is an important step in providing health and safety professionals, employers and worker organizations the knowledge and rationale for minimizing the risk of cancer in the workplace – an important leadership role for NIOSH.	*NIOSH appreciates this positive feedback. However, the NIOSH process for developing GHS classifications has been removed from this policy for further analysis and development. NIOSH will use the GHS criteria for carcinogenicity when developing new chemical carcinogen classifications. NIOSH also notes that the text has been simplified and the figures have been dropped from the document for clarity.*

Commenter/Topic	Public Comment	*NIOSH Response*
Anna Mazzucco, National Research Center for Women and Families (NRCWF)	We thank the National Institute for Occupation Safety and Health for the opportunity to provide feedback on their draft intelligence on carcinogen classification and target risk level policy. Americans rely on these policies to safeguard them from environmental causes of cancer. According to the American Cancer Society, in 2013 alone, more than half a million Americans will die from cancer, thus the gravity of this issue cannot be overstated. A joint 2003 report from the National Cancer Institute and the National Institute for Environmental Health Sciences stated that "exposure to a wide variety of natural and man-made substances in the environment accounts for at least two-thirds of all the cases of cancer in the United States." Yet after reviewing the current state of regulatory policy and research efforts, the President's Cancer Panel reported in 2010 that they were, "particularly concerned to find that the true burden of environmentally induced cancer has been grossly underestimated " and that "environmental health, including cancer risk, has been largely excluded from overall national policy on protecting and improving the health of Americans". When notorious and decades-known carcinogens such as asbestos and radon are still present at unsafe or unknown levels in American workplaces, how can the public have confidence that current regulations can handle new and complex occupational hazards arising every day? Indeed, as only a few hundred out of more than 80,000 chemicals in use in the United States have been tested for safety, such concerns are justified. Current regulatory policy also has weighty and underappreciated economic ramifications. The National Institutes of Health estimated the total cost of cancer in 2008 at 201.5 billion dollars in both direct health care costs and the indirect cost of lost productivity due to premature deaths. Another recent study estimated that cancer is responsible for 20 percent of all health care spending, and considering disability days alone, costs 7.5 billion dollars in lost productivity each year. These figures do not include the billions of dollars being spent by the U.S. government on court settlements and compensation	*NIOSH appreciates this information about cancer in the United States and the support for updating the NIOSH policy.*

Commenter/Topic	Public Comment	*NIOSH Response*
	payments for victims who were exposed to carcinogens from nuclear and other military testing where they lived or worked in Nevada, Arizona, Utah, the Marshall Islands, and other locations, with many legal battles still ongoing. Furthermore, as the global market shifts towards developing economies with new environmental concerns, and as American consumers are increasingly concerned about product safety, with large companies such as Kaiser Permanente, Target and Walmart taking action, the ability to compete in emerging technologies such as "green chemistry" is not just a moral, but also an economic imperative.	

Commenter/Topic	**Public Comment**	***NIOSH Response***
Anna Mazzucco, (NRCWF)	Current regulatory policy also has weighty and underappreciated economic ramifications. The National Institutes of Health estimated the total cost of cancer in 2008 at 201.5 billion dollars in both direct health care costs and the indirect cost of lost productivity due to premature deaths. Another recent study estimated that cancer is responsible for 20 percent of all health care spending, and considering disability days alone, costs 7.5 billion dollars in lost productivity each year. These figures do not include the billions of dollars being spent by the U.S. government on court settlements and compensation payments for victims who were exposed to carcinogens from nuclear and other military testing where they lived or worked in Nevada, Arizona, Utah, the Marshall Islands, and other locations, with many legal battles still ongoing. Furthermore, as the global market shifts towards developing economies with new environmental concerns, and as American consumers are increasingly concerned about product safety, with large companies such as Kaiser Permanente, Target and Walmart taking action, the ability to compete in emerging technologies such as "green chemistry" is not just a moral, but also an economic imperative.	*NIOSH appreciates this information and the support for updating the NIOSH policy.*

Commenter/Topic	**Public Comment**	***NIOSH Response***
John Schweitzer, American Composites Manufacturers Association (ACMA)	The composites industry and the NIOSH carcinogen policy As primarily smaller companies, composites manufacturers rely on authorities such as NIOSH to assess workplace hazards and recommend appropriate exposure limits. Both the health of our industry's employees and the continued viability of our small manufacturers depend on NIOSH fully assessing relevant data and reaching the most scientifically valid conclusions regarding workplace risks. Styrene, an essential component of the resins used safely for over 60 years to make fiber-- reinforced polymer composite products, provides a productive example of the challenges likely to be faced by NIOSH as it evaluates the potential carcinogenic effect of workplace substances. Some authorities such as the National Toxicology Program have registered a cancer concern for styrene, but others such as the European Chemicals Agency (ECHA), the Danish EPA and the Texas Commission on Environmental Quality have come to the opposite conclusion.	*Although NIOSH cannot comment at this time on the carcinogenicity of specific chemicals, as stated in the document, "NIOSH will evaluate whether the chemical is likely to pose a risk in the occupational environment and whether the data underlying the cancer classification is applicable to the occupational setting. NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation. This is because there are likely only very rare instances in which a chemical classified as a carcinogen by NTP, EPA, or IARC would not also be potentially carcinogenic to exposed workers. NIOSH will consider the issues described below in deciding whether a chemical is relevant to the occupational environment."*

Commenter/Topic	Public Comment	*NIOSH Response*
Janet Newton, EMRadiation Policy Institute	EMRPI continues to challenge the inadequacy of the US safety policy on electromagnetic and radiofrequency (RF) radiation exposures by submitting official comment to key federal agencies. EMRPI's record of formal comment as individuals and through our organization dates back to 1997. It includes official comment to key federal agencies such as the NAS, FCC, FDA, GAO, NIOSH, NTIA and DOJ. In 2006, NIOSH sought input for setting agenda of the next ten years of its National Occupational Research Agenda (NORA), its "collaborative program to stimulate innovative research in workplace safety and health." Of importance is this statement found at pp. 49-50 of NORA 10 Years: The Team Document, pp. 49-50: Today, almost everyone owns a cellular telephone. Cellular phones were "a science-based technology that created a new industry or radically transformed an existing one." This is the definition of an "emerging technology." The societal and industrial consequences of such technologies are often positive. However, since their development outpaces the understanding of their implications, they may pose new, unanticipated hazards. The cellular phone was implicated as a causative agent in human brain cancers. As a result, millions of research dollars were expended pursuing an answer. While debate ensued, research was conducted, but individuals continued to be exposed. Should exposure to cellular phones prove to be linked to human brain cancer, costs will be incalculable. Formed in 1996, the NORA Emerging Technologies Team knew that a situation similar to the cellular phone story could unfold in occupational safety and health. Charged with protecting workers, the team faced the conundrum of designing prevention strategies for something that has not yet happened, is unanticipated, and absent of noticeable consequences. The team recognized that a new paradigm that moved from controlling identified hazards to anticipating, eliminating, or controlling the hazard before causing harm was	*This policy focuses on chemical carcinogens in the workplace. Consideration of the carcinogenicity of EMF is beyond the scope of this document; however we will share your concerns with management and researchers at NIOSH.*

Commenter/Topic	Public Comment	*NIOSH Response*
	imperative. Surveillance was absolutely essential in moving from a passive to an anticipatory mode. Predictive capacities for evaluating hazards would be responsive to rapid transformations occurring during the design of new technologies. The new paradigm would overcome the litigious and time-consuming delays in current risk assessments, and would recognize both the benefits and negative effects of emerging technologies. Finally, a proactive design for emerging technologies must consider how to eliminate hazards rather than just control them. (Emphasis added.) EMRPI sponsored participants to attend the NIOSH National Occupational Research Agenda (NORA) Symposium held in Washington, DC in April 2006. EMRPI also filed written Comment. See Appendix A. (To see their written comment please view EMR (NORA)-PC11) At EMRPI's request, Senator Patrick Leahy of Vermont also weighed in with a letter to NIOSH Director John Howard, M.D., M.P.H., J.D., LL.M., and NORA Director Sidney C. Soderholm, PhD, http://www.emrpolicy.org/news/headlines/18sep06_leahy_nora_letter.pdf identifying long-term continuous workplace exposure to low-intensity EMFs and RF radiation as a top priority for federal research funds. The response letter to Senator Leahy from Julie Louise Gerberding, MD, MPH (http://www.emrpolicy.org/news/headlines/cdc_response_to_leahy.pdf) then-Director of the Department of Health and Human Services, discusses two studies in which NIOSH has participated that examine workplace EMF and RF exposures and cancer. One of those studies was the multi-national Interphone Study.	

Commenter/Topic	Public Comment	*NIOSH Response*
Leo Petrilli	Federal Code of Regulations (UNITED STATES) TITLE 29 - Labor OCCUPATIONAL HEALTH AND SAFETY ACT- 1970, §§ 013 (1990) IDENTIFICATION, CLASSIFICATION, AND REGULATION OF POTENTIAL OCCUPATIONAL CARCINOGENS - GENERAL POTENTIAL OCCUPATIONAL CARCINOGEN Means any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and the onset of neoplasms in humans or in one or more mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals. KEYWORDS Exposure and the onset of neoplasms in humans or in one or more mammalian species as the result of any oral, respiratory or dermal exposure. www.gpo. gov/fdys/pkg!CFR-20 l 2-title29-vol9/xml/CFR-20 l 2-title29-vol l 9-sec 19. November 5, 2013 - External Review Draft Current Intelligence Bulletin. Update of National Institute for Occupational Safety and Health (NIOSH) Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace.	*No response required.*