February 13, 2014

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Dear Dr. Schulte:

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 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.

Sincerely,

Jack Snyder
Executive Director

cc: John Howard, MD, Director
National Institute for Occupational Safety and Health

Enclosure
COMMENTS

OF THE

STYRENE INFORMATION AND RESEARCH CENTER, INC.

ON

NIOSH DRAFT “CURRENT INTELLIGENCE BULLETIN: UPDATE OF NIOSH CARCINOGEN CLASSIFICATION AND TARGET RISK LEVEL POLICY FOR CHEMICAL HAZARDS IN THE WORKPLACE”

Docket Number CDC–2013-0023; NIOSH 240-A

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Table of Contents

I. Introduction and Summary .................................................................................................................................................. 5

II. NIOSH’s Cancer Policy Must Support Application of the Best and Most Relevant Science ................................................................. 3
   A. EPA, NTP and IARC Cancer Classifications Fail to Meet NIOSH’s Best Science Criteria .................................................................. 4
      1. EPA IRIS ............................................................................................................................................................................ 5
      2. NTP Report on Carcinogens ................................................................................................................................................. 7
      3. IARC .................................................................................................................................................................................... 7
   B. Pursuant to HCS 2012, NIOSH May Only Use NTP, EPA and IARC Classifications as a Reference ..................................................... 8
   C. NIOSH Must Consider Mechanistic Data ............................................................................................................................... 9
   D. NIOSH’s Determinations Must be Based on Weight of Evidence ............................................................................................ 9

III. NIOSH’s Cancer Policy Must Be Consistent with HCS 2012 ...................................................................................... 12
   A. NIOSH Supports GHS and Should Apply It .......................................................................................................................... 12
   B. Impact of the GHS Amendments to the HCS ......................................................................................................................... 14
      1. HCS 2012 Requires Weight of Evidence ............................................................................................................................ 14
      2. OSHA HCS 2012 Precludes Blind Deference to NTP and IARC ......................................................................................... 15
      3. NIOSH’s GHS Classifications, If Based on IARC and NTP Classifications, are Likely to Cause Conflicts and Confusion .............................................. 16

IV. NIOSH Will Fail to Meet its Statutory Obligations if NIOSH’s Policy on RELs is not Consistent with OSHA’s Policy on PELs ........................................................................... 16
   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 ......................................................................................................................... 18
   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 ......................................................................................................................... 19
   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 ......................................................................................................................... 20

V. Align the Draft Policy Narrative and Figure 1 ..................................................................................................................... 21

VI. Conclusion ........................................................................................................................................................................ 22
I. Introduction and Summary

The Styrene Information and Research Center (SIRC) appreciates the opportunity to submit comments on the draft Current Intelligence Bulletin: Update of NIOSH Carcinogen Classification and Target Risk Level Policy for Chemical Hazards in the Workplace issued by the National Institute for Occupational Safety and Health (NIOSH or Institute) on November 15, 2013 (Draft 2013 Cancer Policy). SIRC was formed in 1987 as the principal focal point for public information and research on styrene. Since its founding, the total cost of SIRC-sponsored toxicological research on styrene exceeds $20 million. SIRC’s commitment to science has produced a credible, reliable—and still growing—information resource for regulatory and private decision-making.2

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).

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2 SIRC is a non-profit organization consisting of voting member companies involved in the manufacturing or processing of styrene, and associate member companies that fabricate styrene-based products. Collectively, SIRC’s membership represents approximately 95% of the North American styrene industry. SIRC serves as a liaison between industry, federal and state governments, and international agencies on health-related issues involving styrene.

3 SIRC has worked cooperatively with OSHA, including the promotion of voluntary worker exposure standards more stringent than the current PEL. After an OSHA rule that would have lowered the styrene PEL to 50 ppm was struck down by a U.S. appeals court in 1992, SIRC and several other associations representing manufacturers of styrene-based products encouraged industry to adopt a 50-ppm exposure guideline. In 1996, OSHA endorsed the styrene industry’s voluntarily 50-ppm exposure level guideline. In 2011, based on new industry-sponsored research indicating mild and subtle hearing loss in long-term workers (15-26 years’ employment), SIRC (along with the European Styrene Producers Association and the Japanese Styrene Industry Association) recommended that the guideline be reduced to 20 ppm. While SIRC’s recommendation has a different basis, it is consistent with the current American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLV®).

4 Draft 2013 Cancer Policy at 3. See also, NIOSH 1978b and NIOSH 1995b, as referenced in the proposal.
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.

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 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 expediency. 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.

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.”

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.

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 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

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6 Hearing Transcript at p. 37.
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.

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. Furthermore, we note that, during the existence of NTP, nine NTP listings have been determined to be inappropriate and withdrawn.

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. 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 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

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criteria used by NTP, and the application of those criteria, reflect science best practices. 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.

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.

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.

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

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10 The National Research Council of NAS, at the request of the Department of Health and Human Services, has undertaken a scientific peer review of the determinations concerning formaldehyde and styrene in the NTP’s 12th Report on Carcinogens (RoC). The review will also consider whether NTP's listing criteria are scientifically defensible.


12 SIRC also supports NIOSH’s plan to obtain peer review of the policy in accordance with the NIOSH Charge to Peer Reviewers, available at http://www.cdc.gov/niosh/review/peer/HISA/carcinogen-pr.html.
of 2013 and 2014. 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.

The current IRIS database has a total of 557 existing IRIS assessments that were performed since its origin in 1987. 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).

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.

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. 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.

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13 See http://cfpub.epa.gov/ncea/iristrac/index.cfm
14 Compare the IRIS track to the current list of IRIS chemicals at http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList
15 Id.
16 EPA footnotes the column labeled as “last Significant Revision” in its IRIS table as follows: “Refers to the most recent statement of or change to a toxicity value [RfD, RfC, slope factor or unit risk], or most recent significant statement of or change to the basis or justification for the conclusions in the assessment. This column is provided for the convenience of the IRIS user. For specific information, see the Revision History for each substance.
17 Id.
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.” 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. 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.

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. 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.” 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.” Accordingly, NIOSH cannot adopt an IARC

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21 See http://www.niehs.nih.gov/health/topics/agents/sya-roc/


23 *Id.*

carcinogenicity determination without performing its own review of the science underlying those determinations and applying the WOE principles as established by HCS 2012.

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.” 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. 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 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

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26 See also comments of Dr. Schulte during December 16, 2013, public meeting: “we have viewed these three agency reviews as all sufficient quality to be part of our determination and we don’t intend to rethink their determination. So we will accept them at face value.”
As both a proponent and user of HCS 2012 to classify chemicals, NIOSH should base its updated Cancer Policy on the HCS 2012 framework.

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.

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. 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.


30 A committee of the NRC will assess the scientific, technical, and process changes being implemented by the U.S. Environmental Protection Agency for its Integrated Risk Information System. 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.

31 GAO High Risk Series (February 2013), available at http://www.gao.gov/assets/660/652133.pdf, found that EPA has not fully addressed recurring issues concerning the clarity and transparency of its development and presentation
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”.  

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 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.  

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.”

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.  Under HCS 2012, manufacturers and importers are required to “consider the full range of available scientific literature and other evidence concerning the potential hazards,” and then apply the applicable classification criteria in Appendix A to Section 1910.1200 under a weight of evidence analysis.  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

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32 Comments of Dr. Schulte, December 16, 2013, public meeting.  
33 See http://ntp.niehs.nih.gov/?objectid=07027D0E-E5CB-050E-027371D9CC0AAACF (emphasis added).  
34 This statement is found in the "automatic" transcript produced by NTP.  
37 29 C.F.R. § 1910.1200, A.0.3 (Classification based on Weight of Evidence).
OSHA’s approach helps avoid the confusion and debate that the terms “strength of evidence” and “weight of evidence” have prompted in other contexts. It also avoids the inherent bias under the NTP toward the presentation of “positive studies”. 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”. 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.

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 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 the scientific evidence is the most current and supports the assigned classification under a WOE evaluation.

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38 77 Fed. Reg. at 17,683 (emphasis added).
40 Under HCS 2012, there is no referenced floor of chemicals deemed to be hazardous chemicals or deemed to pose a particular hazard. Instead, Appendix A provides specific, detailed criteria for each type of health hazard to guide the evaluation of relevant data and subsequent classification of the chemical. Reliance on the detailed and comprehensive classification criteria developed through the GHS international collaborative process means that, except for chemicals identified as potential carcinogens by OSHA through a substance-specific rulemaking, there no longer is a requirement to rely on a cancer determination or any type of chemical hazard determination produced by a governmental agency (such as NTP or IARC) or a non-governmental organization (such as a chemical manufacturer). Under HCS 2012, NTP’s RoC and IARC’s Monographs do not dictate a classification. NTP and IARC are specifically discussed under Appendix F to Section 1910.1200, a non-mandatory section of the rule, which is titled Guidance for Hazard Classification Re: Carcinogenicity (Non-Mandatory).
42 Id.
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, particularly since it intends to publish GHS classifications for those chemicals that it finds to be occupationally relevant.

A. NIOSH Supports GHS and Should Apply It

NIOSH worked through 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. In those comments, NIOSH concluded that the detailed classification criteria of the GHS provided a “significant advantage” in that they:

  (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

45 The NIOSH comments included the following discussion:

Development of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) addressed the need for easily understood information and maintenance of the level of protection offered by its hazard communication system. There is a rich history of unified approaches with broad global utility. These include standards developed by the International Organization for Standardization (ISO) and the American National Standards Institute (ANSI). NIOSH concurs with the expected occupational safety and health benefits of the proposed HCS harmonized with the GHS [NIOSH 2006] as discussed in the preamble to the PR. 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...

NIOSH believes that the proposed modifications to the HCS would align the standard to the GHS approach, and thus do not require the floor of chemicals or the universal one-study rule to achieve the same level of protection as the current standard.
(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 . . .

- 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

46 29 C.F.R. Part 1990, titled “Identification, Classification, and Regulation of Potential Occupational Carcinogens,” is commonly referred to as the OSHA Cancer Policy. The OSHA Cancer Policy does not reflect accepted scientific principles such as the weight-of-evidence analysis and mode of action considerations (see, for example, 29 CFR 1990.144(f), Indirect mechanisms), and it is in direct conflict with the GHS with respect to those principles. Furthermore, that policy is in direct conflict with decisions of the U.S. Supreme Court (Benzene and Cotton Dust), which establish the principle that OSHA may only regulate risks shown to be significant and may not establish a PEL of zero (“no occupational exposure level”) as called for in 29 CFR 1990.146(k). It is unclear why OSHA did not propose to amend or withdraw the OSHA Cancer Policy when it initiated the GHS rulemaking, and unclear how OSHA plans to address the conflicts between them.


48 See http://www.cdc.gov/niosh/topics/ctlbanding/ctlbandingfaq.html.

IPCS has already begun work to maximize the consistency of its hazard and risk assessment products with the Globally Harmonized System for the Classification and Labeling of Chemicals (GHS). This consistency will enable national governments to use these products more effectively in implementing the GHS at the national level.

As a matter of policy, based on NIOSH’s strong and steadfast support for the GHS, NIOSH’s Cancer Policy should adopt the GHS approach and the GHS approach should be implemented with respect to the identification and classification of occupational carcinogens. To do otherwise is inconsistent with NIOSH’s claims that GHS is critical for hazard and risk programs.

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 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.” 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.

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. 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.

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. 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

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51 77 Fed. Reg. at 17,683 (emphasis added).


54 See 29 C.F.R. § 1910.1200, A.6.4.2, which reads “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.”
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 on the hazard classifications for a particular chemical 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.

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. 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 classification to be informational, SIRC recommends it reconsider whether this exercise is of informational value.

IV. 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

\[55\text{ Draft 2013 Cancer Policy at 25.}\]
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.

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.

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.

56 Draft 2013 Cancer Policy at 36.
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:

> The determinations of the Secretary shall be conclusive if supported by substantial evidence [emphasis added] in the record considered as a whole.

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;

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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.

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 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.

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 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.

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:

- 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;
- 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;
- Identifying points of agreement among stakeholders; and
- 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 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.

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 of “occupational carcinogen,” but then later in the next section, NIOSH describes how it will also assign GHS classifications. Based on the presentation and comments during the December 16, 2013, public hearing, we understand that the NIOSH process would follow
Figure 1. The Draft Cancer Policy needs to better clarify this process although, as discussed below, NIOSH should not engage in GHS classification unless it first modifies its approach to conform to the GHS and HCS 2012 framework.

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 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.

VI. Conclusion

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.

Respectfully submitted,

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