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National Institute of Occupational Safety & Health
4676 Columbia Parkway, Mail Stop C-34
Cincinnati, Ohio 45226-1998

RE: Draft Criteria Document for a Recommended Standard:
Occupational Exposures to Metalworking Fluids

VIA: Facsimile transmission and overnight mail.

Dear Dr. Fine:

The American Automobile Manufacturers Association (AAMA) appreciates the opportunity to provide the following comments on the National Institute of Occupational Safety and Health's draft document entitled "Criteria for a Recommended Standard on Occupational Exposures to Metalworking Fluids" (the "Criteria Document"). Additionally, we shall look forward to participating in the NIOSH meeting scheduled for June 13-14 in Cincinnati. AAMA is the trade association for domestic vehicle manufacturers whose members -- Chrysler Corporation, Ford Motor Company, and General Motors Corporation -- generate over 4.5 percent of the nation's gross domestic product, producing over 80 percent of the nation's cars and light trucks in 384 facilities in 36 states nationwide. Approximately 700,000 people are directly employed by America's Car Companies, and the jobs of at least two million more depend on the strength of the automobile industry.

GENERAL COMMENTS

The NIOSH Criteria Document is an extensive compendium of work on understanding health issues associated with using metal removal fluids, and we acknowledge that the compilation and analysis of this large body of knowledge on this very complex subject represents a significant amount of effort.

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Despite the extensive nature of NIOSH's undertaking, there are a number of general areas in which the draft is problematic. First, although the Criteria Document lists several dozen references that make up the bulk of the information from which the analysis of the document is formulated, the reader is left to wonder about the criteria its authors employed in deciding whether to include and/or exclude reference citations. The Criteria Document states (p.18) that "[i]n order to be included in this review an article had to be published in a peer-reviewed journal." Yet for the purposes of establishing a Recommended Exposure Level (REL), the Criteria Document indicates that non-peer review literature comprises a substantial amount of the database used for decision making (p.165). And, in fact, there are many key citations in the Criteria Document from reports that have not entered the peer-review literature, including those cited in the section dealing with the proposed REL. Some refer to manuscripts, some are seminar-type presentations, some are available only in abstract form, and some are published in obscure journals. Often the references are case reports that are not peer reviewed and do not constitute a systematic study, or they are surveys without appropriate exposed and control groups. Therefore, a great deal of the data that is presented does not meet the Criteria Document's self-imposed standards of peer review literature.

Furthermore, as we discuss more fully below in connection with section 9 of the Criteria Document, it is important for the Criteria Document to note that the last versions of unpublished manuscripts seen by the Occupational Health Advisory Board (OHAB) members can be and often are changed during the process of submission to journals. Indeed, this would have to be the case since in some instances the final report to the OHAB would not meet standards for scientific publication. Since changes occur between OHAB review and publication, it is inappropriate for the Criteria Document to suggest (as it does) that such review renders these papers peer reviewed in any meaningful way.

Finally, it is noteworthy that although the NIOSH authors who compiled the Criteria Document appear substantially uncritical of the findings of the authors of the papers cited, the findings and claims of authors of the cited studies often vary in systematic ways. For example, different study authors use different levels of statistical probability to establish that findings are not due to chance. Therefore, there is a lack of consistency in the statistical treatment of data and ultimately, what it means to the issues affecting metal removal fluid. The reader would be served to know how NIOSH approached these discrepancies and why they accept such different standards for accepting statistical significance without explanation.

SPECIFIC COMMENTS

SECTION 1 - Introduction

The Criteria Document identifies a multitude of factors contributing to worker exposure in metal removal operations and then recommends a *Total Particulate Exposure Limit*. We feel that exposure measurements should be more closely related to the metal removal fluids or contaminants in question. With the potential for exposure to metal removal fluid in most areas of modern machining plants, the proposed REL would impose a 0.5 mg/m^3 standard for all particulates including those currently considered nuisance dusts.

SECTION 2 - Background

The section does not clearly define the limits of applicability of the Criteria Document. Since the studies cited in sections four through six of the document address machining and grinding operations, we suggest a definition that encompasses the breadth of these operations using metalworking fluids. Extending the scope of this Criteria Document, beyond the metal removal operations that form the basis of the health research presented here would require significantly more information and analysis. In establishing the broad boundaries of the Criteria Document we strongly recommend the use of the term "Metal Removal Fluids" or "MRFs" as a generic reference to the wide variety of machining and grinding fluids used in these operations.

SECTION 3 - Occupational Exposures to MWFs

3.1 - National Occupational Exposure Survey

NIOSH has correctly estimated the overall number of workers exposed to MRFs. However, not all those exposed are directly involved in the cutting and removal of metal. Indeed, most of these workers are involved in ancillary tasks such as assembly, and as such, their exposures are likely substantially lower or even negligible. So there are really two populations; those employees operating machines or doing set-up, and those in the plant for other functions. The aggregate exposure number may accurately reflect the combination of the two populations, but may not really reflect the magnitude of the regulatory issue.

3.2 and 3.3 - Reported Exposures by OSHA or NIOSH

These results may not be representative of past or current exposures. Since many of these samples were likely collected as part of a complaint investigation, these studies may overstate past levels. And, since users are always modifying and improving their control technologies, these studies may not accurately reflect current exposures.

3.4 - Reported Exposures in the Automotive Industry

Using the results of "cross-sectional" studies in different plants at different times to establish a "longitudinal" change in the industry is inappropriate. Current exposures for the General Motors facilities cited here show significant differences in average exposures between the plants due to differences in products and processes. The October 1993 to April 1995 average personal exposures for the plants in the Grieves, Robins, and Kriebel studies cited were 1.32 mg/m^3, 0.84 mg/m^3, and 0.53 mg/m^3, respectively, as "total particulate" (one Grieves plant is no longer a GM facility). This large difference in arithmetic mean exposures also exemplifies the diversity of environments encountered in our metal removal operations.

There is another problem with the exposure numbers presented in the Criteria Document. The data does not differentiate between source samples, engineering range finding, general area samples and breathing zone samples. Further, data is not divided by machine operators and set-up personnel. The automobile industry data is mixed and jumps back and forth between thoracic and total particulate fractions. Finally, all of these factors are compounded by not knowing more about small and medium size business. While the automobile industry represents a large portion

of the total exposed workers, the data presented in the Criteria Document may not provide a good estimate of personal exposures in small and medium sized businesses.

Automobile company experience indicates that workers involved in metal cutting and removal are exposed to more on the order of between 1.0 mg/m^3 to 2.0 mg/m^3. Conversations with some of our suppliers who machine parts indicate their exposures are in the range of from 1.0 to 3.0 mg/m^3. We are concerned that the use of arithmetic means in this section of the Criteria Document could lead to the false conclusion that our exposures are already in the range of 0.1 to 0.7 mg/m^3, with an average in the range of 0.3 mg/m^3. The reader of the Criteria Document can easily be left with the impression that the automobile industry is already either below or near the draft REL. In light of this industry data, our conclusion is that this section of the Criteria Document seriously understates the magnitude of the regulatory issue.

SECTION 4 - Occupational Health Risks for Workers Exposed to MWFs

4.1 - Cancer Risks for Workers Exposed to MWFs

There is considerable discrepancy in the results of the various cancer studies conducted to date and a lack of dose-response in most of those studies. The largest, and presumably best, of these cancer studies reports the lowest risk for several cancers (e.g., stomach -- not significant). Given the importance of these studies and the extreme heterogeneity of results which make interpretation difficult, we recommend that a meta-analysis, similar to the meta-analysis that was performed for EMF exposure and cancer (JOEM 37:12, 1327-1341), be performed to examine the source of heterogeneity.

4.2 - Nonmalignant Respiratory Effects

4.2.1 - Diseases of the Lung Parenchyma

4.2.1.1 - Lipid Pneumonia

There is no credible evidence that occupational exposure to oil mist in metal removal operations is associated with lipid pneumonia.

4.2.1.2 - Hard Metal Disease

Hard metal disease caused by the inhalation of tungsten carbide/cobalt is a disease that is of concern in operations involved in the grinding of hard metal parts where only a small percentage of workers may be exposed.

4.2.1.4 - Hypersensitivity Pneumonitis

The presentation on hypersensitivity pneumonitis is inadequate in key respects. It is comprised of case studies or Health Hazard Evaluation field studies that are generally not peer reviewed, do not include an experimental design and generally do not include in-depth workups of subjects in the evaluations. The best study that is available is that by Bernstein, and the results of that study are not fully explained in the Criteria Document. It should be noted that 5 of the 6 of Bernstein's subjects admit to smoking. This is not mentioned in the Criteria Document. In addition, the Criteria Document fails to indicate that no data is provided in this study on either the history or the then-current levels of aerosol in the workplace. Therefore, it is impossible to judge

from this data what benefit, if any, derives from changing the exposure to the metal removal fluids, especially since smoking appears to be a predisposing factor.

4.2.3 - Asthma and Other Disorders of the Pulmonary Airways

The section on asthma illustrates the difficulty in understanding metal removal fluid effects. After beginning with some case study type information, the Criteria Document then evaluates *systematic* studies of metal removal fluid on asthma. However, in the scientific studies, both negative and positive correlations of metal removal fluid exposure and asthma are taken as evidence that metal removal fluid causes asthma. It is noteworthy that the negative correlations are more often the case than the positive correlations. This is logically inconsistent. The explanation for this interpretation of the data is that individuals self-select out of the metal removal fluid work environment. Yet no evidence is provided in the Criteria Document to substantiate the claim of self-selection. Since this is such a key point, NIOSH should explain the arguments in some detail, and the specific arguments and evidence should be presented, discussed and evaluated. In addition, the Criteria Document authors' conclusion that the studies provide "substantial evidence of an elevated risk of asthma" is too strong and is dependent on whether one accepts this unsubstantiated interpretation of the data.

In addition, upper respiratory symptoms (rhinitis, sinusitis), irritation, lower respiratory symptoms, and obstructive airway disorders that are acute should be interpreted in terms of occupational exposure and serum IgE determinations. The health risks associated with chronic lower respiratory symptoms are well recognized. There are many identified agents in the home as well as the work place and in cigarette smoke which can ultimately result in symptomatic impairment and pulmonary disability. Clinical asthma induced by metal removal fluids appears to involve specific sensitizers in some cases, but various other agents acting through irritant mechanisms may cause both upper and lower respiratory symptoms. Measurements of acute respiratory symptomatic responses should be considered for use in evaluating the implementation of cost-effective, site-specific interventions.

4.2.4 - Cross-Sectional Studies of Lung Function

Much of this section is spent citing the results of the unpublished Kreibel study. This study was essentially a negative study, and it does not make a good argument that health effects are produced by metal removal fluids. The cogent results of this study were:

- Baseline (morning) PFTs in machinists were within normal limits.
- People who were not exposed to metal removal fluids had greater AM to PM decrements in FEV_1 than those who were exposed to the metal removal fluids.
- The relationship between aerosol exposure and decrease in FEV_1 holds only if those, whose aerosol exposure is not metal removal fluid-related (non-machinists), are included in the data.
- There were no machinists who responded to the lowest exposure category of aerosol. There were non-machinists who did respond to the lowest exposure category of aerosol, even though their exposure was likely not to metal removal fluid aerosol.
- The more culturable bacteria there were in the air, the less was the change in FEV_1.
- There was no statistically significant differences in the prevalence of respiratory symptom reporting between the machinists and non-machinists.

- There was no statistically significant evidence that pre- or post-hire asthma was more prevalent in machinists then in non-machinists.

The results of this study should not be over analyzed in order to cite a health effect while the great preponderance of the results would seem to argue exactly the opposite.

Also in this section, assertions are made regarding chronic lung effects induced by metal removal fluid. There is no indication, however, of how the investigators of the various studies differentiated between chronic irreversible effects and those that were cross-shift changes in lung function (acute and reversible). The lack of objective findings that indicate that progressive lung disease results from metal removal fluid aerosol exposure is striking. No results from any of the typical medical tests used to establish chronic lung disease are presented. These populations have been studied intensively for at least 10 years and the evidence of chronic lung disease is weak. It appears that the authors of this section of the Criteria Document believe that historical exposures may be related to symptoms or to some variation of PFTs, the clinical significance of which is not addressed. In fact the authors of the study (as yet unpublished) interpret the data as indicating asthma, and not necessarily progressive lung disease. In the absence of confirming data, the assumption that this indicates *chronic disease* is *unfounded*. What is sorely needed is a good study that addresses the specific question of progressive lung disease using a variety of objective measures, instead of devoting such substantial time, effort, and money on studying pulmonary symptomatology. Problems with the effort-dependent nature of PFTs is also indicated in these studies. Therefore, objective measures may be more necessary in this particular context.

SECTION 5 - Selected Potentially Hazardous Chemical Ingredients or Additives

Generally speaking, there is a dearth of toxicity information examined in this portion of the draft Criteria Document. There is much more toxicity information available, it is relevant to the concern over metal removal fluids, and it is more dependable than the epidemiological evidence upon which the Criteria Document depends.

It is incorrect to say that there is limited information on chemical components of MRFs. While the actual formula of a given MRF may be proprietary, the chemicals used in MRFs can be readily determined. Furthermore, the chemicals used in MRFs are for the most part, common chemicals used in many applications in addition to MRFs (e.g., cosmetics). There is a substantial amount of toxicity information available for these chemicals. Additionally, the vast majority of chemical products used in the automotive industry are mixtures, generally proprietary mixtures, and it is common in our industry to evaluate the toxicity of chemical mixtures and potentials for synergy, additivity, or competition.

5.1 - Triethanolamine

TEA is summarized as being noncarcinogenic, pending the final report from the NTP. The noncarcinogenic aspect of the review is inappropriately brief, mentioning only that it "may be associated with occupational asthma (Savonius *et al.* 1994)."

5.3 - Biocides

The biocide discussion is also cursory at best. Biocides are toxic by definition, and have considerable toxicity information available on them. A discussion of the likely effects of biocides on machinists in the concentrations used in MRFs is needed.

5.4 - Chlorinated Paraffins

Recent MRF formulations avoid the use of carcinogenic chlorinated paraffins. The discussion is therefore not relevant to current MRF problems, and especially not relevant to the primary problem of pulmonary irritation.

5.5 - Potential Sensory or Pulmonary Irritants

The discussion of potential irritants is important and relevant, and should be expanded. It is important to note, however, the excessive exposures (2,000 mg/m^3) used in the studies. What is the effect of "plant level" exposures (typically 1-3 mg/m^3)? What is the justification for NIOSH's stated reliance primarily on human epidemiologic data and ignoring toxicity information, especially given the Criteria Document's expansive discussion of that data but overall minimization of its significance to current MRF environments? These are questions that the Criteria Document should, but does not, address.

SECTION 6 - Potentially Hazardous Contaminants

6.1 - Nitrosamines

Current MRFs contain little or no nitrosamines. For example, assuming levels as high as 50 ppm of nitrosamine and 5 mg/m^3 of MRF mist exposure, the nitrosamine exposure would be 0.25 $\mu g/m^3$. From the standpoint of toxicology and pulmonary irritation, one could certainly question the significance of that level of exposure. Again, there seems to be an over-reliance in the Criteria Document on historical concerns, and an under-reliance on current toxicology.

6.2 - Microbial Contamination

The diversity of microbial contaminations with their economic impact and potential health effects are presented here. However, few if any of the health effects postulated have been documented through scientific research. While good microbial management of metal removal fluids is important, the current state of knowledge is insufficient to propose microbial standards as part of a health risk reduction strategy for these fluids.

It must be remembered, however, that most materials and locations are not sterile; even hospital operating rooms tolerate levels of bacteria in air. Although microbes are present in MRFs, several questions would need to be answered before microbial standards should be proposed. For example, do microorganisms contribute to infection, or are such results attributable to their endotoxin byproducts? Similarly, the Criteria Document does not address whether we are then exacerbating the problem by adding biocides, and possibly creating additional sources of irritation through the chemical constituents in these products.

SECTION 7 - Current Occupational Recommendations and Standards

In the absence of an identified causative agent or agents for recently reported health effects, the quantitative determinations of total particulate and extractable constituents (oil) are the commonly used indicators of exposure. AAMA's members have reviewed the available data and have adopted control levels that are based on economic and technical feasibility, while providing protection against the health effects that may occur at exposures at the current Threshold Limit Value for oil mists.

SECTION 8 - Sampling and Analytical Method

The principal goal of air sampling in the workplace is to assess and reduce worker health risk posed by contaminants in the workplace air. The total particulate method proposed is non-specific and will have a dramatic impact on all aerosol exposures in facilities using metal removal fluids. A more specific method to measure the putative chemical or biological agents, or at least a method measuring the metal removal fluid portion of the workplace aerosol, is needed to implement control levels substantially below the current 5.0 mg/m^3 oil mist standard. The lack of an identified agent or agents responsible for reported health effects is an additional complicating factor which suggests that a single measure is not appropriate for all machining exposures.

NIOSH method 0500 for total particulate is considered by the Criteria Document to be a feasible method for use with a 0.5 mg/m^3 total particulate standard, but no actual limit of quantitation (LOQ) is estimated for making such measurements. With the lack of precision in analysis and the need to sample well below the standard for overtime work schedules, it would be very difficult to show statistical compliance with the draft REL using full-shift personal samples collected at 2.0 L/min.

There are several additional issues regarding the sampling and analysis of metal removal fluid mist which were not addressed by the Criteria Document. For example, dry machining operations are frequently performed adjacent to operations that generate MRF mist. A single analytical method is not appropriate when comparing exposures in these mixed contaminant situations to exposures in operations where the predominant air contaminant is metal removal fluid mist. Dry machining exposures should measure the mist and the metal(s) exposures separately. Specific Permissible Exposure Limits should be used to assess exposures to the metals, not a limit based on possible effects of exposure to metal removal fluid mist.

The problem of reproducibility of analytical laboratory results was highlighted in a paper published in the Symposium Proceedings by D'Arcy *et al,* (p.196). Coefficients of variation in these triplicate analyses were much greater than expected, significantly affecting the reproducibility of analytical results for both total particulate and extractable mass. This analytical problem is compounded by the Criteria Document's suggested use of an action level of 0.25 mg/m^3. Because this value approaches the background level of the outside air being drawn into many industrial plants, the proposed NIOSH sampling and analytical method would not be able to determine if ambient particulate exposure is a significant component of an employee's apparent metal removal fluid mist exposure.

SECTION 9 - Basis for a Recommended Exposure Limit

9.1 - Introduction

Many of the effects described in the Criteria Document appear unrelated to the specific type of metal removal fluid (straights, solubles, synthetics) used in the workplace. The logical conclusion that can be drawn from this finding is that there are attributes that are generic to different fluid types, despite the fact that each type contains very different chemical constituents. NIOSH does not explain, or even discuss this logical discrepancy. This certainly raises the question of what mechanism or mechanisms account for similar biologic responses from such different materials. In AAMA's view, the lack of a unified understanding of the observed effects as they relate to fluid types or components detracts from the accuracy and scientific basis for the draft REL.

NIOSH explains its use of non-peer reviewed documents as contributing to, -- and actually forming the major part of -- the basis for its recommendations. The agency relies on the internal review by the General Motors OHAB, but, as noted above, such an informal review by a granting agency is not a substitute for a confidential peer review of a prestigious journal. Studies should not be included as the basis for recommendations until they have gone through the rigors of true peer review. All too many times, statistical methods and conclusions are significantly modified based on true expert peer review. The section on the GM OHAB role in review of this data might be interpreted by some as an endorsement of the findings by one or more of the sponsoring organizations. If this is what the authors intended, both the UAW and GM sponsors and the readers should be so informed.

The recommendation for the REL depends heavily on unpublished studies (Kriebel *et al*, 1994; Greaves *et al*, 1995a; Robins *et al*, 1994), which is problematic for several reasons. First, the need to rely on these unpublished studies arises from the fact that the area of respiratory disorders associated with MRF exposures is so embryonic that a body of scientific literature does not yet exist. Second, even though these studies have been reviewed by the UAW-GM OHAB, clinical-based pulmonary specialists are not an integral component of that OHAB. Even if such expertise existed on the OHAB, one critical function of publishing in the open scientific literature is to evoke scrutiny and debate through the peer review journal submission process, and technically-driven letters to the editor with rebuttals by the author(s). Finally, and most importantly, is that any findings based on spirometry and other lung function tests are subject to many variables that can influence the outcome of such tests. Given these difficult issues, and the exceedingly heavy reliance by the investigators on statistical modeling, we submit that these unpublished and non peer-reviewed initial findings should be considered as *indications of areas for further study* and that such studies should be done in a timely manner and published in the open scientific literature. AAMA maintains that these current cited studies, by themselves, should in no way be the basis for a REL.

9.1.2 - Control Technology Issues

We are left to wonder why NIOSH would elect to avoid making any meaningful comment on such a critical issue. Certainly, the applicability and feasibility of controls within 'large' industry, such as ours, *and* in small industry is a critical area that OSHA will not have the luxury of ignoring.

9.2 - Effects from Exposure

9.2.1 - Cancer

It is unclear from the Criteria Document whether or not, in developing the recommended standard with respect to cancer, the authors are treating the carcinogenicity potential of metal removal fluid as a threshold or non-threshold effect? This point should be clarified. If it is being treated as an effect without threshold, then the position must be that the recommended standard will reduce but not eliminate cancer due to metal removal fluid exposures. If this is the approach, the document should answer the following questions: What are the estimates of cancer incidence reduction to be achieved by the recommended standard? How would this reduction compare to higher or lower metal removal fluid standards? How was it determined that this reduction in incidence was the right amount to be achieved? Conversely, if the metal removal fluid-induced cancer is being treated as a threshold phenomena, the Criteria Document should explain how was it determined that 0.5 mg/m^3 should be the threshold.

The draft Criteria Document correctly de-emphasizes the risk of cancer in the rationale for the REL. While there have been many studies evaluating the cancer risk of occupational exposure to metal removal fluids, the exposures that produced those excesses are very different from those that now exist in most large scale machining operations. Improvements in the refining processes for the petroleum components of the fluids have greatly reduced the level of PNAs in the fluids. Components which are capable of producing nitrosamines in the final formulations are no longer used. The magnitude of current exposures is much less than that of 20 to 30 years ago due to significant advances in, and the implementation of control technology. Given the moderate level of cancer risks identified in the UAW-GM and the UAW-Ford cohort studies, the changes in the level of exposure and component chemicals in the current fluids should not produce any detectable future cancer evaluations in worker populations who began work in machining operations within the last 10 to 15 years.

While a full risk assessment may not be possible with available information, an analysis of the reduced cancer risk posed by metal removal fluids that have been reformulated significantly over the past four decades should be attempted.

9.2.2 - Nonmalignant Respiratory Effects

First, as a general matter, lipid pneumonia should not be reported as part of the basis for standard setting. The Criteria Document as much as recognizes this. In section 4.2.1.1, it is stated that "the apparent rarity of lipid pneumonia associated with occupational exposure to oil mists in metal working operations suggests that current exposure concentrations are generally effective in preventing clinical cases of the disease." (Emphasis added.)

Second, certain of the specific statements in this area are unsupported. On page 178 it is stated that, ". . .it is biologically plausible that repeated modest and apparently reversible acute airways effects may ultimately lead to irreversible impairment and chronic disability in some workers, as has been only recently demonstrated with other occupational agents (Becklake,1995)." This statement is pure speculation and should not be part of a rationale for setting exposure guidelines. The mechanism of action of exposure to other agents could be entirely different than that for metal removal fluid exposures and, therefore, the consequence of the exposure entirely different. There are many agents that can cause reversible acute airways

effects that have never been shown to cause permanent dysfunction, such as cold air, ozone, methacholine, etc. In the absence of peer-reviewed scientific evidence, this statement should be removed.

Third, the case that low level exposure is related to lung disease is weak and unsubstantiated. Treatment of the data *post hoc* (e.g., changing what is considered a significant response from 5% to 4%) or relying on subjective evaluations of one or two subjects, or combining control and exposed populations to identify a result is not systematic. The assertion that low levels of exposure produce effects is largely unsubstantiated.

Finally, a difficulty in the interpretation of the pulmonary function studies is trying to determine what agent(s) is causing the respiratory problems. For example, it is our understanding that the Robins study was conducted in a facility that had extremely high microbial counts. While airborne microbes are often associated with MRF mists, to base a REL on operations with a coolant management problem would penalize locations that properly manage their MRF systems, and that have significantly lower microbial counts. To continue this line of reasoning, there are differences in the ability of the various types of MRFs to produce respiratory symptoms. These differences also need to be considered in the recommendation of a REL. Given these issues, the draft REL should be set at a different level, such as 1 or even 2 mg/m^3, until further respiratory research can be completed that would support a lower REL.

9.3 - Rationale for the Recommended Exposure Limit

The draft Criteria Document recommends a standard for occupational exposures to metal removal fluid without ever indicating what will be gained by controlling exposures to that level. For example, the current standard for mineral oils is 5 mg/m^3. Is it the contention of NIOSH that controlling metal removal fluid exposures to 0.5 mg/m^3 will eliminate hypersensitivity pneumonitis, occupational asthma, and irritation of the lungs? Will it reduce the incidence? By how much? What is to be gained in terms of the incidence of pulmonary effects at 0.5 mg/m^3 versus 1.0 or 0.25 mg/m^3? The ultimate purpose of the recommended standard is to protect the health of the workers, and yet no attempt is made to project the level of relief that a standard of 0.5 mg/m^3 will afford the workers. Was this number selected arbitrarily, or does NIOSH have some scientific justification for arriving at the REL? If the latter, then we strongly recommend that NIOSH present the basis and justification in a logical and cogent manner.

9.4 - Technological Feasibility of Controlling Exposures to MWFs

In considering the feasibility of controls it is important to look at the high exposure operations and not just the arithmetic mean exposures. While AAMA members are proud of the improvements that have been made over the years, there are still many operations for which adequate engineering controls are not available to retrofit old equipment in order to achieve compliance with NIOSH's draft REL. The operations representing the upper 10% of the log-normal distribution of exposures should be used in determining technical feasibility. PPE for respiratory protection is quite likely to be necessary for exposure standards below 1 or 2 mg/m^3.

The Criteria Document correctly points out that control of metal removal fluids is possible in theory. However, the reference to mean or median concentrations tends to simplify the

regulatory issue. References are made to the automotive industry data out of context. Again, there is not enough data to define the issue outside the automotive industry.

The data presented from the Symposium Poster Session study by Hands examines only the median concentrations rather than the variability of the data. The purpose of the Hands study was to determine exposures seen in machining operations with different levels of engineering control. In other words, does it appear that retrofit and so-called OEM engineering efforts differ in their ability to control exposures, in "real-world" scenarios? The conclusion of the study was that OEM controls can consistently achieve exposures less than 0.5 mg/m^3, while retrofit controls do not do so on any **consistent** basis. Further, in the study by Hands, other variables that are at work, such as good fluid management programs, are not fully explored. These other variables have a major impact on the total MRF exposure. The Criteria Document does not allow the reader to realize the importance of total systems management in the control of MRF exposure.

SECTION 10 - Recommendations for an Occupational Safety and Health Program

NIOSH is correct to point out that there needs to be a total management system, and that an effective system needs to address the following elements, at a minimum:

- Employee and management health and safety training on hazards and control; employee training alone is not enough.
- Employee and management training on total systems management roles and responsibilities, fluid management, engineering controls, etc.
- Employee participation in the development of control strategies
- Workplace analysis (employee exposure assessment)
- Environmental sampling
- Fluid management and control
- Exhaust ventilation and supply ventilation. In this case the ACGIH Ventilation Manual must be supplemented with the upcoming ANSI Standard. Many ACGIH concepts must be modified.
- Enclosure (Isolation)
- Air cleaning devices
- Personal protective equipment
- Personal hygiene and sanitation

NIOSH's specifications for a health and safety program contains the majority of the elements listed above. The main problem is that the Criteria Document only lightly touches on the issues of engineering control. The impact here again is that the definition of the regulatory issue is understated in the Criteria Document. While this is a cursory overview of an extremely important section of the Criteria Document, we intend to greatly expand our comments on this section at the NIOSH mid-June meeting.

SECTION 11 - Medical Monitoring of the Exposed Worker

Medical monitoring is an important aspect of secondary prevention for adverse health effects associated with metal removal fluids. The early identification of individuals with medical conditions associated with metal removal fluid exposures, followed by appropriate medical management of those individuals is key to these efforts.

In discussing individuals with asthmatic symptoms on page 211, "chronic impairment of lung function" is discussed as one of the disease states associated with metal removal fluid exposure. As we discuss in sections 4.2.4 and 12, there is no direct medical/scientific evidence of chronic lung disease in non-smoking workers from any of the studies to date. While proper medical monitoring would be expected to diagnose chronic lung disease, we believe that attribution of the condition to metal removal fluid exposure is unsubstantiated at this time.

The draft Criteria Document recommends 0.25 mg/m^3 total particulate as a 'trigger level' to include individuals in the medical monitoring and surveillance program. Given the non-specific total particulate method for estimating metal removal fluid exposure, this 'trigger level' would result in the inclusion of virtually all employees in every facility in the nation where machining operations take place.

The role of smoking as a significant risk factor for respiratory disease should be part of the worker education program (Section 10) and it should be re-emphasized by occupational medicine health care providers during medical monitoring.

In general, AAMA supports the elements of a medical surveillance program outlined in the Criteria Document. The program should evaluate the medical and occupational work history, and use standardized skin or respiratory symptoms or periodic questionnaires related to exposures which may have a specific cause or a health risk. This should consist of a pre-placement evaluation for each employee that is included in the monitoring program. The pre-placement evaluation would be inclusive of all employees, newly hired, or transferred from non-exposed areas. Included in the evaluation would be an examination of the skin and baseline spirometric testing with an emphasis on measurement for FEV_1 and FVC.

Employees who are identified for further medical evaluation should be evaluated by the appropriate medical specialist who is knowledgeable in occupational medicine, allergy, lung, or skin disorders related to occupational exposures. Consideration should be given to including serum IgE in the evaluation, where indicated. Employees who are working in an exposed work place should undergo re-evaluation periodically in a medical monitoring and surveillance program under the direction of a qualified occupational medicine specialist.

SECTION 12 - Research Needs

While a large volume of scientific research has been conducted to date, there remains several significant questions associated with metal removal fluids, their use, and potential health effects.

- Toxicity testing of fluid constituents and of complete in-use fluids is needed to allow knowledgeable substitution of fluids with less hazardous ones.
- Work is needed to address directly the question of progressive lung disease and to improve our understanding of microbial exposures and potential health effects.
- The non-specific effects that are associated with all of the metal removal fluids need to be addressed to identify the reason that such different fluid formulations give rise to similar health complaints.
- An improved analytical method is needed; one that is more sensitive and much more specific to the health effects in question, or at least more specific to the fluid in question.
- A total machining environment management plan needs to be developed to integrate the multiple system components.
- Improved understanding of aerosol generation mechanisms is necessary to allow process improvements and to design better aerosol capture systems.
- Further work is needed to improve aerosol control technology.

CONCLUSIONS

A number of substantial and scientifically valid points are made in the draft Criteria Document. First, the historical trend toward reducing exposure to metal removal fluid, which has been in place for decades and all indications are that the trend will continue. This is appropriate for reasons of comfort and providing a maximal margin of safety to protect the working population from adverse health effects. With the advancements of control technologies, we believe that industry can improve significantly on the limit of 5 mg/m^3.

In addition, AAMA agrees that, whenever possible, specific components of fluids that are problematic should be identified and eliminated. This approach has been used to virtually eliminate PAH's from oils and should lead to improvements in the materials. Limitations to this approach include in-use changes to the oils and the fact that many of the effects are nonspecific to fluid type, suggesting that other properties beside specific chemical effects may play a significant role in the health effects produced by metal removal fluids.

We also agree that smoking elimination is a key component to any risk management plan. Active and passive smoking virtually overwhelm any study of respiratory disease. However, in many instances, effects are attributed to metal removal fluid without evidence that the confounding effects of smoking are understood. It is clear that smoking provides a much greater risk to this working population than the effects of metal removal fluid. Cessation of smoking is a critical concern to prevent lung disease from active smoking, from passive exposure, and from interactions that predispose workers to susceptibilities from metal removal fluid than they otherwise would not experience.

On the whole, there is reason to reduce exposure from 5.0 mg/m^3. However, from the pattern of changes seen in the current studies, it is unclear what the exposure level should be in order to achieve substantial benefit to workers in this environment. Smoking is a predominant factor, immunologic sensitization is not largely dependent on dose (or at least we should not

assume so), and the evidence for chronic effects is virtually nonexistent. There is no evidence of low level effects. In addition, there is specific evidence that nonsmokers are *not* affected by metal removal fluid, there is no change in group mean lung function parameters, and the evidence that workers self select out of this environment should be presented more thoroughly. Therefore, we believe that this proposed REL should be reevaluated and alternative or additional approaches to reducing health risk should be identified.

We appreciate the opportunity to provide these comments on the draft Criteria Document, and we should like to thank you for extending the comment period a few days to accomodate us. If you should have any questions or require clarification regarding any of these comments contained herein, please feel free to contact me (313 / 871-5343) at your convenience.

Sincerely yours,

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cc: AAMA MRFTG / OSHC Members