NIOSH Hexavalent Chromium Criteria Document:
Occupational Exposure to Hexavalent Chromium
NIOSH Response to Hexavalent Chromium Public and Stakeholder Comments
December 18, 2012

Background

The *NIOSH Criteria for a Recommended Standard: Occupational Exposure to Hexavalent Chromium* was developed to update the NIOSH evaluation of the scientific literature on occupational exposure to hexavalent chromium (Cr[VI]) compounds and the corresponding recommendations for protecting workers from occupational exposure to Cr(VI) compounds. This criteria document supersedes previous NIOSH documents and policy statements on Cr(VI) compounds [NIOSH 1973, 1975, 1988, 2002, 2005a,b].

The intended audiences for the criteria document are other government agency science and policy experts, occupational safety and health professionals, employers, and workers in workplaces with Cr(VI) exposure. The document provides these audiences with current recommendations for preventing and controlling occupational exposure to Cr(VI) compounds based on the NIOSH evaluation of the available scientific literature.

Cr(VI) Criteria Document History

On October 17, 2008, NIOSH announced the availability of the draft *NIOSH Criteria Document Update: Occupational Exposure to Hexavalent Chromium* [NIOSH 1998 draft] for public comment until January 31, 2009 [73 Fed. Reg. 61874 (2008)]. NIOSH extended the public comment period by 60 days to March 31, 2009 subsequent to a public request for more time to gather and submit information [74 Fed. Reg. 4752 (2009)].

On October 17, 2008, NIOSH also announced a public meeting for discussion of the draft document to be held at the NIOSH Taft Laboratory, Cincinnati, Ohio, on January 22, 2009 [73 Fed. Reg. 61874 (2008)]. The public meeting was attended by NIOSH scientists, peer reviewers, and stakeholders including government, union, and industry representatives.

The peer review of the NIOSH draft document began at the same time as the public comment period and continued for 60 days beyond the end of the public comment period to May 31, 2009. NIOSH requested peer reviewers with Cr(VI) expertise to review the draft NIOSH document and the public comments received. The NIOSH Docket Office received five peer reviewer submissions. The *NIOSH Response to Hexavalent Chromium Peer Review Comments* is available as a separate document.

This *NIOSH Response to Hexavalent Chromium Public and Stakeholder Comments* document contains the NIOSH responses to the public and stakeholder comment submissions received by the NIOSH Docket Office during the public comment period. Information from the public meeting, external review draft document for public comment, and public and peer review comment submissions are available on the NIOSH Hexavalent Chromium Criteria Document Docket page:
http://www.cdc.gov/niosh/docket/nioshdocket0144.html

The eight public and stakeholder submissions are listed here in chronological order of receipt with the link to the full-text comments and the respective abbreviations used for the submissions in the comments and responses below:
1) ENVIRON International Corporation (ENVIRON)
2) Wood Preservative Science Council (WPSC)
3) American Industrial Hygiene Association (AIHA)
4) Color Pigments Manufacturers Association, Inc. (CPMA)
5) California Environmental Protection Agency Office of Environmental Health Hazard Assessment (OEHHA)
6) Electric Power Research Institute (EPRI)
7) Specialty Steel Industry of North America (SSINA)
8) Building and Construction Trades Department, AFL-CIO, and CPWR – The Center for Construction Research and Training (BCTD & CPWR)

Public Comment Issues and Topics

The public and stakeholder submissions included comments on NIOSH policies and recommendations, and suggestions for revised, expanded, or new content for the document. The policy issues commented on included the NIOSH recommendations for the proposed REL, exposure assessment, and medical monitoring. The REL issues commented on included its relevance to all Cr(VI)-exposed workers, particularly the welding and lead chromate pigment industries, and its achievability. Content suggested for revision or expansion included Cr(VI) exposure data with a focus on welders, welding health effects studies, engineering controls with a focus on welding, reproductive toxicity, and chromated copper arsenate (CCA)-treated wood. New content suggested for inclusion was the results of recent chronic oral carcinogenicity rodent studies and information about dermal exposure to Cr(VI) compounds in the workplace with a focus on the construction industry. The public and stakeholder comments were synthesized to provide a collective response to similar comments and topics.

The NIOSH response to comments on the following topics is provided below:
1) The proposed NIOSH REL: general comments
2) The proposed NIOSH REL: its relevance to welding exposures
3) The proposed NIOSH REL: its relevance to chromate pigment exposures
4) The proposed NIOSH REL: its achievability
5) NIOSH exposure assessment recommendations
6) NIOSH medical monitoring recommendations
7) Cr(VI) exposures to welders
8) Welding health effect studies
9) Engineering controls with a focus on welding
10) Dermal exposure and its prevention
11) Reproductive toxicity
12) Oral carcinogenicity
13) CCA-treated wood
14) Additional specific comments

Topic 1) General comments about the proposed NIOSH REL and its basis
Public and stakeholder comments were received in support of and against the proposed NIOSH REL for Cr(VI) compounds. AIHA commented that NIOSH has a transparent and sound basis for its proposed REL. OEHHA agreed with reducing the REL and indicated that scientific evidence supports the inclusion of all Cr(VI) compounds in the proposed REL. OEHHA also agreed that residual risk of lung cancer exists at the proposed REL and urged NIOSH to encourage use of the most stringent controls possible, including the use of substitute compounds, to further reduce exposure to Cr(VI) in the workplace.

BCTD & CPWR supported the NIOSH recommendation that airborne exposures to all forms of Cr(VI) be limited to 0.2 ug/m^3 for an 8-hour time weighted average (TWA) during a 40-hour work week. They also supported the recommendation that all reasonable efforts be made to reduce exposures to Cr(VI) compounds below the proposed REL through the use of work practice and engineering controls. BCTD & CPWR commented that the criteria document provides ample evidence that a REL of 0.2 ug/m^3 is necessary to reduce the risk of lung cancer deaths to approximately one per thousand workers, the risk criteria OSHA has used for other carcinogens.

SSINA commented that the proposed REL of 0.2 µg/m^3 is unnecessary to protect against health risk and infeasible to meet for virtually all SSINA member companies and their customers. SSINA commented that NIOSH selected a very conservative approach to quantify risk as the basis for the proposed REL; there are uncertainties in extrapolating this risk assessment to other industries and exposure conditions.

OEHHA commented that their evaluation of the cancer potency of airborne Cr(IV) identified a unit risk factor of 1.5 E-l(µg/m^3)$^{-1}$ and a slope factor of 5.1 E+2 (mg/kg/day)$^{-1}$ [OEHHA 1999]. OEHHA suggested that using these values to calculate the risk faced by exposed workers would result in a more health protective standard than that arrived at by NIOSH.

NIOSH response: NIOSH detailed the basis and justification for the REL in Chapter Seven of the external review draft. Consistent with the current NIOSH REL policy [NIOSH 1995], the primary basis for the NIOSH REL is a quantitative risk assessment of the strongest available data set. The NIOSH risk assessment is explained in Chapter Six; the content of Park et al. [2004] is provided in Appendix A. This quantitative risk assessment uses standard risk assessment methodology and is consistent with other quantitative risk assessments conducted by NIOSH.

The Baltimore and Painseville cohorts [Gibb et al. 2000; Luippold et al. 2003] are the best studies for predicting Cr(VI) cancer risks because of the quality of their exposure estimation, large numbers of workers available for analysis, extent of exposure, and years of follow-up [NIOSH 2005a]. NIOSH selected the Baltimore cohort [Gibb et al. 2000] for analysis because it had the greater number of lung cancer deaths, better smoking histories, and a more comprehensive retrospective exposure archive.

The OEHHA risk evaluation is based on the EPA evaluation of the Mancuso [1975] data. The Gibb et al. [2000] data set is an improved, stronger data set and so was selected for use by NIOSH in its quantitative risk evaluation. While analyses of data sets other than Gibb et al. [2000] would have provided different risk estimates, NIOSH analyzed the data set that it determined was the strongest overall and most appropriate as the basis for the NIOSH REL.

The peer reviewers who commented on the REL were supportive of the proposed REL and its description. They agreed that the proposed REL has a transparent and sound basis. One peer reviewer suggested more discussion be included in the document explaining the NIOSH selection of the Gibb et al. [2000] data set for evaluation. Peer reviewers had additional comments regarding the NIOSH risk assessment which are addressed in the separate *NIOSH Response to Peer Review Comments* document.

Document revisions: A statement that the Gibb et al. [2000] data was selected by NIOSH for quantitative risk analysis due to the strength of these data was already in the document but was expanded and added in additional locations to make the NIOSH decision more transparent. This statement was added to Sections 6.4 and 7.4; it was already stated in Section 7.9.

Topic 2) Relevance of the NIOSH REL to welding exposures

SSINA noted that there are uncertainties in extrapolating the NIOSH risk assessment to other exposure conditions and industries such as welding. NIOSH should address the disparity of findings regarding the lung cancer risk in the chromate product industry and that for welding. Welders are the most numerous occupation with significant Cr(VI) exposure, and it is questionable whether lung cancer risks from the historical chromate production industry, based on statistical models and cumulative dose from airborne concentrations, can be used to reasonably estimate risks for welders. Because of the differences in carcinogenic potential between welders and historical chromate production workers, and because there are far more welders than chromate production workers in the U.S., the new proposed REL should be based on welding data rather than chromate production industry data.

SSINA commented that while the levels of Cr(VI) exposure among welders are not as high as experienced in the historical Painesville chromate production plant, they are likely similar to that of the Baltimore plant. Although exposure misclassification is a concern with welding studies, giving the preponderance of the findings and the size of the cohorts studied, it is not reasonable to assume that the risk assessment for Cr(VI) developed from the chromate production industry and used for the proposed REL, is representative of the risk experienced by stainless-steel welders exposed to Cr(VI).

SSINA commented that the Criteria Document states that "smaller particles, as in welding fume exposure (<0.5 µm) may be more efficiently reduced [to trivalent chromium] in the lungs than larger particles, such as those of the chromate dust exposure (>10 µm)". They recommend that NIOSH more fully develop this potentially important observation and consider the kinetic differences in exposures experienced by different industries. This disparity may provide a plausible biological basis for the observed lower lung cancer risk among welders than among chromate production and pigment production workers. Specifically, tissue dose in the lung is likely to be a better dose measure than airborne concentration because of variability in the rate at which Cr(VI) is cleared from the lung. Particle size and solubility are two critical parameters to consider when evaluating exposure by industry.

SSINA commented that IARC (1990) states that there is *limited evidence* in humans for the carcinogenicity of welding fumes and gases. There is *inadequate evidence* in experimental animals for the carcinogenicity of welding fumes. The overall evaluation indicates that welding fumes are *possible carcinogens to humans* (Group 2B). It is important to compare these conclusions to IARC's (1990) conclusions regarding the chromate production industry—that "there is *sufficient evidence* in humans for the carcinogenicity of chromium[VI] compounds as encountered in the chromate production, chromate pigment production and chromium plating industries." On the basis of these data, and others, Cr(VI) is described as "*carcinogenic to humans* (Group 1)."

SSINA commented that because of the differences in carcinogenic potential between welders and historical chromate production workers, and because far more workers are welders than chromate production workers in the U.S., the Criteria Document should provide an expanded discussion of the epidemiology literature for welders, and to the extent feasible, should base the new proposed REL on welding data rather than on data for the chromate production industry. Other risk assessment tools such as physiologically based pharmacokinetic modeling and biologically-based dose response modeling could be used to increase the applicability of exposure in the historical chromate production industry to others, and specifically to welding.

SSINA commented that Section 4.1.4, Cancer Meta-analyses, does not include the meta-analysis by Moulin (1997) of stainless-steel and mild-steel welders. Moulin (1997) combined the results of 18 case-control and 31 cohort studies of welders, and calculated relative risks (RRs) for lung cancer for all non-specified welding categories, shipyard welders, nonshipyard welders, mild-steel welders, and stainless-steel welders. The RR for mild-steel welders, who incur minimal to no Cr(VI) exposure, was the same as that for stainless-steel welders who have much higher Cr(VI) exposures. The RR for mild-steel welders was 1.50 (95% CI: 1.18–1.91, based on 137 cases), and the RR for stainless steel welders was 1.50 (95% CI: 1.10–2.05, based on 114 cases). These authors concluded that a 30% to 40% increase in the RR of lung cancer experienced by welders cannot be explained by exposure of stainless-steel welders to Cr(VI) or to nickel. These findings draw into serious question whether the lung cancer risk assessment of chromate production workers can be extrapolated to stainless-steel welders.

EPRI commented that the main bulk of epidemiologic evidence in support of a link between occupational exposure to Cr(VI) and lung cancer comes from studies conducted among chromium production workers and the risk assessment which is the primary basis for the REL is based on epidemiologic data of chromium production workers. Evidence for an association between occupational exposure to Cr(VI) and lung cancer is more limited in epidemiologic studies conducted among welders. As OSHA pointed out in its

Final Rule, these studies were less likely to show a clear trend with exposure duration and cumulative exposure to Cr(VI). Some of these studies – including the study by Simonato et al. (1991), the only epidemiologic study of welders referred to by the NIOSH document – were also limited by their inability to consider the potential confounding effect of other lung carcinogens, such as cigarette smoke and asbestos, and by their potential for exposure classification.

NIOSH response: NIOSH agrees that welders are an important and large population of Cr(VI)-exposed workers. NIOSH also agrees that ideally the workplace risk of Cr(VI) exposure in welders would be based on a quantitative risk assessment of welder data. However, there are currently inadequate data to conduct a quantitative risk assessment on welders exposed to Cr(VI) compounds. NIOSH agrees that the available studies of welders exposed to Cr(VI) have confounding variables, poor exposure assessment, weak statistical power, and other limitations. Moulin [1997] and other welding studies were considered for inclusion in the criteria document. However, only the most robust studies of Cr(VI) exposure are included in Chapter 4, rather than all published studies. Until adequate exposure-response data is available for a quantitative risk assessment of welders, NIOSH supports its use of the quantitative risk assessment of chromate production worker as the basis to protect all Cr(VI)-exposed workers, including welders exposed to Cr(VI).

The relation between excess lung cancer mortality and employment duration in stainless steel welding has been noted to be inconsistent in some studies [Simonato et al. 1991; Gerin et al. 1993]. Several factors may impact the interpretation of these studies and are consistent with an underlying risk associated with duration. These factors include the healthy worker survivor effect and variations across multi-employer worksites. The healthy worker survivor effect is a form of confounding in which workers with long employment durations systematically diverge from the overall worker population on risk factors for mortality. For example, because smoking is a risk factor for disease, disability and death, long duration workers would tend to have a lower smoking prevalence, and therefore lower expected rates of diseases that are smoking related, like lung cancer. Not taking this into account among welders might result in long duration welders appearing to have diminished excess risk when, in fact, excess risk continues to increase with time.

In addition, a consideration in multi-employer studies is that conditions might vary widely across employers, including those involved not only in stainless steel, but also mild steel welding activities. Worker career duration decisions may depend in part on working conditions, such that jobs with high exposures are held, on average, for less duration than jobs with lower exposures. In the absence of detailed individual exposure histories this pattern of employment could result in long duration welding employment appearing to have lower risk than some shorter duration employment when it does not.

The available stainless steel welding studies have limitations as discussed above but qualitative estimates of lung cancer risk are possible. Simonato et al. [1991] reported 20 lung cancer deaths in European welders predominantly working with stainless steel (versus 122 lung cancer deaths in the Baltimore chromate cohort). Among stainless steel welders in the European cohort with more than 30 years since first exposure, the SMR was 3.12 (95% CI: 1.15-6.79) but was based on only 6 cases. Among those stainless steel welders with > 0.5 mg-yr/m^3 Cr(VI), there were 8 lung cancer deaths corresponding to SMR = 1.75 [Gerin et al. 1993]. The four cases with the highest cumulative exposure had a mean cumulative exposure to Cr(VI) of 2.5 mg-yr/m^3. In the Baltimore cohort, there were 24 lung cancer deaths in the range 0.37-5.3 mg-yr/m^3 Cr(VI) for an SMR = 3.41 [Park et al. 2004]. Thus the excess lung cancer mortality among European stainless steel welders exposed to Cr(VI) was roughly comparable to that observed in chromate workers. A review of welder lung cancer risk by Moulin [1997] identified 5 studies in addition to Simonato et al. [1991], with estimated relative risks for lung cancer in stainless steel welding ranging from 1.23 (95% CI: 0.75-1.90) to 3.3 (95% CI: 1.20-9.30).

NIOSH agrees that particle size and solubility are important variables in Cr(VI) toxicity. As stated in the NIOSH document and as noted by SSINA, particle size may affect Cr(VI) reduction. However, the smaller particle size of welding exposures may also result in higher deposition rates into the lungs. NIOSH did not have adequate dose-response data to develop industry-specific assessments of risk other than for chromate production workers.

Most peer reviewers did not comment on the relevance of the REL to welders. One peer reviewer commented that it appears that occupational exposure to Cr(VI) primarily occurs among workers also exposed to other harmful agents; welders exposed to Cr(VI) are also likely to be exposed to nickel, another lung carcinogen. The peer reviewer commented that this raises concerns about the relevance of the Baltimore and Painesville data to these workers and whether the proposed REL is sufficiently (or overly) protective. This peer reviewer suggested that the Criteria Document expand on this issue. The responses and revisions made to the document to address the public comments on this topic also address this peer reviewer's comments.

Document revisions: More information about welders' exposure to Cr(VI) and its prevention and control was added to Chapters Two and Eight of the document. The statement that adequate data is not currently available to conduct a quantitative risk assessment of welders or other Cr(VI)–exposed workers other than chromate production workers was added in the Chapter Six introduction and Section 7.4.

Topic 3) Relevance of the NIOSH REL to lead chromate pigments

CPMA commented that the molecular toxicology study by Nestman and Zhang [2007], taken together with the epidemiological studies of workers exposed to lead chromate pigment alone, show that at least one commercial substance, lead chromate pigments, should not be subject to the proposed REL. The full comments are available at Color Pigments Manufacturers Association, Inc. (CPMA).

CPMA provided the citation and abstract of Nestman and Zhang [2007] which reported that the commercial pigment, Pigment Yellow 34, CAS No. 1344-37-2, used in the plastics and coating industries, did not induce chromosome aberrations in a Chinese hamster ovary cell line. CPMA commented that Pigment Yellow 34 particles have very different properties compared to the pure (or "reagent grade" or "laboratory grade") lead chromate used in the studies quoted by NIOSH. CPMA commented that according to the logic used by NIOSH it may be reasonable to conclude that the pigment form of lead chromate is not carcinogenic.

CPMA commented that virtually all epidemiologic studies that NIOSH (and other government agencies) quote on this topic relating to lead chromate deal with exposures to lead chromate and chromates known to be carcinogenic. Only three studies relating to exposures to lead chromate alone are known to exist: Davies [1984], Kano [1993], and one not in the NIOSH references, Cooper [1983]. CPMA commented that the studies are relatively small but can be combined if two assumptions are made: that the two lead chromate plants in the Kano study account for half of the 660 employees, and that "these are similar to the other two studies, an average of twenty years". CPMA provided their analysis of lung cancer deaths based on combining the data from these three studies and concluded that about 700 people with the greatest exposure to lead chromate pigment, i.e. those working in a production plant, showed no increase in lung cancer.

CPMA commented that the employees of producers of colored products, including paint and plastics concentrate producers, would work with lead chromate pigments for a much smaller part of their working time (likely 1-10%) compared to pigment manufacturers, and would have a much smaller exposure. Much of the exposures analyzed in the studies discussed was during a period in which dust control technology and respiratory protection were far inferior to that used today, so that exposures were significantly greater than would be the case today.

CPMA concluded that lead chromate pigments should not be subject to the proposed REL based on the results of the molecular toxicology study of Nestmann and Zhang [2007] and the CPMA analysis of the combined data from the epidemiology studies of lead chromate pigment only.

NIOSH response: The molecular toxicology study of Nestman and Zhang [2007] was cited as evidence that lead chromate pigments are not carcinogenic. According to Peer Reviewer #5, a molecular toxicologist, the experimental conditions of Nestman and Zhang [2007] might have been expected to give negative results due to the experimental exposure to large particles over a shorter time period than similar studies:

"...The Nestmann and Zhang study, however, is flawed because they used very large particles in CHO cells and Wise et al., 1992 (Wise, J.P., Leonard, J.C. and Patierno, S.R. Clastogenicity of Lead Chromate Particles in Hamster and Human Cells. Mutation Research, 278: 69-79, 1992), showed that very large lead chromate aggregates are nontoxic. The Wise et al., 1993 (Wise, Sr., J.P., Stearns, D.M., Wetterhahn, K.E. and Patierno, S.R. Cell-Enhanced Dissolution of Carcinogenic Lead Chromate Particles: The Role of Individual Dissolution Products in Clastogenesis. Carcinogenesis, 15: 2249-2254, 1994) showed that CHO cells require particle cell contact for genotoxicity to occur. Finally, the Nestmann study exposes cells for 18 h, while previously published studies all used 24 h. It is possible that exposures were simply not long enough in the Nestmann study to exert an effect. Thus, the Nestmann study would be expected to be negative due to the large particle sizes and short exposures. While it would be of value to evaluate the pigment itself, it should be done using respirable-sized particles applied to cells for at least 24 h." (See the *NIOSH Response to Hexavalent Chromium Peer Review Comments*, Peer Reviewer #5, for additional comments.)

Nestman and Zhang [2007] is not sufficient scientific evidence to conclude that lead chromate pigments are not carcinogenic or that they should be excluded from the proposed REL. Some studies demonstrating the genotoxicity of lead chromate particles to CHO cells include Camrye et al. [2007]; Grlickova-Duzevik et al. [2006a,b]; Savery et al. [2007]; and Stackpole et al. [2007].

It is not possible to perform a quantitative risk assessment for lead chromate pigment workers because of the inadequate exposure history and lower statistical power of the available studies [NIOSH 2005b]. CPMA referenced the epidemiologic studies of Davies [1984], Kano [1993], and Cooper [1983 unpublished] as the three studies relating to exposures to lead chromate alone. NIOSH previously evaluated these studies and determined that they do not provide sufficient evidence to exclude lead chromate from the revised REL due to their inadequate exposure history, small sample sizes, and low statistical power. Only the most robust studies relevant to the NIOSH assessment are summarized in the NIOSH document rather than all published studies.

In 1990 IARC concluded that "there is *sufficient evidence* in humans for the carcinogenicity of chromium[VI] compounds as encountered in the chromate production, chromate pigment production and chromium plating industries" and "there is *sufficient evidence* in experimental animals for the carcinogenicity of calcium chromate, zinc chromates, strontium chromate and lead chromates" [IARC 1990]. In its 2012 evaluation, IARC concluded that "there is sufficient evidence in humans for the carcinogenicity of chromium (VI) compounds" and "sufficient evidence in experimental animals for the carcinogenicity of chromium (VI) compounds". No specific Cr(VI) compound is excluded from this classification.

The U.S. National Toxicology Program (NTP), in its Report on Carcinogens, classifies Cr(VI) compounds as *known to be human carcinogens* based on sufficient evidence of carcinogenicity from studies in humans [NTP 2011]. The NTP classification does not exclude any specific Cr(VI) compound from this classification. OSHA also did not exclude any specific Cr(VI) compound from its final rule on Cr(VI) compounds [71 Fed. Reg. 10099 (2006)].

None of the document peer reviewers commented about the inclusion or exclusion of lead chromate pigments or any other specific Cr(VI) compound in the REL. One peer reviewer provided information supporting the inclusion of lead chromate compounds in the REL based on the results of molecular toxicology studies as described above.

The available scientific evidence supports the inclusion of all Cr(VI) compounds in the NIOSH workplace recommendations, including the REL. NIOSH continues to support the classification of all Cr(VI) compounds as occupational carcinogens. This is consistent with the Cr(VI) classifications of OSHA, NTP, and IARC.

Document revisions: Section 5.2, Mechanisms of Toxicity, was updated to include recent review papers and recent molecular toxicology studies as recommended by the peer reviewer with molecular toxicology expertise. These new studies provide additional information about the molecular toxicology of Cr(VI) compounds although the exact mechanism of carcinogenicity is still not fully understood. These recent studies do not change the NIOSH conclusions or recommendations.

Topic 4) The achievability of the NIOSH REL

AIHA commented that it will be very difficult to maintain exposures for welders below the proposed REL in many stainless steel welding operations (or allied processes), even with LEV and respiratory protection.

CPMA commented that NIOSH freely acknowledges the difficulties of working to the proposed REL. The OSHA policy of restricting the use of respirators would make it even more difficult to achieve control to the proposed REL. Their past reviews of the OSHA and NIOSH call reports revealed that many appeared to be of insufficient quality upon which to base even a considerably higher REL such as 5.0 mg/m^3.

CPMA commented that LODs are at best $1/20^{th}$ of the proposed REL. It seems unlikely that “monitoring…. poses no problem”. Even if the LODs do not pose a problem, taking samples of such small amounts likely will. The cost per sample would be high, and many samples are likely to be required. Monitoring may indeed pose problems for many operations.

EPRI commented that their preliminary analysis of Cr(VI) air sampling data collected at electric power companies indicates that for most welding and cutting procedures airborne concentrations of Cr(VI) routinely exceed the proposed REL. For all welding and cutting type considered together, 83% of personal breathing zone air samples exceed the proposed REL. When examining the results from welding in which local exhaust ventilation (LEV) controls were in use, 90% of air samples showed airborne concentrations in excess of the proposed REL. However, in these samples its use was limited to conditions in which high fume concentrations were anticipated. If LEV had been used during all welding activities, the airborne concentrations would have been lower in all cases. This analysis indicates that in order to maintain exposures to concentrations below the proposed REL within the welding hood, respirators would always be required, even when LEV was in use. Unless there are significant technological improvements in LEV, employees engaged in welding activities will likely need to rely on other control techniques to maintain exposures below the proposed REL. This would most likely occur by the use of respiratory protection whenever they are welding on or with any chromium bearing metals. For their full submission including preliminary analyses and summary statistics see Electric Power Research Institute (EPRI).

SSINA commented that the NIOSH proposed REL is infeasible to meet for virtually all SSINA member companies and their customers. Welders' exposures to Cr(VI), particularly stainless steel welders, far exceed the proposed and current RELs of 0.2 and 1 $\mu g/m^3$. NIOSH's determinations of whether industry can meet the REL are not based on the new proposed REL of 0.2 $\mu g/m^3$, and it is reasonable to conclude that virtually no occupations or industries will be able to meet the proposed REL. NIOSH's evaluation of whether industry can meet the proposed REL of 0.2 $\mu g/m^3$ is based on comparisons of its 1999–2001 occupational exposure survey results (Blade et al. 2007) to the current REL of 1 $\mu g/m^3$. This evaluation has not been updated to consider the recommended new REL of 0.2 $\mu g/m^3$. It appears from NIOSH's statements that the relative difficulty for the industry to control exposures to the current REL of 1 $\mu g/m^3$ will be the same as that to control to the proposed REL of 0.2 $\mu g/m^3$. However, from inspection of these data, it is evident that, even though some categories of workers experienced minimal exposures or exposures that were easily controlled to the current REL of 1 $\mu g/m^3$, none of the four categories can meet the proposed REL of 0.2 $\mu g/m^3$. This has significant implications for medical monitoring, because NIOSH recommends monitoring for all workers where exposures exceed the REL or where exposures are unknown. Further, throughout the risk management discussion, references are made to the fact that some exposures will meet the proposed REL, but it may be difficult for others. In reality, it will be virtually impossible for almost all industries and exposures to meet the proposed REL.

BCTD & CPWR believe that there is sufficient evidence that the proposed REL is attainable in most workplace situations. As part of a cooperative agreement with NIOSH, CPWR has sought to collect baseline exposure data for Cr(VI) and to study the effectiveness of LEV. CPWR researchers have demonstrated that the use of LEV systems in construction welding is feasible and, if used properly, can significantly reduce worker exposures to Cr(VI) from welding fumes.

CPWR's first data collection effort, beginning in 2005, assessed the feasibility and effectiveness of LEV to control exposures to Cr(VI) in welding fumes in a controlled setting. Working at a training facility of a local United Association of Plumbers and Pipefitters, the researchers compared Cr(VI) concentrations in a welder's breathing zone in paired trials with and without the use of a portable (33-lb. Lincoln Electric Miniflex) LEV unit. In the last two years, the researchers have surveyed two large coal power plant turn-around projects that involved stainless steel welding. The first site surveyed, in 2007, employed 300 boilermakers and 63 pipefitters over the duration of the project. The second survey, conducted in 2008, involved boilermakers at a project that employed 500 boilermakers and 200 pipefitters at its peak. CPWR provided additional details and the data collected during these efforts which are available at Building and Construction Trades Department, AFL-CIO, and CPWR – The Center for Construction Research and Training (BCTD & CPWR).

BCTD & CPWR commented that many of their samples from welding operations utilizing LEV exceeded the NIOSH proposed REL of 0.2 $\mu g/m^3$. However, the employees in their experimental settings were welding during nearly 100% of the exposure sampling time. On an actual job site, the ratio of arc time to the overall typical workday would be much lower. Thus, the effective use of LEV is likely to reduce many TWA exposures to below 0.2 $\mu g/m^3$ for workers on a typical work shift, where they are not continuously welding but are instead also performing other tasks. Likewise, although the employees sampled were working 10-hour days, the typical sample times were generally not more than 7 hours and tended to exclude both the very beginning (set-up) and very end (pick-up) of the day. Factoring in the unsampled time would likely result in a lower TWA than our shift TWAs, which were only averaged over actual sample time.

BCTD & CPWR commented that LEV use in construction is still very new. In the field setting, CPWR researchers observed that controls were not commonly available, and the equipment that was present on-site was often poorly selected and improperly used. For example, the researchers observed many instances where the LEV hood was placed much farther from the weld than is advisable for optimal capture of welding fumes, at times as far as 2-3 feet away from the weld, when a distance of several inches is desirable. Although the researchers demonstrated that the LEV units they tested were effective at reducing Cr(VI) exposures, much greater effectiveness may be possible through improvements in equipment selection and design and worker training. They believe the proposed NIOSH REL would serve as an important motivation to improve LEV design and worker education to achieve exposure levels within this limit.

NIOSH response: The primary objective of the analysis of Blade et al. [2007] was to evaluate workplace Cr(VI) exposures relative to the OSHA proposed PEL at that time of 1 $\mu g/m^3$; it was not intended to be an analysis of the NIOSH proposed REL. However, these exposure data along with other available exposure data allow a qualitative assessment of the NIOSH REL.

The NIOSH REL is a health-based recommendation. Additional considerations include analytical feasibility and the achievability of engineering controls. Based on a qualitative assessment of workplace exposure data, NIOSH acknowledges Cr(VI) exposures below the REL can be achieved in some workplaces using existing technologies but are more difficult to control in others. Some operations including hard chromium electroplating, chromate-paint spray application, atomized-alloy spray-coating, and welding may have difficulty in consistently achieving exposures at or below the REL by means of work practices and engineering controls (see Table 2-7) [Blade et al. 2007]. The extensive industry analysis of workplace exposures conducted for the OSHA rule-making process supports the NIOSH assessment that the REL is achievable in some workplaces but difficult to achieve in others (see Table 2-8)[71 Fed. Reg. 10099 (2006)]. The Cr(VI) REL is intended to promote the proper use of existing control technologies and encourage the development of new control technologies where needed, in order to control workplace Cr(VI) exposures. The consistent and proper use of control technologies will continue to reduce workplace Cr(VI) exposures.

None of the peer reviewers commented on the achievability of the REL. One peer reviewer questioned the limit of quantitation (LOQ) of NIOSH Method 7703 being higher than the REL. This method is for measuring Cr(VI) levels by field-portable spectrophotometry; it is designed to be used in the field with portable laboratory equipment and has a higher LOQ than other methods. NIOSH Method 7605 and OSHA Method ID-215 have LOQs of 0.06 and 0.03 ug, respectively, which can quantitatively assess Cr(VI) exposures at the REL [Boiano et al. 2000].

The peer reviewer with analytical chemistry expertise commented on the ability of current analytical methods to determine Cr(VI) at lower levels than in the past, i.e. 0.02 µg per sample. The NIOSH and OSHA methods and particularly the ASTM and ISO methods have been developed by consensus and have been tested, validated and are used routinely throughout the world. The results obtained by these methods are acceptable to the scientific community and are valid techniques. The peer reviewer commented that the sampling methods suggested are the acceptable and validated procedures used routinely worldwide.

Document revisions: Additional information about controlling Cr(VI) exposures was added to Section 8.3, Exposure Control Measures, including additional information about controlling welding exposures and the use of LEV. Section 7.7, Controlling workplace exposures, was revised to clarify the NIOSH position of achievability of the Cr(VI) REL consistent with this response.

Topic 5) Exposure assessment recommendations
AIHA commented that the new NIOSH policy of providing general exposure assessment recommendations instead of a specific Action Level (AL) is scientifically justified.

BCTD & CPWR commented that the Criteria Document Update provides minimal guidance on exposure monitoring strategies. Employers are instructed to establish their own exposure monitoring plan "that produces a high degree of confidence that a high percentage of daily 8-hr TWA exposures are below the REL." The Criteria Document further explains this in statistical terms, referencing the *Occupational Exposure Sampling Strategies Manual*, DHHS(NIOSH) Publication Number 77-173 (1977). The *Occupational Exposure Sampling Strategy Manual* is considerably dated. In addition, the statistical models the manual employs tend to overemphasize the importance of variations in sampling and analytic procedure, while underemphasizing the actual variability in exposures. It is well-recognized that analytical variability is generally minor relative to the variability associated with the work environment. The manual does, however, contain some very useful concepts, particularly in *Technical Appendix L: The Need for An Occupational Exposure Measurement Action Level*. In this Appendix, the authors make an argument for why an AL is needed: to minimize the possibility that the exposure limit will be exceeded because elevated exposures were missed during air monitoring. Since exposures vary from day to day, the authors posit that we cannot be certain that sampling on any given day will, in fact, measure the highest exposure on the continuum of exposures in that workplace. The AL therefore provides a small buffer of protection to workers by ensuring that protections are in place when that trigger is met.

BCTD & CPWR agreed with the goals of an exposure monitoring strategy. However, the "general exposure assessment" recommendations lack the specificity needed to ensure that employers will implement effective exposure monitoring where it is needed. They believe an AL is a useful and necessary safeguard to include in a recommended standard. They recommend that NIOSH consider an AL of 0.1 ug/m^3, or one-half the proposed REL.

BCTD & CPWR recognize that exposure variability may differ greatly among workplaces and that less frequent air monitoring may be warranted where both the Cr(VI) mean exposure and variance are low. However, determining the frequency of monitoring based on the unique exposure distribution of each workplace requires expertise that the vast majority of employers will not have. With the exception of very large employers, few companies employ full-time professional industrial hygienists who would be uniquely qualified to develop individualized sampling strategies.

BCTD & CPWR commented that the Criteria Document Update calls for air monitoring to be performed at least annually or when a process change might change exposures. They believe that initial personal air monitoring should be required and the frequency of subsequent air monitoring should depend on the measured exposure levels. Although they believe it is inadequate for the construction industry, the OSHA Cr(VI) (29 CFR §1926. 1126) is instructive in offering one formula for monitoring frequency which was described.

BCTD & CPWR commented that for construction, where jobs are often of short duration and exposures are highly variable, OSHA's monitoring schedule may fall short. It also fails to incorporate corrective action into the monitoring schedule when exposures exceed the PEL. An alternative, more protective approach was suggested; details are available at Building and Construction Trades Department, AFL-CIO, and CPWR – The Center for Construction Research and Training (BCTD & CPWR).

BCTD & CPWR commented that regardless of the frequency of air monitoring, it is very important that NIOSH emphasize the need to document "exposure determinants" or task/process variables that might affect exposure in conjunction with personal air monitoring. Such variables include environmental conditions such as whether work is done inside or outside; the type of ventilation used, if any; the number of workers generating exposure; and materials and processes used. Employers can use this information in making *a priori* exposure estimates to determine control strategies prior to the start of work.

NIOSH response: Historically NIOSH has recommended an action level (AL) with the primary consideration of protecting workers from exposures above the REL. Exposure concentrations measured at or above the AL were thought to indicate with a high degree of certainty that exposure concentrations exceeded the REL which triggered additional controls and administrative actions to reduce worker exposures. NIOSH is re-evaluating its policy of recommending an AL set at one-half the REL.

Cr(VI) exposures are highly variable within and across diverse workplaces. Due to the great range and high variability of Cr(VI) exposures across workplaces it is not possible to recommend one specific exposure monitoring strategy or establish a specific AL for Cr(VI) compounds. Therefore, NIOSH is providing general exposure monitoring guidance for workplaces with Cr(VI) exposures rather than recommending one specific sampling schedule and AL for all Cr(VI) compounds. This will allow each employer to determine an exposure monitoring strategy specific to each workplace that assures that worker exposures do not exceed the REL.

Two peer reviewers commented on the exposure assessment recommendations; both agreed with the NIOSH approach of general recommendations rather than a specific AL. One peer reviewer commented that ALs are better determined on a workplace-specific basis, considering the variability of exposures, monitoring methods, etc., in order to assure protection of the worker at the level of the REL.

Document revisions: The NIOSH exposure assessment recommendations, Section 8.5, were revised for clarification and to be consistent with other recent NIOSH policy documents. The policy of providing general exposure assessment recommendations did not change. The recommendation that task or process variables that may affect exposure should be documented was added as suggested. Information about the variables affecting worker exposures was added to Chapter Two; additional information about controlling worker exposures was added to Chapter Eight.

Topic 6) Medical monitoring recommendations

6a) SSINA commented that even though some categories of workers experienced minimal exposures or exposures that were easily controlled to the current REL of 1 $\mu g/m^3$, none of the four categories can meet the proposed REL of 0.2 $\mu g/m^3$. This has significant implications for medical monitoring, because NIOSH recommends monitoring for all workers where exposures exceed the REL or where exposures are unknown.

SSINA commented that while medical monitoring of workers with Cr(VI) exposures may be the most desirable recommendation, given that resources are limited for monitoring, a recommendation that focuses medical monitoring on those workers with a relatively greater risk of health effects may be more rigorously followed and ultimately more effective. SSINA suggested that the recommendations for medical monitoring be focused on workers with the greatest likely hazard based on exposure level, occupation, or industry with the most significant hazards. It was recommended that NIOSH provide risk management strategies that are based on an exposure level, similar to the OSHA Rule, which recommends medical monitoring for specific conditions or upon attaining certain exposure levels. Medical recommendations consistent with those of the OSHA Cr(VI) Final Rule would more likely improve worker health.

SSINA commented that it is not likely that medical monitoring for lung cancer will reduce the risk of lung cancer mortality, and workers may increase the risk of adverse outcomes by participating in lung cancer medical monitoring programs. For full comments see Specialty Steel Industry of North America (SSINA).

AIHA commented that NIOSH stated that a medical monitoring program for all workers with occupational exposure to Cr(VI) compounds should be established. AIHA recommended that NIOSH be more specific (e.g., when workers are exposed to Cr(VI) above the REL).

NIOSH response and revisions: Based on public and stakeholder comments and in consultation with NIOSH medical experts, the NIOSH recommendations for medical monitoring were revised to focus on:

1. Workers exposed to airborne Cr(VI) concentrations above the REL of 0.2 µg/m^3;
2. Workers with potential high peak airborne Cr(VI) exposures during tasks, jobs, or emergencies;
3. Workers exposed to Cr(VI), regardless of airborne Cr(VI) concentration, who develop signs, symptoms, or respiratory changes apparently related to Cr(VI) exposure;
4. Workers exposed to Cr(VI) in their current job who may have been previously exposed to asbestos or other respiratory hazards that place them at an increased risk of respiratory disease.
5. Workers with dermal exposure to Cr(VI) compounds.

NIOSH agrees that this more focused recommendation will be more effective in targeting workers at risk. In addition, the respiratory and dermal components of the medical monitoring program were revised as separate components of the program. This allows for the tailoring of medical monitoring to each worker's potential route(s) of exposure.

NIOSH recommends a baseline radiograph as one component of the respiratory examination. NIOSH recommends that the value of periodic chest radiographs by evaluated by a healthcare professional, in consultation with the worker, based on current medical recommendations and the scientific literature to assess whether the benefits of testing warrant the additional exposure to radiation.

None of the peer reviewers commented on the medical monitoring recommendations.

6b) AIHA on the last two sentences in 8.6.2.1, Worker Education: Workers should be instructed to inform their supervisor or the medical director of any symptoms consistent with Cr(VI) procedure. They should be instructed to report any accidental exposures to Cr(VI) or incidents involving potentially high exposure levels. Workers should report these to the Medical director, as well as the accidents to their supervisor. They should also inform their personal physician (and any other type of physician they visit) regarding exposures at work and any symptoms they believe are attributed to work. Due to the privacy of personal medical information, the worker should not be expected to inform his/her supervisor of any symptoms consistent with Cr(VI) procedure, unless work-relatedness of symptoms is confirmed by a physician.

NIOSH response and revision: Section 8.6.2.1 was revised in response to the medical privacy issue to reflect that workers should inform their supervisor of Cr(VI) symptoms that are confirmed or suspected by a physician to be work-related. This revision responds to the issue of medical privacy while acknowledging that confirmation of work-relatedness of symptoms may be problematic.

6c) AIHA on the biological markers text: In Section 8.6, NIOSH provided specific recommendations in regards to the medical surveillance program for Cr(VI). In Section 3.3, NIOSH discusses different biological markers that may be considered for the purpose of evaluating Cr(VI) exposure. We agree that such biological markers (e.g., Cr in urine, Cr in blood, plasma, and blood cells, etc.) should not be performed as a routine test in the medical surveillance exams. But NIOSH does not explain why such biomarkers are not listed in the recommended medical exam protocol. To further clarify this point, we suggest that NIOSH add a brief statement in 8.6 to this effect (i.e., there is no medical justification for routine blood or urine analysis for the detection of Cr(VI)-related health effects).

NIOSH response and revision: The following sentence was added to Section 8.6.3.2, "Routine blood and urine analysis is not recommended as these tests are of uncertain value as early indicators of potential Cr(VI)-related health effects." [NIOSH 2005a].

Topic 7) Cr(VI) exposures with a focus on welding

AIHA commented that in Chapter 2, a discussion would be helpful on how Cr(VI) is generated from welding so it is clear to the readers that welders do not normally work with Cr(VI) compounds but instead Cr(VI) is generated when heating chromium-containing steels above its melting temperature.

AIHA commented that there are additional recent sources of occupational Cr(VI) exposure information for welding and other Cr(VI) exposures. Some are published; some are unpublished but have been presented at recent conferences. The exposure monitoring data cited in the NIOSH document does not adequately characterize potential Cr(VI) exposures from common welding operations. There is a lack of usable data and information contained in the document that is specific to Cr(VI) exposure from welding and thermal cutting, especially apparent since more than half of occupational Cr(VI) exposures occur from welding. There is little exposure sampling data cited pertaining to stainless steel welding. The highest TWA cited was 22 ug/m^3, although exposures are known to be much higher. This is no fault of the study cited, however other studies with larger sample sizes have detected higher exposures. Although most welding in industry does not involve a welder using multiple processes with different exposure levels the same day, much of the data collected and provided has this characteristic. The mingling of processes, e.g., TIG, GMAW, PAC, makes it impossible to make any generalizations.

AIHA recommended that NIOSH provide more comprehensive exposure monitoring data for Cr(VI) welding that would give a better indication of actual potential exposures from various welding operations. It would be beneficial for NIOSH to provide some broad exposure ranges in terms of air concentrations by welding process and by consumable chromium composition, or at least a discussion of exposure magnitudes by process, and how the consumable composition for various steel categories (e.g., low chromium allow, medium alloy, and high alloy including stainless, inconel, hardfacing), is a major exposure variable, comprising at least 95% of the fume source. Lack of information on chromium content, when there is a broad range of chromium in steels makes it difficult to make generalizations. We recommend NIOSH describe chromium content for the most common chromium steel consumables.

AIHA commented that although very limited in sample size, the exposure assessment information in the document provided a snapshot of exposures in the other industries surveyed, specific details such as percent chromium in the paint, a major exposure variable, for the abrasive blasting, abrasive paint removal, and spray painting were not provided, rather instead a range of 1-30%, making it difficult to make generalizations. No exposure information was provided regarding power plant coal fly ash or refuse derived fuel ash, or castable boiler refractories. Fly ash exposure from air pollution control device maintenance and cleaning will regularly exceed the REL and coal fly ash will vary by coal rank. Castable refractory exposures will be around the REL.

EPRI commented that NIOSH relied on a relatively small number of welding fume Cr(VI) air sampling data, most with some degree of local exhaust LEV, and many associated with a mixture of welding processes to characterize Cr(VI) exposure among welders. There was almost no information given about important factors, such as the chromium content of the consumable materials being welded, the duration of the tasks, or information about environmental conditions. To better understand derminants and characteristic of occupational exposure to Cr(VI) and its potential health impact among welders, more accurate information is needed on Cr(VI) exposure among these workers.

EPRI provided information about the factors that affect the presence and concentration of Cr(VI) in the work environment associated with welding and cutting on chromium bearing metals. EPRI also provided extensive information about their collection of air sampling data points from different electric power companies representing a wide variety of welding and cutting activities. Summary statistics were provided on the data points that had been evaluated to date. EPRI commented that they would continue to collect and analyze the available Cr(VI) exposure data and were planning to publish it. They believe that more in-depth analyses of measurement-based Cr(VI) data, such as theirs, will be required to fully understand the true scope of occupational Cr(VI) exposure among welders. Their full submission including preliminary analyses and summary statistics is available at Electric Power Research Institute (EPRI).

SSINA commented that Table 2-6 of the Criteria Document provides exposure data for welders that range from the limit of detection to 22 $\mu g/m^3$ and categorizes these exposures as Category 3 processes, with moderate difficulty to control to 1 $\mu g/m^3$. Further, relevant to the cohorts of welders studied for lung cancer risk, historical welding exposures have been much higher than that provided in Table 2-6. SSINA summarized historical welding exposures citing IARC [1990], Sjögren et al. [1987], and Gerin et al. [1993]. Exposures to Cr(VI) among welders vary considerably, depending on the welding process, metals being welded, and available ventilation. IARC (1990) conducted a review of Cr(VI) exposure levels among welders and reported the average range from their review of the industry. Cr(VI) exposure levels from stainless-steel welding varied widely, but most were less than 10 $\mu g/m^3$. In IARC's review, upper-bound exposures from stainless-steel welding were in the range of 400 to 1,500 $\mu g/m^3$. For the cohort of railway-track welders of stainless steel (Sjögren et al. 1987), median levels were estimated using data from a national survey of air pollution in stainless-steel welders (the survey was conducted 10 years prior to the research), to be a time-weighted average (TWA) of 110 μg CrO_3/m^3 (57 $\mu g/m^3$ measured as CrVI) for welding using coated electrodes, and 10 μg CrO_3/m^3 (5.2 $\mu g/m^3$ measured as CrVI) for gas-shielded welding. Peak levels were estimated to be 750 μg CrO_3/m^3 (390 $\mu g/m^3$ measured as CrVI) for welding with coated electrodes, and 440 μg CrO_3/m^3 (229 $\mu g/m^3$ measured as CrVI) for gas-shielded welding. For the Gérin et al. (1993) cohort of stainless steel welders, exposures were estimated to range from 5 to 120 $\mu g/m^3$.

BCTD & CPWR recommended that additional attention be given in the document to specific construction work processes associated with hexavalent chromium exposure, including welding. As noted earlier, there is little exposure data for many of the operations in which construction workers are exposed to Cr(VI). We encourage NIOSH to conduct or promote research aimed at better characterizing Cr(VI) exposures in construction, particularly with the use of controls. Section 2 of the Criteria Document Update uses a NIOSH field research study (1999-2001) and a report from Shaw Environmental (2006) to categorize operations based on a qualitative assessment of the difficulty of controlling exposure. Tables provide exposure ranges and geometric means associated with operations, job titles and tasks at twenty-one sites. While we appreciate the utility of this analysis, the conclusions drawn are based on very limited data. In addition, few of the operations surveyed were in construction.

NIOSH response: NIOSH made a substantial effort to include more information in the document about welding and welding exposures as requested. A literature search was conducted to evaluate the recent relevant literature. Chapters Two and Eight were revised to include additional information about welding exposures and controlling exposures. Information was added to Chapter Two providing information about the different mechanisms of Cr(VI) formation or generation in the workplace and the variables affecting worker exposure. Additional exposure data from the welding and thermal cutting of metals was also added to Chapter Two.

Providing the comprehensive and detailed welding exposure data requested in some public comments is beyond the scope and objective of this criteria document. The objective of this criteria document is to provide the critical information that is the basis for the NIOSH recommendations and describe the general principles of controlling workplace exposures with some examples. Because there are so many different industries and processes with Cr(VI) exposure it is not feasible to provide a detailed presentation of the available exposure data in this document. NIOSH highlights the data collected by NIOSH [Blade et al. 2007] and provides overview information from the extensive OSHA Cr(VI) analyses associated with its Cr(VI) rule-making. Those seeking additional details on the summary exposure data presented or additional exposure data should consult the original NIOSH site visit reports referenced in Blade et al. [2007], the comprehensive data OSHA analyzed for its Cr(VI) final rule [71 Fed. Reg. 10099 (2006)], or the other references cited.

Chapter Four, Human Health Effects, provides additional exposure data from some health effects studies. This chapter is not a comprehensive summary of all available Cr(VI) studies but focuses on quantitative exposure-response studies of health effects not previously reviewed by NIOSH.

Most of the peer reviewers did not comment on the need for additional exposure data. One peer reviewer commented on the inadequate characterization of the workplace exposure concentrations in the epidemiological studies. The average concentrations for the Luippold et al. [2003] study were added to the text as reported in a separate paper by Proctor et al. [2003] (previously the study description had referred readers to that paper.) The mean cumulative Cr(VI) or CrO_3 exposure and/or range was already included in the descriptions of the three studies with air concentration sampling data. For other studies this information was not included in the NIOSH document as these data were not available in the published studies.

Document revisions: Chapters Two and Eight were revised as discussed above to include additional information about welding exposures and controlling welding exposures.

Topic 8) Welding health effect studies

SSINA commented that NIOSH stated that its summary of lung cancer epidemiology is focused on those studies that provided exposure-response data and were published since the IARC update of 1990 or that were not reviewed previously by NIOSH [1975, 1980]. It is not clear why the discussion of cancer epidemiology in the draft Criteria Document is so limited, and we recommend referencing the OSHA risk assessment for the 2006 rule, (OSHA 2006). The Criteria Document sections that provide the discussion of lung cancer (4.1.1.1.1–4.1.1.1.4) primarily discuss lung cancer findings for the chromate production industry. However, the number of chromate production workers in the U.S. is extremely small (150, or <0.03% of all Cr(VI)-exposed workers in 2006) compared to the number of workers exposed by welding (269,379, or 48% of all Cr(VI)-exposed workers in the U.S. in 2006). As such, greater effort should be devoted to describing the risk to welders.

SSINA commented that several studies of welders have been published that could be considered in the Criteria Document because they inform the lung cancer risk assessment and are specifically relevant to the largest occupation with Cr(VI) exposures. Section 4.1.1.1.4 discusses the IARC European welders study (Simonato et al. 1991), in which no dose response was observed with Cr(VI) exposures. Further, Gérin et al. (1993) provides additional evaluations of this cohort to better describe a dose-response relationship using the available data. OSHA (2006) used the Gérin et al. (1993) in quantitative risk assessment; however, the lower bound of the 95% confidence interval included zero. Moulin (1997) conducted a meta-analysis of welders and also determined that there is a no dose-response for Cr(VI) exposure and lung cancer risk among welders.

SSINA commented that because of the differences in carcinogenic potential between welders and historical chromate production workers, and because far more workers are welders than chromate production workers in the U.S., the Criteria Document should provide an expanded discussion of the epidemiology literature for welders, and to the extent feasible, should base the new proposed REL on welding data rather than on data for the chromate production industry. Other risk assessment tools such as physiologically based pharmacokinetic modeling and biologically-based dose response modeling could be used to increase the applicability of exposure in the historical chromate production industry to others, and specifically to welding.

SSINA commented that Section 4.1.4, Cancer Meta-analyses, does not include the meta-analysis by Moulin (1997) of stainless-steel and mild-steel welders. Moulin (1997) combined the results of 18 case-control and 31 cohort studies of welders, and calculated relative risks (RRs) for lung cancer for all non-specified welding categories, shipyard welders, nonshipyard welders, mild-steel welders, and stainless-steel welders. The RR for mild-steel welders, who incur minimal to no Cr(VI) exposure, was the same as that for stainless-steel welders who have much higher Cr(VI) exposures. The RR for mild-steel welders was 1.50 (95% CI: 1.18–1.91, based on 137 cases), and the RR for stainless steel welders was 1.50 (95% CI: 1.10–2.05, based on 114 cases). These authors concluded that a 30% to 40% increase in the RR of lung cancer experienced by welders cannot be explained by exposure of stainless-steel welders to Cr(VI) or to nickel. These findings draw into serious question whether the lung cancer risk assessment of chromate production workers can be extrapolated to stainless-steel welders.

AIHA commented that OSHA cites and discusses, in its preamble to the Final Rule for Controlling Cr(VI) Exposure, more research studies related to health effects from stainless steel welding than the welding studies cited in the NIOSH document.

NIOSH response and revisions: Chapter Four, Human Health Effects, presents the most robust studies of workplace Cr(VI) exposures and associated adverse health effects; it is not a comprehensive summary of all available published studies. As the NIOSH risk assessment focused on Cr(VI) exposure in chromate production workers this is the focus of the health effects studies presented. The available welding health effect studies have limitations including confounding variables, poor exposure assessment, and limited statistical power (see the NIOSH response to topic 2 above).

Comprehensive compilations of the available welding studies are available in other U.S. Government documents including the ATSDR Toxicological Profile for Chromium [2012] and the OSHA Cr(VI) Final Rule [71 Fed. Reg. 10099 (2006)]. References to the comprehensive review of welding studies available from ATSDR [2012], IARC [1990], and OSHA [71 Fed. Reg. 10099 (2006)] were added to the Chapter Four Introduction for those looking for additional information about welding health effect studies. NIOSH did not duplicate these comprehensive review efforts in this document but instead focused on the most robust studies and those most relevant to the NIOSH assessment.

None of the peer reviewers recommended the inclusion of additional welding studies to the document.

Topic 9) Engineering controls, focus on welding
AIHA commented that other than LEV, there was a lack of information provided on engineering controls for exposure reduction. Not mentioned is fume extraction built into the welding nozzle of MIG machines used for FCAW and GMAW. There has been a significant amount of work published and presented at the aforementioned conferences regarding exposure levels by welding process and process selection for exposure reduction. For example, the high to low rank order of hexavalent chromium exposure levels by stainless or other chromium steel welding process is flame spraying, shielded metal arc welding, flux cored arc welding, gas metal arc welding, and last, gas tungsten arc welding and submerged arc welding. Decreasing the oxygen potential of shielding gases for flux cored arc welding and gas metal arc welding, and for gas metal arc welding, operating in pulsed mode reportedly also reduce exposure levels. Mechanical cutting in place of thermal cutting, will eliminate exposures. Recently reported, is the development of lower hexavalent chromium fume emission electrodes.

AIHA commented that for chromate paint abrasive paint removal, methods such as power tools such as needle scalers and grinders with shrouded heads and HEPA vacuum attachments were specified in the OSHA Lead Construction Standard. Also available for paint removal are vacuum blasters. With regard to spray painting chromate paints, high zinc substitutes are in use. Work practices to keep dust levels lower in power plant coal fly ash cleaning will reduce exposure levels.

BCTD & CPWR urged NIOSH to recommend that LEV and welding process selection (e.g., use of TIG welding or other lower fume generating process in lieu of stick welding) be used as engineering controls whenever performing stainless steel welding in construction. In addition to reducing inhalation exposures, use of LEV will reduce the dispersal of the Cr(VI) contaminant that may represent an ingestion hazard when eating, drinking or smoking. Although this issue is not addressed in the Criteria Document Update, as discussed above, recent research has demonstrated that Cr(VI) may be carcinogenic not only through inhalation exposures but also through ingestion.

BCTD & CPWR commented that while respiratory protection may still be needed to supplement engineering controls until control technology effectiveness is improved, there are a number of practical obstacles to the use of respiratory protection in construction welding, including hindered mobility and communication, heat stress, and compliance. Our experience has also shown that non-LEV mechanical ventilation, which may be used in lieu of LEV in complying with the OSHA Cr(VI) standard, is not as effective as LEV at reducing worker exposures and would not offer the additional housekeeping advantages. In light of the observations of CPWR researchers, they also recommended that NIOSH provide guidance regarding proper selection, placement, maintenance and use of LEV to ensure its effectiveness.

NIOSH response: NIOSH conducted a literature search on this topic as many of these public comments did not provide supporting references. A new section was added to Chapter Eight which contains additional information about engineering controls for welding and thermal cutting as requested.

NIOSH provides information about and examples of general and specific engineering controls in this document but providing detailed information about each possible engineering control for each possible workplace Cr(VI) exposure is beyond its scope. The references cited should be consulted for those needing additional or further detailed information.

Document revisions: A new section was added to Section 8.3.1.4, Engineering controls to reduce Cr(VI) exposure, to address these comments. Additional information about welding exposures was added to Chapter Two.

Topic 10) Dermal exposure to Cr(VI) compounds and its prevention
SSINA commented that the Criteria Document has been in preparation for many years, and it seems evident that some of the discussion is dated and does not reflect information that is currently available in the scientific or regulatory literature. For example, supplemental information is available regarding dose response for dermal exposures and elicitation of allergic contact dermatitis. The discussion of dermal effects states that there are no dose-response data for occupational exposures (Criteria Document, p. 58). While that is true, there are dose-response data that can be used to assess occupational exposures, and the U.S. EPA Office of Pesticide Programs has recently used it to evaluate exposures to treated wood (Proctor et al. 2006a,b). The studies by Proctor et al. were conducted in human subjects allergic to Cr(VI), using repeated, open application of test solutions containing Cr(VI). They studied two different types of Cr(VI) compounds—potassium dichromate, commonly used for studying environmental exposures, and acid copper chromate (ACC), a wood pesticide. In their technical reports that were submitted to EPA's Office of Pesticide Programs, Proctor et al. reported a clear dose-response effect for the occurrence of allergic contact dermatitis with increasing dose of Cr(VI) (as mass of Cr(VI) per unit area of skin). Proctor et al. (2006a,b) also performed dose-response modeling of the data obtained in these studies using EPA's Benchmark Dose software and reported minimum elicitation thresholds for Cr(VI)-induced allergic contact dermatitis (i.e., the minimum dermal dose of Cr(VI) required daily to elicit allergic skin reactions in sensitized individuals on repeated exposure). It is noteworthy that the study methodology of repeated, open applications is not only representative of community or environmental exposures to Cr(VI), but is also typical of occupational exposures. This is in contrast to other studies that have used occlusive dermal exposures to Cr(VI) using patch tests, which are not representative of real-life exposures (Nethercott et al. 1994).

SSINA commented that would be more helpful if the Criteria Document provided the levels of exposure that have resulted in adverse health effects and offered recommendations for preventing exposures to those levels, or measures to reduce hazards. For example, the Document states that more than 1,000,000 workers are exposed to Cr(VI) in wet cement (page iv). In the EU, there is a limit of 2 mg/kg Cr(VI) in dry cement, and to reduce Cr(VI) levels, cement is manufactured with a reducing agent, typically ferrous sulfate. A similar recommendation for U.S. workers is more likely to reduce dermal effects than a recommendation to prevent all contact with Cr(VI), which would be difficult to implement or monitor.

BCTD & CPWR supported NIOSH's recommendation that measures be taken to prevent workplace exposures leading to adverse dermal effects. They support the recommendation that all Cr(VI) compounds be designated as corrosives and as substances that cause skin sensitization or allergic contact dermatitis.

BCTD & CPWR commented that Portland cement represents both a dermal and inhalation hazard in construction. Approximately 600,000 construction workers have frequent exposure to wet cement as a part of their trade. However, the number of workers periodically exposed to wet cement is far larger. Ruttenberg estimates approximately one million additional construction workers who, while not likely to be exposed daily over their careers, are also frequently exposed to wet cement. Skin contact with wet cement can result in burns, irritant contact dermatitis (ICD) and allergic contact dermatitis (ACD). Burns and ICD result from the caustic or basic (low pH) nature of cement, and ACD occurs following sensitization to Cr(VI) found in cement. While burns heal and the symptoms of ICD decrease with treatment and the end of exposure to cement, a person is sensitized to Cr(VI) for life and may experience ACD following even the smallest exposure, placing the worker at risk of debilitating illness and loss of income if no longer able to work at his or her trade.

BCTD & CPWR commented that in addition to these dermal hazards posed by wet cement, construction workers also risk inhalation exposures to Cr(VI) when working with dry Portland cement. For example, tile and terrazzo workers who work directly with dry Portland cement when mixing dry-beds and mixing slurries in which tiles are set may handle hundreds of pounds of Portland cement indoors. They may also use roto-tillers to mix mounds of sand with the cement. In addition, construction workers who mix mud for mortar and/or cement finishing may also be intermittently exposed to high levels of Cr(VI) in Portland cement through both inhalation and dermal exposures. Unfortunately, there is little, if any, exposure data for many of these operations.

BCTD & CPWR supported NIOSH's emphasis on sanitation, particularly in construction where basic hand-washing necessities such as soap and warm water are typically lacking. However, in the case of Portland cement, we urge NIOSH also to encourage process changes to reduce the exposure risk at the source. Reducing the Cr(VI) content of cement has been shown to reduce the prevalence of allergic contact dermatitis (ACD), which is the most severe and long-lasting health effect of exposure to wet cement. The European Economic Community (EEC) began limiting hexavalent chromium in cement to 2 parts per million in 2005. Denmark, Finland, Sweden and, to a lesser extent, Germany have used ferrous sulfate to control the hexavalent chromium content of cement since 1981, 1987, 1989 and 2000, respectively. The prevalence of ACD has decreased since the addition of ferrous sulfate to Danish cement.

BCTD & CPWR commented that the Cr(VI) content of cement is dependent on environmental conditions during production (primarily temperature and moisture) and on the trivalent and Cr(VI) content of the fuel, raw materials, refractory brick in the kiln, and grinding media in the finishing mill. The Cr(VI) content of cement can be lessened by using materials with lower chromium content during production or with the addition of agents that chemically reduce hexavalent chromium to trivalent chromium. Raw materials for the production of Portland cement (limestone, shale, clay, etc.) often contain trivalent chromium, some of which may be converted to Cr(VI) during the production process. Blended cements containing slag from iron blast furnace processing, in place of a portion of the Portland cement, have been found to have lower Cr(VI) content. Improvements to the slagging process and decreased availability of clinker has made slag a less expensive substitute for clinker, which has been used regularly in cement manufacturing in the United States and Canada since the mid-1980s and in Singapore since the late 1980s. While the addition of slag does not eliminate or chemically reduce Cr(VI), it produces cement with lower concentrations by diluting the Cr(VI) from the clinker and the manufacturing process. While not as well-documented in peer-reviewed literature as ferrous sulfate, stannous sulfate is also marketed and used as a reducing agent in cement production. Other reducing agents, including manganese sulfate, stannous chloride, ammonium and antimony, have been considered but not yet shown to be viable options for reduction of hexavalent chromium in cement.

BCTD & CPWR commented that the belief that reducing hexavalent chromium content in U.S. cement is not feasible are based on limited and outdated data. NIOSH should conduct and promote research that will assist in reducing the Cr(VI) exposure risk associated with Portland cement, including the kinds of process changes that have been made in Europe. Material substitutions and process changes are more effective and, in the long-term, less costly than relying entirely on work practices and personal protective equipment.

NIOSH response: NIOSH agrees that dermal exposure to Cr(VI) compounds is an important workplace issue. The importance of dermal exposures was emphasized in previous NIOSH policy responses [NIOSH 2002, 2005a]. Additional information about dermal exposure and recommendations for controlling dermal exposures was added to the document as suggested.

NIOSH concurs with OSHA in its evaluation of the dermal literature that no threshold has been demonstrated for the dermal effects of Cr(VI) compounds [71 Fed. Reg. 10099 (2006)]. Proctor et al. [2006a,b unpublished] are unpublished studies that were not included with the SSINA submission. These studies were not added to the document.

Document revisions: The external review draft of this document focused on airborne Cr(VI) exposures as that is the focus of the proposed REL. In this revised draft additional information about dermal exposure to Cr(VI) compounds was added to Chapter Two. Additional information about controlling dermal exposures and protecting workers exposed to Portland cement was added to Chapter Eight.

Topic 11) Reproductive toxicity

OEHHA commented that the NIOSH draft document's treatment of the data relevant to the reproductive toxicity of Cr(VI) compounds was incomplete and failed to identify this serious hazard posed by occupational exposure to Cr(VI). OEHHA's recent evaluation, *Evidence on the Developmental and Reproductive Toxicity of Chromium (hexavalent compounds),* dated September 2008, presented in detail the scientific evidence supporting Cr(VI) as a reproductive and developmental toxicant. Only a few of the relevant studies summarized in OEHHA's document are referenced in the NIOSH document. A panel of scientific experts, the Developmental and Reproductive Toxicant Identification Committee of the OEHHA Science Advisory Board, considered the evidence presented in the OEHHA document. They determined that chromium (hexavalent compounds) have been "clearly shown, through scientifically valid testing according to generally accepted principles, to cause developmental toxicity, male reproductive toxicity and female reproductive toxicity. As a result, effective December 19, 2008, chromium (hexavalent compounds) was listed as known to the State of California to cause reproductive toxicity.

OEHHA's document considered 16 epidemiologic studies, primarily welding exposures, and 15 of 16 animal studies that demonstrated adverse male reproductive effects. The NIOSH document stated that chronic inhalation studies provide the best data for extrapolation to occupational exposure. OEHAA commented that in the absence of such data, it is not scientifically appropriate to ignore experimental studies that were carried out using other routes of exposure. For reproductive effects, it has been empirically demonstrated that Cr(VI) exposure by oral or other routes poses a hazard. Careful consideration should be given to toxicokinetic extrapolation from such empirical studies to potential adverse reproductive effects resulting from inhalation exposures.

OEHAA recommended that workers be warned of the potential adverse reproductive effects of Cr(VI) compounds. The OEHHA document (August 2009) is available at: http://www.oehha.ca.gov/prop65/hazard_ident/pdf_zip/chrome0908.pdf

***NIOSH response*:** NIOSH has not conducted quantitative analyses of the reproductive data. NIOSH selected lung cancer as the critical effect of occupational airborne exposure to Cr(VI) compounds. The REL, which is intended to protect workers against lung cancer death, should also protect workers against non-cancer health effects.

The peer reviewers of the document did not comment on the lack of information about the reproductive effects of Cr(VI) compounds in the draft document.

Document revisions: A new section, Section 5.3.6, Reproductive Studies, was added to Chapter Five providing information about other agencies' reviews of the reproductive effects of Cr(VI) compounds, including the California EPA OEHHA assessment.

Topic 12) Oral carcinogenic potential of Cr(VI) compounds

BCTD &CPWR urged NIOSH to consider recently published reports by the National Toxicology Program showing that chronic ingestion exposures to Cr(VI) are carcinogenic. Ingestion of Cr(VI) in the workplace may occur through inhalation (and subsequent ingestion) of Cr(VI) on particles that lie in the size range between respirable and inhalable particles, or through contact with contaminated tools, workpieces or other surfaces and subsequent hand-to-mouth contact. Since construction work is transient and often conducted in areas remote from sanitation resources, workers are likely to eat lunch or take snack/coffee/cigarette breaks in areas close to where they were working and therefore with potentially contaminated surfaces, and without washing their hands. Take-home exposures on work clothes are an additional concern. Thus, more detailed or stringent recommendations for work practices and the maintenance of hygienic workplace conditions may be warranted. Effective engineering controls are also likely to reduce inhalation of non-respirable particles, workplace/surface contamination, and subsequent ingestion exposures.

***NIOSH response and revisions*:** Information summarizing the NTP Cr(VI) oral studies was added to the document as suggested in a new Section 5.3.5, Chronic oral studies.

Topic 13) CCA-treated wood

WPSC comments focused on the last paragraph in the Chapter Two summary which described the decreased use of CCA wood and associated worker exposure. WPSC commented that this paragraph mischaracterized the actions undertaken by both registrants of CCA and the U.S. EPA, misidentified the registered uses of CCA, and incorrectly identified potential exposures to hexavalent chromium associated with both the manufacture and use of CCA-treated wood. WPSC commented that the wording in the draft document does not clearly explain the mandatory nature of the label change and suggests that treatment of wood for use in residential settings would be permitted which is not the case.

WPSC commented that statements in the NIOSH draft document referring to potential exposure to Cr(VI) are incorrect and should be deleted. WPSC commented that the NIOSH draft document incorrectly asserts that carpenters working with CCA-treated wood might be exposed to Cr(VI). WPSC commented that because there is only Cr(III) in CCA, this statement should be deleted. WPSC commented that because there is no exposure to Cr(VI) when working with wood that has been treated with CCA, even discussing this in relation to worker exposures to Cr(VI) in air and the feasibility to control those exposures is irrelevant.

WPSC commented that the potential exposure to pesticide applicators is within the jurisdiction of EPA under FIFRA, not OSHA, so it is inappropriate for NIOSH to be focusing on these exposures in its document. A proposed specific paragraph revision was included in the WPSC submission. WPSC suggested that other text and references in the document related or referring to CCA wood be revised or deleted. The full text comments are available at Wood Preservative Science Council (WPSC).

NIOSH response: The manufacture of pesticides containing Cr(VI) and the use of wood treated with pesticides containing Cr(VI) is covered under the OSHA Cr(VI) Final Rule and appropriate for NIOSH evaluation [71 Fed. Reg. 10099 (2006)]. OSHA determined in its exposure profile that working with wood treated with pesticides containing Cr(VI) can involve Cr(VI) exposure above the PEL and so did not exempt the use of wood treated with Cr(VI) from its Cr(VI) standard.

The text about CCA wood in the NIOSH draft document was presented as an example of worker exposure to Cr(VI) that would be expected to decrease due to EPA regulatory changes. Due to changes in the organization, content, and focus of Chapter Two based on the public comments received, the CCA text that WPSC requested be revised is not included in this final document.

The CCA information in Tables 2-4 and 2-8 of the NIOSH document is adapted from published sources, Blade et al. [2007] and Shaw et al. [2006], respectively. This information was retained in the document and is presented in the NIOSH document as published.

Document revisions: The CCA text was removed from the last section of Chapter Two due to the reorganization and refocusing of this Chapter based on the public comments received. The CCA information in Tables 2-4 and 2-8 was not removed or changed as it is adapted from published sources.

14) Additional specific comments listed in chronological order of submission
Specific public and stakeholder comments that did not fit in the topics above are listed below:

Comment 1, ENVIRON: Birk et al. [2006] was not considered in the review. It should be of interest as exposure is estimated based upon biomonitoring (urinalysis) data and demonstrates a clear relationship with lung cancer.
NIOSH response and revision: Birk et al. [2006] was added to the document, Section 4.1.1.1.5.

Comment 2, AIHA: It has been recognized for years and specified by OSHA and the American Welding Society that welding exposure sampling should be conducted inside the welding hood to more accurately represent exposure. It would be helpful to include this in the document as even today this is not well understood yet in industry. Standardization of data collection methods would be useful for future epidemiology studies.
NIOSH response and revision: This recommendation was added to Section 3.1.1, Air Sample Collection, citing OSHA [1999] and ISO [2001].

Comment 3, AIHA: In 3.2, NIOSH discusses some wipe sampling methods. However, to our knowledge there are no current consensus criteria to assist in the interpretation of wipe sampling data. We suggest that NIOSH either summarize such criteria/guidelines (if it exists) for interpreting wipe sampling data or make a statement that there is no existing consensus criteria or guidelines for interpreting wipe sampling data.
NIOSH response and revision: The statement that there currently are no guidelines for interpreting wipe sampling data was added to Section 3.2.2, Wipe Sampling Methods.

Comment 4, AIHA: In 8.5 and 3.2, it would be beneficial for NIOSH to include a discussion of the possibility of Cr(VI) reduction that may occur to the samples and to stress the importance of prompt lab analysis following field sampling.
NIOSH response and revision: Cr(VI) reduction and other air sampling considerations are discussed in Section 3.1.2, Air Sampling Considerations. A sentence was added to

Section 8.5, Exposure Monitoring Program, to refer the reader to this discussion.

Comment 5, AIHA: NIOSH's assigned protection factor for a full face powered air-purifying respirator (PAPR) of 50, equivalent to a negative pressure full face respirator, seems inadequately low considering ANSI and OSHA have assigned a protection factor of 1000 for a full face PAPR.
NIOSH response: There can be considerable model-to-model variation and the air pressure inside the facepiece may become negative during inhalation with respect to the ambient air pressure outside the respirator during some conditions. Only a few models have been evaluated in workplace or simulated workplace protection factor studies. The OSHA and ANSI APFs of 1000 represent reasonable judgment in assessing the values for the level of protection that should be expected for those tested models of respirators. Lacking data that those NIOSH-certified respirators can perform consistently and reproducibly with an APF of 1000, the NIOSH recommended APFs have not been revised.

Comment 6, AIHA: NIOSH refers to OSHA as having a Cr(VI) standard that covers general industry, maritime, and construction. But OSHA actually has separate Cr(VI) standards for each of these industries.
NIOSH response and revision: OSHA has one final standard that separately regulates general industry, maritime, and construction. The introductory text of Chapter Eight was revised to clarify this information with a citation added to the OSHA Final Rule on occupational exposure to Cr(VI) [71 Fed. Reg. 10099 (2006)].

Comment 7, AIHA: In Chapter 8, NIOSH states that gloves and chemical protective clothing (CPC) with maximum body coverage should be provided for all employees exposed to Cr(VI) compounds. We recommend NIOSH be more specific (e.g., when workers are exposed to Cr(VI) above the REL), or when there is a skin or eye hazard (as OSHA addresses protective clothing). "Skin and eye hazards are considered to be minute in typical welding operations (per OSHA). We are not aware of a prevalence of episodes of skin or eye effects due to Cr(VI) exposure from welding operations. NIOSH should address their recommendation for gloves and CPC specific to welding operations." We recommend NIOSH address their recommendation for gloves and CPC specific to welding operations.
NIOSH response and revision: The text of Section 8.3.3.1, Protective Clothing and Gloves, was revised to clarify that these recommendations are for those workers with potential skin or eye contact to be consistent with the OSHA standard [71 Fed. Reg. 10099 (2006)].

Comment 8, AIHA: In 8.7 and 8.3.2, NIOSH states that smoking shall be prohibited in areas where workers are exposed to Cr(VI) compounds. We recommend NIOSH be more specific (e.g., when workers are exposed to Cr(VI) above the REL).
NIOSH response and revision: NIOSH recommends that smoking be prohibited in areas where workers are exposed to Cr(VI) compounds at any concentration, not only above the REL. NIOSH also recommends that smoking be prohibited in the workplace and that workers who smoke participate in a smoking cessation program. This policy is consistent

with that of the *NIOSH Criteria for a Recommended Standard: Occupational Exposure to Refractory Ceramic Fibers* [NIOSH 2006]. The text in Sections 8.3.2, Administrative Controls and Work Practices, and 8.7, Smoking Cessation, was revised to be consistent with the RCF document text.

Comment 9, AIHA: Just a minor comment on 2.5.1 Blade et al. 2007. The document can state that the number of samples collected for some operations was too small (i.e. only 1 or 2) and is a limitation of the study.
NIOSH response and revision: This statement was added to the first paragraph of Section 2.6.1, NIOSH Multi-Industry Field Study [Blade et al. 2007].

Comment 10, CPMA: At the time of the Gibb and Luippold studies, chromate production operations used calcium carbonate in their processes, presumably leading to sodium dichromate mixed with calcium chromate. Is it not possible that these studies measured the toxicity of calcium chromate, and not sodium dichromate, assuming that calcium chromate is more toxic than sodium dichromate [Levy 1986]? This would mean that some of the (very) insoluble chromates (e.g. lead chromate) might be even less toxic than sodium dichromate [Levy 1986], and far less toxic (if at all) than the substances present in chromate manufacturing.
NIOSH response: Although confounding exposures have been considered and cannot be ruled out, the NIOSH analysis concluded that the primary exposure to these chromate production workers was sodium dichromate, a relatively soluble Cr(VI) compound. Although all Cr(VI) compounds are considered carcinogenic, some evaluations assert that insoluble compounds may be even more toxic that the soluble compounds, based on the results of in vivo and molecular toxicology studies. No change was made to the document.

Comment 11, CPMA: The Draft Criteria Document indicates an unwarranted editorial bias when describing lead chromate. For example, Page 88 – summary of animal studies when describing the Levy study the Draft Criteria Document state “soluble CrVI compounds produced tumors but “not statistically significant”. When describing the available date for lead chromates, lead chromate compounds were also described as producing tumors which were “not statistically significant”. However, the authors add the gratuitous statement “but may be relevant” for lead chromates, without explanation or substantiation.
NIOSH response: In Section 5.5, Summary of Animal Studies, NIOSH stated that “Some lead chromate compounds produced squamous carcinomas, which although not statistically significant may be biologically significant, due to the absence of this cancer in control rats.” NIOSH determined that because this type of cancer was not found in control rats its development in test rats was biologically significant. No revision was made to the document.

Comment 12, SSINA: Page 8 provides a list of industries and operations that are associated with Cr(VI) exposure. However, the summary does not mention wood treating or construction, the latter of which involves exposure by contact with wet cement.
NIOSH response: The information in Section 2.3, Potential Sources of Occupational

Exposure, is based on the analysis of Shaw Environmental [2006] which focused on airborne exposures.
Document revision: A new section was added to the document, Section 2.3.2, Dermal Exposure, which provides additional information about dermal exposures including wet cement in construction workers.

Comment 13, SSINA: Page 40**,** Section 4.1.1.1.1 discusses the North Carolina chromate production worker study by Pastides et al. (1994) but does not include the update by Luippold et al. (2005).
NIOSH response: Luippold et al. [2005] reported mortality results in two cohorts (i.e., Plant 1 and Plant 2). Plant 1 was studied and reported in Pastides et al. [1994]; results from Plant 2 were not published.
Document revision: A description of Luippold et al. [2005] was added, Section 4.1.1.1.4.

Comment 14, SSINA: Page 43, in the first paragraph, Mancuso is cited as Mancuso et al., but Mancuso is the sole author of that study. Also in that paragraph, it should be clarified that exposures occurring at Castle Hayne were included in the exposure reconstruction for Painesville workers (Proctor et al. 2004).
NIOSH response: Proctor et al. [2004] (p. 755) states that 17 of the Painesville workers who transferred to Castle Hayne "were included in the cohort because exposures had been estimated previously and could be incorporated into their exposure profiles". However, the paper described in this section (Luippold et al. 2003) did not report the number included and states (p. 452) that "Exceptions were made for workers who subsequently worked at the plant in North Carolina because quantitative estimates of cumulative exposure were available for those employees." Revised the draft text with this information.
Document revisions: Section 4.1.1.1.3: deleted "et al." as suggested; revised and clarified text as described above.

Comment 15, SSINA: Page 51 of the Criteria Document provides a discussion of exposures to Cr(VI) from welding fumes among shipyard workers in Korea (Lee et al. 2002). Airborne concentrations range from approximately 1 to 500 $\mu g/m^3$. Although the authors characterize this exposure as "low level," and their conclusions are cited as such in the Criteria Document, it should be noted that these are not low exposures, especially when considering that the proposed REL is 0.2 $\mu g/m^3$, and these exposures are above the current REL of 1 $\mu g/m^3$. (NIOSH should also convert these exposure data from mg/m^3 to $\mu g/m^3$ to reduce confusion).
NIOSH response: It would be confusing to the reader to convert the measurements as suggested because the study descriptions in this section report measurements in mg/m^3.
Document revision: Section 4.2.1.1, Work Site Surveys, added at the end of description of Lee et al. [2002]: "(mean concentrations exceeded the current and proposed Cr(VI) RELs.)"

Comment 16, BCTD & CPWR made the following additional recommendations for worker protection in addition to engineering controls:

Dermal - Hygiene: Emphasize the importance, and ensure the availability of water and soap for hand washing, which are often lacking on construction sites.
Work practices: In areas in which there are potential exposures to Cr(VI), restrict access of any employees who are not engaged in the operation generating the exposure. Although engineering controls are the preferred method for controlling welding fume exposures, workers engaged in welding should also be trained to avoid exposure to welding plumes, *e.g.*, by not leaning into the plume and by working upwind from the direction of the plume.
Dermal - Housekeeping: When using Portland cement, use wet clean-up methods (e.g., hose, then use squeegee or mop), rather than dry sweeping. Additionally, employers should make sure that the surfaces of all tools are cleaned before and after use wherever hexavalent chromium dust may accumulate, whether in Portland cement or any other source.
NIOSH response and revisions: These recommendations were added to Section 8.3.2, Administrative Controls and Work Practices.

Comment 17, BCTD & CPWR: We urge NIOSH to work with the construction unions representing workers exposed to Cr(VI) to conduct further research regarding the health effects of Cr(VI) exposure, including:
1. mortality studies for lung cancer and cancers involving the gastrointestinal system;
2. prevalence of occupational asthma; and
3. the incidence of dermatitis in workers entering the trades and the prevalence of dermatitis among those in the trades.
NIOSH response: These comments were shared with the NIOSH coordinators of the National Occupational Research Agenda (NORA) Construction Sector Council. This Sector Council includes representatives of construction unions, employers, and other partners including CPWR. This working group considered public input in developing a National Construction Agenda for the construction sector including strategic goals, performance measures, and intermediate goals, available at http://www.cdc.gov/niosh/nora/comment/agendas/construction/. No change was made to the Cr(VI) document.

Comment 18, BCTD & CPWR: Section 8 of the Criteria Document Update includes recommendations that employers be required to establish comprehensive safety and health training for workers who make, handle, use or dispose of Cr(VI). We strongly support this recommendation and suggest that information on how to implement controls for reducing exposure and the preference for engineering controls be required as part of this training.
NIOSH response and revision: The following sentence was added to Section 8.2.1, Safety and Health Programs, second paragraph (training): "Workers should be trained about the industrial hygiene hierarchy of controls and how to implement controls to prevent and reduce exposures."

NIOSH Conclusion
NIOSH followed a rigorous peer review, stakeholder review and public review process in order to develop the *NIOSH Criteria for a Recommended Standard: Occupational*

Exposure to Hexavalent Chromium. This response to public and stakeholder comments document summarizes the policy and content revisions and additions to the criteria document made by NIOSH in response to the public comments and suggestions provided during the review process. NIOSH appreciates the time and effort taken by all those who publicly submitted comments and believes that this guidance document is stronger as a result of this participation. NIOSH intends to issue the final document as: *NIOSH Criteria for a Recommended Standard: Occupational Exposure to Hexavalent Chromium.*

References

71 Fed. Reg. 10099 [2006]. Occupational Safety and Health Administration: Occupational exposure to hexavalent chromium; final rule. (29 CFR Parts 1910, 1915, 1917, 1918, 1926). Docket No. H-0054A.

73 Fed. Reg. 61874 [2008]. National Institute for Occupational Safety and Health: Notice of request for public to submit comments and attend meeting. Docket No. NIOSH-144.

74 Fed. Reg. 4752 [2009]. National Institute for Occupational Safety and Health: Notice of request for public to submit comments; extension of comment period. Docket No. NIOSH-144.

ATSDR [2012]. Toxicological profile for chromium. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry.

Birk T, Mundt KA, Dell LD, Luippold RS, Miksche L, Steinmann-Steiner-Haldenstaett W, Mundt DJ [2006]. Lung cancer mortality in the German chromate industry, 1958-1998. J Occup Environ Med 48(4):426–433.

Blade LM, Yencken MS, Wallace ME, Catalano JD, Khan A, Topmiller JL, Shulman SA, Martinez A, Crouch KG, Bennett JS [2007]. Hexavalent chromium exposures and exposure-control technologies in American enterprise: results of a NIOSH field research study. J Occup Environ Hyg *4*:596–618.

Boiano JM, Wallace ME, Sieber WK, Groff JH, Wang J, Ashley KE [2000]. Comparison of three sampling and analytical methods for the determination of airborne hexavalent chromium. J Environ Monit *2*:329–333.

Camyre E, Wise SS, Milligan P, Gordon N, Goodale B, Stackpole M, Patzlaff N, Aboueissa A, Wise JP Sr [2007]. Ku80 deficiency does not affect particulate chromate-induced chromosome damage and cytotoxicity in Chinese hamster ovary cells. Toxicol Sci *97*(2):348–54.

Cooper WC [1983 unpublished]. Mortality in employees of three plants which produced chromate pigments. Unpublished. Supported by the Dry Colors Manufacturers' Association.

Davies JM [1984]. Lung cancer mortality among workers making lead chromate and zinc chromate pigments at three English factories. Br J Ind Med *41*(2):158–169.

Gerin M, Fletcher AC, Gray C, Winkelmann R, Boffetta P, Simonato L [1993]. Development and use of a welding process exposure matrix in a historical prospective study of lung cancer risk in European welders. Int J Epidemiol *22 Suppl 2*:S22–28.

Gibb HJ, Lees PSJ, Pinsky PF, Rooney BC [2000]. Lung cancer among workers in chromium chemical production. Am J Ind Med *38*(2):115–126.

Grlickova-Duzevik EG, Wise SS, Munroe RC, Thompson WD and Wise JP Sr [2006a]. XRCC1 protects against particulate chromate-induced chromosome damage and cytotoxicity in Chinese hamster ovary cells. Toxicol Sci *92*(1):96–102.

Grlickova-Duzevik EG, Wise SS, Munroe RC, Thompson WD, and Wise JP Sr [2006b]. XRCC1 protects against particulate chromate-induced chromosome damage and cytotoxicity in Chinese hamster ovary cells. Toxicol Sci *92*(2):409–415.

Hayes RB, Sheffet A, Spirtas R [1989]. Cancer mortality among a cohort of chromium pigment workers. Am J Ind Med *16*:127–133.

IARC [1990]. IARC monographs on the evaluation of the carcinogenic risk of chemicals to man: chromium, nickel, and welding. Vol. 49. Lyon, France: World Health Organization, International Agency for Research on Cancer.

ISO [2001]. ISO 10882-1: Health and safety in welding and allied processes -- Sampling of airborne particles and gases in the operator's breathing zone -- Part 1: Sampling of airborne particles. Geneva, Switzerland: International Organization for Standardization.

Kano K, Horikawa M, Utsunomiya T, Tati M, Satoh K, Yamaguchi S [1993]. Lung cancer mortality among a cohort of male chromate pigment workers in Japan. Int J Epidemiol *22*(1):16–22.

Lee CR, Yoo CI, Lee J, Kang SK [2002]. Nasal septum perforation of welders. Ind Health *40*(3):286–289.

Levy LS, Martin PA, Bidstrup PL [1986]. Investigation of the potential carcinogenicity of a range of chromium containing materials on rat lung. Br J Ind Med *43*(4):243–256.

Luippold RS, Mundt KA, Austin RP, Liebig E, Panko J, Crump C, Crump K, Proctor D [2003]. Lung cancer mortality among chromate production workers. Occup Environ Med *60*(6):451–457.

Luippold RS, Mundt KA, Dell LD, Birk T [2005]. Low-level hexavalent chromium exposure and rate of mortality among US chromate production employees. J Occup Environ Med *47*(4):381–385.

Mancuso TF [1975]. Consideration of chromium as an industrial carcinogen. Presented at the International Conference of Heavy Metals in the Environment, Toronto, Canada, October 27-31, 1975.

Moulin JJ. [1997]. A meta-analysis of epidemiologic studies of lung cancer in welders. Scand J Work Environ Health *23*(2):104–13.

Nestmann ER, Zhang B [2007]. Chromosome aberration test of Pigment Yellow 34 (lead chromate) in Chinese hamster ovary cells. Mutat Res *633*(2):126–132.

Nethercott J, Paustenbach D, Adams R, Fowler J, Marks J, Morton C, Taylor J, Horowitz S, Finley B [1994]. A study of chromium induced allergic contact dermatitis with 54 volunteers: implications for environmental risk assessment. Occup Environ Med *51*(6):371–380.

NIOSH [1973]. Criteria for a recommended standard: occupational exposure to chromic acid. Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW Publication No. (NIOSH) 73–11021.

NIOSH [1975]. Criteria for a recommended standard: occupational exposure to chromium (VI). Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW Publication No. (NIOSH) 76–129.

NIOSH [1977]. Occupational Exposure Sampling Strategy Manual. Cincinnati, OH: U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, DHEW (NIOSH) Publication No. 77–173.

NIOSH [1980]. Summarization of recent literature pertaining to an occupational health standard for hexavalent chromium. Rockville, MD: U.S. Department of Health, Education, and Welfare, Public Health Services, Centers for Disease Control, National Institute for Occupational Safety and Health, Contract No. 210-78-0009 for Syracuse Research Corporation, Center for Chemical Hazard Assessment, SRC TR 80–581.

NIOSH [1988]. NIOSH testimony on the Occupational Safety and Health Administration's proposed rule on air contaminants, August 1, 1988, OSHA Docket No. H-020. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health.

NIOSH [1995]. NIOSH recommended exposure limit policy. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

NIOSH [2002]. NIOSH comments on the Occupational Safety and Health Administration request for information on occupational exposure to hexavalent chromium (CrVI): OSHA Docket No. H-0054a. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

NIOSH [2005a]. NIOSH testimony on the Occupational Safety and Health Administration's proposed rule on occupational exposure to hexavalent chromium, January 5, 2005, OSHA Docket No. H-054A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

NIOSH [2005b]. NIOSH posthearing comments on the Occupational Safety and Health Administration's proposed rule on occupational exposure to hexavalent chromium, March 21, 2005, OSHA Docket No. H-054A. NIOSH policy statements. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health.

NIOSH [2006]. NIOSH criteria for a recommended standard: occupational exposure to refractory ceramic fibers. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2006–123.

NIOSH [2008 draft]. NIOSH Draft Criteria Document Update: Occupational Exposure to Hexavalent Chromium. Draft for external peer and public review available at http://www.cdc.gov/niosh/docket/pdfs/NIOSH-144/0144-090108-ExternalReviewDraft.pdf

NTP [2011]. Report on carcinogens, twelfth edition. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program.

OEHHA [2009]. Evidence on the developmental and reproductive toxicity of chromium (hexavalent compounds). Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency [http://www.oehha.ca.gov/prop65/hazard_ident/pdf_zip/chrome0908.pdf].

OSHA [1999]. Metals sampling. In: OSHA Technical Manual, Section II, Chapter 1. Office of Science and Technology Assessment: U.S. Department of Labor, Occupational Safety and Health Administration.

Park RM, Bena JF, Stayner LT, Smith RJ, Gibb HJ, Lees PS [2004]. Hexavalent chromium and lung cancer in the chromate industry: a quantitative risk assessment. Risk Anal. *24*(5):1099–1108.

Pastides H, Austin R, Lemeshow S, Klar J, Mundt KA [1994]. A retrospective-cohort study of occupational exposure to hexavalent chromium. Am J Ind Med *25*(5):663–675.

Proctor DM, Panko JP, Leibig EW, Scott PK, Mundt KA, Buczynski MA, Barnhart RJ, Harris MA, Morgan RJ, Paustenbach DJ [2003]. Workplace airborne hexavalent chromium concentrations for the Painesville, Ohio, chromate production plant (1943-1971). Appl Occup Environ Hyg *18*(6):430–449.

Proctor DM, Panko JP, Liebig EW, Paustenbach DJ [2004]. Estimating historical occupational exposure to airborne hexavalent chromium in a chromate production plant: 1940--1972. J Occup Environ Hyg *1*(11):752–767.

Proctor D, Gujral S, Fowler J [2006a unpublished]. Repeated open application test for allergic contact dermatitis due to hexavalent chromium [Cr(VI)] as CopperShield®: risk assessment for dermal contact with Cr(VI). Unpublished study conducted by Dermatology Specialists, PSC, and Exponent under Project No. FPRL #012506. 324 p. (MRID 46884001).

Proctor D, Gujral S, Fowler J [2006b unpublished]. Repeated open application test for allergic contact dermatitis due to hexavalent chromium [Cr(VI)] as potassium dichromate: risk assessment for dermal contact with Cr(VI). Unpublished study conducted by Dermatology Specialists, PSC, and Exponent under Project No. FPRL #012406. Includes Supplemental Information documenting ethical conduct of the research. 664 p. (MRID 46930701).

Savery LC, Grlickova-Duzevik E, Wise SS, Thompson WD, Hinz JM, Thompson LH, Wise JP Sr [2007]. Role of the fancg gene in protecting cells from particulate chromate-induced chromosome instability. Mut Res, *626*(1-2):120–127.

Shaw Environmental [2006]. Industry profile, exposure profile, technological feasibility evaluation, and environmental impact for industries affected by a proposed OSHA standard for hexavalent chromium. Cincinnati, OH: Shaw Environmental, Inc. Contract Nos. J-9-F-9-0030, Subcontract No. 0178.03.062/1, PN 118851-01 for OSHA, U.S. Department of Labor.

Simonato L, Fletcher AC, Andersen A, Anderson K, Becker N, Chang-Claude J, Ferro G, Gerin M, Gray CN, Hansen KS, Kalliomaki P-L, Kurppa K, Langård S, Merló F, Moulin JJ, Newhouse ML, Peto J, Pukkala E, Sjogren B, Wild P, Winkelmann R, Saracci R [1991]. A historical prospective study of European stainless steel, mild steel and shipyard welders. Br J Ind Med *48*:145–154.

Stackpole MM, Wise SS, Goodale BC, Duzevik EG, Munroe RC, Thompson WD, Thacker J, Thompson LH, Hinz JM, Wise, JP Sr [2007]. Homologous recombination protects against particulate chromate-induced genomic instability in Chinese hamster cells. Mut Res *625*:145–154.

Wise JP, Leonard JC, Patierno SR [1992]. Clastogenicity of lead chromate particles in hamster and human cells. Mut Res 278:69–79.

Wise JP, Orenstein JM, Patierno SR [1993]. Inhibition of lead chromate clastogenesis by ascorbate: relationship to particle dissolution and uptake. Carcinogenesis *14*(3):429–434.