FINAL REPORT
of the
OSHA METALWORKING FLUIDS
STANDARDS ADVISORY COMMITTEE

Submitted by

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Chairperson
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CHAPTER ONE
Introduction and Scope

1.1.GENERAL INFORMATION

The OSHA Metalworking Fluids Standards Advisory Committee (MWFSAC) was formed to provide OSHA advice on how to address metalworking fluids (MWFs) in the workplace. This committee had ten meetings at which it heard presentations and discussed and deliberated a wide range of issues associated with MWFs. Committee members were provided handouts from speakers as well as literature to review. The issues discussed included the scope of the fluids, machining processes and workplaces, and these topics are addressed in this first chapter. The committee reviewed the health issues, and the technological and economic feasibility of actions to mitigate health effects and these topics are found in Chapters Two through Four. Discussions of Best Practice are found in Chapters Six through Nine.

This final report is the product of the committee's deliberations. The information reviewed, concerns noted, views expressed, and decisions made are included in this report. The style used in this report reflects the voices of the individual committee members, speakers and participants. The deliberations are referenced in parentheses noting the meeting number and the page number of that meeting's minutes using the format "M #:page". In some cases the format "T #: page" is used and this refers to the page in the transcript of meeting number (#) listed. Author, date referencing is used for speaker's handouts and cited references. A list of references cited is found after Chapter Nine and before the Attachments. A list of additional references that the committee reviewed but were not cited is in Attachment #6. A list of committee members, speakers and other participants is found in Attachment #2.

1.2 COMMITTEE ORGANIZATION

1.2.1 Speakers and Presentations

Assistant Secretary of Labor for OSHA, Charles Jeffress addressed the committee multiple times to clarify what OSHA wanted from the committee. Prior to Jeffress' appointment, Acting Assistant Secretary of Labor for OSHA, Greg Watchman charged the committee with its responsibilities (M1:1). Issues such as duties, finances and ethics were addressed by Dr. Adam Finkel, OSHA Office of Health Standards, Greg Sentowski, OSHA Office of Financial Management and Robert Shapiro, Miriam Miller and Susan Sherman from the Department of Labor's Solicitor's Office (M1:1).

1.2.2 Formation of the Committee

On August 29,1996, the Occupational Safety and Health Administration (OSHA) requested nominations for membership on an advisory committee on MWFs (Federal Register, 1996). Names were submitted by a variety of stakeholders. OSHA formed a committee of five representatives of employees, five representatives of employers including two representing small business, five public members including one federal agency representative and one state agency representative. Two alternates, one representing employers and one representing employees, were chosen. The proportions of employer, employee and public membership were as stated in the OSHA statute, section 7(b) of the OSHAct. A Designated Federal Officer (DFO), representatives from the Department of Labor Solicitor's office, and OSHA staff members were assigned to assist the committee. The list of MWFSAC members and alternates and their affiliations, along with OSHA personnel is provided in Attachment #2.

1.2.3 Advisory Committee Charter (Reproduced from the Charter, a Signed Copy is found in Attachment #3)

1.2.3.1 *The Committee's Official Designation*

Standards Advisory Committee on Metalworking Fluids

1.2.3.2 The *Committee's Objective and the Scope of Its Activities*

The committee will be established under Section 7 (b) of the Occupational Safety and Health Act to recommend a standard, a guideline or other appropriate response to the dangers of occupational exposure to metalworking fluids. Such recommended action should be that which most adequately assures, to the extent feasible, the highest degree of health protection for employees based upon the best available evidence and latest scientific data. In addition, the recommended action(s) should take into consideration technical and economic feasibility as well as the impact of such recommendations on small business. In making its recommendations, the committee will review documents and information from the National Institute for Occupational Safety and Health and other pertinent data available to the committee from other sources.

The specific objectives of this committee will be to recommend an occupational safety and health standard, guideline or other appropriate response to mitigate the adverse health effects associated with occupational exposure to metalworking fluids. The following issues should be addressed in the report or recommendations of the committee: 1)definition of the scope of fluids to be covered; 2)identification of the adverse health effects associated with exposure to metalworking fluids, or specific types of fluids; 3)consideration of whether health effects associated with the various types of metalworking fluids can be generalized to all such fluids within a given category; 4)consideration of whether one or more permissible exposure limit (s) should be recommended and if so, what it/they should be; 5)determination of the significance of risk to workers exposed to metalworking fluids; 6)consideration of whether a medical surveillance program should be instituted, and if so, what components should be included;

7)consideration of whether the problem can be adequately addressed by a systems approach to fluids management (including consideration of components and degradation products) and the appropriate elements to be included if such an approach is recommended; 8)the technical and economic feasibility and small business impacts of any actions recommended by the Committee; and 9)analysis of subsidiary issues which may, in the Agency's opinion, be necessary to resolve in order to support the resolution of the above listed issues.

1.2.3.3 The Period of Time Necessary for the Committee to Carry Out its Purpose

Two years from the date of establishment.

1.2.3.4 The Agency or Official to Whom the Committee Reports

Assistant Secretary
Occupational Safety and Health Administration
U.S. Department of Labor

1.2.3.5 The Agency Responsible for Providing Necessary Support for the Committee

Occupational Safety and Health Administration (OSHA)

1.2.3.6 A Description of the Duties for Which the Committee is Responsible

The Committee is responsible for representing various points of view in advising the Assistant Secretary regarding the appropriate approach for the Agency to take to help mitigate the adverse health effects encountered by those exposed to metalworking fluids in the workplace. The Committee members will be expected to discuss and analyze information on the risks involved in working with these fluids, possible solutions that will decrease the health risks posed to workers exposed to these fluids during the course of their employment, the costs of various solutions under consideration, the benefits associated with suggested solutions, as well as the technological and economic feasibility and the small business impacts of any recommended solutions. The Committee's recommendations and conclusions will be detailed in a report submitted to the Agency.

1.2.3.7 Membership

The Committee will be composed of not more than 15 members who have been selected to represent the various interests involved. The makeup of the Committee shall comply with Section 7(b) of the OSHAct which requires the following: at least one member who is a designee for the Secretary of Health and Human Services; at least one designee of a State health and safety agency, and equal numbers of representatives of employers and employees. Section 7(b) of the Occupational Safety and Health Act allows the selection of additional members from professional organizations and national standards-setting groups.

1.2.3.8 Estimated Annual Operating Costs in Dollars and Staff Years for Such a Committee

Staff Salaries	2.5. FTEs
Committee Expenses and operating costs	$68,000

1.2.3.9 The Estimated Number and Frequency of Committee Meetings
Meetings will be held as necessary; it is estimated that a minimum of eight meetings will be held over a span of two years.

1.2.3.10 The Committee's Termination Date
Two years from the date this charter is filed.

1.2.3.11 Filing Date
This charter is filed on the date indicated below.
Signed by Alexis M. Herman, Secretary of Labor, 8/28/97

1.2.4 Deliberations of the Committee

The committee conducted their deliberations through public meetings that consisted of invited speakers and panelists, committee discussion, and as time permitted, comments from the audience attending these meetings. In addition to the specific issues related to the duties of the committee, individual committee members were tapped to provide general information to educate the committee on basic concepts such as epidemiology. A list of speakers and panelists for each topic area is provided in the beginning of each chapter of the report. An overall alphabetized list of all committee members, OSHA staff, speakers and other participants is provided in Attachment #2. The meeting agendas are found in the Attachment #4. A court reporter provided transcripts of each meeting. Meeting minutes, referenced to the transcript, were compiled by the chairperson and the minutes for meetings one through nine are provided in Attachment #5. The minutes for the final meeting will be available through the docket office as they become available.

In preparation for discussion at meetings, documents were provided for committee members to review. These materials included government documents such as the NIOSH *Criteria for a Recommended Standard:Occupational Exposure to Metalworking Fluids* (1998) and reports from OSHA. The committee assessed peer reviewed articles, NIOSH Health Hazard Evaluation reports, state government reports, analyses by industry consultants, union reports, and news articles. The proceedings from two MWF Symposia, and ANSI and ASTM standards were reviewed. The committee, and particularly some specific members, provided significant input into the development of the second edition of Organization Resources Counselors' (ORC) *Management of the Metal Removal Fluid Environment,* 1999. Items specifically referenced in this report are found in the references section of this report which is provided after Chapter Nine. Additional references, not specifically cited but reviewed by the committee are provided in Attachment #6. The items the committee reviewed including

publications and speakers' handouts along with other materials were submitted to the docket for this committee. The docket list is provided in Attachment #7.

1.2.5 Organization of the Committee and Final Report

Prior to the first meeting, the chairperson decided to include the two alternates in all discussions. The purpose of this action was two-fold: each alternate would be fully prepared to step in, if needed, to replace a committee member, and these individuals had much to give the committee in terms of expertise and experience. The comments and concerns of committee members as well as these alternates are provided in the report. Neither alternate was allowed to vote.

In 1997, the committee was organized by the chairperson into work groups to address specific issues. In 1999, a change in the work group structure was made by the chairperson with the groups asked to address certain questions developed by the committee and the chairperson.

The members of each original working group were: *Government Options:* Mirer, Cox and White; *Systems:* Lick, O'Brien, Shortell, Sheehan; *Cooperation and Comparison:* Burch, Howell, McGee, Day; *Health:* Wegman, Teitelbaum, Newman, Anderson, Frederick, Kushner. The members of the revised work groups were: *Health:* Wegman, Anderson, Newman, Teitelbaum, White, and Cox was half time; *Cooperation and Comparison:* Burch, Day, McGee, and Howell and Kushner were each half time; *Systems:* Lick, Shortell, and O'Brien half time; and *Exposure Assessment:* Mirer, Frederick, and Kushner, O'Brien, Howell and Cox each half time. The original duties of each group and questions the revised groups were asked to address are in Attachment #8. The products of these groups are found in the appropriate chapters of this report and meeting minutes. The leaders of each group are named first in the above list.

A duty of all work groups was to visit worksites that use MWFs. These visits included a large facility outside of Cincinnati, three small businesses in the Cleveland area, and a mid sized facility outside of Detroit. In order to better understand the issues related to diagnosis and medical monitoring of respiratory disease, the work groups visited a respiratory disease medical research center in Denver. These visits were discussed at meetings, so information on them is found in the minutes.

In order to provide the most useful information to both OSHA and those employees and employers who use MWFs, the final deliberations, and this report were organized into two major divisions. These divisions include: deliberations on actions OSHA should take (Chapters 1,2,3,4 and 5) and best practices for MWFs (Chapters 6,7,8 and 9). The second section of Chapter One addresses the scope of MWFs. Chapter Two deals with the committee's deliberations on the health issues related to MWFs. The committee's input on the technical feasibility is found in Chapter Three. The economic feasibility of actions that could be taken by OSHA is provided in Chapter Four. The committee's recommendations for OSHA actions related to MWFs are found in Chapter Five. The committee's assessment of the best practices for those working with MWFs include: Chapter Six - Systems

Management, Chapter Seven - Exposure Assessment, Chapter Eight - Medical Surveillance and Chapter Nine - Training and Information Outreach.

Many of the chapters overlap in content. Sections of the Second through Fifth Chapters of this report could be incorporated in an OSHA action. Chapters Six through Nine were developed as an almost "stand alone" document. These latter chapters are designed to provide guidance to OSHA, and also to provide immediate recommendations to the entire MWF community of stakeholders.

1.2.6 What is Expected of the Committee

Watchman and Jeffress noted their desire for the committee to investigate various options (M1:1). The charter provides a list of duties for the committee. Jeffress emphasized a focus on best practice activities for protecting workers in the MWF environment. Individual committee members had their own individual perspectives on what the committee should accomplish. Overall, the committee decided to provide OSHA in this report: documentation of committee discussions, majority and minority recommendations and rationale for OSHA actions, and detailed instructions for best practice related to Systems Management, Exposure Assessment, Medical Surveillance, and Training and Information Outreach.

1.3 SCOPE OF THE MWF ISSUE

1.3.1 Speakers and Presentations

The scope of the MWF issue was primarily addressed at the first, second and fifth meetings and discussed at other meetings. Committee member, Dr. Dennis O'Brien provided an overview of the types of machining operations using MWFs (M1:1). Committee member, Dr. John Howell explained the composition and use of MWFs (M1:1). Committee member, David Burch presented information about characteristics of machining in small business (M2:3). Dr. William Lucke, Cincinnati Milicron, explained the development of MWFs. Robert Burt, OSHA Office of Regulatory Analysis, presented an industry profile of companies potentially affected by an OSHA action. Greg Piacitelli, NIOSH provided information about characteristics of companies that participated in the NIOSH Small Business Study.

1.3.2 Review of Available Information

1.3.2.1 *Experiences and Resources Related to the Scope of the Machining Processes*

Committee member, Dr. Dennis O'Brien provided an overview of machining processes at the first meeting and provided handouts. Machining processes include: turning, milling, grinding, drilling, sawing, and threading. Turning uses a single point tool that is fed into a rotating workpiece. Turning operations include cylindrical turning, boring, facing and taper turning. Milling uses a rotating multipoint tool and the workpiece is fed into the cutter. Milling operations include slab milling, face milling, end milling, broaching and hobbing. Broaching is milling with a linear tool. Hobbing is a specialized milling operation with a complex rotation of the workpiece. Grinding is done with an abrasive wheel and the workpiece may

rotate or move in a plane. Grinding operations include cylindrical grinding, centerless grinding and surface grinding. Drilling short holes can be done using a radial drill and the tool rotates in the operation. Drilling deep holes may require a gun drill and the workpiece may rotate in this operation. Sawing is similar to using a narrow broach or grinder. Threading can be done by turning, tapping, grinding or rolling. (O'Brien, 1997). Diagrams of these processes and general machining characteristics can be found in handouts of O'Brien (1997) and Burke (1998).

Burch described machining and the use of MWFs in small businesses such as those represented by his organization, Precision Machined Products Association (PMPA) (M2:3). Burch explained that machine tools in his organization's companies include: single-spindle automatic screw machines (ASMs), multiple spindle ASMs, Computer Numerically Controlled (CNC) turning machines and rotary transfer machines (Burch, 1997). Internal machining operations include: drilling, reaming, cross drilling, cross reaming, broaching, counterboring, polygon boring, recessing, tapping, boring, chamfering and bank-end drilling (Burch, 1997). External machining operations include: turning, forming, roller shaving, skiving, broaching, thread rolling, die head threading, single point threading, milling, deburring, slotting, sawing, cutoff, polygon turning, knurling and roll marking (Burch, 1997).

O'Brien explained that MWFs can be applied to the tool/workpiece interface through the tool, as an air carried mist, or by flooding. He noted that MWF mist can be generated by nozzle atomization, centrifugal atomization, evaporation/condensation, splash and the cola effect. The cola effect is due to air entrapped in the fluid and the effect is similar to a carbonated beverage (O'Brien, 1997; T1:85).

Lick explained that traditional machining should be the scope (M2:23). If other materials are machined in these environments, these other materials may be covered in the context of that machining plant (M2:24). Lick noted that defining the operations may be more important than defining the fluid (M2:23). Grinders are used in other environments (M2:23). Including stamping would lead to including forge plants and the fluid components start to differ from MWFs, according to Lick (M2:23).

1.3.2.2 *Experiences and Resources Related to the Scope of MWFs*

Committee member, Dr. John Howell provided an overview of the MWFs along with handouts (M1:2). Howell explained that metal removal fluids are a subset of metalworking fluids (M1:2). Howell described the term metal removal fluids as those used for cutting, machining, grinding and honing (M2:23). For the purpose of this report, MWFs were used instead of metal removal fluids, the term Howell used. A diagram used by Howell is provided in Attachment 9.

The primary functions of MWFs are to cool and lubricate the machine tool/workpiece interface. In addition, MWFs provide corrosion protection, removal of chips and swarf, and lubricate the machine tool. Components are added to enhance these effects as well as address issues such as rancidity control and foaming. Howell explained, and Lick later stressed, how important chip removal is

for transfer line operations and for the integrity of the machined part (M2:15). Waste management is another issue (Howell, 1997a).

The four categories of MWFs are: straight or neat oils, soluble oils, semisynthetics and synthetics, according to Howell. Howell provided typical components and characteristics of each of these categories and these can be found in his handout (Howell, 1997a). Typical components of MWF categories were provided by the Independent Lubricant Manufacturer's Association (ILMA) (ILMA, 1998). Howell addressed the issues of changes in refining affecting the petroleum oils used in straight and soluble oils and semisynthetics. He explained that soluble oils are diluted 5-20 times with water, while semisynthetics are diluted 2.5 to 10 times with water, and synthetics 1 to 10 times with water (Howell, 1997a).

Specific components such as alkanolamines and biocides were explained by Howell. More on alkanolamines is provided in Lucke's presentation provided later in this chapter. Triazine and formaldehyde issues have been associated with biocide use although Howell noted that the background level of formaldehyde was the problem in some studies. (Howell, 1997a).

Howell explained the effect of use on MWFs, noting that water soluble fluids are very dynamic. MWFs are vulnerable to contaminants such as tramp oil from e.g. leaking hydraulic oil from the machine, as well as particulates, dissolved metals and abrasives. Concentrations can shift and with water soluble fluids, microorganisms and their byproducts can cause problems. All of these interactions can result in the production of a fluid that is very different from what it was originally, according to Howell. Managing the fluid is the key to success (Howell, 1997a; T1:153).

Burch described the use of MWFs in small businesses such as those represented by his organization, PMPA (M2:3). In companies represented by PMPA, 26.9% use straight oils only; 1.9% use water-soluble MWFs only; 0.6 % use semi-synthetics only; and, 0.6% use synthetics only (Burch, 1997; M2:3). Looked at a different way, 95.5% of the companies use some straight oils in their operations; 58.3% use some water solubles; 12.8% use some semi-synthetics; and, 16.0% use some synthetics. (M2:3). Once a company finds a fluid that fits its needs, the business usually will not change fluids (M2:3). O'Brien, Burch and Howell explained that screw machines will continue to use straight oils, and that CNC machines and grinders were more apt to use or change to non-straight oil MWFs (M2:3).

Burke cited a Cincinnati Milicron study (Burke, 1998). This study estimated that 100,000 small businesses use MWFs, 20,000 medium size companies use MWFs and 150 large businesses use MWFs (Burke, 1998).

In Lucke' s presentation about the history of MWFs, he explained the changes in MWFs chemistry over time (M5:16). He noted that the earliest use of MWFs occurred in the 1830's and the fluids were water, soap solutions, and animal and fish oils (M5:16). Around 1850, with the production of crude oil, straight oils were used (M5:16). The first synthetic, a saturated solution of sodium carbonate and water, was used in 1883 (M5:16). Soluble oils came into use

around 1915, and in 1947, semi-synthetics were developed (M5:16). Soon after, modern synthetics with sodium nitrite, a rust inhibitor were used (M5:16). One change made in the 1950's by the oil industry was more severe refining with reductions of the PNA content (M5:16). Kerosene was used in straight oils as a viscosity improver but removed in response to customer demands (M5:16). PCB's were used in straight oils and soluble oils as extreme pressure lubricants, but in 1970 they were taken off the market (M5:16). Since whales became a protected species, it became illegal to use sperm oil (M5:16). Chloroform and carbon tetrachloride were used as tapping fluids but are no longer used (M5:16). In 1976, nitrosamines in metalworking fluids were found at the parts per hundred level and by 1984-1985, most nitrites had disappeared from the market (M5:16). There are still products being sold in the US that have up to 16 percent nitrite but these suppliers are not members of the ILMA, according to Lucke (M5:17). Most formulators replaced the nitrites and also labeled those fluids that contained the nitrites according to Lucke (M5:16). Lucke stated that some products with diethanolamines (DEA) are being reformulated without DEA, and others formulated with lower amounts but with warnings on the material safety data sheets (M5:16). Use of phenolic biocides was reduced around 1970 due to a waste disposal issue, and PTBBA was also removed due to concern about skin absorption in the presence of dimethylsulfoxide (M5:16). He noted that PTBBA and some of its replacements have been associated with the "cola" type of aerosol generation in which the additive acts to entrain air into the fluid and there is fizzing in the sump (M5:16) Lucke explained that dichromates were used as corrosion inhibitors but have been replaced (M5:17). Lucke explained that some of these additives can be found in the mist at 10 to 100 times greater levels that they are in the bulk fluid (M5:17). Additional information on fluid components and the history of fluid formulation can be found in articles by Howell, Lucke, his presentation handout, and an article by Kelly (Howell, 1997b; Lucke, 1993, 1996, 1998; Kelly, 1996).

1.3.2.3 *Experiences and Resources Related to the Scope of the Workplaces*

OSHA economic feasibility determinations, according to Burt, indicate that 1.1 to 2 million employees use MWFs (M7:24). These workers are in 169 third digit SIC groups but if a 2 digit level is used, there are 6 principal SIC code groups, 33 though 38 (M7:24). According to Burt, using the NIOSH NOES data, there are 15 occupations primarily exposed to MWFs (M7:23). Another 10 to 15 occupations occasionally use MWFs (M7:23).

According to Burt, 185,000 workplaces have metalworking machines that might use MWFs and 140,000 of these are in the 6 SIC codes (M7:24). According to Piacitelli, SIC codes 34 through 37 are estimated to represent 98% of the machining in the US (M4:1). About 88% of the 185,000 workplaces and 75% of the 140,000 workplaces are establishments with less than 500 employees (M7:24).

Burt explained that there are about 3.1 million machines in the 6 SIC code groups with about 1.3 million used by the smallest businesses with 1-19

employees (M7:24). SIC code 35 contains 43% of all the machines (M7:24).

According to Burch, forty is the average number of employees of companies that are members of PMPA (M2:3). Ninety percent of these companies are family owned (M2:3). Family members are commonly employees of these companies (M2:3). Operations can change minute to minute, depending on customer demands, according to Burch (M2:3).

Shortell disagreed with Burch's assessment of the changing nature of the work in small businesses (M2:3). Shortell noted that many small businesses, also known as job shops, have a regular product they turn out and also do smaller volume jobs that may change frequently (M2:3). Shortell explained that the jobs may change, but usually the tool does not (M2:3).

O'Brien noted the number of industry types that could have MWF exposures (M2:23). He listed: pneumatic tool use, steel rolling mills, coal strip mills, printing shops, railroads, quenching oils, drawing compounds and plastic molding (M2:23).

1.3.2.4 *The Scope of the Stakeholders*

The companies that use MWFs consist of small, medium and large facilities. Some of these facilities belong to trade groups. In addition to the users of the fluids, there are other stakeholders for this issue. Fluid components are provided by a variety of chemical companies and these components are blended into formulations by fluid manufacturers. Machine tool manufacturers produce the tools and are involved in the enclosure of tools. Users, consultants and some fluid manufacturers conduct fluid management. Users and consultants determine ventilation, mist control and other engineering approaches. Industrial hygienists provide exposure assessment and evaluate exposure control strategies. Trade groups, union and company industrial hygiene and safety representatives, and fluid manufacturers provide training and training materials. Medical care professionals including nurses, primary and advanced care physicians, may work for employers or contractors of the employer, or work in private patient care. Employees, employers, fluid component suppliers, fluid formulators, machine tool manufacturers, industrial hygiene and safety professionals, and medical care professionals are all stakeholders in this issue. The committee has sought the input of these groups to address and make recommendations for protecting the users of MWFs.

1.3.2.5 *The NIOSH Criteria Document*

NIOSH defines the MWF aerosol as "the mist and all contaminants in the mist generated during grinding and machining operations involving products from metal and metal substitutes" (NIOSH, 1998). Characteristics of the mist are a function of MWF type, contaminants, additives, how the fluid is applied, and tool and process factors such as tool speed and type (NIOSH, 1998 citing, ANSI 1997). Ventilation, air cleaning and splash guarding will affect the mist (NIOSH, 1998 citing, ANSI 1997). NIOSH defines the metalworking environment as "any environment in which workers are exposed to the following: metals, metal alloys being machined, chemical residues from preceding operations, MWF additives,

MWF contamination from housekeeping and cleaning processes, biological contaminants (bacterial toxins and metabolic products), or physical contaminants (e.g. chips and fines) from MWFs (NIOSH, 1998). NIOSH uses the same four categories of fluids as noted in Howell's presentation (NIOSH, 1998; Howell, 1997). Additional information about fluid characteristics can be found in Tables 2-1 through 2-5 of the NIOSH Criteria Document (NIOSH, 1998). Tables 3-1 and 3-2 of the NIOSH Criteria Document provide information from 1983 on MWF using industries and workers potentially exposed to MWFs (NIOSH, 1998).

1.3.2.6 *Additional Resources*

More information on MWFs and processes associated with them can be found in *Metalworking Fluids* (Byers, 1994), Metalworking Fluids: Composition and Use by Howell, Lucke and Steigerwald, and *Cutting and Grinding Fluids: Selection and Application* (Silliman, 1992). Extended abstracts in the Proceedings from the two MWF Symposia (AAMA, 1996, 1998) can provide additional information.

1.4 CONCERNS AND LIMITATIONS

1.4.1 Size of Business

According to Burt's data, 75-88% of the workplaces using MWFs are small business (M7:24). Butch explained that anecdotal information from his member companies about OSHA citations and databases, indicate that the companies he represents do not have excess exposure (M2:3). With close to 96% of the companies in Burch's study using some straight oils, some consideration of this issue may be needed (Burch,1997).

Cox was concerned about the data sources OSHA uses (M7:24). According to Cox, the Department of Commerce data only tracks companies down to a certain size which Cox thought was ten (M7:24).

Throughout discussions, Burch was concerned about the potential conflict between any proposed OSHA action and the Americans with Disabilities Act (ADA) (2:21). These conflicts would be difficult for a small business to resolve, according to Burch (2:21). More on this issue is addressed in Chapter Five.

1.4.2 Variability of Environments and Fluids

Members emphasized that there is not any standard machine or standard fluid. McGee noted that there is not any standard employer of management approach to MWFs (M3:11). McGee explained that there are differences between the three American auto makers and even differences that can be found at plants of the same company at the same site (M3:11).

O'Brien was concerned that we need to address the degree of contamination of the fluids (M2:23). Members and presenters reinforced the concept of how the fluids change with use. Members noted the importance of viewing not just the fluids, but the metalworking environment.

Issues cited repeatedly were product stewardship to properly develop fluids and a user's program to properly select fluids. More on these issues can be found in Chapters Three, Six and Nine. One aspect of product stewardship is removal of

a potential problem product from the market or alteration of the formulation of the product. Lucke noted customer concerns about successful products being altered (M5:16).

1.5 LINKAGE OF DISCUSSIONS TO OSHA ACTION

Mirer explained the rationale for the UAW MWF petition (M2:23; 9:25). He noted that the term machining fluids did not include grinding and the term cutting fluids does not include grinding and some machining (M2:23). As a result the petition focused on what is used in engine, transmission and parts plants (M2:23).

Lick recommended limiting the scope, noting that sticking to the original petition would be difficult enough (M2:24). OSHA should limit the scope to what is do-able, according to Lick (M2;23). He explained that the ANSI document addressed traditional machining (M2:23).

O'Brien liked the term, material removal fluids (M2:23). He explained that the Byers text uses the term MWF (M2:24). O'Brien cited the NIOSH Criteria Document as referring to machine shop type operations, including machining and grinding (M9:24-25; NIOSH, 1998).

Howell noted that most of the health and other literature was devoted to metal removal fluids (M2:23;9:24). Howell explained that the work done by ASTM and the NIOSH Small Business Study addressed metal removal fluids (M2:23).

Mirer noted that the term metal removal fluids was a relatively new term (M9:25). Mirer wanted the metal contaminants included (M2:24).

Wegman noted that we need to limit the scope to move forward (M2:23). Wegman urged those workplaces beyond the scope of metal removal fluids to not be complacent since some of the same problems may occur (M9:25). The same solutions may work in these environments (M9:25). He recommended that we note in our final report that although these other areas were not included, it does not mean there is a lack of potential problems in these environments (M2:23). Lick agreed that there could be problems in these other areas (M2:24).

Shortell and Burch thought OSHA should define the scope (M2:24). Mirer thought OSHA should write the language and the committee should determine what we think it means (M2:24).

Teitelbaum saw the benefit of both a fluid and an environment approach but noted that the committee was named MWF, not MWF environment committee (M2:24).Teitelbaum recommended that OSHA clearly define terms in whatever action is taken (M9:25).

Discussion provided a scope as wide as including almost any machining process using fluids, to just including those processes in which metal is removed. According to Burch, the committee has to make sure it does the right thing and not the wrong thing to solve MWF issues (M2:3).

1.6 COMMITTEE DECISIONS AND RATIONALE

The committee did not vote on the scope of the fluids but a general consensus developed. The committee recommends that the scope of any OSHA action includes that subset of metalworking fluids that are also known as metal

removal fluids. These fluids are those used in traditional operations on metal including cutting, machining, grinding and honing. The fluids and the environment they are in have to be considered together due to the changing nature of the fluids as they are used in their environment.

The rationale for this approach includes: the need to clearly differentiate the types of fluids involved, and the knowledge base available for health effects, exposure levels, exposure assessment methods and/or control. The exclusion of any related fluid, process or environment does not imply the lack of a potential problem in these related fluids, processes or environments.

CHAPTER TWO
Deliberations Related to Actions OSHA Should Take: Health Issues

2.1 GENERAL INFORMATION

The major health issues related to MWFs include: dermatitis, acute and chronic respiratory disease, skin cancer and other cancers (M9:21). These issues were addressed by the committee primarily during the second, fifth and seventh meetings and discussed at other meetings. This chapter addresses the presentations, literature review and discussion related to these health issues. This chapter is organized in a different way from the other chapters with each major category represented under the individual health issues.

In preparation for discussions about the health issues, committee member Dr. David Wegman provided an overview of epidemiology. He explained the different types of epidemiological studies, and the pros and cons of each. In addition, comments by Dr. Daniel Hoffman also provided background for the committee. More information about basic epidemiology can be found in their handouts (Wegman, 1997; Hoffman, 1998a) and in Monson's *Occupational Epidemiology* (1990) and *Research Methods in Occupational Epidemiology* by Checkoway (1989). The *NIOSH Criteria for a Recommended Standard - Occupational Exposure to Metalworking Fluids* was the starting point for the committee's discussion of health issues.

2.2 DERMATITIS

2.2.1 Speakers and Presentations

Dermatitis was discussed in detail during the second meeting of the committee and was discussed at later meetings. Dr. Robert Adams, Professor Emeritus from Stanford University and practicing clinical dermatologist addressed the group (M2:2-3). Adams, and Dr. Boris Lusniak from NIOSH, explained the skin problems associated with exposure to MWFs (M2-3;13-15). Lusniak described the studies cited in the NIOSH Criteria Document. Stephen Gauthier, a machinist at a large East Coast manufacturer described his own experiences with dermatitis and MWFs (M2:17-18; M8:18-19). Dr. Larry Fine, NIOSH, mentioned dermatitis in his overview of the NIOSH Criteria Document (M2:2). Greg Piacitelli, NIOSH, noted dermatitis cases in his description of the NIOSH Small Business Study (M4:3; M7:4). Tom Beeman, a machinist at a mid to large facility in the Western part of the US provided some limited information about his own skin disorder (M5:3). Dr. William Lucke, Cincinnati Milicron, in his presentation noted formulators' efforts to reduce dermatitis (M5:21). Dr. Ed Stein, OSHA, provided background information on previous OSHA and NIOSH recommendations for dermatoses (M5:28-29). John Burke, Eaton Corporation, noted dermatitis during his discussion of problems in middle size facilities using MWFs (M627). Michelle Lantz, Caterpillar Corporation, cited incidents of dermatitis in her presentation on systems

management (M8:10-11). Committee member, David Burch, noted dermatitis in his presentation on machining in small business (M2:4). The OSHA Office of Regulatory Analysis provided an overview of statistical information on occupational dermatitis. Presentation notes of Laura Nakoneczny, Precision Metalforming Association (PMA) were provided by David Burch, committee member. Other committee members and alternates provided their experiences and interpretations throughout the meetings.

In the discussion of rates of adverse health effects, three types of data were presented: anecdotal or case reports, surveys of plant experience and formal cohort or cross-sectional studies. The first type provides only evidence that the problem exists in the setting from which the report comes and may exist in comparable settings. The second type is limited by the quality of the different reporting units (plants) and no effort has been made to determine that each was equally aggressive in identifying and recording adverse health effects. Generally these surveys were based on OSHA 200 logs which may or may not have been complete. These survey results, therefore, should be seen as offering a different type of information than case reports with less quantitative reliability than systematic scientific studies. These survey results are limited by the sources of data. The third type of data, formal studies, is the most reliable, although these types of studies have been carried out only to a limited extent in occupational environments using MWFs (Wegman, tenth meeting)

2.2.2 Background Information

Lusniak cited Bureau of Labor (BLS) statistics indicating that occupational skin diseases represent 12% of all occupational illnesses, are the second highest reported occupational illness category, and are responsible for annual expenditures of $22 million (1984 dollars) (M2:13). From 1973 though 1987, dermatitis was the leading occupational illness in the US (Stein, 1998, NIOSH,1998). Twenty-one percent of all occupational skin disease reported to the BLS result in days away from work, according to Lusniak (M2:13). The rate of skin disorders was 76/100,000 workers in 1993 and health professionals have a target of 55/100,000 by the year 2000 (M2:14).

Lusniak believed that the BLS data underestimates values because this agency bases its numbers on OSHA 200 logs and he has seen individual cases that were not reported (M2:13,14). He stated that dermatitis represents 90-95% of all occupational skin disease (M2:13).

The OSHA Office of Regulatory Analysis used BLS data to provide estimates of skin disease (OSHA Office of Regulatory Analysis, 1998). In 1996 there were 58,100 recordable skin diseases and disorders in private industry. This is an average rate of 6.9 per 10,000 full time equivalent workers (FTEs) (OSHA Office of Regulatory Analysis, 1998).

2.2.3 Experiences and Resources

2.2.3.1 *Presentations and Related Discussions*

Lusniak and Stein cited deBoer's study indicating a 14% prevalence rate of

dermatitis among those exposed to MWFs (M2:13). In his handout, Stein cites studies by Rycoft with a prevalence rate of 30% and Sprince with 27.2% (Stein, 1998a). NIOSH Health Hazard Evaluations (HHE) indicate a prevalence rate from 14-67% (M2:13; Stein, 1998a). Adams disagreed with the HHE numbers and estimated that 1-2% of machinists have dermatitis (M2:3).

Burch noted that in his survey of members of the PMPA, 120 out of 580 member companies sent in 667 OSHA 200 summaries (M2:4). In these 667 summaries, a total of 410 dermatitis cases were listed (M2:4). Burch explained that this was a rate of 1.6 OSHA recordable cases per hundred full time employees (M3:13). This works out to 1 worker in 61 may develop dermatitis related to MWFs (Nakoneczny,1998).

For another small business organization, PMA, 1 worker in 3,339 may develop dermatitis based on OSHA 200 logs (Nakoneczny, 1998). For PMA, in 66,739 employee-years of exposure, there were 20 reports of dermatitis for a 0.001 incidence rate (Nakoneczny, 1998).

Piacitelli cited 4 OSHA 200 logs out of 39 collected during the NIOSH Small Business Study that indicated dermatitis (M4:3). In a later update, Piacitelli cited 2 cases of dermatitis out of 30 OSHA 200 logs evaluated (M7:4).

Lick noted the dermatitis case observed at one of the site visits to a small business (M4:6). Day explained that every MWF plant he visits has cases of dermatitis (M3:13). McGee believed that dermatitis is the leading cause of lost work time in MWF plants (M3:14).

Mirer cited a MIOSHA inspection of a MWF plant with 60 employees and 2 cases of dermatitis, at exposure levels slightly above the NIOSH REL (M6:37). Mirer noted the disparity between another MWF plant whose OSHA 200 logs listed one dermatitis case (M6:37). An HHE report for this second plant indicated that of 8 randomly selected employees, five had visible rashes and all eight complained of skin symptoms (M6:37).

Lusniak explained that the factors contributing to the development of MWF related skin disease include: degree of skin contact, individual susceptibility, personal protective equipment, overall work environment, climate, machine types, control methods and the types of MWFs used (M2:13). Barrier creams, cleansers, work habits, machine type, and workplace climate are additional factors (Adams, 1997). Adams noted the MWF exposure to the machinist's skin during the changing of machine parts and during maintenance (M2:2). Burch explained that different machining operations have different degrees of contact with the fluids (M2:20). Stein cited reuse of MWF soaked clothing or materials as a potential source of problems (Stein, 1998a).

Burke explained his experiences with severe dermatitis in his mid size facilities, citing individual fluid formulations, on-site chemical addition and lack of proper fluid maintenance as the causes (M5:27). Lantz noted dermatitis occurs when tramp oil in the MWF is allowed to rise to approximately 5% of the fluid (M8:10). Howell explained that individual machines provided more opportunity for skin contact with fluids than transfer lines (M8:26).

In 90-95% of occupational dermatitis cases, the primary site is the hands

followed by forearms, face and neck, according to Lusniak (M2:13). Gauthier provided an example that his hands were the area for his dermatitis (M2:17). Beeman suffered from rashes on his arms during the first six years of his employment at a plant using MWFs (M5:3). Lantz noted a case of dermatitis in the stomach area which contacted fluid when a worker reached across a machine (T8:274-276). Gauthier explained that skin in contact with shop rags saturated with MWFs often is an area with dermatitis (M8:18).

Lusniak explained that MWFs can cause irritant and contact dermatitis along with folliculitis, oil keratosis, pigmentary changes and oil granulomas (M2:13). He noted that straight MWFS are associated with folliculitis, keratosis and skin cancer (M2:13; M5:28). Folliculitis is associated with infectious agents and these microorganisms are more of a problem for someone with already irritated skin that is not intact (M2:13). Skin cancer was associated with polyaromatic hydrocarbons that are no longer in use, so skin cancer is rarely seen, according to Lusniak (M2:13). He explained that irritant contact dermatitis and allergic contact dermatitis are seen more often with soluble, semi-synthetics and synthetics (M2:13). According to Lusniak, 50 - 80% of MWF related skin diseases are irritant contact dermatitis, while 20-50% are allergic contact dermatitis (M2:13). Lusniak had no doubt that MWFs cause both irritant and allergic dermatitis (M2:14). Stein reiterated many of Lusniak's comments in his talk (M5:28). Gauthier explained the personal pain and embarrassment caused by these disorders (M2:18).

Lusniak explained that irritant contact dermatitis is associated with MWF ingredients such as alkaline emulsifiers and solvents, microtrauma from shaving contaminants and hand-washing with irritating detergents (M2:13). Howell noted that excess alkalinity in MWFs causes defatting of the skin (M2:19). Howell explained that fluid producers take special care to formulate MWFs that will not cause dermatitis on a routine basis (M2:19). Lucke noted that some suppliers conduct dermal toxicity testing of formulations prior to marketing (M5:21).

Allergic contact dermatitis can be due to metals, additives such as biocides, and emulsifiers, according to Lusniak (M2:13). Adams explained that once anyone is sensitized to an allergen it takes contact with a very small amount to elicit a response (M2:2). Adams noted that overuse of biocides can lead to an irritation reaction that eventually becomes an allergic contact dermatitis (M2:2). Biocides known to cause allergic contact dermatitis include: Grotans (BK, HD, HD-2 and K) which are, Biobans (PS-1487, CS-1246, CS 1248, CS-1135), Proxels, Kathons, Forcide 78, 1-H benxothiazole, o-Phenylphenol, p-Chloro-xylenol and Tris Nitro (Adams, 1997). Other sensitizers that can be present include: rosin, mercaptobenzothiazole, nickel, cobalt and chromium (Adams, 1997). Day noted his own allergic contact dermatitis related to MWFs and how the site visit in March, 1998 elicited a hives reaction (M3:13). Adams explained that workers may not realize that the dermatitis they have is related to MWFs until they are tested (M2:2-3). This clarified the lower self reported dermatitis cases than physician reported cases in the Sprince study (M2:2-3). Allergies to some individual MWF components can be determined by patch testing, but according to Adams, the FDA restrictions on allergen test kits hamper the dermatologist's diagnosis and

treatment (M2:2).

2.2.3.2 *Additional Information from the NIOSH Criteria Document*

NIOSH discusses dermatologic conditions at the end of Chapter Five of its Criteria Document (NIOSH, 1998). Lusniak and Stein reviewed many of the issues discussed in the Criteria Document. Some earlier statistics are cited such as the 1991 occupational skin disease incidence rates of 7.7 per 10,000 workers for all industry (NIOSH, 1998). NIOSH cites Coenraads, 1983 indicating a general population prevalence of dermatitis of 4.6% compared to the ranges indicated in the previous section of 14-30% for machining environments (NIOSH, 1998).

The NIOSH Criteria Document provides specific chemical names for some of the components of MWFs that are allergens (NIOSH, 1998). These are found in section 5.4.3, page 141 of the Criteria Document (NIOSH, 1998). The document includes some similar conclusions as Adams about the limits of patch testing (NIOSH, 1998). According to Alomar as cited in the NIOSH Criteria Document, biocides, corrosion inhibitors, coupling agents, and emulsifiers produce the most frequent positives on skin patch testing (NIOSH, 1998).

The document lists control strategies for MWF related dermatitis (NIOSH, 1998). These include: substitution of fluids or additives or constituents; process modification, isolation, and ventilation; work practice and administrative controls to assure fluid maintenance and workplace cleanliness; proper use of personal protective equipment; education and training of employees; minimal contact with fluids; and personal hygiene such as clothing changes and cleaning with non-abrasive soaps (NIOSH, 1998).

2.2.3.3 *Other Resources*

A handout prepared by Stein provided some statistics on dermatitis and MWFs (Stein, 1998a-d). In 1991, the Department of Labor (DOL) noted that the highest incidence rates for skin disease included fabricated screw machine products with 33.3 cases per 10,000 full time equivalent workers (FTEs), and general industrial machinery with 22.0 per 10,000 FTEs (Stein, 1998a-d).

Information provided by the OSHA Office of Regulatory Analysis used BLS statistics for 1996 to estimate skin disease in SIC codes 33-37 (OSHA Office of Regulatory Analysis, 1998). In these industries, there were 14,300 recordable skin diseases and disorders, accounting for approximately 25% of all recordable skin diseases and disorders in private industry (OSHA Office of Regulatory Analysis, 1998). SIC codes 33-37 had an average rate of 18.3 recordable skin diseases and disorders per 10,000 FTEs, almost three times the average for all of private industry (OSHA Office of Regulatory Analysis, 1998). The transportation equipment industry (SIC 37) had the highest skin disease and disorder rate of any industry group using MWFs, 33.9 cases per 10,000 FTEs (OSHA Office of Regulatory Analysis, 1998). Each of the five industry groups in SIC 33-37 were at least 70% above the rate for all private industry (OSHA Office of Regulatory Analysis, 1998). More information on lost work days and economic costs of

dermatitis based on the OSHA Office of Regulatory Analysis work is provided in Chapter Three.

An article by Sluhan (1997) cites the following causes of dermatitis from MWFs: alkalinity, acidity, solvents, metals, the use of straight MWFs, filthy MWFs, misapplication of biocides, handling equipment, concentration problems and misuse of protective creams. Sluhan also warns that the cause could be contamination from an external source or outside activities and not MWFs (Sluhan,1997). He provides examples of solutions that are similar to what has already been reported (Sluhan,1997).

An article by Itschner, 1996 was cited by Teitelbaum at the tenth meeting. Additional references on dermatitis are found in Chapter Eight, Medical Surveillance and in Attachment #6.

The UAW publication How to Prevent Skin Disease outlines causes of dermatitis and how management and workers can prevent these disorders (UAW, 1997). Adams provided a list in his handout of recent references on MWFs and dermatitis (Adams, 1997). Stein provided in his handout, a list of references, a glossary and information on the OSHA Standards Advisory Committee on Cutaneous Hazards and other early efforts by NIOSH and OSHA (Stein, 1998a-d). The two MWF Symposia Proceedings provide additional information and discussion (AAMA, 1996,1998).

2.2.4 Concerns and Limitations

2.2.4.1 *Size of Business*

As noted earlier, Burch reported that out of 667 OSHA logs for his members, a total of 410 dermatitis cases were listed, for a rate of 1.6 cases per hundred full time employees (M2:4). Comparing PMPA data to the OSHA Office of Regulatory Analysis assessment, and assuming the same method of calculating cases and FTEs was used: the rate for PMPA would be 160 cases per 10,000 FTEs. Using Nakoneczny's data, the rate for PMA would be 2.9 per 10,000 FTEs (Nakoneczny,1998). Nakoneczny's combined dataset of PMA and PMPA produces a rate of 45.6 cases per 10,000 (Nakoneczny, 1998). Assuming the same method was used for calculating cases, these values can be compared with 6.9 cases per 10,000 FTEs for private industry, 18.3 cases per 10,000 for SIC codes 33-37 and 33.9 cases per 10,000 FTEs for SIC code 37 (OSHA Office of Regulatory Analysis, 1998).

Piacitelli cited 2 cases of dermatitis out of 30 OSHA 200 logs evaluated (M7:4). No calculation per FTE was made. Day and McGee explained that dermatitis is seen universally in MWF plants (M3:13,14). Based on MIOSHA inspection reports and NIOSH HHE, Mirer thought there was an underreporting of dermatitis on small business OSHA 200 logs (M6:37).

2.2.4.2 *Atopy*

Adams stated that 10-15% of the US population is atopic; 3-5% have atopic skin reactions (M2:3). Adams noted that atopic individuals have a greater chance of developing any allergic skin reactions, but not all will react to MWFs (M2:2).

Three or more major features are required for a diagnosis of atopic dermatitis: itching, typical morphology and distribution, chronic and relapsing course and personal and family history of atopy (Adams, 1997 citing Hanifen, 1980). Extremes of temperature, presence of irritants and certain microorganisms and emotions aggravate atopic dermatitis (Adams, 1997). According to Lusniak, atopics have a greater risk of irritant contact dermatitis but no increased risk of allergic contact dermatitis (M2:14). Adams questioned the legality of preventing atopics from working with MWFs (M2:2). Newman and McGee warned that even if we exclude susceptible individuals, dermatitis will still occur with MWFs (M2:19).

2.2.4.3 *Other Issues*

Teitelbaum and Frederick expressed concern about skin absorption (M2:2,14). It was noted by Fine that no urine or other analyses were available for MWFs (M2:2). Lusniak explained that absorption of any workplace chemical will be enhanced if the skin is not intact (M2;14). Howell noted that some MWF components could pass through the skin (M8:26). Teitelbaum noted that after review of the ILMA handout with CAS numbers, he was less concerned about benzene absorption since the benzene content appeared to be *de minimus* (M8:26; ILMA 1998).

2.2.5 Linkage of Discussions to OSHA Action

Adams and Lusniak emphasized early detection of dermatitis, but Adams thought medical surveillance may not provide enough "return on investment" (M2:3). If an agent is truly removed from an individual's environment, any dermatosis is reversible according to Adams (M2:3). Lusniak cited a study by Pryce, 1989 that showed a poor rate of healing even with removal from the MWF environment, and stressed the importance of prevention (M2:13).

Gauthier noted that his dermatitis improved and went away after reducing exposure (M2:17). Gauthier, Howell, Burke and Kushner explained the importance of good fluid management and Teitelbaum and Shortell agreed (M2:17 & 19; M4:8; M6:27 & 40; M8:4). Shortell noted the presence of dermatitis when fluids were not well managed in plants he worked in during his career as a machinist (M2:19). Mirer agreed based on his experiences (M3:13). Stein showed a downward trend in dermatitis, and Cox believed this trend will continue with the purchase of new machines and better education (M5:28). Ways to reduce exposure are discussed in Chapter Three of this report, Technological Feasibility.

Burch was concerned that we not issue a blanket statement that MWFs cause dermatitis because not everyone working with MWFs experiences dermatitis (M2:19). Newman emphasized that having 100% of workers affected is not required for action (M2:20). At the tenth meeting, Wegman and Teitelbaum agreed with Newman, stating that this is true for any disease and any exposure. Burch agreed with Newman, but questioned what level is required, and what the Americans with Disabilities (ADA) implications of any action would be (M2:20).

Wegman viewed dermatitis as the third most important health effect associated with MWFs, listing it after asthma and HP (M5:31). Mirer cited

Gauthier's experience of dermatitis and the potential economic impact of job transfer as an example of material impairment of health (M2:19). Howell agreed that unresolved dermatitis can be a material impairment of health (M2:20). Stein explained that there were no OSHA standards based solely on dermatitis although many include dermatitis as one of the important health effects (M5:28).

2.2.6 Committee Decisions and Rationale

The majority (13) opinion of the committee was that dermatitis is known to be associated with exposure to MWFs (M9:21-22). Members cited their own experiences: working with individuals who had dermatitis, treating employees with dermatitis, and observations at a MWF plant visited by the work groups (M9:21-22). In addition, presentations by Adams, Lusniak and Gauthier (M2:23;13-15; 17-18), the NIOSH Criteria Document and the letters sent by small business to Jeffress were noted as evidence (M9:22; NIOSH, 1998; PMPA, 1999; PMA, 1999). Dermatitis from MWF is a material impairment of health (M2:19; M9:22).

The minority opinion (Burch, Howell) of the committee was the evidence was equivocal (M9:21). These members noted their own experiences and statements that dermatitis is associated with poorly managed fluids (M2:19; M3:13). Manufacturers test and produce fluids that when new, generally do not cause dermatitis (M 2:19).

Two members noted that all MWFs can cause dermatitis (Teitelbaum, Mirer) (M9:22). Two other members (Day, McGee) explained that all MWF plants they have been in had workers with dermatitis (M9;21-22). Two members (Cox, Burch) stated that although there are dermatitis problems, these problems are controllable (M9:21-22).

2.3 ACUTE AND CHRONIC RESPIRATORY EFFECTS

2.3.1 Speakers and Presentations

Acute and chronic respiratory effects were discussed in detail during the second and fifth meeting of the committee and were discussed at other meetings. Committee members and alternates provided background information, their own studies, experiences, expertise and interpretations throughout the meetings. Individual researchers presented their work and a worker provided his experience. NIOSH and OSHA provided representatives to explain their analyses of the studies. Industry consultants provided an overview and critique of studies. The NIOSH Criteria Document was used as a starting point for discussion (NIOSH, 1998).

Dr. Lee Newman, committee member, provided an overview of the respiratory system and diseases (M2:5-6). Committee member, David Burch addressed respiratory issues in his presentation on machining in small business (M2:4). Dr. Kenneth Rosenman, Michigan State University, discussed asthma in his presentation on the Michigan SENSOR program (M4:7-8). Dr. Ellen Eisen, University of Massachusetts - Lowell, described her study of asthma and MWFs

(M5:1-2). Dr. Kevin Fennelly, National Jewish Research and Medical Center, provided information on the clinical aspects of asthma (M5:2-3). Tom Beeman, a machinist at a mid to large facility in the Western part of the US documented his own experience with asthma and MWFs (M5:3). Dr. Henry Anderson, committee member, explained his study of an HP outbreak in Wisconsin (M5:3-4). Dr. Cecile Rose, National Jewish Research and Medical Center, documented various case studies of HP and addressed medical removal (5-6). Dr. Michael Hodgson, University of Connecticut, described investigatioqs of HP outbreaks in his state (M5:6-7). Dr. Thomas Robins, University of Michigan, described asthma, cross shift pulmonary function tests and other respiratory effects related to MWFs (M5:8-10). Dr. Michelle Schaper discussed her inhalation toxicity tests of MWFs (M5:18-19). Dr. Harold Rossmoore described the importance of the microbiology of MWFs and cited respiratory problems related to these organisms (M5:19-20). Dr. William Lucke, Cincinnati Milicron, in his presentation noted formulators efforts to reduce respiratory effects (M5:21). Dr. Gordon Reeve, Ford Motor Company, presented prevalence data and hospital admissions related to non-malignant respiratory disease at his company (M6:1-6; M7:27-28). John Burke, Eaton Corporation and committee alternate member, Ken Kushner noted respiratory symptoms during their discussions of problems in middle size facilities using MWFs (M6:27-29; M6:33).

Dr. Larry Fine, NIOSH, explained the respiratory disease section of the NIOSH Criteria Document (M2:6-7). William Perry and Dr. Steven Bayard, OSHA, outlined OSHA's progress on risk assessment on non-malignant respiratory disease (M6:19-23, 10th meeting). Dr. Daniel Hoffman, George Washington University, explained his evaluation of the articles summarized in the respiratory effects section of the NIOSH Criteria Document which he did as a consultant for ILMA (M5:10-14).

A panel discussion consisting of Dr. Fennelly and Dr. Rose along with committee members, Dr. David Wegman, Dr. Lee Newman, and Dr. Henry Anderson, fielded committee questions on respiratory disease and MWFs (M 5:7-8). Schaper, Rossmoore and Lucke joined Dr. Daniel Goon, Castrol and committee member, Dr. Daniel Teitelbaum in a panel discussing MWF components (M5:20-26). Dr. Eugene White, NIOSH, provided an update on endotoxins (M9:1).

In the discussion of rates of adverse health effects, three types of data were presented: anecdotal or case reports, surveys of plant experience and formal cohort or cross-sectional studies. The first type provides only evidence that the problem exists in the setting from which the report comes and may exist in comparable settings. The second type is limited by the quality of the different reporting units (plants) and no effort has been made to determine that each was equally aggressive in indentifying and recording adverse health effects. Generally these surveys were based on OSHA 200 logs which may or may not have been complete. These survey results, therefore, should be seen as offering a different type of information than case reports with less quantitative reliability than systematic scientific studies. These survey results are limited by the sources of

data. The third type of data, formal studies, is the most reliable, although these types of studies have been carried out only to a limited extent in occupational environments using MWFs (Wegman, tenth meeting).

2.3.2 Background Information

Newman explained that respiratory diseases can be divided into those that affect the conducting airways and those that affect the alveoli, the gas exchange region (M2:5). Asthma is a conducting airway disease, while hypersensitivity pneumonitis (HP) affects the alveoli (M2:5). He noted that much misclassification of respiratory disease occurs (M2:6).

A variety of studies were investigated by the committee. Limited toxicology studies were available (M5:18). Methods for testing toxicity have been developed for water miscible MWFs (ASTM,1993). Epidemiological studies included a range of types as explained by Wegman and Hoffman (M2:7-9; M5:11-14). Studies included exposure measurement or estimation using different exposure metrics. A variety of health endpoints were covered in the epidemiological studies. Symptom reporting using questionnaires was included in some studies (M4:7).

Medical testing was used in some investigations. Pulmonary function changes such as forced expiratory volume ($FEV_{1.0}$) and forced vital capacity (FVC) were used as indicators of underlying disease or potential disease. Newman explained that forced expiratory volume ($FEV_{1.0}$) represents the volume of air one can force out in one second (M2:5). He noted that the forced vital capacity (FVC) is the total amount of air that a person can inhale in one breath (M2:5). These tests are part of pulmonary function testing and change with disease (M2:5). Reeve noted the difficulties in obtaining consistent pulmonary function test results (M6:1).The comparison of these pulmonary function tests before and after a work shift is called cross-shift pulmonary function testing.

According to E. White, endotoxins have been associated with respiratory symptoms such as: coughing, wheezing, fever, chills and decreased $FEV_{1.0}$ (M9;1). Endotoxin can potentiate immunological reactions, exacerbate illness caused by other agents but may not be the instigating cause of a disease (M9:1). Endotoxins are a class of pyrogenic compounds derived from the outer cell membrane of Gram negative bacteria and consist of lipopolysaccharides (E.White, 1999). The lipid A portion of the molecule is responsible for its toxicity (E.White, 1999).

Additional information on general concepts on respiratory disease can be found in Newman's handout (Newman, 1997), and his chapter on Pulmonary Toxicology in the book *Clinical Principles of Environmental Health* (Newman, 1992).

2.3.3 Experiences and Resources Related to Asthma and Airway Effects

2.3.3.1 *Overview*

Newman defined asthma as an inflammatory disease of the airways in which an inhaled substance can trigger a narrowing of the bronchial passage (M2:5). Fennelly clinically defined asthma as reversible air flow obstruction with

fairly common symptoms usually chest tightness, shortness of breath and may include wheezing (M5:2). Fennelly cited a review of asthma by Chan-Yeung (1995). Rose explained that about 16% of asthma is occupational (M5:8). Occupational asthma has become the most common work-related respiratory disorder, representing 26% of these disorders in the United Kingdom (Newman, 1995). According to Wegman, chronic obstructive pulmonary disease (COPD) refers to significant decrements in lung function and increases in symptoms such as chronic bronchitis, cough and phlegm (M5:31).

Induction of asthma can have a long latent period between initial exposure and first manifestation according to Newman and Fennelly (M2:5; M5:2). Fennelly explained that "without latency type" is called irritant asthma (M5:2). "Latency type" can be divided into "IgE allergic antibody dependent" or "IgE independent", according to Fennelly (M5:2). Ethanolamines, low molecular weight compounds may be IgE independent, while microbiological toxins may not follow any distinct pattern stated Fennelly (M5:2). He noted that sensitization may take years of exposure to an agent and may require large amounts of the agent inhaled or on the skin (M5:2). Fennelly noted that once an individual is sensitized, only minute amounts are needed to elicit the allergic reaction (M5:2). He explained that peak exposures may be more important than averages but it depends on how a toxin behaves in the respiratory tract (M5:2).

Teitelbaum noted that an upper airway version of asthma, called reactive upper airway dysfunction syndrome, can be due to large particles (M2:5). Newman explained that sinusitis and asthma are on a continuum that relates upper and lower airway problems (M2:6). Newman noted that asthma and bronchitis are obstructive diseases which make it difficult for the individual to blow air out of the lungs (M2:5). Bronchitis is inflammation of the bronchial tubes and more often has cough associated with it, while asthma is a reactive narrowing of the bronchial tubes according to Newman (M2:6). Burch noted the increase in asthma in the general population and Teitelbaum agreed that this increase is occurring (M2:6).

2.3.3.2 *Researchers' Reports of Their Own Studies*

Eisen reported on her analysis of asthma in the cross sectional study of auto workers done by Greaves (M5:1). After suspecting her original analysis was affected by the healthy worker effect, Eisen focused on when asthma was diagnosed in these workers (M5:1). One hundred and twelve workers out of 1800 had asthma and of these, 29 cases were post-hire (M5:1). She formed a control group of other workers without asthma who had worked in the plant for the same time as each of the 29 workers, and corrected for date of hire and other variables (M5:1). Eisen specifically examined exposure in the two years prior to asthma onset in the cases, and a comparable two year period for the controls (M5:1). She found an odds ratio exposed/control of 2.1 for synthetic MWFs (M5:1). Based on her study, she thought synthetics were more of an asthma problem than straights which were more of a problem than solubles (M5:2). Additional information can be found in her article (Eisen, 1997).

Robins explained his study comparing two machining departments, "case"

and "valve body" in an auto plant using soluble fluids with minimal use of biocides and no *Mycobacteria* found (M5:8). The mean seniority of machinists was 19 years (M5:8). His study consisted of three rounds of baseline questionnaires, pre and post shift questionnaires and spirometry including $FEV_{1.0}$, FVC and the ratio between these values (M5:8). Robins study was a case series design according to Wegman (M2:7-8). Area and personal air samples including personal thoracic sampling with a PEM were taken (M5:8). Viable and nonviable bacteria and endotoxin were measured (M5:8). Thoracic particulate means were 0.54 mg/m^3 for "case", 0.28 mg/m^3 for "valve body" and 0.13 mg/m^3 in an assembly area away from MWFs (M5:8). Robins used 1.25 as a "rule of thumb" ratio of total/thoracic particulate (M5:8).

Robins defined the development of post-hire asthma as a 12% or greater drop in cross shift lung function (M5:9). This occurred in 11 out of 83 machinists and 2 out of 44 assemblers (M5:9). Machinists were more likely to have this drop, but it was not significant (M5:9). Six out of 83 machinists had a drop of 19% or more, while none of the assemblers had this great a drop (M5:9). Robins found that machinists were more likely to have a 10% decrement in cross shift lung function than were assemblers (M5:8).

Robins found that twenty five percent of machinists who were obstructed smokers had a greater than 10% decrement in cross shift lung function compared to 3% of non-obstructed non-smokers (M5:8). He compared groups of workers to non-obstructed, non-smoking assemblers and found odds ratios for cross shift lung function changes ranging from 2.75 to 6.22 (M5:9). With obstruction, the ratios increased with exposure, while in the groups without obstruction, the cross shift change did not increase with exposure (M5:9). Bacterial and thoracic particulate fit the health effects well (M5:9). Robins was concerned that repeated cross shift lung function decrements could lead to permanent irreversible changes (M5:9).

Robin's questionnaire data showed a higher proportion of machinists reported symptoms as compared to people in assembly (M5:9). Key symptoms he reported were: phlegm production, dry cough, wheezing, chest tightness and dyspnea, all lower respiratory tract symptoms (M5:9). He explained that there are false positives for answers on questionnaires (M5:9). Despite higher endotoxin levels in the case area, symptoms were different from valve body (M5:10). More details about Robin's study can be found in his presentation handout (Robins, 1998).

Asthma sentinel cases should prompt medical surveillance according to Rosenman (M4:7). His review of symptom questionnaires and medical records of the individuals that report physician identified asthma cases, provided strong enough evidence for him to say there is a cause and effect relationship between exposure to MWFs and asthma (M4:8). Rosenman found for 5400 questionnaires: 1000 reported daily or weekly symptoms of asthma, and only eight of these showed up on OSHA 200 logs (M4:8). Rosenman reported that in Michigan, the 146 MWF work related cases of asthma he studied represented 12.4% of all work related asthma for that time period (M4:7).

Respiratory symptom reporting has a background value in control plants without exposure to known irritants, of about 10%, so values above this number are significant, according to Rosenman (M4:7-8). He explained that his work showed a trend of an increase in the number of symptomatic people with increased exposure (M4:7). Hoffman noted that Rosenman found higher values of asthma in plants using soluble or synthetic fluids (M5:11). Rosenman indicated that there were more symptomatic people in plants with synthetic MWFs, while individuals in plants with straight fluids had less need to see a physician for shortness of breath or sinus problems (M4:7). Rosenman explained that MiOSHA recommends a medical surveillance program for facilities when 20% or more of the workers are symptomatic (M4:7). Such programs catch people in the early treatable phase of the disease and can help remove people from contact with a sensitizing agent, according to Rosenman (M4:7). More information about the characteristics of the workers in Rosenman's study can be found in his handout and articles (Rosenman, 1993;1997;1998).

Burch explained that in his survey of members of the PMPA, 120 out of 580 member companies sent in 667 OSHA 200 summaries (M2:4). In these 667 summaries, a total of 34 respiratory cases were listed and only one of these was related to MWFs (M2:4). This works out to an incidence rate of 0.004, or 1 worker in 25,118 may develop a MWF induced respiratory disease (Nakoneczny, 1998).

Data for PMA showed one reported respiratory condition for an incidence rate of 0.001 (Nakoneczny, 1998). This works out to 1 case per 66,739 workers (N akoneczny, 1998).

Reeve reviewed his assessment of Ford's medical surveillance database which includes visits to the medical department, OSHA logs, workman's compensation and compensated private doctor or emergency room visits (M6:16). He compared the respiratory diagnosis data for 11 MWF-using plants to 6 glass plants without MWF or suspected irritants (M6:2). For 1997, the MWF plants had 20,000 workers representing 45 million hours of work while the glass plants had 4000 workers with 7.7 million hours worked (M6:2). He included the cases with reported symptoms of upper respiratory tract irritation, cough, congestion, throat irritation, tightness in chest, shortness of breath, wheezing, sinus problems, difficulty breathing, allergy, asthma and pneumonia (M6:2). He eliminated non-relevant cases and for 1997, found a rate of 0.66 cases per 200,000 hours worked for the MWF plants and 0.34 cases per 200,000 hours worked for the glass plants (M6:2). There were 148 respiratory cases in the MWF plants and 13 respiratory cases in the glass plants (M6:2). The lost time case rate was 0.05 per 200,000 hours and the severity rate was 0.54 per 200,000 hours for the MWF plants in 1997 and there were 121 lost days of work. There were no lost days of work at the glass plant related to their cases in 1997 (M6:2). Reeve found 7 cases of asthma initiated or made worse by working in MWF plants and none in the glass plants (M6:3). Reeve noted that it is difficult to track asthma treated by private physicians (M6:3). Additional information such as plant by plant data and diagnoses considered can be found in his handouts (Reeve, 1998a).

Reeve provided an additional assessment of the treatment of Ford workers

outside of the occupational arena and compared the results of MWF plants to non-MWF plants (M7:27). Reeve assessed the data from the third quarter of 1994 to the second quarter 1997 from five engine plants and 6 transmission/chassis plants (M7:27). He used information about 14,000 workers who represented about 60% of the worker population in these plants (M7:27). The control group of about 5,000 workers were from 3 glass plants, 9 parts depots and 2 parts plants and none of these plants had MWFs (M7:27)

In Reeve's study, for the MWF plants, there were 91 in-patient admissions for a primary diagnosis of non-malignant respiratory disease, and 21 for the control plants (M7:27). These admissions produced age adjusted rates of 6.2 per 1000 workers for the MWF plants compared to 4.1/1000 workers for the control plants (M7:27; Reeve, 1998b). The MWF/control relative rate for various years fluctuated between 1.4 to 1.5, indicating a 50% excess risk of hospital admission for non-malignant respiratory disease in a MWF plant (M7:27). Using one year's data, this translates for a typical Ford plant of 2000 people, to about 3.5 to 4 people put in the hospital each year (M7:27). Reeve compared Ford hospital admissions to other Midwest manufacturing and found that admissions in the MWF plants were 7% higher than average in 1996-1997, and 18% higher in 1995-1996 (M7:28). Lick clarified that Ford uses about 80% solubles, 15% synthetic or semi-synthetic and 5% straight MWFs (M7:28).

Fennelly explained a case study in which a worker sensitized to MWFs had a drop in $FEV_{1.0}$ from 4 liters when not exposed, to 1.92 liters when exposed to MWFs (M5:3). He noted that it was impossible to discern the causative agent in the MWFs in this case (M5:3). Fennelly noted that this situation could have been prevented by better exposure control or at least secondarily by medical removal (M5:3). Additional details about the clinical treatment Fennelly used can be found in his handout (Fennelly, 1998).

Beeman outlined the temporal nature of his sensitization, his asthma was worse at work (M5:3). Beeman described the physical and emotional trauma he experienced from asthma and his efforts to improve his condition (M5:3).

2.3.3.3 *Speakers' Analyses of Studies*

Fine explained three positive studies, two of which were significant, that related asthma to synthetic MWFs (M2:6). Kennedy's study showed pulmonary function changes in new employees in smaller shops but none had developed asthma (M2:6). NIOSH thinks the evidence linking asthma to synthetics is quite strong, according to Fine (M2:6). The largest study on synthetics had concentrations of 0.36 to 0.91 mg/m^3 with a mean of 0.6 mg/m^3 (Fine, 1997). He explained that there are five studies (two significant) relating asthma to soluble MWFs (M2:6). Robin's study of solubles found that 11 out of 83 machinists had $FEV_{1.0}$ decrements of greater than 12% (Fine, 1997). NIOSH believes the overall evidence points to a relation between asthma and exposure to soluble MWFs (M2:6). According to Fine, despite the weaker link between asthma and straight oils, other evidence such as cross shift pulmonary function changes and symptom reporting points to a link (M2:6). Risks are likely lower for straights than for

solubles and synthetics (Fine, 1997).

Fine explained that for asthma, the risk is elevated above the REL and maybe below the REL (Fine, 1997). The risk is likely dose-dependent but independent of cigarette use (Fine, 1997). Cases of asthma and MWFs range in severity and not all cases recover after removal from exposure (Fine, 1997).

Fine explained four studies of lung function changes and MWFs (M2:6-7). Two of the three positive studies showed lung function decrements at levels averaging below the REL (M2:7). Greaves calculated a statistically significant relationship between lifetime exposure to straight oils of about a 5 ml drop in function per mg-yr of exposure (M2:7).

Hoffman summarized his work noting for asthma that the surveillance evidence showed a crude association with job title and fluid class but they did not quantify risks or clarify the nature of the association between exposure or fluid category (M5:13). Hoffman explained Gannon and Burge's study that stated a rate of 36 cases of asthma per million for metalworkers compared to 12 cases per million for a non-exposed group (M5:11). Hoffman cited Meredith's study that found a 25 fold increase in asthma in metalworkers compared to clerical workers (M5:11). Hoffman noted that these and Rosenman's study were examples of surveillance studies and that these types of studies may be under-reported or selectively reported (M5:11). Rosenman provided no quantification of risk (Hoffman, 1998a).

According to Hoffman, the European studies found no evidence for association between physician diagnosed asthma and machine fluids (M5:13). Both the Massin and Ameille studies (mean exposures between 2 and 3 mg/m^3) found no difference between the total positive test to the methacholine challenge, but did see a similar steep-dose response curve for those who were methacholine positive (M5:13). Methacholine challenge testing is a possible surrogate for airway hyperresponsiveness (Hoffman, 1998a).

Hoffman interpreted the Greaves' study which produced an exposure matrix from measurements taken during the study and past industrial hygiene records (M5:12). Assembly workers had exposures at about 0.12 mg/m^3, machinists had 0.45 mg/m^3 for straights, 0.55 mg/m^3 for soluble and 0.41 mg/m^3 for synthetic according to Hoffman (M5:12; Hoffman 1998a). Greaves used a questionnaire and found that odds ratios for asthma and chronic bronchitis did not differ across job category or fluid group although bronchitis values were elevated (M5:12). Grinders had elevated symptoms of chronic bronchitis, cough and phlegm (M5:12).

Kreibel's cross-sectional, nested case control study was explained by Hoffman (M5:12). Kreibel used a 7 hole sampler for aerosol mass concentration and measured microorganisms and endotoxin (M5:12). Assemblers had exposures from non-detectable to 0.28 mg/m^3 with a mean of 0.08 mg/m^3, while machinists had exposures of 0.24 mg/m^3 for straight fluids and 0.22 mg/m^3 for soluble (M5:12). Relative risk of 5% or greater decrease in lung function of machinists/non-machinists was 0.4, according to Hoffman (M5:12). Hoffman explained that the relative risk increased significantly from 1 at lowest exposure to 3.2 at the highest exposure (M5:12). Hoffman noted the incidence of $FEV_{1.0}$

decline found by Kreibel was higher among non-machinists in all concentrations (M5:12). There was no evidence of increased sensitivity to machine fluids for those people who tested positive for atopy in Kreibel's study, according to Hoffman (M5:12).

Hoffman noted other studies such as Sama's who used the same population as Kreibel but focused on sulfur concentrations using X-ray spectroscopy (M5:13; Sama, 1997). Sama found an increase in the relative risk of $FEV_{1.0}$ decrement with increased sulfur concentrations and thought sulfur was a stronger predictor of this decrement, according to Hoffman (M5:13; Sama, 1997). Sama found a decrease in six-day peak flow with exposure to sulfur (M5:13; Sama, 1997).

Hoffman explained Sprince's study which used a mini-RAM for particulates, and measured airborne microbials, endotoxin and bacteria (M5:13). Total oil measurements were 0.3 mg/m^3 for machinist and 0.08 mg/m^3 for assemblers (M5:12). Questionnaires indicated elevated relative risks for cough, phlegm and post-shift cough in the exposed but the Monday post-shift pulmonary function tests decrement greater than 5% was not significantly different (M5:12).

Hoffman noted that the lung function studies looked at either point estimates of $FEV_{1.0}$ at the start of the Monday shift or cross-shift decrements in $FEV_{1.0}$, FVC, and $FEV_{1.0}$ as a percentage of FVC as a measure of lung obstruction (M5:13). Hoffman explained that several studies have shown point and cross-shift decrements in $FEV_{1.0}$, FVC or the $FEV1_{1.0}$/FVC ratio (Hoffman, 1998a). Risks range up to 6.9 in the Kennedy study and 6.2 for persons who were obstructed in Robins' study for exposure to soluble machine working fluids (M5:13). Kennedy's exposures for machinists were 0.16 to 2.03 mg/m^3 vs. assembler's exposures from 0.07 to 0.44 mg/m^3 (M5:12). Kennedy did not observe a decline at concentrations below 0.2 mg/m^3 and found no evidence of asthma (M5:12). According to Hoffman, the exposure levels for studies that demonstrated cross-shift decrements ranged between 0.13 and 0.6 mg/m^3, although they were substantially higher in the Kresniak study, up to 99 mg/m^3. The prevalence of symptoms were based upon the MRC and ATS survey instruments which have proven to be fairly valid and repeatable instruments, according to Hoffman (M5:13). Ely and Oxhoji did not demonstrate any significant associations or elevations in the prevalence data for these symptoms, even when accounting for smoking status (M5:13). According to Hoffman, the more recent American and French studies did see increased prevalence ratios at levels ranging from 0.16 to 4.6 mg/m^3.

According to Hoffman, the American studies are quite mixed (M5:13). Greaves found no association with asthma, although when Eisen corrected for transfer bias she did see an increased risk to exposure to synthetic fluids at a 0.4 mg/m^3 thoracic about a 0.6 mg/m^3 total particulates concentration (M5:13). Because of the size of the populations they studied, good power, good methods of exposure assessment, the way they measured health effects he gave the GM studies (Greaves, Eisen, Kennedy) more weight as compared with the earlier studies (M5:13). Additional analysis can be found in Hoffman's handout (Hoffman, 1998a).

Perry provided information about how OSHA could approach risk assessment for nonmalignant respiratory disease (M6:19). He noted that OSHA does risk assessment to gain a better understanding of the relationship between exposure and disease and to develop better standards (M6:19). Using Kennedy's 1989 study, Perry's preliminary work showed that at least 16-19% showed at least a 5% decrement in lung function at 0.5 mg/m^3 and 2.5-4% had this decrement at 0.1 mg/m^3 (M6:20). Based on the Robins 1997 study, Perry showed for 0.5 mg/m^3:11.4-35.3% of individuals with obstructive lung problems had cross shift lung function changes (M6:20). Perry noted that Robins attributed some differences to diurnal variation (M6:20). Using Greave's 1997 study on respiratory symptoms and focusing on chronic bronchitis prevalence, 12.1% indicated this problem at 0.5 mg/m^3 while 2.7% showed this at 0.1 mg/m^3 (M6:20). Looking at the % of workers with $FEV_{1.0}$ less than 80%, Greaves (1996) was close to Kennedy (1989) with 12% at 0.5 mg/m^3 and 2% at 0.1 mg/m^3 (M6:20). The dose response was only evident for obstructed individuals in Robins study and Greave's study could be used to determine the percentage of people who have a given percent decrement that OSHA could define as a critical value (M6:20). Perry cited, based on the Kennedy (1989) study, an excess risk estimate of 189/1000 workers at 0.5 mg/m^3 and 41/1000 at 0.1 mg/m^3 (M6:23). At the tenth meeting of the committee, Bayard provided an update of this preliminary risk assessment and included more studies such as Kennedy's 1999 article. Additional information can be found in Perry's and Bayard's handouts (Perry, 1998; Bayard, 1999).

Information related to asthma and airway effects may overlap with the later section of this chapter on other non-malignant respiratory effects. Check that section for additional information.

2.3.3.4 *Additional Information from the NIOSH Criteria Document*

Section 5.1.2 of the NIOSH Criteria Document addresses asthma and other airway disorders (NIOSH, 1998). Additional case reports and surveillance program information is provided (NIOSH, 1998). The document explains how repeated exposure to an irritant can evolve into chronic bronchitis (NIOSH, 1998). Tables 5.1 through 5.4 in the Criteria Document summarize respiratory studies (NIOSH, 1998). As noted by Fine in his presentation, the summarized studies provide evidence indicative of an elevated risk of asthma (NIOSH, 1998). Irritation and sensitization appear to be involved (NIOSH, 1998). According to NIOSH, "with the exception of Ely's study, epidemiological studies of respiratory symptoms present generally consistent and (in the case of the more recent studies) compelling epidemiological evidence indicating that occupational exposure to MWF aerosols causes symptoms consistent with airway irritation, chronic bronchitis, and asthma" (NIOSH, 1998). The cross-sectional studies of lung function and three of four cross shift lung function studies generally follow the respiratory symptom data (NIOSH,1998).

2.3.3.5 *Other Resources Related to Asthma*

Kennedy published a longitudinal study on machinist apprentices in 1999.

Questionnaires, spirometry, methacholine challenge and allergy skin tests were used to compare machinist apprentices with apprentices from other trades. The mean "total" particulate exposure for machinists was 0.46 mg/m^3. At baseline, before starting their apprenticeship, both groups did not differ. At follow-up after two years apprenticeship, the average change in bronchial responsiveness was double for machinists compared with controls, and machinists were more apt to have developed new bronchial hyperresponsiveness (BHR) with symptoms resembling asthma. In mathematical modeling, duration of exposure to both synthetic and soluble MWFs was the predictor of the increase in BHR.

The UAW submitted a MiOSHA SENSOR study of the Federal Mogul, Greenville, MI plant (UAW, 1999). The investigation was triggered by one physician reported case of asthma (UAW, 1999). One new case of asthma was revealed by survey of 54 people and 5 additional persons had symptoms of asthma or bronchitis (UAW, 1999). This represents an attack rate of 7/54 or 13% (UAW, 1999). None of these cases was reported on the company's OSHA 200 log (UAW, 1999). The highest measured MWF exposure at the plant was 0.33 mg/m^3 (UAW, 1999).

The UAW submitted a MiOSHA SENSOR study of the GM Delphi plant (UAW, 1998). Three sentinel asthma cases prompted an investigation using a questionnaire (UAW, 1998). A 10% prevalence rate for reported asthma was found with no reports on the OSHA log (UAW, 1998). Other MiOSHA reports on Carpenter Enterprises and American Axle indicate a similar pattern of underreporting (UAW, 1998; UAW, 1999). A NIOSH HHE report indicated two cases of exacerbation of existing asthma at the Caterpillar Mossville plant (NIOSH, 1998).

Committee member, Dr. David Wegman, provided the committee a summary of many variables associated with non-malignant respiratory disease, including asthma in the MWF studies (Wegman, 1998). The summary consists of tables which define the study, design, population, fluid class, aerosol exposure concentration, health effect, #cases/#exposed, and risk estimate (Wegman, 1998). Hoffman's handout provides additional information on these studies (Hoffman 1998a).

The article, Occupational Asthma, Diagnosis, Management and Prevention by committee member, Dr. Lee Newman provides a detailed review of this disease and how physicians can address it (Newman, 1995).

A report by Cole for Caterpillar provides a critique of the NIOSH Criteria Document's assessment of non-malignant respiratory effects (Cole,1996). Cole disputes the use of surveillance data, case studies and how the studies and NIOSH interpret risk (Cole, 1996).

A general article on asthma is Enarson, D. *et al,* Asthma, Asthma like Symptoms, Chronic Bronchitis, and the Degree of Bronchial Hyperresponsiveness in Epidemiologic Surveys (1987). This article addresses the use of questionnaires and clinical measurements of bronchial hyperresponsiveness and recommends the development and use of a validated asthma questionnaire.

Chan-Yeung (1995) was cited by Fennelly as a good overview of asthma.

Examples of other relevant general asthma articles include: Rijcken, B. *et al*, Longitudinal Analysis of Hyperresponsiveness and Pulmonary Function Decline (1996); Huovinen, E. *et al,* Mortality of Adults with Asthma: A Prospective Cohort Study (1997); Lange *et al,* A Fifteen Year Follow-up Study of Ventilatory Function in Adults with Asthma (1998), and Toren, K *et al,* Asthma and Asthma-like Symptoms in Adults Assessed by Questionnaires, A Literature Review (1993).

Additional references are cited in Chapter Eight, Medical Surveillance and are also found in Attachment #6.

Other sources of questionnaire design and recommendations on questionnaire use include Appendix C to 1910.134 OSHA Respirator Medical Evaluation Questionnaire; and Rosenman, K. Recommended Medical Screening Protocol for Workers Exposed to Occupational Allergens (Rosenman Handout, 1998). The two MWF Symposia Proceedings provide additional information and discussion (AAMA, 1996,1998).

2.3.4 Hypersensitivity Pneumonitis

2.3.4.1 *Overview*

Rose defined hypersensitivity pneumonitis (HP) as a granulomatous lung disease resulting from repeated inhalation of, and sensitization to, a wide variety of organic dusts and some low molecular weight chemical antigens (M5:5). Rose noted that a complex pathogenesis involves antigen exposure and sensitization that leads to cellular events that cause lung injury and granuloma formation (M5:5). Newman explained that HP affects the alveoli, thickening and stiffening the alveolar lining and making it difficult to exchange gases and move air (M2:5). Anderson noted that HP is a restrictive disease in which the lung volume is smaller and the patient cannot expand the lungs as much as a normal individual (M5:4).

Anderson and Rose cited symptoms of HP including: cough, shortness of breath, fever, crackles, nodules and certain diffusion and pulmonary function changes (M2:5; M5:5). Rose noted precipitins in serum and the presence of a defined white cell profile in the lung lavage are also criteria (M5:5). According to Anderson, HP can resolve quickly in some acute cases or develop into a chronic, disabling and potentially fatal disease (M2:5). Anderson explained that it is very difficult to diagnose HP and define the case criteria (M5:4). Rose stated that if an individual has an acute flu like illness, subtle progressive shortness of breath, chest tightness, coughing, muscle aches, weight loss and decreased appetite, HP should be suspected (M5:5).

Rose explained that a wide range of agents can cause HP including: microbial antigens, animal proteins and reactive chemicals (M5:5). Microbial antigens and reactive chemicals may be the categories of importance with MWFs, according to Rose (M5:5).

Rose noted that HP is seen more often in non-smokers than chronic smokers (M5:5). Rose explained that attack rates can be high when you follow a sentinel HP event to find other cases (M5:5)

2.3.4.2 *Experiences and Resources Related to HP and MWFs*

Rossmoore indicated that microorganisms may cause HP, but this has not been demonstrated unequivocally (M5:19). Rossmoore stated that in any MWF facility he has investigated that has had an incident of HP, organisms of the genus *Mycobacteria* were present (M5:19). He noted that he has found this genus in situations where there has been no HP diagnosed (M5:19). According to Rossmoore, gram positive microorganisms such as *Streptococcus, Staphylococcus* and *Mycobacteria* can survive aerosolization (M5:19).

The extent of endotoxin's involvement in respiratory illness such as HP related to MWFs is uncertain (E.White, 1999). Symptoms similar to HP have been associated with endotoxin in general (E.White, 1999).

Anderson described an HP outbreak he investigated in Wisconsin (M5:3). Five employees were diagnosed with HP at a plant of 1600 employees, prompting surveillance of employee contacts with the medical department (M5:4). Seventy-one records of specialist referrals were reviewed and of these, 22 mentioned a definite HP diagnosis and 12 mentioned HP/chronic bronchitis as a diagnosis (M5:4). Of these cases, 20 fit the case criteria for HP but only 18 individuals were available for study (M5:4). Twenty four of 32 cases of bronchitis were diagnosed as occupational (M5:4). Forty percent of the HP cases were in non-MWF parts of the plant, but Mirer pointed out that many of these individuals worked close to MWF areas (M5:4). All exposures to particulate, vapor and metals were low, but biocide use doubled to tripled in the months prior to HP diagnosis (M5:4). According to Anderson, he found four predictors of disease were: 1)diagnosed having pneumonia by a physician; 2)out for at least one 3 day sick leave; 3)restrictive spirometry pattern or 4)decreased pulmonary diffusion capacity (M5:4). Anderson explained that pneumonia may be a misdiagnosis of HP (M5:4).

In Anderson's study, fifty-one randomly selected workers agreed to participate: filling out questionnaires, giving a medical history and taking a pulmonary function test (M5:4). Of these workers, 65% had at least one hallmark respiratory symptom for HP, but none of these met the medical criteria for HP (M5:4). Thirty-one percent had abnormal spirometry or diffusing capacity (M5:4). Anderson interpreted these results as exposure to many irritants in their environment (M5:4). Time lines and clinical information can be found in Anderson's presentation handout (Anderson, 1998).

Hodgson outlined an HP study he conducted in Connecticut (M5:6). He compared the MWF plant with HP index cases to two control plants (M5:6). All oil mist measurements were below 0.5 mg/m^3 and endotoxin levels were not significantly different between the case and control plants (M5:6). Some *Mycobacteria* were detected (M5:6). He cited many difficulties in diagnosing HP (M5:6). He urged use of a very sensitive and specific questionnaire, and that only 9 out of 13 confirmed cases responded to questions indicative of HP (M5:6). Hodgson believed that HP was endemic in MWF plants (M5:6).

Reeve reviewed data related to HP from the Ford database collected from 10 MWF plants from 1994-1996 with 19,000 workers involved (M6:2). He checked for cases with symptoms of shortness of breath, persistent coughing or difficulty breathing, repeat visits to medical, and symptoms that did not improve with

antibiotics (M6:2). After eliminating some cases that were non-relevant based on the patient's narrative, 17 surveillance cases were included (M6:2). These surveillance cases were not confirmed as HP by pathology exam, and Reeve thought that some of these may be asthma, not HP (M6:2,5). Based on these surveillance cases, this represented a rate of 3 cases of potential HP per 10,000 workers (M6:2). Adding the 15 proven cases from the Connersville Ford Plant HP outbreak, produced a rate of 5 per 10,000 workers or 0.5 per 200,000 hours worked (M6:2). If only the confirmed Connersville cases are used, the rate is 2.3 per 10,000 workers or 0.02 per 200,000 hours worked (M6:2).

Fine mentioned HP and eight clusters associated with water based MWFs and that more are occurring (M2:7). Some of these cases are associated with *Mycobacterium chelonae* (Fine, 1997). Mirer explained that biocide use often makes HP situations worse (M2:13). Lick noted an example of an HP outbreak where the airborne MWF exposure was less than 0.5 mg/m^3 but biocides were misused (M2:15).

2.3.4.3 *Additional Information about HP from the NIOSH Criteria Document*

In section 5.1.1.4 of the NIOSH Criteria document, HP is discussed (NIOSH, 1998). Another term for HP, allergic alveolitis, is explained (NIOSH, 1998). NIOSH cites Merideth's surveillance report of two cases of HP associated with MWFs in a three year period in the United Kingdom (NIOSH, 1998). Work by Bernstein (1995), Rosenman (1994), Rose (1996) and Kreiss (1997), indicates that HP associated with MWFs can occur in different size facilities (NIOSH, 1998). HP may have been occurring unrecognized for years in MWF facilities or could be the result of recent changes in these work environments (NIOSH, 1998). Prevention of contamination and careful use of biocides are noted as control strategies (NIOSH, 1998).

2.3.4.4 *Additional Resources about HP*

The UAW submitted articles by Stephens (1996), and a UAW Hazard Alert on HP. A NIOSH HHE report indicated four probable cases of HP at the Caterpillar Mossville plant (NIOSH, 1998). A NIOSH HHE report is available about the Chrysler Kenosha Engine plant that was discussed by Anderson (NIOSH, 1997). The UAW submitted articles by Wickham (1997) and Webber (1997) about an HP cases at the GM Flint engine plant.

A NIOSH HHE report on the Ford Connersville, OH plant indicated that 14 workers had HP (NIOSH, 1998). The average total particulate exposure in the Connersville plant was 0.4 mg/m^3 with a range from 0.08 to 1.17 mg/m^3 (NIOSH, 1998). *Mycobacteria chelonae* was the dominant organism found in the sump at the Connersville plant (NIOSH, 1998).

A NIOSH HHE report of the Meritor Automotive with a worker with HP, indicated a range of total particulate from 0.33 to 1.29 mg/m^3 (NIOSH, 1998). *Mycobacterium chelonae* was the most common organism found in some sumps with many different gram negative bacteria found in others (NIOSH, 1998).

Additional information on recommendations for remediation are included in the report (NIOSH, 1998).

An article by Freeman (1998) reported a case study of a machinist who was diagnosed with HP. The machinist's HP worsened when he returned to his job where he was exposed to MWFs (Freeman, 1998). Removal from the MWF environment improved his clinical conditions (Freeman, 1998).

The two MWF Symposia Proceedings provide additional information and discussion (AAMA, 1996,1998). Additional references are cited in Chapter Eight, Medical Surveillance and are also found in Attachment #6.

2.3.5 Other Non-Malignant Respiratory Effects

2.3.5.1 *Overview*

Newman explained the disorder lipid or lipoid pneumonia which is damage to the alveoli following inhalation of oil droplets (M2:5). He noted that hard metal disease is an immunological reaction to metals such as cobalt that may be a component of the machined metal (M2:5). Infection and irritation are other responses of the respiratory tract.

Rossmoore discussed the importance of the microorganisms in the MWFs (M5:19-20). According to Newman and Rossmoore, Legionellosis is an infectious disease that can result from exposure to microorganisms in MWFs (M2:5; M5:19). Shortell was concemed that other infections due to immune system impairment may be associated with MWFs (M9:23). Rossmoore explained that endotoxins from gram negative microorganism may be responsible for the acute respiratory syndrome associated with MWFs (M5:19).

2.3.5.2 *Speakers' Reports and Analyses of Studies*

Rossmoore emphasized the problem of misuse of biocides that can lead to respiratory irritation and alteration of the balance of microbial species present (M5:20). Rossmoore cited an incident in a plant using biocides where workers had respiratory distress and counts of 10^5 *Mycobacteria/ml* of MWF were found in the sump (M5:20). Rossmoore was concerned about the development of biocide resistance microorganisms (M5:20). He noted that biocides are the only additive to MWFs required to have acute toxicity testing done to be registered by EPA (M5:22). He has found biocide levels in plant sumps at two to three times the limited defined by the biocide's EPA registration (M5:22). Rossmoore suggested a separate MSDS for the biocide in MWFs (M5:22).

Mirer noted that in microbial related outbreaks, 20-30% of employees have complaints (M5:25). He urged consideration of the problem of formaldehyde release by some biocides used to counter high microbial numbers (M5:26).

Burke noted the potential exposure of formaldehyde, not from biocides but from propane forklift trucks in plants (M6:28). Burke explained that some of the irritant health effects he has seen were associated with grinder use and a sulfurized MWF (M6:29). Burke urged attention be given to the role vapors may play in irritation and other effects (M6:29).

Schaper explained her irritation inhalation studies (M5:18). According to

Schaper, sensory irritation refers to the response of the upper respiratory tract, while pulmonary irritation is the reaction in the lower respiratory tract (M5:18). Schaper worked with seven neat fluids that had not as yet been introduced into the work place and included one synthetic, one semi-synthetic, four solubles, and one straight (M5:18). She tested three in-use fluids that matched three of the unused fluids, for a total of 10 tested fluids (M5:18). Schaper also tested fluid ingredients (M5:18). She explained that the ASTM method she used looks for changes in both the respiratory pattern as well as the breathing rate of the animals when they are exposed to either single chemicals or mixtures (M5:18). Schaper calculates the concentration that depresses the respiratory rate to 50% of normal, the RD_{50} (M5:18).

Schaper noted that most of the components of the fluids do not have any PELs or TLVs (M5:18). For the individual components in the most irritating category, the RD_{50}s ranged from sodium sulphonate around 100 mg/m^3 to tolutriazole at 205 mg/m^3 (Schaper, 1998). Some of these showed either sensory or respiratory irritation and some showed both of these (M5:18). Other compounds, such as some ethanolamines and oils had much higher RD_{50}s (Schaper, 1998). Some biocides were very irritating and, more importantly, some of the mice died 24 to 72 hours after exposure to them (M5:18). Schaper explained that for the whole MWFs she studied, all were irritating to the respiratory tract, both upper airway, sensory, as well as pulmonary, so it is no surprise that the components were irritating as well (M5:18). Schaper cited work she published in 1991, stating the most irritating fluids were the synthetic and semi-synthetics and her estimated projected occupational exposure limits range from 1 to 2 mg/m^3 (M5:23).

Schaper warned about the use of biocides that are so irritating when airborne (M5:18). Schaper noted that the animal bio-assay can be a rapid, inexpensive tool for evaluating respiratory irritancy, sensory and pulmonary of fluids as well as components, and be a starting point for other information so we can protect workers from sensory and pulmonary irritants (M5:18) This information along with epidemiological data can help determine a safe exposure level and the mouse bioassay can be used by MWF manufacturers to screen out those new components that may be very irritating when airborne (M5:19).

Lucke was skeptical about the predictability of the respiratory irritation test (M5:21). Lucke stated that the respiratory irritation test could not distinguish a used fluid from a fresh fluid in a situation that turned out to be an HP problem (M5:24). He believed that workers manifest symptoms at concentrations lower than would be predicted by the RD_{50} and did not believe RD_{50}s should be included in MSDSs (M5:21).

According to Lucke, some formulators do conduct acute inhalation testing on their MWFs (M5:21). Howell explained that companies generate toxicity information to comply with premanufacturing notification requirements of the Toxic Substances Act (TSCA) (M5:22). TSCA requires an acute toxicity battery to determine what happens after a single acute exposure to relatively high exposure level (M5:22). Inhalation or an RD_{50} studies are not usually done, according to

Howell (M5:22). He noted that few ILMA members get involved in the TSCA registration process because they are formulators, not makers of chemicals (M5:22). Formulators rely on suppliers for this testing (M5:22).

Aerosolization related to components was discussed as a factor in respiratory effects. Tramp oil in the sumps may increase aerosolization according to Lucke (M5:23). Anti-misting additives can reduce aerosolization according to Lick and toxicity testing on at least one compound, PIB has been done (M5:23). Lucke noted that some of the compounds used as anti-misting agents are extensively used in cosmetics and personal care products, so the toxicity should be known (M5:23).

Schaper stated it is important to have some perspective on what it is we are putting in the workplace before we do, and this is one of the values of toxicology (M5:23). Schaper noted that health complaints in the work place may not always be tied strictly to the product itself but to what it has become (M5:23).

Kushner provided information on a questionnaire NIOSH used on a population of 174 people at a roller plant (6:32-33; Kushner, 1998). The primary reported symptoms were upper respiratory irritation such as throat dryness, nose irritation and watery eyes (Kushner, 1998). Comparing grinding and inspection, they reported that there was not any significant difference in symptoms (Kushner, 1998). Exposures were 1.6 to 2.6 mg/m^3 for grinders and 0.3 mg/m^3 in inspection (Kushner, 1998).

2.3.5.3 *Additional Information on other Non-Malignant Respiratory Effects from the NIOSH Criteria Document*

Sections 5.1.1.1 through 5.1.1.3 of the NIOSH Criteria Document discuss the diseases lipid pneumonia, hard metal disease and legionellosis (NIOSH, 1998). The relative rarity of lipid pneumonia may be due to current lower concentrations of MWF aerosols as compared to past exposures (NIOSH, 1998). Hard metal disease can develop quickly and is associated with the grinding of hard metal parts such as cutting tools (NIOSH, 1998). These machined parts contain cobalt and/or tungsten carbide (NIOSH, 1998). Species of the *Legionella* genus have been isolated from MWF reservoirs and one form was associated with an outbreak of Pontiac fever, a self limited form of legionellosis (NIOSH, 1998). Lipid pneumonia, hard metal disease and legionellosis appear to be relatively unusual in MWF environments, according to NIOSH (1998).

2.3.5.4 *Other Resources*

Committee member, Dr. David Wegman, provided the committee a summary of many variables associated with non-malignant respiratory disease, in the MWF studies (Wegman, 1998). The summary consists of tables which define the study, design, population, fluid class, aerosol exposure concentration, health effect, #cases/#exposed, and risk estimate (Wegman, 1998). See the section on asthma and airway problems in this chapter. Some items from that section and this one overlap, such as Reeve's work and Burch's. The two MWF Symposia Proceedings provide additional information and discussion (AAMA, 1996,1998).

Additional references are cited in Chapter Eight, Medical Surveillance and are also found in Attachment #6.

2.3.6 Concerns and Limitations

2.3.6.1 *Size of Business*

Burch and Cox were concerned that the studies did not reflect all MWF business segments (M5:31; M6:21; M6:22). Perry explained that this would be a problem if there was evidence that the risks are different in different sectors, instead of with different exposures (M6:21). Cox noted that the operating profile of the machines used in auto plants do not fit the profile of a small company (M6:22). Cox cited differences such as the number of shifts, constant running of high misting machines in big business while a small business may run a dirty machine once per month (M6:22).

Combining the data from PMPA and PMA, results in a risk of 1 worker in 45,928 may develop a MWF induced respiratory illness (Nakoneczny, 1998). Nakoneczny stated that only minimal incidence of respiratory illness occurs (Nakoneczny,1998).

2.3.6.2 *Smoking*

Howell cited Ameille's, Robin's and Greave's studies as evidence for smoking as an issue (M2:11). Howell was concerned that machinists who smoke may be more at risk (M2:11). Teitelbaum warned against blaming the smoker (M2:11).

Fine believed that smoking had at least an additive effect with MWFs and other respiratory toxins (M2:2). All four lung function studies showed a significant interaction between smoking and exposure, according to Fine (M2:7).

Rosenman noted that smoking is reported in his SENSOR questionnaire and any interpretations he makes are based on categorizing workers as current, ex, or non smokers (M4:7). Fennelly explained that the temporal variability in the asthma case he described could not be related to smoking (M5:3). Reeve noted that he could not link Ford's hospital admission dataset to smoking but wanted to investigate this issue (M7:28).

Although he saw more dramatic effects with obstructed smokers, Robins did not think there was good evidence that smoking was related to cross shift changes in pulmonary function (M5:10). Wegman acknowledged that smoking could play a role (M8:17). He noted a study underway that is reassessing Kennedy's 1989 data correcting for smoking and that Robin's conclusions about obstruction may not be borne out (M8:17). The Health Work group viewed that smoking should be banned in MWF plants (M8:26). Sherman recommended differentiating between smoking and smoking where MWFs are present (M8:27).

2.3.6.3 *Healthy Worker Effect*

The healthy worker or survivor effect was debated. Eisen explained that in her study, for each of her 29 post hire asthmatics, she selected four individuals of the same age and race who did not have asthma, but were exposed to the same

conditions as the asthmatic up to the time of diagnosis (M5:2). She tracked all of these workers and found that more asthmatics had transferred to assembly work by the time Greave's study was conducted (M5:2). She followed these workers until 1994 and found that 66% of the asthmatic machinists had terminated their employment compared to 40% termination in the rest of the population (M5:2). She noted that the 1994 study was not corrected for date of hire (M5:2).

Lick did not believe this phenomenon occurred in the auto industry (M2:9). He noted that machinists have the highest paying jobs and transfers would tend to be to machining, not away (M2:9). He also explained the minimal turnover in the auto industry (M2:9). Mirer stated that people leaving machining departments because of health effects has to be considered despite the higher pay, opportunity for overtime and less strenuous work involved in machining (M6:4).

2.3.6.4 *Respiratory Disease Diagnosis*

Diagnosis of respiratory disease and the relation of this disease with occupational cause were concerns. Newman explained that asthma can be diagnosed using lung function testing and more involved methacholine challenge tests (M2:5). Bronchial responsiveness test and peak flow meter can be used in the workplace to monitor asthma, according to Fennelly (M5:2). Fennelly stated that challenge tests to determine a specific agent are complex and the usefulness of questionnaires is limited (M5:2).

HP is clinically diagnosed, according to Newman, using lung biopsy supplemented by immunological tests (M2:5). Rose was very concerned that medical schools do not provide adequate preparation of physicians to diagnose HP (M5:5). Newman noted that HP is often confused with sarcoidosis and other granulomatous disease (M6:3). Rose noted the poor predictive value of spirometry, chest X-rays and job designation in detecting HP (M5:5). Rose opined that questionnaires could be helpful in finding sentinel HP cases (M5:5). Rose explained that viable microbial sampling is inadequate since the antigens causing HP may be nonviable (M5:5). Rosenman indicated that questionnaires may pick up people that spirometry doesn't and spirometry may pick up what questionnaires do not (M4:8)

2.3.6.5 *Symptoms vs. Disease*

Another concern addressed was the relevance of symptoms vs. disease. According to Fine, NIOSH looks at symptoms as surrogates of serious health problems because symptoms can represent conditions that are truly impairing and disabling (M2:6). Burch stated that symptoms are not semantically or clinically equal to having a disease (M5:15).

Robins noted that obstruction may be a predictor symptom that an individual would have a problem in a MWF environment (M5:10). He warned that his study had workers with 19 years seniority and obstruction may not be present, nor a predictor in young workers but should be monitored (M5:10).

Hoffman noted that cross-sectional studies cannot address the issue about the long-term effects of people who exhibit short-term decrements in $FEV_{1.0}$ or who

exhibit prevalent symptoms of cough, of phlegm, over a long period of time (M5:13). Hoffman questioned what does transient $FEV_{1.0}$ decrement and/or a positive methacholine challenge test mean in the long term (M5:13).

White agreed with Burch and Hoffman questioning the meaning of a 5% decrement in lung function and presence of certain symptoms (M5:31). Lick questioned what amount of lung function decrement was significant (M6:22). Newman noted that a 5% lower mean $FEV_{1.0}$ in a population shows that a sizable number in that population have much larger drops reflective of aggravation of asthma at work (M6:22). The 19% decline seen in some of Robin's workers is a dramatic decline according to Newman (M6:22). Newman explained that cross shift decrements are reflective of embedded cases of asthma and probably HP in these populations (M6:21).

Wegman explained that Becklake reviewed the association between acute and chronic respiratory changes (M5:13). According to Wegman, Becklake's evidence supports the fact that a short-term change in $FEV_{1.0}$ is predictive of long-term change in several different occupational settings (M5:13; M6:21).

2.3.6.6 Peak *Exposures*

Another issue discussed was peak values. Sheehan was concerned that peak exposures and work patterns may be different in different sites (M6:22). Lick opined that toxicity data on peak values would be helpful (M6:22). O'Brien noted that peaks may be related to upper airway disease (M7:15). Wegman explained that there are hypotheses that peak exposures may be associated with the onset of reactive airway dysfunction or acute irritant asthma (M8:26). Mirer noted that most of the evidence is based on clinical impression (M8:26).

2.3.6.7 *Other Limitations of Studies*

Other limitations of studies were discussed. Howell was concerned about the common ventilation systems in areas defined as exposed and unexposed in the respiratory studies (M2:11). Rosenman explained that carryover could occur in the MiOSHA plants (M4:8).

Greave's study was a cross sectional study according to Wegman, and these studies suffer from survivor effect (M2:8). Howell was concerned about the limitations of the odds ratios in Greaves study (M2:11).

Howell noted misclassifications of fluid types (M2:11; M6:21). Howell expressed his concern about Eisen's study misclassifying the synthetics (M5:14,31). Howell suggested that if one is combining classes to combine semi-synthetics with soluble oils because the chemistry is more similar than semi-synthetics with synthetics (M5:14). Howell noted that the effect seen in Eisen's work might disappear with reclassification of fluids (M5:14). Howell recommended that OSHA use the raw data from studies to avoid such limitations (M6:21).

In Hoffman's analysis for ILMA of the studies cited in the NIOSH Criteria Document, he reviewed about 300 papers (M5:13). Hoffman questioned the use of different exposure assessment techniques and that long-term exposure versus short-term exposure limits need to be considered (M5:13). He also questioned the

use of total particulate as a surrogate (M5:13). Hoffman noted that Sama used total sulfur concentrations and Robins looked at endotoxins and bacteria (M5:13). Robins found the bacteria exposures were quite substantial in terms of the relative risks (M5:13). Hoffman criticized Krzesniak's study for the wide exposure range (M5:11). Teitelbaum explained that Krzesniak's study was not peer-reviewed but was a report of a conference (M5:12). Hoffman explained that more work needs to be done on exposure assessment (M5:13).

Hoffman viewed the UAW/GM studies of Kennedy, Greaves and Eisen as having the greatest weight due to the size of the populations, the quality assurance in the exposure assessment and the assessment of health outcomes (M5:12). Hoffman was concerned about participation bias in Kennedy's study (M5:12)

Hoffman warned that relative risk values of 1.3 or 1.5 could be easily confounded (M5:11). Wegman stressed the need to look at not only rates but the confidence interval, explaining that wide confidence intervals indicate low statistical power and low precision (M2:8). Hoffman evaluated the studies in the context of Hill's criteria for causality and noted that there was a temporality of the relationship between exposure and response, but questioned whether there was constantly strong relative risks, consistent across studies (M5:14). Schaper noted that her work on mice provides the basis of biological plausibility and causality for the effects of MWFs (M5:18).

Burch thought Reeve's numbers overestimated the effect of MWFs based on Reeve's inclusion of any case, even if later it was determined by workman's compensation as non-occupational (M6:4). Newman viewed Reeve's estimates as lower than the real number, noting that Reeve did not include all private physician data and could have misclassified cases (M6:7). Shortell thought Reeve's numbers were an under-reporting because in his experience, many workers avoid going to the medical department (M6:5). Shortell stated workers avoid medical due to their lack of knowledge about the occupational basis for their disease and workers view medical as an unpleasant place (M6:5). Reeve viewed the symptom prevalence rate somewhere between the passive and active numbers (M6:4). Lick acknowledged that the Ford database needs improvement but stated that it did show a rationale for controlling MWFs (M6:5).

2.3.7 Linkage of Discussions to OSHA Action

Speakers and committee members linked studies and concepts to potential action by OSHA. They addressed issues such as an exposure limit, the weight of the evidence, health endpoints, risk assessment, relevant studies, material impairment of health and whether an exposure limit would be effective.

Fine explained that NIOSH based its criteria for the REL primarily on the respiratory effects (M2:1). Fine explained that studies by Kreibel, Robbins and Kennedy indicated adverse effects below the REL (M2:2). Rosenman noted that symptoms are reported at levels below the REL (M4:7). Eisen showed asthma in populations exposed to 0.6 mg/m^3 according to Fine (M2:6). NIOSH could not find evidence that a limit for endotoxin or bacterial counts would be protective (M2:2).

Mirer stated that the NIOSH Criteria Document presented a very strong body of evidence and compared to most OSHA rule-making, an overwhelming body of research studies and case reports at levels below the REL (M2:10). He noted that NIOSH did do quantitative assessment of statistically significant studies (M2:10).

Hoffman agreed with Mirer that the general approach of public health authorities is to say that there may still be something going on at the no effect level (M5:14). According to Howell and Mirer this level furnishes no assurance of safety because you cannot account for sub-clinical health effects and the limits of statistical power (M5:14).

Teitelbaum explained that from Ely in 1970, articles have shown an increasing awareness and a greater precision in the diagnostic categories of illness which are found in persons exposed to metalworking fluids (M5:14). Teitelbaum noted that there are papers from the 1930's which demonstrate pulmonary disorders associated with metalworking fluids, and after 60 or 70 years of a growing literature, it is clear that there is respiratory disease associated with the exposure (M5:14). Teitelbaum explained that we have a literature which demonstrates consistency and biological plausibility (M5:14). Teitelbaum stated that there is disease and that it is occurring at the level which is currently achievable, which is one-tenth of the level which is permitted under the existing OSHA standard, so we need to respond to this (M5:14).

Infante asked for guidance about endpoints for material impairment (M5:31). Infante questioned if cumulative dose using current exposures should be used (M5:31). Wegman noted lung function changes and other factors would have to be considered but that morbidity studies are more difficult to assess than mortality ones (M5:31).

White agreed that respiratory endpoints could be used, but questioned which ones, and what relevance they have (M6:22). He questioned if the studies used (Kennedy, Greaves, Robins) by Perry were appropriate for risk assessment (M6:20).

Wegman questioned why Kriebel and Eisen studies were not included in Perry's assessment (M6:21). Perry noted that an outside contractor viewed that these were not amenable for this assessment (M6:21). Wegman noted the important papers to review include: Sprince, Greaves, Eisen, Kriebel and Robins for asthma and COPD (M5:31). Anderson's upcoming paper could be used for HP (M5:31). Wegman viewed asthma and HP as first and second priorities and COPD fourth with dermatitis third (M5:31).

Mirer recommended that MiOSHA data be included in OSHA's assessment since it included 50-70 different locations and Rosenman related asthma and symptoms (M6:21). Lick disagreed, stating that this dataset was not on par with the other studies (M6:21). Wegman thought that Rosenman's work could help interpret the risk assessment (M6:22).

Mirer noted that Ford's passive medical surveillance data presented by Reeve showed a significant increase in respiratory complaints to medical in MWF plants (M6:2). Mirer viewed Reeve's estimate as low compared to the actual

workers exposed since according to Mirer only 1/3 of the workers in a MWF plant would be in machining areas (M6:4). Mirer highlighted active surveillance studies including Anderson's report of HP at the Chrysler Kenosha plant, the Sprince study at Chrysler's Kokomo plant, the 3 GM studies of Greaves, Kennedy and Eisen, Robins study of one GM plant, and Rosenman's surveillance of multiple small and large facilities (M6:4). Mirer noted that 20-25% had substantial respiratory symptoms and occupational asthma rates were 15-30% higher in machining departments (M6:4). Symptom prevalence rates were 15% in active surveys and 0.5 to 1% in passive reporting, according to Mirer (M6:4). Mirer used Reeve's number of 0.02 cases of HP/200,000 hours worked multiplied by a 30 year working life and calculated a rate of 6 cases of HP per 1000 workers (M6:4). Mirer viewed this as evidence of a material impairment of health (M6:4).

Lick stated that respiratory effects are harder than cancer to disregard (M5:15). O'Brien also questioned if straight oils represent the same respiratory hazard that water solubles do (M5:16).

Howell noted that the diseases, chronic bronchitis and asthma, might represent a material health impairment (M2:11). Howell agreed with Burch that he cannot conclude that exposure to metalworking fluids, new or used, caused non-carcinogenic respiratory disease (M5:16). Howell noted that metal removal fluid exposures have declined significantly over the last 25 years and acknowledged there may be consensus that at least long-term exposure to some in use metal removal fluids can be associated with some non-carcinogenic respiratory disease in some individuals (M5:16).

Howell explained that either the absence of good fluid management and/or the presence of microbial contaminants of one form or another are more likely to lead to acute and chronic non-cancer respiratory disease (M5:16). Howell noted that reducing exposure to less than or equal to 0.5 mg/m^3 total particulate alone, absent any other program elements, is unlikely to further reduce the prevalence of non-cancer respiratory disease (M5:16). Howell questioned Perry's data, showing effects at the 0.1 mg/m^3 level and believed something else may be causing problems at these levels (M6:23). Howell noted that product stewardship is a proper and necessary step (M5:16). Howell explained for employee health, reduction of work illness and injury, that it is the management of fluids and the education of users at all levels that will yield the greatest payoff in the shortest time (M5:16).

2.3.8.Committee Decisions and Rationale

The majority (13) opinion of the committee was that acute and chronic respiratory effects are known to be associated with exposure to MWFs (M9:2223). Members cited the epidemiological studies, the limited toxicology studies and their own experiences: in plants, in discussions with workers and in clinical practice (M9:22). Presentations by Rose, Fennelly, Eisen, Hodgson, Fennelly's patient, the NIOSH Criteria Document and papers by Kennedy were noted as additional evidence (M9:23). Data from Wegman (Wegman,1998), and Rosenman (1998)

were cited (M9:23). One member, White, stated that there was some evidence to support the association of acute and chronic respiratory effects and MWFs (clarification provided in meeting #10). Another member, Cox indicated that there was no evidence in small plants, although there was in large ones (M9:22).

The minority opinion (Howell) of the committee was the evidence was equivocal. Concerns were expressed about the categorization of fluids, and other confounders in the studies. Risk ratios were close to one, making them vulnerable to confounders (M6:22). The relevance of some of the health endpoints was questioned (M5:6).

Two members (O'Brien, Sheehan) explained that the effects were associated with end-use fluids (M9:22). One member (McGee) noted that there was more evidence for acute effects than chronic effects (M9:22). One member (Burch) had no comment (M9:22). One member (Mirer) explained that HP is more associated with in-use water-based fluids and asthma is associated with all MWFs (M9:23). This same member (Mirer) viewed that material impairment of health related to respiratory problems is more associated with water-based fluids (M9:23).

2.4 CANCER

2.4.1 Speakers

The issue of cancer was discussed at the fifth and seventh meetings and at other meetings. Dr. Boris Lusniak, NIOSH, addressed skin cancer in his presentation on dermatitis (M2:13). Committee member, Dr. John Howell mentioned cancer testing methods in his discussion of consensus standards (M4:4). Dr. Geoffrey Calvert, NIOSH, summarized the cancer studies noted in the NIOSH Criteria Document (M5:33). Committee member, Ken Kushner, noted a study he did of cancer rates in his company's plants (M6:33). Committee member, Dr. Daniel Teitelbaum presented an overview on cancer in the December, 1998 meeting (M7:6-8).

In the discussion of rates of adverse health effects, three types of data were presented: anecdotal or case reports, surveys of plant experience and formal cohort or cross-sectional studies. The first type provides only evidence that the problem exists in the setting from which the report comes and may exist in comparable settings. The second type is limited by the quality of the different reporting units (plants) and no effort has been made to determine that each was equally aggressive in identifying and recording adverse health effects. Generally these surveys were based on OSHA 200 logs which may or may not have been complete. These survey results, therefore, should be seen as offering a different type of information than case reports with less quantitative reliability than systematic scientific studies. These survey results are limited by the sources of data. The third type of data, formal studies, is the most reliable, although these types of studies have been carried out only to a limited extent in occupational environments using MWFs.

2.4.2 Background Information

Teitelbaum explained the old definition of cancer is a malignant tumor of potentially unlimited growth that expands locally by invasion and systemically by metastases (M7:6-7). Currently, according to Teitelbaum, cancer is viewed as a malady of genes and most if not all causes of cancer act by damaging genes directly or indirectly (M7:7). Scientists accept that cancer is clonal and is due to the progressive accumulations of mutations, interactions of different genetic alterations and complementation between different mutant genes (M7:7).

According to Teitelbaum, in 1990, the age adjusted cancer death rate in the US was 174 per 100,000 (M7:7). The cancer rate has increased steadily since 1930 but if tobacco related deaths are removed, the rate would not have increased for males and would have decreased for females (M7:7). According to Teitelbaum, 1 in 3 people in the US will get cancer and 1 in 4 will die from it (M7:7). Additional rates for specific types of cancers are in Teitelbaum's handout (Teitelbaum, 1998).

Teitelbaum explained if you have had one cancer, your chance of a second, new cancer is vastly increased due to mechanistic reasons (M7:7). Heredity, lifestyle, diet, viruses, bacteria, worms, radiation and workplace exposures are factors related to cancer (M7:7; Teitelbaum, 1998). Host factors include: age, gender, nutritional status, genetic makeup and presence of some infectious and genetic diseases (M7:7-8). Exposure differences and habits such as smoking can account for a wide variety of special risk groups who are more likely to develop cancer (M7:8).

According to Teitelbaum, a series of rare events in the right sequence and right time can lead to cancer (M7:7). The more carcinogens, the more cancer that is seen (M7:7). Many agents cause the same type of cancer and one carcinogen can be multi-potential, i.e. can cause different types of cancer (M7:8). He noted that simplistic approaches to understanding cancer do not work (M7:8). More details on the mechanisms of carcinogenesis are in his handout (Teitelbaum, 1998).

Workers enter a workplace with pre-existing histories and predispositions to cancer (M7:8). Removing carcinogens from the workplace lowers the likelihood of the interactions which will cause more cancers (M7:8).

Teitelbaum provided the designations of carcinogens of the International Agency for Research on Cancer (IARC) (M7:8). Group or Class 1 cause cancer in humans based on evidence in humans and arsenic is an example (M7:8). Group 2A probably causes cancer in humans while 2B possibly causes cancer in humans (M7:8). The two designation is based on animal evidence with limited human evidence and examples include formaldehyde and methylene chloride (M7:8). Group 3 is not classifiable usually due to inadequate evidence and Group 4 include agents for which a fair amount of research has been conducted and all results are negative (M7:8). He noted that the National Toxicology Program also has its own classifications (M7:8).

2.4.3 Review of Studies

2.4.3.1 *Presentations*

Calvert reviewed the NIOSH Criteria Document section on cancer and his publication in the March,1998 issue of the *American Journal of Industrial Medicine* (M5:33). He explained that NIOSH identified six animal studies but that these were viewed as inadequate evidence for carcinogenicity of MWFs (M5:33). These animal studies were inconsistent and had inadequate characterization of the MWF fluid (M5:33).

Calvert explained that NIOSH focused on epidemiological studies in their review (M5:33). NIOSH viewed that the Tolbert and Eisen studies conducted in 3 auto plants and including over 23,000 workers, had the most statistical power (M5:33). Workers were studied from 1941 to 1984 (M5:33). The studies indicated an association between MWFs and laryngeal, rectal and pancreatic cancer (M5:33). There was a dose response for laryngeal cancer and it was significant for exposure to greater than 0.5 mg/m3 of straight fluids (M5:33).

NIOSH used Silverman's study as evidence for an association between bladder cancer and MWFs (M5:33). Silverman's study corrected for smoking and had more power than studies by Howe, Schiffler and Gonzales (M5:33). There is a relation between exposure to MWFs and bladder cancer, but the type of fluid responsible cannot be assessed, according to Calvert (M5:33).

Calvert noted that laryngeal, rectal and pancreatic cancer are primarily associated with exposure to straight fluids, and there is some evidence of association with synthetics (M5:33). He explained that scrotal and skin cancer are associated with PAHS in earlier formulations (M5:33). Lusniak noted that straight fluids were associated with skin cancer as well as other disorders (M2:13). Skin cancer was associated with polyaromatic hydrocarbons that are no longer in use, so according to Lusniak, skin cancer is rarely seen (M2:13).

Substantial evidence was found of an increased risk of cancer of the larynx, rectum, pancreas, skin, scrotum and bladder (Calvert, 1998). Studies could not assess a causative agent and changing formulations make interpretation difficult, stated Calvert (M5:33). The conclusions are all based on exposures prior to 1970 and there are not any studies that determine the risk of current exposures to currently used fluids (M5:33). Since exposures have been reduced, Calvert felt that the risk of cancer has been reduced (M5:33).

Howell noted the availability of an ASTM method for formulators and fluid component suppliers to use to assess components and fluids (M4:4). This standard is E-1687 Test Method for Determining the Carcinogenic Potential of Base Oils Used in MWFs (M4:4).

Kushner compared death from cancer rates in his company's bearing plants which use MWFs, to the company's steel plants, which do not use MWFs (M6:33). The rates of deaths from GI cancer for machinists was 5.6% of the total deaths (M6:33). Kushner noted that this was a lower percentage than rates found in MWF cancer studies (M6:33). He also compared his company's rates to the statistics of the counties in which the plants were located (M6:33). He did not correct using standard mortality analysis (M6:33). Additional information can be found in his handout (Kushner, 1998). Wegman commented on the need for these data to be analyzed by proper epidemiologic methods (clarification at tenth meeting).

2.4.3.2 *Additional Information about Cancer from the NIOSH Criteria Document*

Calvert explained the information provided in the NIOSH Criteria Document sections 5.2 and 5.3 and this information is in the previous section of this report (NIOSH, 1998). Tables 5-5 through 5-17 in the Criteria Document summarize the various types of studies on cancer (NIOSH, 1998). Table 5-18 addresses aerosol concentrations at different time periods (NIOSH, 1998).

2.4.3.3 *Additional Resources about Cancer*

Hoffman provided a draft, unpublished document without references that addressed cancers studies and MWFs (Hoffman, 1998b). He highlighted studies on stomach cancer, pancreatic cancer, lung cancer, and laryngeal cancer (Hoffman, 1998b). He noted that the studies he reviewed had problems with small study populations and many were PMR studies which cannot evaluate causation (Hoffman, 1998b). No attempt was made in these studies to estimate individual exposures and analyze dose-response relationships (Hoffman, 1998b). No individual information was obtained by these studies on personal risk factors (Hoffman, 1998b). He cites other studies and provides limitations in this draft document (Hoffman, 1998b). In his report, Hoffman noted that the UAW/GM studies at three auto plants have been given the most weight due to sample size and resulting statistical power to identify rare cancers (Hoffman, 1998b). In the UAW/GM studies Hoffman explained that individual information on potential confounding factors was not obtained (Hoffman, 1998b).

Overall, Hoffman explained in his report that evidence has been presented for slight increased risks for certain types of cancer as a function of exposures to various classes of MWF (Hoffman, 1998b). It is possible that certain subgroups of workers may exhibit slight increased risks of laryngeal cancer. Due to the margin of the increased risk, Hoffman believed that the risk could be due to these confounders (Hoffman, 1998b). The patterns of exposure indicate that historical exposures play a more prominent role than more recent exposures (Hoffman, 1998b). Plant conditions, MWFs used and exposures prior to 1960 are very different from today (Hoffman, 1998b).

The UAW provided a packet of studies to the committee (UAW, 1997). Included in this packet are studies by Park (1996), Silverstein (1988) and a summary of these studies (UAW, 1997). Another article and analysis was provided by UAW, the article was Sullivan *et al* (1998). UAW provided a variety of articles noting the award of workman's compensation to the family of a worker exposed to MWFs who died from cancer (UAW, 1998).

Lucke provided an article he wrote for *Lubrication Engineering,* Health and Safety of MWFs, Fluid Formulations: A View into the Future (1996). This article addresses his analysis of the cancer studies on MWFs as well as other issues (Lucke, 1996).

In Cole's report for Caterpillar, he criticizes the draft version of the NIOSH Criteria Document (Cole, 1996). He was concerned about the use of causal interpretation of some studies, the exposure to different types of fluids confounding

different studies and the emphasis on certain types of cancer (Cole, 1996).

The two MWF Symposia Proceedings provide additional information and discussion (AAMA, 1996,1998). Additional references are cited in Chapter Eight, Medical Surveillance and are also found in Attachment #6. The NIOSH Criteria Document has been cited throughout and is a comprehensive source of other articles (NIOSH, 1998).

2.4.4 Concerns and Limitations

2.4.4.1 *Size of Business*

Throughout all health discussions, Burch and Cox were concerned about the relevance of studies done in large auto plants to small business.

2.4.4.2 *Other Issues*

The committee was concerned about: lifestyle factors, the strength of the evidence, biological plausibility, formulations and consensus. Burch viewed that lifestyle was a very important factor in carcinogenesis (M5:33). Calvert agreed that it is very difficult to control for lifestyle factors in the cancer studies (M5:33).

Mirer viewed that the NIOSH Criteria Document underestimated the strength of the evidence for cancer (M7:9). He referenced page 96 of the Criteria Document on risk ratios (M7:9). NIOSH used agreement among studies and study size to determine the risk, according to Mirer (M7:9). Mirer commented that neither the National Toxicology Program nor IARC have very clear decision rules on how they aggregate epidemiologic studies (M7:8). According to Mirer, there are clear rules for animal carcinogens (M7:8).

Lick cited the inconsistencies among studies (M9:24). He noted no discernible pattern but the articles indicate something is going on even if there is not a good fit (M7:8). He noted NIOSH's interpretations such as rectal cancer associated with straight fluids (M7:10). The Ford Cleveland plant population showed evidence of rectal cancer in the studies but did not use straight fluids (M7:10). He questioned why lung cancer is not seen in the studies (M7:10).

Anderson noted that as an epidemiologist, he did not have a problem with the lack of agreement, noting it could be due to different populations and different plants (M7:9). Anderson cited some consistency in pancreatic cancer (M7:9). The dearth of animal studies bothered Anderson (M7:9). Anderson noted some limited skin painting studies resulted in skin cancer (M7:10).

Howell noted the difficulty of proving biological plausibility (M5:33). Calvert agreed but indicated that early synthetic and semi-synthetic fluids were associated in Wang's animal study with pancreatic cancer (M5:33). Calvert indicated that nitrosamines in animal studies show some biological plausibility (M5:33).

Anderson noted that the polynuclear aromatic hydrocarbons (PAH) animal studies show biological plausibility (M5:34). Mirer felt the human studies show and component studies show biological plausibility (M5:33-34; M7:9). Teitelbaum warned of the differences in biotransformation between animals and humans and the potential for multi-target carcinogens in the MWF mixture (M5:34).

Howell noted that formulations have changed over the years and

ingredients known to cause health problems have been removed by fluid manufacturers (M7:9). Anderson cautioned against thinking all potential problems have been eliminated by formulation changes (M7:10). Mirer agreed that nitrosamines and other carcinogenic compounds like ethanolamine have been reduced, but trace amounts still exist (M6:38). McGee and Anderson were concemed that the fluids from the manufacturer are very different from what they become at the plant after contamination (M7:9,10). Kushner warned that PAHs are still a question and that manufacturing processes can increase or decrease certain aromatic compounds (M6:38). Howell explained that some in process cleaners can contain nitrites and any uses of secondary alkanolamines could result in nitrosamines in the used fluids (M7:9).

There was an overall impression from the committee, and especially Howell and Mirer, that disagreement would continue during any cancer debate (M6:40; M7:9). Mirer persuaded the committee not to debate the carcinogenic potential of current fluids since we cannot really know the cancer effect of a currently used fluid for 20-25 years (M6:38). Howell stated that disagreeing on cancer did not preclude or prevent the committee from moving forward (M7:9)

2.4.5 Linkage of Discussion to OSHA Action

The committee addressed issues such as what class of carcinogen MWFs would be in, acknowledging that these discussions were to help determine the weight of the evidence. The committee did not view its role was to determine an actual class for MWFs. How the cancer issue related to other health issues and potential action were discussed.

Teitelbaum indicated that he thought there was enough information to classify MWFs as IARC type 2B or maybe 2A (M7:8). Teitelbaum suggested reviewing Calvert's paper and that this type of paper would be reviewed by IARC in classifying MWFs (M7:8). In response to Burch's question about which MWFs would be classified, Teitelbaum noted that this is a difficult question to answer (M7:8). Ethanolamines are known carcinogens stated Teitelbaum (M7:8). The old straight oils with PAHs would be classified in Class 1 while nitrosamine containing ones could be in 2A or 2B, according to Teitelbaum (M7:8). Teitelbaum explained that the multiple exposures many workers have had makes knowing what they were exposed to a difficult determination (M7:8). Teitelbaum cautioned against waiting for complete information prior to action (M7:8),

Lick commented that if MWFs were Class 1 or even Class 2 carcinogens, he would see more consistent cancers from plant to plant (M7:8). Cancer was not the defining disease for Lick (M7:8). Lick noted that HP and other nonmalignant respiratory diseases are quite significant to act on, but all actions need a systems approach (M7:10). A PEL, the usual way to address carcinogens, would be inadequate, according to Lick (M7:10).

Teitelbaum agreed with Lick that air exposures are not the only concern (M7:10). He recommended getting the workers hands out of the fluids (M7:10).

Hoffman viewed the complexity of MWFs made it very difficult to assess potential IARC categories (M7:9). He did not think they could be put into one

category (M7:9).

Based on the studies of earlier formulations and the precautionary principle, Anderson would categorize MWFs as carcinogens Class 1 or 2A, until proven otherwise, because there was sufficient evidence in humans (M7:9,11). He thought preventing dermatitis may reduce the risk of skin cancer (M7:10). He did not think a standard should be based on carcinogenicity (M7:10).

McGee stated that we know people exposed to MWFs 30-40 years ago have a higher incidence of cancer (M7:10). Mirer noted that the bulk of recent evidence is for soluble, synthetic and semi-synthetic fluids (M7:8). Mirer and McGee were concerned that too many carcinogens are in dispute too long before action is taken (M7:9). Mirer thought there was enough evidence to support MWFs as a human carcinogen but we can protect people without this conclusion (M7:11).

Wegman noted that cancer is a secondary reason, after respiratory disease and dermatitis, to control MWFs (M7:10). He noted that additional cancer studies are on-going (M7:10).

Howell explained that it was impossible to prove today's formulations will not cause cancer under all of the circumstances of use (M7:11). Howell explained that the significant reduction in exposure coupled with a significant reduction in impurities that have been associated with cancer has reduced and will continue to reduce any future possible carcinogenic risk (M7:9). He cited the role of product stewardship by fluid manufacturers in reviewing new health studies and making recommendations for members to remove components of concern (M7:10).

2.4.6. Committee Decisions and Rationale

The committee addressed skin cancer and cancer at other sites as separate issues. Skin cancer was addressed first. The opinions were separated into evaluating "old formulations" versus "current formulations".

The majority (10) opinion was that skin cancer is known to be associated with exposure to old formulations of MWFs (M9:23). The opinions were mixed for current formulations of MWFs (M9:23). White believed that old formulations were a problem, two members (Lick, Teitelbaum) believed there was no evidence for current formulations, three members (Sheehan, Mirer, Frederick) viewed evidence for current fluids as equivocal and one (Anderson) thought it was reasonably anticipated that there was evidence for current fluids (M9:23). Three members (Wegman, Newman, Day) believed there was known evidence for old and current formulations (M9:23).

Chapter Five of the NIOSH Criteria Document was cited (M9:23). An alternate who is a machinist noted his own experience with squamous cell cancer (M9:23). Issues such as the difficulty of assessing the effects of current exposure due to the latency period and the possible presence of co-carcinogens and promoters were noted (M9:23).

The minority (Burch, Cox, Howell) opinion was that the evidence was equivocal for old formulations (Mg: 23). As noted above, the opinions for current

fluids were mixed (M9:23). The members who presented the minority view on the older formulations believed there was no evidence for current formulations (M9:23).

Two members (O'Brien, White) did not think they had adequate information to make a decision (M9:23).

The committee addressed the issue of cancer at other sites. *The majority (10) opinion was that old formulations of MWFs are known to cause cancer at various sites (M9:24).* Epidemiological studies, MSDSs, and the NIOSH Criteria Document were cited (M9:24).

The minority opinion (Burch, Howell, Lick) was that the information on the older formulations was equivocal (M9:24). The inconsistencies among the epidemiological studies regarding sites were noted for a rationale (M9:24).

Two members (Cox, White) had no opinion (M9:24).

The committee was split on the issue of cancer related to current formulations of MWFs (M9:24). Four members (O'Brien, Lick,Teitelbaum, Frederick) viewed that evidence was equivocal for current formulations (M9:24). Four members (Day, Newman, Sheehan, Anderson) viewed the evidence as reasonably anticipating cancer associated with current fluids (M9:24). Three members (Howell, Cox, Burch) thought there was no evidence that currently formulated MWFs cause cancer (M9:24). Three (Wegman, Mirer, McGee) noted that prudence dictates that we view current formulations as carcinogenic, and one (White) had no opinion (M9:24). Latency periods, and reductions in nitrosamines and PAHs were noted as a rationale and concern (M9:23).

CHAPTER THREE
Deliberations Related to Actions OSHA Should Take: Technological Feasibility

3.1 GENERAL INFORMATION

The committee discussed if the recommendations considered by the committee are technologically feasible. White defined technological feasibility as the ability of most operations in each industry affected to comply with a Permissible Exposure Limit (PEL) most of the time (M9:30). Robert Burt from OSHA's Office of Regulatory Analysis, indicated that an action is technologically feasible if it can be done in most operations (M2:4). Burt noted that if there are companies that meet the regulatory requirements, and/or technology is currently available or soon will be, the action is technologically feasible (M2:4). Estimations of feasibility can be based on: data from existing operations, data from similar operations, data from demonstrations, application of "rules of thumb",

observation of exposure trends and technology forcing (O'Brien, 1998).

Members used "technically" and "technologically" as synonyms throughout the discussion (M9:30-31). The third and sixth meetings focused on technological feasibility and this issue was discussed at other meetings and addressed by site visits by work groups to small, medium and large facilities using MWFs.

In order to understand if an action is technologically feasible, it is necessary to determine what current conditions are and the factors that are important in reducing exposure and protecting workers from MWFs. The committee focused on systems management and exposure control. It is very difficult to separate the issues of systems management and exposure control, since the latter is part of the former. Additional information on systems management can be found in Chapter Six, Best Practices for Systems Management. Exposure assessment and medical surveillance were also discussed in the context of technological feasibility and these topics can be found in the Chapters Seven and Eight of this report.

3.2 SPEAKERS AND PRESENTATIONS

Committee member, Dr. Hank Lick, provided an overview of systems management and addressed exposure control (M2:15-17). Another committee member, Frank White discussed the development of the ORC Guide for Systems Management of MWFs (M2:16). Stephen Gauthier, a machinist at a large East Coast manufacturer described his own experiences with controlling dermatitis using systems management of MWFs (M2:17-18; M8:18-19). Charles Guy, Ford Motor Company, addressed issues of worker acceptance of control technologies (M3:7). Tom Beeman, a machinist at a mid to large facility in the Western part of the US provided some limited information about his company's fluid management (M5:3). Dr. Henry Anderson, committee member, explained some system factors in his study of an HP outbreak in Wisconsin (M5:3-4). Dr. Daniel Goon, Castrol, addressed issues related to systems management during his participation in a panel discussion (M5:23). Dr. Harold Rossmoore described the importance of the microbiology of MWFs and its relation to systems management (M5:19-20). A panel of machine tool manufacturers, and ancillary companies that support the design and installation of machine tools and enclosures in machining facilities, discussed enclosures and systems management (M6:6). The panel consisted of Jeff Hedley of Tamer Industries, Stephen Stevens from Cross-Huller; William Fay from H.M. White, Dan McCarthy of Lamb Technicon, Ken Steele of Grob, and Al Woody of Giffels Associates (M6:6). Charles Carlson of the Association for Manufacturing Technology also joined this panel (M6:7). Dr. Robert Adams, Professor Emeritus from Stanford University and practicing clinical dermatologist addressed the group (M2:2-3). Adams, and Dr. Boris Lusniak from NIOSH, explained the skin problems associated with exposure to MWFs and how these problems can be controlled (M2-3;13-15). Committee member Dr. Frank Mirer referred to exposure control in his presentation on exposure measurement (M2:12). Committee member, Dr. Dennis O'Brien provided an overview of the available control technologies for reduction of airborne MWFs (M3:1-2). William

Johnston, Ford Motor Company, provided a review of the ANSI B11 Mist Control Document and gave his perspectives on technology design (M3:2-3). Dr. David Leith, University of North Carolina, explained mist collector performance (M3:3-5). David Hands, Ford Motor Company, presented data on the effectiveness of enclosures (M3:5-7). Robert Kramer, Ford Motor Company, addressed some technological feasibility issues in his discussion of economic feasibility (M3: 6,9-10) Dr. William Watt and Jack Hartwig, Chrysler Corporation and Dr. James d'Arcy, General Motors provided their companies' experiences with the technology needed for MWF control (M3:7-9). A panel consisting of Kramer, Watt, Hartwig, d'Arcy and committee members, Dr. Frank Mirer and Arthur McGee addressed the issue of economic and technical feasibility in the American auto industry (M3:11). Greg Piacitelli from NIOSH discussed exposures and controls found in the small businesses surveyed in the NIOSH Small Business Study (M4:1). Dr. Ed Stein, OSHA, provided background information on previous OSHA and NIOSH recommendations for dermatoses (M5:28-29). Robert Burt, OSHA addressed technological feasibility in his presentation of OSHA's work on feasibility (M7:24). Ike Tripp, Etna, addressed issues on systems management as part of a discussion of the ORC Document (M8:8). Michelle Lantz, Caterpillar Corp, discussed systems management factors that can reduce health concerns (M8:10).

3.3 BACKGROUND INFORMATION

3.3.1 Components of Systems Management

Lick noted that many different issues are encompassed in systems management (M2:12). These include: fluid application, MWF cycling, tool speed, part loading and unloading, chip removal, types and effectiveness of enclosures, lock out, exhaust ventilation, supply air, duct design, air cleaner quality, fire protection, and waste disposal (M2:15-16). The systems work group defined the role of a systems approach as managing the fluid, integrating and controlling systems that result in exposure control and enhanced coolant and machining performance (M8:3). Systems approach and control are modern management practices for continuous improvement and avoid the "whose problem is it" phenomenon (M8:3). Engineering controls provide enclosure and removal of mist using ventilation and provide improved housekeeping (M8:3). Fluid management maintains the quality of fluid and deals with unknown hazards e.g. microorganisms (M8:3).

White explained that systems management also includes: a written management program with stated goals, a designated individual in charge, written standard operating procedures for fluid testing and data collection, a tracking system for determining trends, and a training program (M2:16-17). Lick and White highlighted the importance of employee participation and feedback (M2:15,17).

White noted that use and maintenance of the fluids are integrally related to issues such as ISO 9000 (M2:16). More companies are realizing that product quality and fluid management are related, according to White (M2:16). The

systems work group viewed that systems management could be put into an overall ISO program as it was done at Valenite, but ISO programs are not a replacement for OSHA action (M8:3). The systems work group recommended streamlining any information gathering required or recommended by OSHA so that multiple uses of the information could be served (M8:3). Making the fluid management system integrate with ISO can be useful and Howell recommended that OSHA consider this aspect (M8:3).

Burke cited 10 steps for better management of the fluid: use good water, maintain pH, control concentration, use established biocides and follow biocide use guidelines, fix leaks, pick the right fluid, filter the fluid, dispose of old fluid and enclose the machine (M6:29).

Guy noted the term dry floor guarding, another name for full enclosure of a machine and its fluid (M3:7). Dry floor guarding is the part of systems management that keeps the mist out of the air, MWFs off workers and makes it easier to see in the plant (M3:7). He stressed the importance of team work and training (M3:7).

The fluid supplier's part of systems management is a product stewardship program, according to Howell (M4:4). Product stewardship includes: policies, management practices, fluid customer education, outreach, product selection guidelines, accountability and performance evaluation, according to Howell and Goon (M6:35; 8:11). Management commitment includes leadership and resources to integrate health, safety and environmental considerations into the design, manufacture, responsible use and disposal of MWFs (M8:11). More on product stewardship is in Chapters Six and Nine.

Additional details of systems management are provided in Chapter Six, Systems Management in the Best Practice Section of this report. Additional references are found in Attachment #6.

3.3.2 Enclosure Technology for MWFs

An important part of systems management is the enclosure technology used to reduce mist exposure and lessen contact with MWFs. Mirer defined direct airborne exposure as that from a specific machine to that machine's operator, and indirect exposure as that to anyone else due to carry-over from work stations (M2:12). He described the exposure sources as the machine, the fluid recirculation system, the air cleaner recirculation and the carry-over (M2:12).

O'Brien explained the different ways MWF mists are generated (M3:1). There is not any average particle or average mist due to different processes, types of MWFs and concentrations (M3:2). O'Brien highlighted the use of general and local exhaust ventilation to remove mist (M3:1). Hood designs include receiving, capture and enclosure types (O'Brien, 1998). He noted that enclosure type hoods are the only type recommended by the ANSI B11 committee on Mist Control (O'Brien, 1998).

O'Brien provided an overview of the different types of mist removal, mechanical, filtration and precipitation (O'Brien, 1998). Filtration is the most common approach and he noted that filtration efficiency depends on particle size

(O'Brien, 1998). Volatile compounds may evaporate from the filter and the filter media may support microbial growth (O'Brien, 1998).

3.3.3 Other MWF Controls

Details on how the fluid can contact skin are provided in Chapter Two of this report. It is critical to reduce contact with the fluid both by direct contact and airborne exposure.

Substitution is a strategy used in fluid management and is part of fluid selection (M8:4). Howell recommended any user to ask suppliers for information on their products (M8:4). See Chapter Six for more discussion on Product Stewardship.

3.4 REVIEW OF AVAILABLE INFORMATION

3.4.1 Experiences and Resources Related Fluid Management Technology

Gauthier cited the improvement in his moderate to severe contact dermatitis by applying systems management techniques (M2:17). Gauthier monitors fluid concentration, pH, hardness and tramp oils and charts these variables (M2:17). Gauthier uses a hand held computer to enter these variables for future analysis (M8:18).

Gauthier stressed control of microbial growth, proper selection of fluid, prevention of contamination, proper use of biocides, filtration and cleaning of the MWF system (M2:18). His company installed a chip filtration system and through his efforts paid attention to fluid management (M2:18). He writes articles for union and company publications to enlighten workers and management (M8:18). His systems management group meets monthly to identify and solve problems and there is a quick response team to address a crisis (M2:18). In a crisis, this team immediately checks current values and trends in pH, hardness, concentration, and tramp oils, visually assesses residue and ventilation, and makes recommendations for action (M8:19). He cited one example of microbial contamination exceeding 10^5 organisms per ml of MWF and how the company supported the recommendation to dump and clean out the system (M8:19). No health effects were seen due to prompt action (M8:19).

Gauthier explained that eating and drinking are not allowed on the shop floor although work clothes are taken home at his site (M8:18). He cited a problem with shop rag cleaners and has found a less irritating cleaner for the company that cleans the rags (M8:18). He thought people should view MWFs as a liquid tool to take care of and use effectively (M8:18). Gauthier noted it took five years to implement the changes that resulted in his improved health (M2:18). More details on Gauthier's program, its benefits and some diagrams of components can be found in his handout materials (Gauthier, 1997).

Beeman noted that there was very little fluid management at his facility (M5:3). Some machinists did limited fluid checks on their own machines (M5:3). Further information on his experiences is found in this report in the non-cancer respiratory section of the chapter on health issues.

Microbial management is important according to Rossmoore (M5:24). He

recommended keeping the number of organisms in the sump below 10^5 to 10^6 organisms per ml of MWF and Goon agreed (M5:24). Fluctuating biocide and microbial levels can result in resistant bacteria and fungi, according to Rossmoore (M5:24-25).

Biocides and fluids have to be compatible, according to Goon (M5:23). The history of biocide use is important because slug dosing can allow the build up of endotoxin (M5:24). Goon and Rossmoore noted that slug dosing is an example of improper fluid management and a likely cause of evacuations or sudden irritation (M5:23). Tank side addition of biocide should be avoided; it is better to add fresh concentrate, replenishing the original chemistry, according to Goon (M5:25).

Anderson noted a dramatic change in biocide use during the HP outbreak he studied (M5:4). Biocide use doubled to tripled in the months prior to the peak of the outbreak (M5:4).

Burke outlined causes for health effects at his facilities including: over-addition of biocide, use of monoethanolamine or pine oil, overgrowth of bacteria, miscalculation of fluid concentration and shutting off plant make-up air (M6:27). He warned against fluid formulation problems such as improper matching of biocide and MWF, the use of a lacrimator biocide, inconsistent product quality and purchase of bad smelling oils (M6:27). He highlighted the importance of minimizing tramp oil, noting that zinc dialkyldithiophosphate is an excellent culture medium for bacteria (M6:28). Suppliers sometimes provide incorrect information to plants (M6:28). Proper fluid selection can solve dermatitis problems, according to Burke (M6:28). More CNC machines are in use in mid size plants and these have enclosures (M6:28). Increased cutting speeds test fluids, enclosures and designs (M6:28).

Kushner explained his company's MWF management program that includes four lubricant engineers overseeing the program (M6:32). There is rigid screening and selection process for fluids using various tests (M6:32; M8:4). He noted that if the fluid passed these tests, it was less likely to have adverse health effects because the chemistry stays intact and additive use is minimized (M8:4). Kushner's company has never used a nitrite containing fluid (M6:32). He noted that his company only uses four to six fluids and once it selects a fluid, stays with it (M6:32; M8:4). Daily and weekly fluid testing of the in use fluid is done (M6:32). Kushner noted that systems are routinely dumped once per year and are constantly circulated to maintain less than 10^5 microorganisms/ml of MWF (M6:32). His company rarely uses tankside addition of biocides (M6:32).

Lantz stated that greater than 0.2% particulate in many MWF systems indicates an inadequate fluid filtration system (M8:9). Concentrations of contaminants that are allowable may be different for different fluids (M8:10). She stressed the importance of finding problems early and solving them before a health effect occurs (M8:10). If one person has a complaint, she views that there is a problem with MWFs (M8:10). She noted the importance of a MWF committee and of talking with the "oiler", the person who adds hydraulic fluid to machines (M8:10). This individual knows what machines are leaking (M8:10).

Frederick noted that some of the activities done as fluid management are also part of exposure assessment for dermal exposure (M8:24). He noted that fluid management would reduce potential exposure to endotoxins and excess biocides (M8:24).

Other issues were addressed briefly. Howell noted that it may be important to occasionally check for *Mycobacteria* in systems to prevent HP (M8:25). The potential for automation of pH and bacterial counts was discussed by Teitelbaum (M5:29). Some companies use single purpose lubricants that function as MWFs and as lubricants, lessening the opportunity for tramp oil contamination. Tripp explained that single purpose lubricants are difficult to use on older machines because of machine characteristics like tolerances (M8:9). The variety of machine types require formulations to develop many different fluids (M8:9).

3.4.2 Additional Information about Fluid Management from the NIOSH Criteria Document

The NIOSH Criteria Document places fluid management under work practices in section 9.3.1 of the document (NIOSH, 1998). Ways of minimizing mist generation, fluid evaluation and selection and fluid maintenance are noted (NIOSH, 1998). NIOSH recommends monitoring of the fluid level in the sump, MWF concentration, fluid pH, microbial counts, and the degree of tramp oil contamination and notes that monitoring should be done more frequently in warm weather (NIOSH, 1998). NIOSH views that what constitutes a safe microbial level has not been established and this contradicts Rossmoore's recommendation of less than 10^5 to 10^6 organisms/ml of fluid (NIOSH, 1998). NIOSH recommends adding premixed fluids, not concentrate, and urges time limits on storage of fluids (NIOSH, 1998). Other issues such as servicing, aerating, and cleaning are addressed (NIOSH, 1998). Judicious use of biocides is stressed (NIOSH, 1998).

3.4.3 Additional Resources for Fluids/Systems Management

The second edition of the ORC Document on Metal Removal Fluid Management was outlined for the committee (M8:6). d'Arcy noted in addition to the items listed above, the importance of active management of the fluid and attention to the facilities and equipment used (M8:6). Quality assurance and self assessment can help manage the system (M8:6). Selection of a fluid supplier was outlined by Howell (M8:7). Misting characteristics, raw materials and the toxicity of the whole fluid as compared to the components are important for fluid selection (M8:7). More information on the ORC document is in Chapter Six.

Another source noted by Howell is the National Center for Manufacturing Sciences (NCMS) Fluids Optimization guide (M8:7). The 10 year old ASTM E1497 Standard Practice on Safe Use of Water Miscible Fluids addresses concerns such as additives, biocide use, system design and worker protection, according to Howell (M4:5). This ASTM document is due for review by ASTM (M4:5).

Handouts provided by Rossmoore and Stein provide additional information

(Rossmoore, 1998; Stein, 1998a-d). Rossmoore's company, Biosan, Warren MI, can provide a list of additional references for microorganisms in MWFs. Additional details of systems management are provided in the section on Systems Management in the Best Practice Section of this report (M8:6).

3.4.4 Research and Experiences Related to Enclosure Technology

3.4.4.1 *Speakers' Comments*

Johnston outlined the ANSI B11 Document on Mist Control and recommended its use in a company's decision making (M3:2,3). He explained how MWF delivery design can influence mist generation and the flume can be an additional source of mist (M3:2). Johnston noted that this design document stresses the use of enclosures and explained some important features such as: telescoping doors for easy access, interlocks, easy overhead access and mechanical assist devices to avoid ergonomic problems (M3:2). Enclosure seals must be compatible with the MWF to avoid leaks due to seal degradation according to Johnston and Watt (M3:2,8). Take offs for enclosures should not be positioned to catch chips, these should end up in the trench, not the ducts (M3:2). Ducts should be designed to enhance mist collection in the ductwork by using slower duct velocities and sloping ductwork (M3:2). More details can be found in the ANSI B11 document (1997).

In additional discussion of technical feasibility, Johnston stressed that only a ventilated enclosure will reduce exposure to 0.5 mg/m^3 (Johnston, 1998). The tighter the enclosure, the less ventilation needed to keep the system under negative pressure (Johnston, 1998). New machine enclosure are preferable due to effectiveness and less problems working around production and existing structures (Johnston, 1998). A cross functional team including the following is needed: process engineer, OEM machine builder, enclosure sub-contractor, machine operator, mechanical engineer and safety/environmental engineer (Johnston, 1998).

Leith outlined his research group's study of mist collector technology (M3:3-5). He noted that the best filter will have the highest fractional efficiency curve, i.e., it will effectively collect droplets of all sizes (M3:3). He stressed the importance of pressure drop across a filter, the difference in static pressure between the inlet of a collector and its outlet (M3:3). Leith noted that a high pressure drop does not necessarily mean high collection efficiency but pressure drop will affect the filter's cost of operation (M3:3,4).

According to Leith, multi-stage filters have a low efficiency pre-screen, second stage of either a pocket filter, renewable fabric, roll-type media or cartridge filter, and a final stage of either a 95% DOP filter or HEPA filter (M3:3). The first and second stages reduce the loading on the very effective, but short-lived HEPA filter (M3:3). With good first and second stages, the HEPA filter can have lifetime of a year (M3:4). HEPA filters are very effective for capture of fine particles (M3:5).

From his research, Leith recommends a first stage metal mesh filter, either a pocket filter or good cartridge for the second stage, and a final HEPA filter

(M3:4). The second stage's efficiency needs to be monitored due to particle loading (M3:4). Deterioration of the second stage can result in a premature loading of the final stage and drop the final stage efficiency in half (M3:4). With well maintained HEPA filters, mist concentrations re-entering the workplace can be 0.05 mg/m^3 (M3:4). Additional details on the test methods Leith used can be found in his handout (Leith, 1998).

Hands presented two studies comparing airborne MWF exposures with different levels of enclosure (M3:5). One study looked at already collected exposure data and categorized the exposure controls associated with the data (M3:5). The control categories were three types: original equipment manufacturer (OEM) or total enclosures, retrofit or partial enclosures, and no enclosures (M3:5). For this study, the median exposure for the OEM enclosures was 0.21 mg/m^3, for retrofit was 0.45 mg/m^3 and for no enclosures was 0.45 mg/m^3 (M3:5). OEM was significantly different from the other two conditions (M3:5). Due to the retrospective nature of the study, there were many uncontrolled variables (M3:5). For more details about this study, see Hands *et al,* 1996.

Hands described a second study that compared two existing transmission case lines, one with OEM technology and the other with retrofit, partial enclosures (M3:5). The two lines were identical except for the degree of enclosure (M3:5). The OEM line had significantly lower personal and area airborne concentrations and more consistently lower results (M3:6). 10% of the OEM line exposures exceeded 0.5 mg/m^3 (M3:6). For more details, see his handout (Hands, 1998).

Guy outlined the improvements enclosed transfer lines provide for workers (M3:7). Guy noted that transmission plants typically run shifts on case lines of 10 hours per day, 6 to 7 days per week due to demand (M3:70). He cited the conditions present when only perimeter type guards were available where mist levels were so high that workers had to ring out their time cards (M3:7). When only perimeter guards were available in the 1980s, the case lines were always a source of complaints, according to Guy (M3:7).

Watt noted that retrofit enclosures are used to upgrade existing conditions because typical machine tools have an average lifetime of 28 years (M3:8). He outlined the difficulties finding skilled workers called tinnies to make the retrofit enclosures (M3:8). Lines have to be shut down to retrofit or retrofitting is done during scheduled downtimes according to Watt (M3:8). Even with the best design retrofit machines, 7-8% of them will exceed 0.5 mg/m^3 (M3:8). Watt was concerned about the difficulty retrofitting around moving machining heads, parts, pallets, loaders and hoists (Watt, 1998).

Watt viewed the best enclosure as a room size one that spans the entire operation and uses access doors (M3:8). He noted that these enclosures require high ventilation rates (M3:8). He worried that even these enclosures would not protect a sensitized individual (M3:8). Degradation of the enclosure due to seal failure, gaps, and covers not replaced combined with increased MWF flow, allow mist problems to develop (Watt, 1998).

Hartwig cited the importance of make up air and tempering this air as

needed (M3:8). He was concerned about the trends in machining to higher pressures and higher tool speeds which will challenge the integrity of enclosures (M3:9).

d'Arcy explained that air probes are used in machining to flush out chips from deep holes (M3:10-11). He urged replacing the use of air probes with fluid flushes to significantly reduce mist production (M3:10). d'Arcy noted that the air supply house can significantly contribute to the mist load in recirculated air (M3:11). In air conditioned plants, more air is recirculated in the summer than in the winter according to d'Arcy (M3:11).

Mirer highlighted the feasibility of enclosure, easy access, exhaust to achieve 150 fpm capture through openings and a 3 stage collector with HEPA (Mirer, 1998a). He explained that other feasible controls are flume enclosure, MWF cycling, fluid maintenance, improved air cleaning and vapor capture (Mirer, 1998a).

3.4.4.2 *NIOSH Small Business Study Results*

Hughes provided a demonstration of the database of the NIOSH Small Business Study (Hughes, 1998). Over 50 variables can be assessed using the database (Hughes, 1998). The NIOSH database provides exposure and control information about small business.

Piacitelli explained that 25-26% of the machines in the shops surveyed in the NIOSH Small Business Study had full enclosure, about 20-25% had partial enclosure, about 33-40% had splash guards and the remaining had no controls (M4:1; M7:3). Air handling systems for general ventilation were rare in these plants (M4:2). Thirty percent of the total particulate samples were less than 0.25 mg/m^3, 63% of the exposures were less than 0.5 mg/m^3, 88% were less than 1.0 mg/m^3, and all but two of the 940 samples were less than 5.0 mg/m^3 (M4:1). Comparing NIOSH data to the OSHA database, Piacitelli noted that OSHA found 65% of samples were below 0.5 mg/m^3 (M4:2). In the NIOSH study, using thoracic sampling data, all were below 5.0 mg/m^3, and 75% were below 0.5 mg/m^3 (M4:1). Background values in non-machining areas were 0.06 mg/m^3 for total and 0.04 mg/m^3 for thoracic, according to Piacitelli (M4:1). Smoking may have contributed to the background values (M4:2).

Piacitelli explained that the average plant in the NIOSH Small Business Study had 51 workers, 45 operating machines and used 4000 gal of MWF/year (M7:2). The average machine density was two machines per 1,000 square feet of floor space or one machine per 10,000 cubic feet of room volume (M7:2). Twenty seven percent of all facilities made screw machine products (M7:3). Turning operations made up 45% of all samples (M7:3).

According to Piacitelli, fifty percent of samples from turning operations were less than 0.5 mg/m^3 (M7:4). For grinding: 35% of the aerosol was respirable (<3.5 Fm) and 65% was in the thoracic range (<9.8 Fm) (M7:3). Hobbing produced 60% respirable particles (M7:3). For the four major types of operations, 60-70% of the aerosol was thoracic (M7:3). Forty percent of the samples were taken in areas using straight fluids and these fluids produced the highest

geometric mean concentrations (M7:3). Soluble produced the next highest followed by the semi-synthetics and synthetics (M7:3).

Seventy percent of plant mean exposures, according to Piacitelli, were less than 0.5 mg/m^3 and 90% were less than 1.0 mg/m^3 (M7:4). Eighty percent of shops had at least one sample over 0.5 mg/m^3 (M7:4). Twenty-two plants had 50% of their samples above 0.5 mg/m^3 and 10 shops had 100% of their samples over 0.5 mg/m^3 (M7:4). Of the plants predominantly using straight fluids, 22 out of 24 plants had at least one sample greater than 0.25 mg/m^3 (M7:3). For thoracic sampling, 40% of shops had at least one sample greater than 1.0 mg/m^3 (M7:4).

Piacitelli noted that samples taken in areas with full enclosure had a geometric mean of 0.4 mg/m^3 and 65% of these samples were less than 0.5 mg/m^3 (M7:3). All the full enclosures were OEM (M7:3). Sheehan noted that for the same conditions in the Hands study, 90% of the samples were less than 0.5 mg/m^3 (M7:3). Piacitelli's study looked at individual machines, while Hands' study investigated transfer lines (M7:3). Piacitelli explained that in areas without total enclosure but with local exhaust ventilation, the exposure was about twice that of the total enclosure (M7:3). Interpretation on other degrees of enclosure was limited due to sample size (M7:3).

Piacitelli noted that the average machine age was 20 years in shops whose geometric mean was less than 0.5 mg/m^3 and 25 years in those whose geometric *mean* was greater than 0.5 mg/m^3 (M7:4). Lick noted the similar numbers found by an AMT study (M7:5). The majority of the control technology was on machines less than 10 years old, but 85% of all machines had some degree of control (M7:4).

Preliminary analysis indicated that a trend of higher exposure with older machines was significant (M7:4). O'Brien noted that subsequent multivariate analysis demonstrated that exposures were lower in plants where the mean age of equipment was higher. Flooding was the most common fluid application noted during the small business study (M7:6).

Exposures in the NIOSH Small Business Study were found to be higher for operations on machines with enclosures than those without enclosures. An explanation could be that enclosures were not employed on machines using processes that inherently produce less mist. Another possible explanation is that different types of machine tools with different mist generating capacities produce different exposures.

3.4.4.3 *Machine Tool Industry Representatives' Comments*

McCarthy explained the importance of machine guarding and that the enclosure adds to the guard and is a selling point (M6:9). McCarthy noted the history of enclosure development from guard to splash guard to total enclosure and highlighted Grob's European experience changing the US market (M6:9). Steele explained that Grob does not build a metal cutting machine that is not totally enclosed to contain mists and that this has been company practice for over 5 years (M6:10). Steele noted that this was done primarily to meet the European requirements (M6:10).

Carlson explained the European Union (EU) requirements for machine tool safety (M6:10). For a machine to be sold in the EU market, it has to meet hundreds of requirements including those addressing noise, mist control and guarding (M6:10). If a manufacturer does not meet the requirements, the manufacturer can be forced to take it out of Europe and not sell any others for a given period of time as a penalty (M6:10). Carlson noted that there are EU machine tool safety requirements on the machine tool manufacturer and safety in the workplace requirements on the user of the machine (M6:10). McCarthy noted that the EU requirements prompt tool makers and users to work together (M6:10). McCarthy noted that an agreement to meet European requirements was made by manufacturers (M6:10). McCarthy explained that the European divisions of the large US machine tool companies do this work and that eventually, conformity among EU, ANSI and OSHA may occur worldwide (M6:10).

Customers want the machine to have any required safety equipment and do not want to spend any extra money for total enclosure unless it is required, according to Stevens (M6:9). Cross-Huller builds to 5.0 mg/m^3 unless it is specified otherwise (M6:16). McCarthy stated that customers want the machine safe, quiet, clean and the floor dry (M6:9). McCarthy explained the Big 3 have requirements of 80 dBA, dry floor and 0.5 mg/m^3, beyond what is required by OSHA noted Stevens (M6:9,19). Only ventilated, enclosed machines meet these requirements according to McCarthy (M6:9). The next tier companies also require 0.5 mg/m^3, according to McCarthy (M6:16). Below this tier, companies may not request enclosures but get them anyway (M6:16). According to Kushner, all-new equipment for his mid size facilities arrives enclosed (M6:33). Smaller companies are starting to ask for total enclosure or dry floor according to McCarthy (M6:16). He stated that all transfer lines and CNC machines have enclosures (M6:16). Other machines have standard safety guarding and have a dry floor guarding mist enclosure package that can be included and is required by the Big 3 (M6:16). The Big 3 are pressing their suppliers to have enclosures (M6:16). Fay noted that if his customer wants him to meet a regulatory standard or a voluntary standard, he can design to that specification (M6:18). Having a supplier meet different needs in different plant environments is difficult, according to Hedley (M6:19). Most of this is done by specifications (M6:16). Woody noted that today most machines come into a new plant or into major retrofits of existing plants, are enclosed (M6:9). Woody noted this is regardless of the size company involved (M6:9). Hedley noted that half of the machines his company encloses are directly for the manufacturer of the machine; the other half are requests from customers for enclosure (M6:10). According to McCarthy, machine tool companies and the customers and their suppliers are working together to figure out how to effectively reduce the mist (M6:16).

Burch was concerned if machines conforming to a specific voluntary standard may be sold without enclosures (M6:10). McCarthy clarified that multiple standards may apply for one type of machine (M6:10). Carlson explained that it would not be good to sell a machine without an enclosure due to noise and mist concerns and that one enclosure could address each of these problems

(M6:10). Carlson noted that the ANSI B-1113 standard for screw machines was done in 1990 and is due for reaffirmation, revision or revocation (M6:10). Cadson believed a revised version would include enclosure (M6:10).

Stevens explained that many single US machine centers are not totally enclosed but do have side guarding while the majority of transfer lines are totally enclosed (M6:11). Fay noted that some manufacturers sell what are called total enclosures but when he designs the ventilation, he finds that the machine is not adequately enclosed (M6:11).

McCarthy explained for some small machines making very small parts, an enclosure may not be needed (M6:11). Lamb designs the machine so a hood can be dropped on if the output of the machine is increased beyond the original design (M6:11). McCarthy noted that when his company does a class B re-tool, tearing the machine completely down and completely rebuilding it, the guarding is redesigned for total enclosure (M6:11). He explained that a class A re-tool which includes rebuilding a couple of stations from a machine, you cannot enclose just those stations, so they build to the as-built standard (M6:11). McCarthy highlighted for a class A re-tool, the builder has to consider consistency within a machine and the knowledge and experience of the operator (M6:11).

Design for enclosures has to include air flow, and a distribution of pick up points across the enclosure, according to Woody (M6:12-13). Fay also noted MWF movement and in-draft and baffles (M6:13). Fay cited an in-draft of about 200 FPM to control mist (M6:13).

Most of the representatives of companies that provide enclosures noted that 75-95% of their enclosures are custom made (M6:7). McCarthy explained that Lamb Technicon has four sets of standard enclosures that will fit about 85% of their machines but each standard enclosure is customized to fit the given situation (M6:7). According to Carlson, about 80% of machine tools sold by AMT members are for production and 20% used for upkeep and repair of other machines (M6:7).

Testing procedures to determine that a machine tool enclosure is effective were discussed in light of the NIOSH/OSHA Asphalt Paving Agreement (M6:12-13). Hedley explained that he did, e.g. noise testing, before and after enclosure on a retrofit (M6:12). McCarthy explained for stand alone machines, the customer's industrial hygienist could come to the manufacturer's plant and measure the output (M6:12). For transfer lines, the flume complicates the measurement of mist and the design of effective enclosure according to McCarthy (M6:12). McCarthy explained different variables that could affect a test such as the volume of coolant used (M6:13). O'Brien opined that the company could run the test at the specified MWF rate (M6:13). McCarthy was concerned that the test could not be applied in real situations and that there is not any standard number of stations in a transfer line, so how could this be tested (M6:13). Stevens was concerned about a machine passing a test today but after three months of operation may not, because of how the customer uses the machine (M6:13). Stevens cautioned that it would be difficult to develop a specification because where you test the machine and what machines are

operating nearby can influence the outcome (M6:13).

Howell agreed with Burch that the variety of operations and conditions preclude the use of any standard test (M6:14). Lick noted the difficulties of trying to develop a test method in the ANSI committee (M6:14). Lick explained that a direct reading meter could be used but that shop trials and what occurs in the plant are not the same (M6:14). Woody explained that there are different types of enclosures with varied openings and structures complicating the testing (M6:14).

McCarthy explained that he did not know of any machine tool manufacturer in the US who was set up to test the ventilation system, so the work is done on the plant floor after installation (M6:14). The customer does the testing along with the coolant supplier (M6:14). McCarthy noted that design teams like Giffels help put the whole operation together (M6:14). Burch noted that a tool will not be doing just one thing for the rest of its work life (M6:13). Many shops have a wide variety of jobs done by the same machine tool (M6:14).

Steele noted that air conditioning improves the accuracies of the cuts made in machining but does not affect tool life (M6:15). McCarthy clarified that by keeping a constant temperature in a plant, the machine will be more consistently accurate (M6:15). McCarthy noted that there will be less maintenance and less misting (M6:15).

3.4.5 Additional Information about Enclosure Technology from the NIOSH Criteria Document

Many of the same topics addressed by O'Brien, Johnston and Hands are covered in section 9.33 of the NIOSH Criteria Document (NIOSH,1998). NIOSH acknowledges situations where enclosure may not be possible (NIOSH,1998). The document stresses the use of established criteria such as the ANSI Mist Control document and the ACGIH *Industrial Ventilation, A Manual of Recommended Practice, 1995* (NIOSH, 1998). NIOSH notes the limitations of recirculation and the criteria outlined in the NIOSH document on *Recirculation of Industrial Exhaust Air* (1978).

3.4.6 Additional Resources Related to Enclosure Technology

Howell noted the ASTM E1972 Practice for Minimizing Aerosols in the Wet Metal Removal Environment (M4:5). Many committee members and speakers cited the ANSI B11 Document on Mist Control. Others noted that the ACGIH ventilation manual should be consulted for many design criteria. The ORC Management of the Metal Removal Fluid Environment (1999) addresses issues related to enclosure technology and a wide range of ancillary issues. The Ford Motor Company Economic Report provides additional information on exposures by plant (Henry 1998). Articles by Leith address mist control and vaporization (Leith,1996a; Leith, 1996b). Additional references found in Attachment #6.

3.4.7 Research and Experiences Related to Other Controls

Lusniak and Teitelbaum highlighted the traditional control approaches of substitution, elimination, personal protective equipment, training, housekeeping,

materials handling, administrative control and ventilation (M2:13-14, 20). Adams noted that protective clothing can help prevent dermatitis but that gloves often interfere with tasks (M2:2). Stein noted the difficulty of separating out the controls for dermatitis from respiratory effects (M5:29). For dermatitis prevention, the systems work group added: automation, fluid maintenance, decreasing contact, improving hygiene, and proper use of soaps (M8:5).

Lusniak stressed the importance of hand washing with mild soaps (M2:14). He recommended several washings with mild soaps during the day, and an end of the day washing with a more aggressive soap (M2:14). He urged careful attention to the MSDSs for the soaps used (M2:14). Lusniak suggested pat drying with a soft cloth and the avoidance of rubbing (M2:14). Wiping without diluting the MWFs, as with a shop rag, will often do more harm than good because the MWFs are mashed into the skin and the rag is saturated (M2:14). Kushner explained that his company have made a science of handwashing (M2:14).

Lusniak noted that barrier agents do not work well with MWFs but could act as a moisturizer (M2:14). Kushner explained that his company provides skin lotion throughout the plant (M2:15). Lusniak noted that lotion needs to be free from contaminants and that some workers are allergic to lanolin (M2:15).

Shortell explained the need for ways to reduce skin contact during insert changes (M8:5). Inserts are the parts of the cutting tool that wears out and have to be replaced frequently (M8:5). Burch noted that Valenite, the mid size plant visited by work groups, made inserts (M8:5). Shortell explained ways of reducing contact such as using valves and directing MWF tubes away from the insert (M8:5). Depending on the machining process, these recommendations may be easy or difficult to accomplish (M8:5).

Mist suppression was discussed by the committee (M8:4). O'Brien noted the Lubrizol/Wayne State work that shows anti-misting additives can reduce the mist levels by a factor of two (M2:16). Lick noted that these compounds do not always work and may be maintenance intensive (M2:16).

Watt cited 40-50% reduction in mist in some Chrysler work (M3:8). For soluble fluids, the current suppressants are not shear stable and they degrade with each cycle through the system (Watt, 1998). Constant addition of suppressant is required and the suppressant is expensive but the price is dropping (Watt, 1998).

d'Arcy stated that GM had mixed results with these compounds (M3:11). There was concern expressed about adding more problems to the fluids (M8:4). Additional information on mist suppression is found in the proceedings of the two Symposia on MWFs (M8:4; AAMA, 1996,1998).

The system work group thought respiratory protection was technically feasible but not practically feasible (M8:5). Any use of respirators would have to follow the OSHA standard on respiratory protection (M8:4). Anderson opined that respiratory protection would not be a primary control, but could be a secondary one, and questioned what would trigger this need (M8:4).

Wegman noted the importance of reducing the amount of MWF used

(M8:11). A systematic approach is essential, according to Fay and practices such as using compressed air should be avoided (M6:18).

Mirer explained that shutting down the fluid circulation and maybe the flume when no machining is occurring may reduce mist (M3:11). Mirer emphasized the importance of a well functioning general ventilation system, restoring enclosures, cleaning and repairing duct work, checking air filters and thought 90% of the problem could be solved without anything new (M2:12). O'Brien noted that fluid management must come first and containment and ventilation may eliminate some of the peak exposures(M5:16).

The NIOSH Criteria Document cites the potential need for personal protective equipment (NIOSH, 1998). Protection against punctures, cuts, abrasions, splash and skin contact is noted (NIOSH, 1998). Proper selection and use criteria are defined (NIOSH, 1998).

3.5 CONCERNS AND LIMITATIONS

3.5.1 Size of Business

Burt studied data on companies of all different sizes within 6 major SIC codes (M7:24). There are approximately 3.1 million machines with about 1.3 million used by the smallest businesses of 1-19 employees (M7:24). SIC code 35 contains 43% of the machines (M7:24).

Burch noted that systems management is essential in small business, especially with water soluble fluids (M4:8). He explained that many small business avoid these types of fluids (M4;8).

Howell commented that a systems management approach to fluid management is good and works in both large and small shops, no matter what type of fluid is used (M2:16). The ways to solve problems may be different (M2:16). He cited the need for systems management in the small shops the work groups visited (M4:8). He noted that a stewardship program would reduce situations such as the one observed in a visited facility in which a fluid salesman gave incorrect information to make a sale (M4:4).

Lantz also thought the best way to address small business was through their supplier's product stewardship program (M8:12). Burch noted that small business needs answers quickly, especially in a crisis situation (M8:12). A good relationship with the fluid supplier may be the way to address crises.

Burch was concerned about representation of small business on the machine tool panel (M6:7). All of the companies represented on the machine tool panel except Tamer Industries primarily served the auto industry (M6:7).

Off the shelf, commercially available solutions are needed for small business, according to O'Brien (M6:39). Mirer noted that if each company fully applied good specifications, exposures would be less than 0.5 mg/m^3 (M6:40).

Piacitelli thought it would be difficult for some of the shops in the Small Business Study to comply with 0.5 mg/m^3 (M7:4). Wegman noted that Piacitelli's data could not determine the difficulty of compliance (M7:4).

Woody noted that small and medium size businesses are handicapped on the logistics side since they don't have the resources to gather information

needed to make a modification (M6:17). Larger companies have internal staffs to guide their decision making (M6:17). Carlson agreed that smaller plants probably have lower exposures (M6:17). Carlson noted that small plants have lower speeds, fewer machines and you see less mist (M6:17).

Howell agreed with O'Brien and White that the biggest burden would fall on the mid sized business (M6:40).

Rossmoore noted that the large central systems are the ones that are difficult to control (M5:24). Mirer believed that controlling a big aluminum transfer line presents more of a challenge than individual machines (M3:16). Lick and Shortell viewed that the larger industries have a tougher time with feasibility because they have higher pressures and volumes of MWFs (M4:7).

Howell noted that what PEL is chosen defines the burden for small business (M8:17). Burch did not think medical surveillance could work for small business without resources due to the infrastructure needed (M8:15). He urged the group to make any action do-able so small business can take care of employees with their limited resources (M8:16).

3.5.2 Determining the Effectiveness of Systems or Fluid Management

O'Brien was concerned how to define what a good fluid management program is (M5:16; M7:21). White and Howell stated it is easier to state what good MWF management is, than what is inadequate (M6:27). Burch opined that if the MWF did not go bad, you had a good program (M6:27).

Sheehan cited the indicators before a system failed and Howell explained that good management prevented excursions out of normal operating range (M6:27). Biocide use and the potential of endotoxin build up are reduced with good management, according to Howell and Sheehan (M6:27).

Lick stated before systems management was used at Ford, 95% of their exposures were from 1 to 200 mg/m^3 and after implementation, 95% were below 1 mg/m^3 (M2:17). Case studies can be used to demonstrate effectiveness according to Lick (M2:17).

The extent of MWF management in the studies done at GM is a problem, according to Howell (M6:21). As a result, it is difficult to interpret the influence of fluid management that was in effect at the time on health.

Wegman noted the criteria for a fluid management program could work with medical surveillance (M8:15). Benchmarks are needed according to Wegman and d'Arcy (M8:16). Having the fluid management integrate with medical surveillance could make the surveillance less burdensome, according to Howell (M8:17).

3.5.3 Other Concerns about Systems Management

O'Brien noted that industrial hygienists do not know anything about fluid management (M7:21). Lick disagreed and believed that industrial hygienists can take advantage of short courses and other resources (M7:22). O'Brien explained that people at the plant can be trained and based on his observations at Valenite, be very motivated (M7:21).

The systems group noted that product stewardship has to be integrated into a systems approach (M8:4). Mirer cited incidents where even with product stewardship and an external MWF manager, the user did not follow the manager's suggestions (M8:4). He noted some of the litigation involved with these situations (M8:4). Sheehan explained the group's concern that there was product stewardship and "good" product stewardship (M8:4).

Howell commented that product stewardship is part of systems management (M8:4). He noted that integrating the user and supplier's programs provides a more successful program (M8:4). He cautioned that there will always be human error (M8:4). Shortell explained that accountability by the manufacturer or blender or vendor is necessary (M8:4). Teitelbaum was concerned about the limited information on MSDSs and urged fluid formulators to provide information about allergenicity (M2:20). Teitelbaum questioned if product stewardship has been shown to reduce injury and or illness (M7:32; M8:4,11).

The committee questioned the advice given in some situations by formulators. Goon explained the complexity of the formulator, distributor, user relationships (M5:25). He noted that fluid formulators often provide technical assistance to customers (M5:25). Distributors, not formulators, usually sell to small and medium size companies (M5:25). This complicates the provision of technical advice (M5:25). Some company managers do not want to take advice when a system goes bad, according to Mirer (M5:25). As a result they misuse biocide (M5:25).

The smoking issue was raised related to systems management. If eating and drinking are not recommended in MWF areas, smoking should not be allowed in these areas as well (M8:27).

3.5.4 Problems with Full Enclosures

Hedley explained that the enclosure should not affect the life of the machine (M6:14). Hedley noted that acceptance by the operator and maintenance can be a problem (M6:14). His firm tries to inform the operator upfront so the operator is not surprised by the enclosure (M6:14). Hedley recommended getting the operator and maintenance people involved in the design (M6:14). Guy noted complaints from workers about interlocks delaying work and full enclosures complicating troubleshooting (M3:7).

Stevens explained that heat can build up in total enclosures, potentially affecting the part and upsetting the gauging people on a line (M6:14). He noted one situation without a collector that became so pressurized that the temperature was 20 degrees warmer inside than outside the enclosure (M6:14). A letter to a trade group indicated a fire in a complete enclosure (PMPA, 1999).

Some total enclosure designs can capture the chips and bring them into the ductwork, according to Stevens (M6:14). Stevens explained that access can be difficult with certain designs and to put the system back together after maintenance is critical to maintain a dry floor and mist control (M6:14).

Shortell noted that most new machines were fully enclosed and many of these were turning machines, the biggest mist producers (M4:6). He noted that

companies buy new machines to compete for contracts, so there are other incentives for having the new machines (M4:6).

3.5.5 Problems with Retrofit Enclosures

Lick cited the Hands' study which indicated for OEM enclosures, there was less variability as compared to retrofits (M7:5). Johnston noted that he can routinely meet 0.5 mg/m^3 with OEM enclosures but not with retrofit (M3:9). Lick did not think retrofits could do the job (M7:5).

O'Brien disagreed with Lick and believed that retrofit technology would work (M2:16). O'Brien noted that off the shelf retrofits can be used in small business and will have the added advantage of noise reduction (M2:16). Mirer noted that individual machines could be successfully retrofitted and that he had some case studies on this (M8:4).

The systems group defined refurbished or remanufactured equipment as second hand machine tools that have been retooled (M8:5). The group thought that a stripped down and reconstructed machine with a full enclosure should work (M8:5). Burch clarified that some machine tool rebuilding is not this extensive (M8:5). He noted that some automatic machines could be totally enclosed with off the shelf equipment (M8:5).

Cox explained that there are such a wide range of machines in small businesses, that builders would have a difficult time building retrofit kits that work (M4:6). He was concerned about product liability, noting that manufacturers would rather sell a new machine and enclosure than retrofit an old one (M4:6; M8:5).

The retrofit market is not attractive to companies producing enclosures, according to Hedley (M6:8). Retrofits require intensive engineering and time for limited quantities of product (M6:8). Companies would rather enclose a new machine and new enclosures are better accepted by employees (M6:8). Retrofitting requires enclosure while the machine is still in production, according to Fay (M6:12). Warranties on retrofits are a problem according to the machine tool panel (M6:12).

3.5.6 Other Concerns about Enclosures

McCarthy expressed his concern that the same people we are protecting take off the guards and do not replace them (M6:14). McCarthy explained how some of the guards get thrown away, and are only replaced after an OSHA inspection (M6:14). Burch thought the problems with retrofits may be due to operators overcoming the barrier (M2:16). Watt had this concern as well (M3:8).

McCarthy stressed that enclosures have to be user friendly (M6:14). There are different degrees of user friendly and the most difficult worker to deal with is one who has worked a long time and does not want to bother with the guard (M6:14). McCarthy noted that the newer employees are more used to working with total enclosures and cooperate better (M6:14).

McCarthy noted that Lamb uses rollers, hinges and sliding panels for their transfer line enclosures and these are not taken off (M6:14). Steele agreed with

McCarthy that any panel designed to come off will be taken off and may not be replaced (M6:14). Steele recommended sliding doors, hinged doors that lift up or come out of an adjoining lift (M6:14).

3.5.7 Recirculation

O'Brien explained that recirculation of air back into the plant is used in some facilities with MWFs due to concerns about energy conservation costs and avoidance of EPA volatile organic compound (VOC) emission limits (M3:1). He highlighted the disadvantages of recirculation including the need for high efficiency filtration and the problems of increased relative humidity, microbial growth on filters and MWF vapor production from the filters (M3:1-2).

Guy did not view recirculation as a problem since 95% outside air is brought into his plant (M3:7). Kushner and Burke noted that some of their mid sized plants recirculate air (M6:33).

O'Brien noted the leak in a HEPA filter at the plant the work groups visited and was concerned about unmonitored recirculation (M3:15). O'Brien suggested a back up HEPA or use of a direct reading aerosol monitor to detect filter failures because a simple magnehelic gauge would not pick up a leak (M3:15). Lick did not think an additional HEPA was technologically feasible (M3:15).

Woody recommended against using recirculation in almost any plant, and that air brought from the enclosures be sent outside (M6:15). He noted that any direct fired heating plants have to bring in make up air and typically this volume is greater than any leaving the plant from enclosures (M6:15). Woody noted that the economics of heating or cooling this air show no penalty (M6:15).

Lick noted that variables such as air volumes, types of enclosures and plant age affect the decision to recirculate (M6:15). Lick noted that location in an EPA non-attainment zone also influences the choice to recirculate (M3:5; 6:15). He agreed with Woody that plants might be cleaner without recirculation, but in some instances recirculation may be needed (M6:15).

The systems work group noted an additional concem about fine particles with recirculation (M8:4). If recirculation is used, a 3 stage collector with HEPA filter, perfectly run and monitored with no defects and a bypass system should be used (M8:4). Some of these same criteria could be used before sending the air outside (M8:4). Mirer agreed with these recommendations (M8:4). Howell noted that the ORC document provides some general information about these issues (M8:4).

3.5.8 Vapor Production

Vapor generation from mist collectors into the work environment was noted by Leith who stated that the collectors can emit vapors even when the MWF using process is not operating (M3:4). Vapor output can be in the mg/m^3 range according to Leith (M3:4).

Lick thought that if the total mist is below 0.05 mg/m^3, the vapor issue is also addressed (M3:4). O'Brien suggested not operating the mist collector when the process is down (M3:5).

Kushner noted that he showed very little vapor problem when he

monitored processes in his plant (M3:5).

3.5.9 Other Concerns about Ventilation

Mirer noted that consideration of criteria for the general ventilation system is important (M8:4). Lick and Howell were concerned with the lack of ventilation in the small shops the work groups visited (M4:6). Lick cited other reasons such as forklift use for improving general ventilation (M4:6). Mirer agreed that the ventilation needed to be improved and air blowoffs avoided (M4:7).

3.5.10 Limitations of Studies

Piacitelli explained that NIOSH selected out the dirtiest SIC codes to try to find the worst shops to sample (M4:3). Newman was concerned that only a third of eligible shops participated (M4:3).

Burch indicated that the OSHA Database is biased because the plants in it had an unrequested OSHA inspection due to an employee complaint or other reason (M4:2). White explained that the OSHA dataset may not be biased as indicated by studies that have shown OSHA inspections driven by complaints do not find any more violations than random inspections (M4:2).

Background levels found in the studies were a concern. Typical assembly areas according to Mirer, citing Eisen's study, are 0.1 mg/m^3 (M2:12). Burch was concerned about outside levels and Mirer noted that they were in the 0.03 mg/m^3 range (M2:12). Mirer noted that if the background is 0.4 mg/m^3, and the operator's exposure is 0.6 mg/m^3, 0.4 mg/m^3 is the best that can be achieved (M7:5).

3.5.11 Time and Resource Factors

Members were concerned about the time it would take for new technology to be available. According to Lick and Carlson, the average age of a US machine tool is 29 years (M6:7). Burch noted that some of his member companies still use World War II vintage machines while others need very new machines to meet customer demands (M6:8). Burt explained that 75% of establishments own some machines less than 5 years old, 7% have ones 6-10 years old and 95% have at least one machine older than 11 years old (M7:24). Machine replacement is slow and many old machines are still in these workplaces (M7:24). Teitelbaum noted the age of the machines used and explained that it would be a long time before new machines would replace old ones (M7:5).

The time line is long even when a company decides to order a new machine. McCarthy explained that Lamb Technicon could deliver an off the shelf CNC machine in 28 days while a transfer line could take from 40-62 weeks depending on the completeness of information provided by the buyer (M6:9). Steele noted that 12 months is a good number for special machine groups and Stevens agreed (M6:9). Substantial backlogs of orders were noted by all machine tool companies (M6:9).

Lick noted the time it takes to reduce exposure and that OEMs are easier than retrofits (M3:16). He cited the Sharonville plant's efforts as 30% complete and

it has taken 10 years to accomplish (M3:16).

Carlson explained that the real problem was skilled individuals to manufacture machine tools; there is a shortage of machinists (M6:9). Use of machines was discussed by Burch and Cox, each noting that newer machines are used less early in their work life (M7:4). As more applications evolve, new machines have more work (M7:4). More information on time factors is provided in Chapter Four.

3.5.12 Trends in Machining

Broad trends in machining can affect how technologically feasible a control method is. Burch stated in small business, machines are purchased to meet customer demands (M6:8). Lick explained that the auto industry is purchasing machines to provide better accuracy, higher machining speeds and improved production (M6:8). McCarthy agreed that in the US, faster cutting is the trend with a part cut every 17-18 seconds (M6:8). In Europe, due to concerns about mist and noise, the trend is reversed with lower speeds and fluid pressures (M6:8).

Kushner noted a trend away from metal removal since the metal is a waste to be reprocessed (M6:8). Some companies are using more hot and cold forging instead of cutting, according to Kushner (M6:8-9).

3.5.13 Other Concerns

Burch stated that regulating contact out of some jobs would be impossible (M2:20). He questioned the potential action of a small shop having to change fluids if someone gets dermatitis (M2:20). He was concerned about the role of the ADA (M2:20).

Shortell was concerned about 100,000 small shops having to hire industrial hygienists (M7:22). He hoped that shop people could be trained to reduce this limitation (M7:22).

The issue of how controls would change if cancer was the major driver for regulation was discussed. Ventilation would be more important for carcinogens, according to Mirer (M7:11). Since he viewed any standard as feasibility driven, the issue of cancer would not affect the ultimate air concentration used (M7:11). Kushner noted that labeling, providing work clothes and waste management would change based on carcinogenicity (M7:11).

The systems work group urged integration of any recordkeeping with other existing systems and maintenance of historical tracking of data (M8:5). Mirer suggested having MWF maintenance records available to workers (M8:5). Audience member Gary Farwick noted that most of the time these types of records are posted to spur employees and the organization to do a better job (M8:5).Howell agreed with Farwick and Mirer that they should be available but there was not any current legal requirement (M8:5).

3.6 LINKAGE OF DISCUSSIONS TO OSHA ACTION

3.6.1 Systems Management

Infante was concerned on how OSHA would show that it significantly

reduced a significant risk without a PEL (M2:17). White explained that data on injuries and illnesses could be used to show a reduction in these after implementation of a systems management program (M2:17). He noted that something like a VPP site program could be used (M2:17).

Lick explained that the pattern of respiratory disease presented by Reeve followed the extent of the fluid management in some Ford plants, and not others (M6:3). Lick noted that even with an exposure limit of 0.5 mg/m^3, if the fluid is not managed, problems will develop (M2:15). Systems management will do a better job of controlling HP and respiratory irritation than a PEL, stated Lick and White (M2:16,17).

Howell noted that Perry's data showing a risk at 0.1 mg/m^3 indicate other variables than airborne exposure at work (M6:23). Management of fluids will reduce occurrences of at least the irritant dermatitis, according to Howell (M2:20). He noted that without systems management, reducing exposure to less than 0.5 mg/m^3 is unlikely to further reduce non-cancer respiratory disease (M5:16).

McGee stated a standard is needed because not all users are managing fluids the way they should (M6:41). Management's attitude about MWF management varied from plant to plant within the same corporation (M6:41).

O'Brien explained that NIOSH's recommendation included a comprehensive safety and health plan of which fluid management and a systems approach are components (M2:16). Systems management would address dermatitis and asthma, according to O'Brien (M13).

Stein explained that early NIOSH and OSHA recommendations about machining operations included components of what is today called systems management (M5:29). Recommendations such as daily monitoring of pH, bacterial counts, daily machine cleaning, exhaust systems, oil collectors and clean shop rags were addressed (M5:29).

3.6.2 Enclosures/Other controls

NIOSH based its recommendations on respiratory effects and believes that 0.4 mg/m^3 thoracic particulate or 0.5 mg/m^3 "old total particulate" is technologically feasible, according to Fine (M2:1).

According to Howell, voluntary or consensus guidelines with a target exposure level appeals to many because it covers so many factors that can affect employee health (M2:17). Howell noted it may be important to recommend to the ACGIH that an "S" designation be given to MWFs for its TLV (M8:26).

Exhaust ventilation of an enclosed machine is needed to get consistently below 0.5 mg/m^3, according to Lick (M2:15). Lick noted that dermatitis just about goes away when you keep everything in the machine (M2:15). He explained that Ford physicians are not seeing dermatitis (M2:21). Wegman noted that there will be background levels of dermatitis in plants not caused by MWFs (M2:21).

Mirer noted that controlling one machine may result in reducing levels for that operator as well as others due to cross contamination (M3:11). He viewed that mean exposures of 0.25 mg/m^3 were clearly achievable (M3:11). Mirer cited

a NIOSH HHE report and noted that in a foundry, all the air samples were below the NIOSH REL and this points to the feasibility of 0.5 mg/m^3 (M6:37).

Machine tool panel members Carlson, Hedley, Stevens and McCarthy believed it was technically feasible to achieve 0.5 mg/m^3 (M6:16-17). They stated concerns about cost, liability and maintainability of the enclosures and mist control equipment (M6:16-17). McCarthy thought it may be better to grandfather in older machines (M6:17). A high percentage of machines are older than 10 years, according to the panel (M6:17). McCarthy, Fay and Steele thought it would be difficult for older machines in smaller shops to meet 0.5 mg/m^3 (M6:17). Carlson thought that requiring an enclosure on machines that do not generate much mist would be an unnecessary burden (M6:18).

Burke noted that many of his plants have exposures between 1.0 and 2.0 mg/m^3 (M6:28-29). Using area samples, the majority of his plants were below the NIOSH REL (M6:29). He noted that the open grinders his company uses generate a lot of mist and are difficult to enclose (M6:29). It would be tough to have the grinders comply with 0.5 mg/m^3 (M6:34).

Lick was concerned about the time it would take to comply (M3:16). Lick noted that the conclusion that everyone is already at 0.5 mg/m^3 is erroneous, and most companies were between 1.0 to 2.0 mg/m^3 moving toward 0.5 mg/m^3 (M6:34). He thought it would take a long time to achieve control across all industries (M6:41).

Wegman noted that Piacitelli's data could not determine the difficulty of compliance (M7:4). Wegman thought the difference between mean values found in the Small Business Study and individual samples was striking (M7:4). Howell noted that based on the current approach to a 6b standard, citing for one exposure, many of the plants in the small business study would be affected (M7:4).

The Systems Work Group cited the discussion of d'Arcy, Johnston, Kramer, Hartwig, Watt, Hands and the NIOSH Small Business Study (M8:3). The group viewed it was technically feasible with new equipment to reduce exposure significantly below what it is today (M7:3). It would not be easy to do this for transfer lines (M:3). New equipment enclosures are more consistent reducing exposure than are retrofits, although less is known on retrofit use on individual machines (M8:3).

Mirer noted that OSHA cannot establish a standard that everyone has already met (M7:5). He explained that if the geometric mean of exposures in a plant was 0.5 mg/m^3, 5% of samples would be over 1.0 mg/m^3 (M7:5). Not every machine has to be replaced to meet the 0.5 mg/m^3 value according to Mirer (M6:8). Mirer noted that if each company fully applied good specifications, exposures would be less than 0.5 mg/m^3 (M6:40).

3.7 COMMITTEE DECISIONS AND RATIONALE

The majority (12) viewed that the recommended PEL was technically feasible (M9:30-31). Day, Teitelbaum, Mirer and O'Brien cited their own experiences, presentations before the committee, site visits, the machine tool

builders discussion and data provided by industry as a basis for this decision (M9:30). The downward trend in exposures with time, the evaluation of controls study done by Hands *et al,* and the NIOSH Small Business Study were also noted by O'Brien as a rationale (M9:30). O'Brien and Mirer urged more effective use of general ventilation to achieve the targeted PEL (M9:30-31). O'Brien noted that straight fluids are more difficult to control and opined that anti-mist additives may be helpful to control exposure in small business (M9:31).

The minority (Howell) opinion was that although the PEL could be achieved with new equipment, it could not be with old, existing equipment (M9:31). A discussion of the limits of retrofits cited the Hands *et al* study on transfer lines (M9:30-31). Sheehan noted that retrofits may work better on individual machines than on transfer lines, and Lick explained that retrofits are difficult to do well (M9:30, 31).

Burch focused on the technical feasibility of measuring exposures at the PEL and thought it was feasible (M9:30). He did not have enough information to determine the feasibility of a PEL (correction noted at tenth meeting). He questioned the technical feasibility of measuring the action level (M9:30). Cox could not separate technical feasibility from economic feasibility, noting that some companies would be more able than others to comply based on their financial condition (M9:30).

The majority (12) explained that medical surveillance, as defined by the best practices document prepared by the committee, was technically feasible (M9:30-31). Newman based this decision on his own experience developing programs for businesses (M9:30). Sheehan cited the long track record for these types of tests (M9:30). McGee urged training of workers about medical surveillance (M9:31). Alternate member, Shortell, noted that medical surveillance may present some problems for small businesses but that our recommendation should be crafted with this in mind (M9:31).

The minority (Burch, Cox, Howell) opinion on the technical feasibility of medical surveillance was that the program specified in the best practices document prepared by the committee was not technically feasible (M9:30-31).

All members (15) viewed that systems management was technically feasible (M9:30-31). Members cited the presentations, site visits and their own experiences as contributing to this decision (M9:30-31).

CHAPTER FOUR
Deliberations Related to Actions OSHA Should Take: Economic Feasibility

4.1 GENERAL INFORMATION

The committee discussed if the recommendations noted in Chapter Five are economically feasible. After discussion of many issues, members discussed the economic feasibility of a PEL, systems management and medical surveillance as distinct items (M9:31-32). The third and sixth meeting primarily addressed economic feasibility and this issue was discussed at other meetings.

4.2 SPEAKERS AND PRESENTATIONS

Robert Burt, senior economist with the OSHA Office of Regulatory Analysis discussed OSHA initiatives, industry profiles and economics (M2:4). Dr. Hank Lick, committee member, noted costs in his description of systems management (M2:15). Stephen Gauthier, a machinist at a large East Coast manufacturer described his own experiences with potential economic loss due to dermatitis from MWFs and provided some cost saving data (M2:18). Dr. David Leith, University of North Carolina, explained mist collector performance and how it affects operating cost (M3:3-5). Robert Kramer, Ford Motor Company, Dr. William Watt and Jack Hartwig, Chrysler Corporation provided their companies' views of economic feasibility (M3:6,7-9,10). A panel consisting of Kramer, Watt, Hartwig, d'Arcy and committee members, Dr. Frank Mirer and Arthur McGee addressed the issue of economic and technical feasibility in the American auto industry (M3:11). Greg Piacitelli and Dr. Robert Hughes, NIOSH, discussed some limited cost information in their presentation on the NIOSH Small Business Study (M4:2-3). Tom Beeman, a machinist at a mid to large facility in the Western part of the US provided some limited information about his company's fluid management (M5:3). A panel of machine tool manufacturers, and ancillary companies that support the design and installation of machine tools and enclosures in machining facilities, discussed costs of enclosures and issues concerning their industry (M6:6). The panel consisted of Jeff Hedley of Tamer Industries, Stephen Stevens from Cross-Huller, William Fay from H.M. White, Dan McCarthy of Lamb Technicon, Ken Steele of Grob, and Al Woody of Giffels Associates (M6:6). Charles Carlson of the Association for Manufacturing Technology also joined this panel (M6:7). Michelle Lantz, Caterpillar Corp, discussed cost and systems management (M8:10).

4.3 BACKGROUND INFORMATION

Burt defined an action as economically feasible if the action does not substantially alter the competitive structure of the affected industries (M2:4). Burt explained, in the screening analysis OSHA does, the overall costs are compared to the revenues of a typical affected firm (M2:4). If these costs are relatively high, more economic analysis may be needed (M2:4). OSHA defines significant cost

as more than 5% of profits or more than 1% of revenue, with the profit percentage more binding, according to Burt (M2:4). Burt takes the estimated cost for establishments by industry and size class and compares the cost to revenues and profits (M7:24).

Burt explained that data sources used by OSHA include Department of Commerce data, data provided by individual companies, and reports from Dunn and Bradstreet and Robert Morris Associates (M2:4). Only the additional cost of a standard is used, according to Burt (M7:25). He noted that typically, the engineering controls are 50-60% of the cost and the ancillary provisions are 20-30% of the cost (M2:4).

4.4 REVIEW OF AVAILABLE INFORMATION

4.4.1 Experiences and Resources Related to Costs

4.4.1.1 Employee Job Transfer Costs

Gauthier explained that if his dermatitis had not been improved through systems management, he would have lost his $20/hour job and would have had to take a $11/hour job (M2:18). There would have been no cost of living adjustment based on his medical condition (M2:18).

Beeman explained that he had to transfer from machining to a lower paying job in assembly due to his asthma (M5:3). He had to take a $2.50 per hour pay cut and his seniority dropped from 9 years to 1.5 years (M5:3). He later found a better paying job in dry machining at another company (M5:3).

4.4.1.2 *Costs to Provide Enclosures and Ventilation*

Hartwig outlined the process for any power train project, noting the many steps involved that are economic and engineering (M3:8). Power train refers to the engine and transmission of a vehicle and requires substantial machining in its manufacture. Some steps in development are sequential while others are parallel, according to Hartwig (M3:8). He explained that the process typically takes 3 to 4 years to accomplish (M3:8).

Hartwig cited new OEM jobs that had been priced out by Chrysler (M3:8). He explained that one line was estimated to cost $4 million to have OEM enclosures (M3:8). On another job, the vendor estimated the cost to enclose and ventilate as $1 million, but with close attention given to checking the vendor, and tightening up the enclosure, the end cost was $540,000 (M3:4). The savings was due to less ventilation being needed (M3:4).

It is important to put costs in context. Lick cited the cost in the auto industry to replace one transfer line as $35 million and the cost to rebuild one plant as $800 million (M2:15). Hartwig explained that a totally refurbished Chrysler plant that cost $1 billion had to spend $4.4 million on OEM enclosures, ductwork and collectors (M3:8).

Watt explained the work needed to install a retrofit enclosure on an existing machine (M3:8). To limit the use of materials, the existing fixture could be used and sheet metal added to it, but even this would take 50 hours of labor (M3:8). He noted the limited number of tinnies available to do this work (M3:8).

McCarthy explained that the cost of putting on sheet metal on a machine is only half the cost (M6:8). The other half is the re-piping, rewiring and other changes related to control of the machine that enable the machine to work with the new design (M6:8).

Watt and Hartwig explained that one Chrysler plant spent $10 million increasing their general ventilation (M3:8). A typical installation of improved ventilation on a line cost $150,000 to $300,000, according to Watt (M3:8). A retrofit of an engine block line at Chrysler required $1.3 million and took more than four years (M3:8). Another similar line was also estimated to cost this much, and the plant has not committed to doing it because of the cost (M3:8). A smaller piston line project cost $51,000 to retrofit, according to Watt (M3:8). More specific examples along with exposures at these jobs can be found in Watt's handout (Watt, 1998).

Ninety percent of machining operations at Ford use MWFs (Kramer, 1998). Forty percent of machines have mist collection and less have total enclosure (Kramer, 1998). Kramer based his costs on what he would do if someone told him to retrofit a plant tomorrow and how much he would request to accomplish the job (M3:10). Costs would include: ductwork installation, enclosures for single machines, enclosures for transfer lines and maintenance and operating costs including makeup air (M3:10). Kramer based his estimates on data from the previous five years from seven machining plants, ranging in size from 1 to 3 million square feet (Kramer, 1998). Actual costs of individual items were from bid sheets on past jobs done for Ford (M3:10). He noted the importance of clearly written and detailed specifications for any component of the systems (M3:10).

Kramer estimated enclosure costs of $8000 for a single machine enclosure from the machine vendor (M3:10; Kramer, 1998). The cost of a retrofit version is $12,000, this cost is higher due to the redesign needed (M3:10, Kramer, 1998). Retrofit costs were based on the costs determined for over 30 machines recently enclosed by Ford (Kramer, 1998).

Costs for transfer lines have to include some idle stations on which money can be saved since the controls are the same (M3:10). Each station in a transfer line needs an average of 1000 CFM of air which has to be factored into cost, according to Kramer (M3:10). OEM installation is $8000/station and retrofits cost between $13,000 and $16,000/station (Kramer, 1998). These costs were based on 167 stations that were enclosed at Ford between 1994 and 1997 (Kramer, 1998).

Ductwork costs have to be factored into any ventilation job. Ductwork costs should average about $3.75/CFM of air moved (Kramer, 1998). For an average new machine ductwork costs an average of about $1,900 (Kramer, 1998). Overall installation costs have to be considered and for an average new machine this will be $15,900 (Kramer, 1998). Operating costs per year for one new machine average $900 and maintenance costs per year are $1,100 (Kramer, 1998).

OEM enclosures are better accepted, according to Kramer (M3:10).

Retrofitting is only done when they have to do it (M3:10). Kramer explained that production can be affected to do a retrofit (M3:10). Replacement with OEM is an on-going process (M3:10). Many single machines get complete overhauls and a total enclosure is put on them (M3:10).

McCarthy stated the cost of enclosing a machine today is about 40-50% of what it was 10 years ago, due to standardization (M6:11). The guarding system of a machine represents about 2.5 to 3.5% of the total machine cost (M6:11). It is impossible to define the cost of the enclosure itself, according to McCarthy (M6:11).

Hedley estimated the cost of a standard enclosure for a screw machine or a high speed stamping press at 3-5% of the machine cost (M6:11). A floor mount system to only control mist and not splash, would not be as expensive as a machine mount custom enclosure (M6:11).

Stevens cited a 10% extra cost to add an enclosure or close the roof on small machining centers (M6:11-12). Stevens estimated enclosures costing as much as 30% of the cost of a large machine such as a vertical spindle machine due to the difficulties of enclosing such a machine (M6:12). Stevens noted that with the need to move in and out large parts, the price of enclosure goes up (M6:12). Stevens explained that transfer machines are easier to enclose since they have common stations (M6:12). Steele agreed with the 3 to 5% cost as did Carlson (M6:12).

Fay noted that fitting the proper enclosure around an existing machine is expensive (M6:12). Hedley explained that retrofits are more expensive than OEM enclosures (M6:12). Steele noted that retrofitting is an unknown, and if a machine tool builder is busy making new machines, they will not go after the retrofit market (M6:12). Hedley agreed that it is easy to lose a lot of money retrofitting because it is similar to prototype work (M6:12). McCarthy explained that retrofitting an old machine may cost more than the machine is worth (M6:17).

Mirer stressed the importance of good general ventilation to reduce carryover and background values of mist (M3:11). He proposed a rule of thumb: \$5 million enclosing would yield 0.1 to 0.3 mg/m^3 carryover, so some machines operating at 0.7 mg/m^3 would be in compliance (M3:11). He felt that using other methods in addition to enclosure would reduce the need for enclosure on every machine (M3:11). He noted that the number of machines that need to be enclosed is debatable (M3:11).

4.4.1.3 *Capacity and Concerns of the Machine Tool and Enclosure Industry*

Stevens stated for transfer lines the market is on the upswing (M6:7). McCarthy noted a backlog at his company of \$450 million in orders and that all machine tool companies appear to be doing very well (M6:7). According to Steele, Grob's backlog is \$600 million (M6:9). Both McCarthy and Steele explained that their companies' growth depended on the auto industry (M6:9). Carlson explained that AMT members are currently at 60-75% capacity, so there is room for growth (M6:8).

Turnover time is the time it takes for a machine to be replaced. According to Carlson, turnover time depends on how competitive the company buying the tool is (M6:8). Carlson noted it was important to look at how many tool makers there are, the total number of machines, and how many companies are available for design (M6:8).

How a machine tool company is organized affects how easily they can expand production. Vertically integrated companies cannot expand production easily, while others can out source, according to Steele (M6:9). Steele explained that Grob is vertically integrated and does all work in house (M6:9). According to McCarthy and Stevens, Lamb and Cross Huller do the basic work inside the company, and overflow can be handled by outside vendors (M6:9). Use of outside vendors allows for capacity expansion to meet demand, according to McCarthy (M6:9).

Cox asked about the warranties associated with retrofit work and most of the group was reluctant to address this issue (M6:12). Fay noted that it depended on the specification his company receives (M6:12). Fay explained the difficulties of trying to warranty work that is dependent on another vendor doing his job well (M6:12). McCarthy noted that enclosures are provided today due to cost and liability concerns (M6:10).

Carlson thought the cost issue was the concern, not technical feasibility (M6:16). Stevens noted that cost and maintainability of the enclosure and mist control equipment are concerns (M6:16). Preventive maintenance is essential and not done enough in customer companies, according to Stevens (M6:16).

4.4.1.4 *Mist Collector Costs*

The cost of operating a mist collector is a function of pressure drop and can be estimated from the pressure drop, according to Leith (M3:3,4). Trade offs occur between pressure drop and efficiency of the filter, although a high pressure drop does not always mean good efficiency (M3:4). Careful maximization of efficiency while minimizing pressure drop can reduce operating costs (M3:4). Reducing loading on the third stage HEPA filter by using a well designed mist collector, can reduce costs of replacing the HEPA filters (M3:3).

For recirculation, Woody noted that the economics of heating or cooling this air show no penalty (M6:15). He noted an exception to this was a plant that uses hot water or steam for heat, and does not air condition in the summer (M6:15). Lick noted it does not cost as much to cool air as it once did (M6:15).

O'Brien recommended a back up HEPA filter for mist collectors used in recirculation (M3:15). Lick noted that this would affect the housing and would probably double the cost of the collector (M3:15).

Kramer explained that collectors can cost $6000 for a 500 CFM capacity version and up to $12,000 for a 2000 CFM version (M3:10). HEPA filters need to be added to most collectors at Ford, according to Kramer (M3:10). He noted that operating costs are mostly electrical costs (M3:10). Twice yearly steam cleaning of collector screens is needed and take 30 minutes of labor (Kramer, 1998). Second stage filters cost $150 and HEPA filters cost $225 (Kramer, 1998). Fans,

motors and belts have to be maintained (Kramer, 1998). Including labor, parts and electricity, it costs about $1,300 yearly to maintain a 2,000 CFM collector that is run for two shifts/day (Kramer, 1998). For $8 million dollars worth of collectors, it would cost about $0.5 million in operating costs (M3:10). Using the data he assembled on collectors and square footage of plant floor, Kramer estimated cost for collector purchases of $13 to $14 million in the next 10 years at Ford (M3:10). Additional criteria for collectors can be found in his handout (Kramer, 1998).

4.4.1.5 *Medical Surveillance Costs*

Lick presented the idea of not having to do medical surveillance if the mist is managed (M5:8). Newman noted that categories of workers with different exposures may have different needs for medical surveillance (M5:8).

Sheehan noted Valenite received quotes of $46/person for on site medical evaluations including history, physical data, heart-lung assessment, general skin appearance, pulmonary function testing and medical clearance for respirator use (M7:30). Frederick received a quote of $40/person for 40 people at a site for a similar assessment and Kushner cited $40/person from his source (M7:30). McGee thought these were reasonable prices (M7:31)

At the tenth meeting, Wegman explained some data he obtained from NIOSH studies. Spirometry done for clinical purposes is reimbursed by Medicare and third-party insurance carriers. The median charge for a spirometry test (without bronchodilator, but including a physician interpretation) is about $40, with a range of $20 to $60. This range may be used as a benchmark for the reimbursement of the tests done in the occupational setting. According to Wegman's interpretation of the NIOSH work, the test requires a total of 20 minutes (range 10-30 minutes) of technician time (at $1.20/hour salary). Overhead time for the technician is also needed to calibrate, clean, and maintain the spirometry system, perform biologic control tests, complete the forms (questionnaires), and enter the responses into the personal computer (distributed data entry). The cost of technician training and recertification courses must also be considered. The supply cost for clinical spirometry is about $2 per test for a disposable flow sensor. The only supply cost for occupational spirometry tests done using a volume spirometer is a 5 cent mouthpiece, but a $5 breathing tube must be cleaned daily and periodically replaced. The capital equipment cost for purchasing the spirometry system recommended for this program (including the personal computer and calibration syringe) is $3000 to $4000. The life of the volume spirometer is more than 10 years, but the $1000 personal computer will probably need replacement every 5 years. The annual maintenance costs are about $200 (including printer ink cartridges).

Sheehan noted that OSHA should obtain additional standard insurance costs (M6:25). Newman cited Medicare as a source, along with the medical departments of companies represented on the MWFSAC (M6:25).

Wegman agreed that medical surveillance costs would not be trivial (M5:8). Wegman noted that periodic medical monitoring that only included a

questionnaire would decrease the cost burden of medical surveillance (M6:25). Fennelly thought that the cost of conducting a questionnaire would not be much because it could be folded into existing programs such as respiratory protection (M4:8). Mirer wanted to know what percentage of companies already do similar tests so the whole cost is not assessed as due to MWFs (M7:31).

4.4.1.6 *Exposure Assessment Costs*

White was concerned that a machine by machine assessment may be needed and this would be expensive (M8:25). Mirer noted that exposures are relatively homogeneous in highly automated plants, so less samples may be needed (M8:25).

Piacitelli cited analytical costs of $10/sample for total particulate and $50-60/sample for the extraction method (M4:2). O'Brien gave a cost of $5-10/sample for total particulate (M7:19). Mirer cited $80/sample for extractable (M7:20). Other lab costs such as the need to purchase a microbalance were noted (M7:19).

Howell explained that the industrial hygienist's time is more of a factor than the analytical method (M7:21). According to the exposure assessment work group, sampling costs could be reduced by: OSHA consultation services, fluid supplier product stewardship, union efforts, and small grants (M8:25). After professional assessment, workers could be trained to take samples (M8:25). Mirer noted that at GM, workers are trained to take samples and this brings the cost down (M7:21). A primer on sampling is needed to make sure these people are sampling properly (M7:21).

4.4.1.7 *Other Costs*

The cost of obtaining and managing information was noted by the group. Howell investigated ways of packaging ASTM standards to reduce cost. Johnston noted that the cost of the ANSI document is $30 (M3:3).

The database system set up by Ford cost $12 million to develop but Reeve explained that the costs have come down due to improved technology (M6:6). He noted that development cost is immaterial today because programs are now available (M6:6). For companies of 10,000, Reeve thought a system would cost $50,000 plus licensing fees (M6:6).

Mirer noted that software for OSHA 200 log maintenance is available for a few hundred dollars (M6:6). Ford's system was expensive due to the integration with payroll and its size (M6:6).

Another issue is the cost of employee time managing fluids. Gauthier now spends two hours per day managing MWFs (M8:19). This value is much lower as compared to the time needed when the program was started (M8:19).

The per item cost for centrifuges to remove tramp oil from MWFs is $133,000 (Watt, 1998). Mist suppressants have cost $120,000/year for 2 machining lines at Chrysler (Watt, 1998). Segregation of assembly areas could cost $400,000 to build one wall (Watt, 1998). A new air supply house can cost $10 million (Watt, 1998). Burke provides some factors that influence the cost

effectiveness of machining processes (Burke, 1998).

4.4.1.8 *Estimates of Total Costs*

The 1998 value of the baseline costs required by Ford to achieve the NIOSH REL in its US and Canadian plants would be approximately $328 million (Henry, 1998). This value assumes a 20 year useful life of the enclosures and collection equipment and a discount rate of 8%, (Henry, 1998). Initial investment costs are estimated at $205.2 million and annual operating and maintenance cost add $12.5 million (Henry, 1998). Issues such as delayed supplier availability, training, monitoring and medical surveillance costs could increase the regulatory burden to $433 million (Henry, 1998). Plants that already have most machines fully enclosed were not included in these estimates (Henry, 1998). A specific plant by plant cost breakdown can be found in Henry's report (1998).

Using Ford's estimates, the American Automobile Manufacturer's Association (AAMA) calculated estimated costs for DaimlerChrysler and GM (Felinski, 1998). Total estimates for DaimlerChrysler were based on before merger conditions for the former Chrysler Corporation (Felinski, 1998). The direct estimated cost for DaimlerChrysler is $250 million with estimated indirect costs of $250 million for a total of $500 million (Felinski, 1998). The direct estimated cost for GM is $560 million with estimated indirect costs of $420 million for a total of $980 million (Felinski, 1998). Adding these costs to Ford produces an overall estimate of $1.9 billion for the "Big 3" (Felinski, 1998). Earlier less refined estimates indicated a cost of $1.5 billion for the "Big 3" (Card, 1997). Voluntary exposure reduction efforts since the early 1980's of the "Big 3" are estimated at over $1 billion (Felinski, 1998). Using Burke's estimates that large industry represents about 10% of the whole, overall costs are estimated at more than $19 billion (Felinski, 1998).

Mirer submitted the UAW's interpretation of the automaker's cost estimates (Mirer, 1999). He viewed the values presented by Ford, Daimler-Chrysler and GM as overestimates (Mirer, 1999). According to Mirer, the overestimation is due to: charges for installing controls on equipment already in compliance, failure to take into account the exposure reductions from installing controls on some but not all emission sources, charges for controls that will reduce exposures substantially below the proposed PEL, and possible higher than actual unit costs (Mirer, 1999).

Allen estimated costs across several industries (Allen, 1998). She assumed a machine enclosure cost of $11,750 based on UAW estimates (Allen, 1998). *American Machinist* was cited as estimating that 57-78% of machines used in the US are over 10 years old, and that there are 1.9 million machines in use (Allen, 1998). Allen noted that these older than 10 year old machines are probably not well enclosed (Allen, 1998). Using these values, an estimated range of overall US cost between $13 billion to $18 billion was determined to enclose 1.1 to 1.5 million machines (Allen, 1998). If machines were replaced with new machines, with an average cost of $139,500/machine, the estimated cost would be between $150 to $200 billion with over $100 billion of this spent by small

businesses (Allen, 1998). In 1997, all industries in the US purchased approximately $5 billion in new machine tools (Allen, 1998). Allen noted that these estimates are high because not every machine would have to be replaced to meet 0.5 mg/m^3 (Allen, 1998). She also noted another concern, that since 1980, the population of metal cutting production workers has dropped 54% (Allen, 1998).

Additional data about specific SIC codes including number of employees, sizes of businesses, and number of businesses in each code can be found in tables provided by the OSHA Office of Regulatory Analysis (Corsey, 1999). These tables include specific characteristics about MWF using companies and have information such as the number of employees, machine tool characteristics and number of potentially affected industries (Corsey, 1999). Factors such as planned machine purchases can affect potential cost. According to Burt, based on a 1994 study by American Machinist, 73% of businesses in the affected SIC codes expected to add new machines in 1995 (Burt, 1998). 75% planned to replace some of their machines and 82% expected to either add or replace some machines in 1995 (Burt, 1998). Additional costs are provided in some letters sent to trade groups (PMPA, 1999).

4.4.2 Experiences and Resources Related to Offset Costs

Burt explained that OSHA does not usually include offsets in its considerations of cost (M2:5). Not including these offsets has contributed to OSHA's historical overestimation of costs of compliance, according to Burt (M2:5). The Office of Technology Assessment's report also indicates this limitation (OTA, 1994).

Frederick noted potential offsetting costs such as productivity increases due to new machine purchases (M2:4). Gauthier cited less down time (M8:19). Lantz noted higher productivity and less down time with well managed fluids (M8:10).

Gauthier showed cost savings because less MWF was needed to make up what is wasted (M2:18; 8:18). This also resulted in lower waste management costs (M2:18; 8:18). He cited waste reduction savings of $100,000. McGee also noted less waste due to fluid management (M3:12). Gauthier listed 54% less water use and longer tool life as important savings (M8:19). He was allowed to re-invest $500,000 in equipment due to overall savings from fluid management (M8:19). Methods of calculating savings can be found in Gauthier's handout (Gauthier, 1997).

Microorganisms in the fluid are an economic concern, according to Rossmoore, because they degrade the fluids (M5:19). McGee explained that money would be saved by better control of systems, resulting in less contamination of MWFs, less fluid use, less downtime and less use of biocide (M3:12).

According to Burke, implementing a very basic MWF management system for his company saved the company $15 million in their US plants (M6:34). Burke stated that if a company is doing nothing for MWF management, doing

something will save them a substantial amount of money (M6:34).

Teitelbaum thought there would be reduced medical costs such as less lost time due to dermatitis (M2:5; 3:13). O'Brien cited an article by Leigh and Miller in the December, 1997 issue of the *Journal of Occupational and Environmental Medicine* (M4:6). This article explained the costs of job related injuries and illnesses, noting that lathe and turning machine operators were number 18 on the list (M4:6). The estimated cost per worker was $1026/year and for a plant of 85 people, O'Brien calculated a cost of $85,000 per year (M4:6). According to O'Brien, this cost could be reduced by reducing health costs by enclosing the mist, and reducing injuries by keeping the floors dry (M4:6). Burch criticized O'Brien for making a leap from a per person cost to a whole plant cost and O'Brien agreed that plants the work groups visited were probably better than this average (M4:6).

The article by Leigh and Miller ranked machinists as 38th in a list of cost of injuries and illnesses by specific occupation (Leigh,1997). Annual costs based on 1985-1986 data, were estimated for all machinists at over $41 million (Leigh, 1997).

Reeve stated there were 148 respiratory cases at MWF plants compared to 13 in control plants (M6:2). He estimated a lost time case rate of 0.05 per 200,000 hours, a severity rate of 0.54 per 200,000 hours at MWF plants, and 121 lost days of work (M6:2). There were no lost days of work at the control plants in Reeve's study (M6:2). Howell cited work done at Kodak indicating that keeping workers working saves money (M6:41).

Burke cited the financial importance of protecting workers due to the need for a skilled workforce and decreased medical costs (M6:29). Howell noted that good fluid management reduces health effects and companies will do the fluid management because of the cost and time involved in solving fluid management problems (M6:40).

Medical costs can cause liability problems. Fennelly cited liability costs such as latex allergy cases that were settled for $0.25 to 1.5 million (M5:8).

Lantz cited recordable incidents reduced (M8:10). Teitelbaum noted being able to detect problems early and solve them would reduce workmans' compensation costs (M8:16).

Lick summarized, noting that MWF management can save a company money (M3:16). These savings would make sense to most managers (M3:16).

4.4.3 Other Resources Related to Costs

Lost work days were analyzed by the OSHA Office of Regulatory Analysis, 1998, using BLS 1996 data (OSHA Office of Regulatory Analysis, 1998). SIC codes 33-37 had 1,099 recordable cases of dermatitis accounting for 16% of all lost workday cases of dermatitis in private industry (OSHA Office of Regulatory Analysis, 1998). The median lost work days per case of dermatitis was three for SIC codes 33-37 (OSHA Office of Regulatory Analysis, 1998). Machinists experienced 660 lost workday cases of dermatitis, assemblers potentially exposed to MWFs experienced 205 lost workday cases of dermatitis, for a total

of 865 cases (OSHA Office of Regulatory Analysis, 1998).

The OSHA Office of Regulatory Analysis cited Argonaut insurance data for 1992-1994 stating that the average cost of a worker compensation claim for dermatitis for Argonaut was $661. This average costs includes medical only and indemnity claims (OSHA Office of Regulatory Analysis, 1998). Using the system developed for OSHA's Safety Pays program which is based on studies of the Business Roundtable, the average indirect costs for a claim of the size noted by Argonaut are $2,710 (OSHA Office of Regulatory Analysis, 1998). The total costs of claim and indirect costs are $3371 per claim. These costs represent costs to employers and insurers, not employees (OSHA Office of Regulatory Analysis, 1998). If all 1,099 recordable cases of dermatitis noted in the BLS data cost the amount Argonaut projected, this would represent a total annual cost of $3.7 million.

Additional information can be found in material submitted by Ford Motor Company, the AAMA, Allen as well as Gauthier (Henry, 1998; Felinski, 1998; Allen, 1998; Gauthier, 1997). Additional references are cited in Chapter Eight, Medical Surveillance and are also found in Attachment #6.

4.5 CONCERNS AND LIMITATIONS

4.5.1 Size of Business

The Regulatory Flexibility Act and the Small Business Regulatory Enforcement Fairness Act (SBREFA) require an assessment of other options to alleviate significant effects or costs on companies, according to Burt (M2:4). Advocacy panels and guidance for small business are part of SBREFA (M2:4). Burt thought the SBREFA requirements may be triggered by one of the 169 sectors associated with MWFs (M7:24).

In discussions of the NIOSH Small Business Study, Teitelbaum noted that the economic impact of improvement may be different for different companies (M4:3). Burch noted Chrysler's concems about spending $20 million to comply and that small businesses the work groups visited were at this level without much effort (M4:6). Shortell thought that small plants were already close to the REL without any further expenditure (M4:6). Mirer thought it would be cheaper and easier to control exposures at small plants (M3:16).

Burch explained that systems management may be more important to small business due to cost effectiveness and slimmer profit margins (M2:16). Goon noted there was a cost difference between dumping large systems of 40,000 to 50,000 gallons versus a 40 to 100 gallon one (M5:26).

Reeve did not think a small business of a few hundred workers would need a computerized medical data tracking system (M6:6). He recommended using a good medical services vendor who had a tracking system (M6:6).

Cox noted that member companies in his organization have their own insurers so medical costs determined from large company estimates may be different (M6:25).

Cox noted the difficulty small business would have bringing a professional in to take samples (M7:22). Mirer noted in Michigan, the state provides small

businesses with sampling pumps and mail back media to decrease cost (M8:25).

Other factors influence costs. Cox noted the slowdown in some small companies due to the Asian financial crisis (M6:8). Burch explained that the “Big 3" require a 3-5% annual reduction in cost by parts manufacturers (M6:39). Burke cited the increased competition in mid size companies that require more efficient operation and higher production rates (M6:28). The competition and requirement by customers such as the “Big 3" to keep costs down, may work against health and safety, according to Burke (M6:30).

McCarthy noted that small shops have a lot of old machines (M6:17). Woody cited cash flow problems in small and medium size businesses that make it difficult for them to run ventilation systems in the winter (M6:17). Burch cited data for one of the companies, the work group visited (M4:6). The company had $8 million in sales, $500,000 in capital expenditures per year and a profit margin of 1 to 3% (M4:6). PMPA members have a total annual shipment of goods of about $3.66 billion (Burch, 1997). This does not provide much money for enclosures or any other improvements, according to Burch (M4:6).

Cox noted that if small business had to purchase new machines, the financial burden would be obvious (M4:6). Allen estimated a cost of over $100 billion for small business if this approach was used (Allen,1998). Companies have to balance the costs of expansion, new machine purchases, regulatory issues and obtain financing (M4:6). Cox was concerned how the IRS would view certification of MWF managers or any other enhancement of business activities (M6:32). Burch explained the difference between a small and large business, noting that for the small business the expenditure for regulatory compliance comes out of the owner's pocket, not some unknown corporate entity (M4:6).

4.5.2 Time Factors

This topic is addressed in this section of the previous chapter. Related to both economic and technical feasibility, some members (Burch, Lick, Teitelbaum, Mirer, O'Brien, White) addressed the issue of phasing in any compliance requirements (M9: 30-31). Lick and Teitelbaum cited the machine tool builder discussions and Lick cited Ford Motor Company data that showed the timing issue was critical (M9:30,32).

Lick commented on the Chrysler Kenosha plant retrofit that took 5 -7 years to complete (M9:32). Lick noted at large companies, retrofit work is restricted to holiday shutdowns (M9:32-33). Lick explained the difficulty obtaining sheet metal workers and other construction personnel due to the number of operations to improve, and the booming economy (M9:33).

Lick noted that large companies have timing constraints while small companies have capital constraints (M9:33). White suggested that middle size companies may need a long phase-in as well (M9:30). Lick urged a 10 year phase-in and O'Brien agreed with the proviso that the clock starts immediately (M9:33). Mirer was concerned that we should not provide any incentives to have junk equipment kept on the shop floor (M9:33). Mirer explained that many companies will not act until the phase in time is almost completed (M9:33). Burch

urged that data collection on all issues continue during any phase in period (M9:33).

4.6 LINKAGE OF DISCUSSIONS TO OSHA ACTION

Burke estimated costs for the 40 plants in his mid size company, Eaton, to reduce all exposure to below 1.0 mg/m^3 would be $7.5 million (M6:29). To reach 0.4 mg/m^3 would cost $17 million (M6:29). To comply with 0.25 mg/m^3 would cost $35 million (M6:29). These costs would not put them out of business, but the money would have to come from profits and could not be passed on to customers to stay competitive (M6:28-29).

Hartwig noted that the newly refurbished Chrysler plant that cost $1 billion with $4.4 million in exposure controls, had exposures of less than 0.5 mg/m^3 during intermittent operation (M3:8). Hartwig estimated the overall cost of reducing exposure to 0.5 mg/m^3 would cost Chrysler about $40 million with a long lead time (M3:9).

About two thirds of Ford's machines do not have enclosure, according to Kramer (M3:10). Ford's estimate of enclosure related costs is $328 million (Henry, 1998). Kramer explained that some retrofit jobs take three years due to production and still may not work well (M3:10). Mirer cited Hands study's median for old equipment, indicating that about half the exposures were below the REL (M3:11). Because only half of the equipment did not meet the REL, Mirer felt that the cost estimates should be cut in half (M3:11).

Mirer stated that based on Ford Motor Company estimates, the cost of a potential standard is similar to those OSHA has promulgated in the past (M3:11). O'Brien noted that Chrysler's estimate of $50,000 per station were higher than Ford's estimates of $10,000 to $15,000 per station (M3:9).

In the context of explaining that not everyone is at 0.5 mg/m^3, Lick opined it will be costly to improve but there is not a financial incentive to do it yet (M6:34). Lick thought MWF control would be more expensive than ergonomics (M4:15). White questioned if feasibility can be demonstrated and if OSHA can justify the cost (M3:16).

4.7 COMMITTEE DECISIONS AND RATIONALE

The *majority (12) viewed that achieving the PEL was economically feasible* (M9:31-32). O'Brien cited data submitted by Ford and an Office of Technology Assessment report (M9:31). Mirer viewed the Ford data as a high estimate, noting that many exposures at Ford were below 0.5 mg/m^3 (M9:32). Mirer stated that small companies would have lower ventilation system costs and that all companies would benefit from less expensive improvements in general ventilation (M9:30,32). Sheehan noted that not every work station has to be improved for the overall exposure to be reduced and urged a focus on the worst machines (M9:32). Day explained that companies find the money when OSHA puts pressure on them (M9:32). Lick and White stated that achieving the PEL was economically feasible with enough time allowed to phase in changes (clarification provided at tenth meeting).

The *minority (Burch, Cox) stated that achieving the PEL would be very expensive and economically infeasible* (M9:31-32). Burch cited the evidence provided by Ford (Henry, 1998) and the American Automobile Manufacturer's Association (Felinski,1998) (M9:31).

There was one abstention (Howell) who noted that there was not adequate information to reach a decision on the question of the economic feasibility of a PEL (M9:31-32).

White stated that the costs could be on par with the proposed ergonomics standard (M9:32). Cox cited small business problems with cash flow and tax laws related to regulatory compliance (M9:32). Lick estimated that ventilation costs for some small businesses would be a few thousand dollars (M9:33). There was general agreement that more information is needed on this issue (M9:31-32).

All members (15) viewed that systems management was economically feasible (M9:31-32, corrections noted at tenth meeting). The committee stated that it was economically infeasible not to do systems management (M9:31-32). O'Brien cited clear economic benefits of systems management including: reduced painting, reduced accidents due to slippery surfaces, and improved retention of employees (M9:32). White cited Gauthier's presentation as showing cost effectiveness of systems management (M9:32). Mirer noted that systems management may enhance exposure reduction and provide jobs (M9:32).

The *majority (12) thought that medical surveillance as outlined in the best practices document was economically feasible with some limitations* (M9:31-32, corrections noted at tenth meeting). Members noted the per test costs, and their own experiences with medical surveillance as rationale. White cautioned that his decision was based on the high threshold defined for economic feasibility (correction noted at tenth meeting).

The minority (Burch, Howell, Cox) stated that the medical surveillance as outlined in the best practices document was not economically feasible (M9:31-32). Burch noted that the cost would depend on the level of detail required (M9:32). *Howell refined his minority opinion that some degree of medical surveillance was economically feasible but not the one stated in the best practices chapter* (correction noted at tenth meeting).

CHAPTER FIVE
Deliberations Related to Actions OSHA Should Take: Recommended OSHA Actions

5.1 GENERAL INFORMATION

The committee reviewed information on the actions OSHA can take to address protection of employees. These options were investigated along with the topics of health effects, technological feasibility and economic feasibility to help the committee in its deliberations. The working group, Government Options, was charged with researching potential OSHA actions. In addition, OSHA staff and representatives of the Solicitor's office, Department of Labor, provided information.

5.2 SPEAKERS AND PRESENTATIONS

Assistant Secretary of Labor for OSHA, Charles Jeffress addressed the committee on what OSHA needed from the committee (M7:1). Acting Assistant Secretary of Labor for OSHA, Greg Watchman and Adam Finkel, OSHA Health Standards Office addressed the initial meeting of the committee (M1:1). Robert Burt, OSHA, provided some background on OSHA's requirements in his presentation of OSHA's work on feasibility (M2:4). Dan McCarthy, Lamb Technicon explained the impact of regulation on machine tool manufacturers. Dr. William Lucke, Cincinnati Milacron discussed voluntary standards in his presentation on fluid formulation. John Burke, Eaton, noted voluntary standards in his presentation on the MWFs in mid size companies. Dr. Larry Fine, NIOSH explained NIOSH's basis for a Recommended Exposure Limit. Susan Chastain, Department of Labor, explained the relationship between the Americans with Disabilities Act and the action of OSHA and employers.

5.3 BACKGROUND INFORMATION

Burt explained that OSHA regulates when there is a significant risk to workers and when the risk can be reduced substantially by measures that are technologically and economically feasible (M2:4). Infante explained that OSHA has to act in some way if a substance is on their regulatory agenda (M7:26). Mirer explained that the UAW recommended 0.5 mg/m^3 as a provisional limit until a complete review of the health effects and feasibility could be done (M2:12).

5.4 REVIEW OF AVAILABLE INFORMATION

5.4.1 What OSHA Needs from the MWFSAC

Jeffress hoped the MWFSAC could speed up the regulatory process (M7:1). He and Watchman provided examples of potential recommended actions (M1:1; 7:1). Watchman asked for consensus if possible (M1:1). Finkel urged the committee to be creative and stressed the importance of rigorous analytical work by the committee and OSHA (M1:2). Jeffress asked that the group not focus too much on whether the action should be a rule or a guideline but to provide best

practices for someone who is trying to protect employees working with MWFs (M7:1). Sherman noted the importance of providing a clear rationale for any recommended action (M8:1).

5.4.2 Non-regulatory Approaches

5.4.2.1 *Governmental Non-Regulatory Actions*

According to Watchman, examples of non-regulatory approaches include: guidelines, technical manuals, directives, compliance materials and voluntary agreements with industry (M1:1)

The government options work group began by attempting to list all the actions which government could take regarding MWF, both regulatory and non-regulatory. "Non-regulatory" was initially taken to mean any activity other than promulgating an MWF standard. The exhaustive list was presented to the full committee. The list of non-regulatory actions includes: OSHA Guidelines for machining operations; OSHA Hazard Information Bulletin and other informational materials (OSHA or NIOSH); On-Site Consultation; Targeted Training programs; SENSOR Program for machining facilities; adoption of industry guidelines; voluntary agreements; and/or OSHA recognition of existing industry consensus standards (M7:35, additional clarification at tenth meeting).

Michigan OSHA's SENSOR program was described in detail and is considered in this section, although aspects of it are regulatory. The summary of the SENSOR protocol was provided by the UAW (UAW, 1998). This program started by sending industrial hygiene compliance officers to facilities where physicians have reported MWF-related occupational asthma, and was expanded to a special emphasis program for all health inspections in MWF using facilities. The protocol consists of a symptom survey conducted by the industrial hygienist, review of injury and illness records, bulk samples and analysis of fluids, and air samples. These inspections could be the basis for general duty clause citations, if recommendations were not implemented. The work group identified, but did not endorse the possibility of an OSHA national emphasis program based on this model.

The work group suggested that an OSHA hazard information bulletin could be considered (M7:35).

Voluntary agreements between industry and OSHA to reduce exposure have been used in the past. The styrene agreement was provided as an example of non-regulatory actions. In exchange for an OSHA commitment not to include styrene in the initial list for the PEL update, industry agreed to medical surveillance, development of education and training programs, exposure assessment and reporting back to OSHA on exposure levels (M7:35).

The work group recommended that OSHA implement specialized on-site consultation and targeted training programs and not wait any longer to establish these (M7:35). The work group thought OSHA should use the Susan Harwood Training Grant program to provide directed grants to employers or employee groups for training of employers and employees in facilities where MWFs were used (M7:35).

Burke cited EPA voluntary programs such as: 3350, Green Lights, Energy Star, Waste Wise, Common Sense Initiatives and Strategic Goals Program (M6:29). He noted OSHA programs such as the styrene and asphalt agreement (M6:29).

5.4.2.2 *Consensus Standards and other Non-governmental Voluntary Action*

The government options group identified the following non regulatory actions taken by industry and other groups. These include industry guidelines like the ORC document, and existing industry consensus standards such as the ANSI Mist Control and ASTM sampling standards (M2:2; 3.12). Other initiatives could include industry certification programs.

Howell explained that ASTM is the largest voluntary standards development organization in the world with 132 committees and the E-34 committee addresses occupational health and safety issues (M4:4). About 10,000 standards exist with most addressing testing of materials (M4:4). Howell explained that ASTM has very strict rules for developing standards and different durations for provisional standards such as PS-42 (M4:4). A draft standard is developed by a committee of concerned individuals who get together to formulate a consensus approach, the draft moves up through the committee review hierarchy and is voted on by the ASTM Committee on Standards (M4:4). Input from members and nonmembers of ASTM can occur throughout the process (M4:4). The E-34 committee addresses a wide range of issues and has 10 subcommittees (M4:4). The E-34.50 subcommittee was formed in the early 1980's and is related to MWFs (M4:4). Howell explained that every standard has to be reviewed every 5 years and if no one reviews it, a standard is no longer active (M4:4). Provisional standards are reviewed every two years (M4:5). Every negative vote in an ASTM committee has to be addressed to move the standard forward (M4:5).

Howell cited relevant ASTM standards such as: the *PS 42 -97ASTM Method For Measuring Metal Removal Fluid Aerosol In Workplace Atmospheres;* E-1370, *Guide for Air Sampling Strategies for Worker and Workplace Protection* and E-1497, an old standard set for revision called *Safe Use of Water-Miscible Metalworking Fluids* (M4:4). Two standards aimed at formulators are E-1302 *Standard Guide for Acute Animal Toxicity Testing of Water-Miscible Metalworking Fluids* and E-1687 *Test Method for Determining the Carcinogenic Potential of Base Oils Used in Metalworking Fluids* (M4:4).The ten year old *Standard Practice On Safe Use Of Water Miscible Fluids* addresses concerns such as additives, biocide use, system design and worker protection (M4:5). Howell introduced two other method under development, the Provisional Practice for Personal Sampling and Analysis of *Endotoxin in MWFs* and *Practice for Minimizing Aerosols in the Wet Metal Removal Environment* (M4:5). Howell explained the dedication of the individuals involved keep these standards updated (M4:5). Mirer recommended that OSHA distribute the available consensus standards to expedite improvement (M4:5).

Lucke cited voluntary action of fluid formulators who worked individually and collectively and redesigned fluids as needed (M5:17,21). Movement away from chlorinated paraffins was due to regulatory forces while the nitrosamine is more driven by market forces (M5:24). The diethanolamine issue is in response to NTP studies and also market driven (M5:24).

Burke suggested a standard setting organization for MWFs (M6:29). He recommended that suppliers develop a code of standards and standard labels (M6:29). He urged conservative development of new products and limited on site chemical addition (M6:29). Burke cited organizations such as Underwriters Laboratory (UL) and National Electrical Manufacturers Association as groups who check quality and dictate design (M6:29). The accountability would be on these groups (M6:31). McCarthy noted that hazard analysis is part of ISO certification (M6:11)

5.4.3 Regulatory Approaches

Regulatory options according to the Government Options Work Group include: a complete OSHA health standard; a PEL with and without mandatory or voluntary ancillary provisions; OSHA PEL or standard for particular MWF components; general duty clause enforcement; compliance directives and cooperative abatement program (M3:12). A standard would require compliance directives and Mirer recommended that these be issued at the same time as any standard (M3:12)

Cooperative abatement programs are pre-citation commitments to institute controls (M3:12). Employers with a particular compliance program could get relief from penalties from OSHA as long as they were moving toward compliance (M6:23). A potential application to MWFs could include a provision that if the employer was above the PEL, but has implemented all feasible engineering controls, the employer could not be cited as long as respiratory protection is properly provided (M6:23). A sample cooperative abatement program was provided by Mirer (Mirer, 1998).

In the lead battery agreement, a compliance manual was developed by labor, industry and government (M5:23). OSHA conducted an outreach program and made a commitment not to cite those implementing directives in the manual (M6:23). Industries not in compliance had to develop their own compliance plans to be approved by OSHA (M6:23). Assessing these plans was difficult (M6:23).

Jeffress noted that standards and rules do alter behavior (M7:1). Jeffress explained that OSHA is looking more at systems approaches and cited the health and safety program standard development (M7:2).

White noted that OSHA has moved to performance based standards, allowing companies to determine how to attain the performance (M7:22). Due to the ASTM standards, it may be easier for industry to determine how to do sampling, according to White (M7:22). Kushner noted that the Industrial Truck Standard has language indicating that OSHA reviewed voluntary consensus standards and used them extensively in developing the standard (M7:26).

Other actions can include an EPA test rule for fluids and components or a

relief rule for emissions (M3:12). An EPA product rule similar to the European machinery guideline could be used (M7:36).

Additional details on standards including typical components is provided in the handout of the Government Options Work Group (Government Options, 1998).

5.4.4 Risk Assessment

White explained that OSHA does not have a defined, documented method to determine quantitative risk and does not provide what factors are considered (M3:14). OSHA has to look at the quality of the support data, the reasonableness of the assessment, the fit to mathematical models and the type of health effects (M3:14). The benzene decision stated that OSHA must make a threshold finding that a worksite is unsafe due to the presence of significant risks (M3:14). It must show that there are ways to reduce these risks (M3:14).

A one in a billion risk is probably not significant but a 1 in 1000 is, according to White (M3:14). Sherman clarified that OSHA can regulate risks less than 1 in 1000 (M3:14). Infante explained that a qualitative assessment has to come before a quantitative one (M2:10).

White recommended that the committee identify risk assessment models instead of determining the significance of risk (M1:2). White was concerned that NIOSH did not sort out which studies are more reliable and more appropriate for risk assessment (M2:9).

White outlined that OSHA views the quantitative risk assessment results from several perspectives: what is the magnitude of risk posed at current exposure levels, what is the magnitude of the risk reduction expected at the new level, what is the residual risk at the proposed new level, is the remaining risk significant and what is the level of confidence in these projections (White, 1998).

Mirer explained that three levels of proof have to be shown: the validity of the risk assessment data Perry showed, the amount of proof needed to sustain a rule and the amount of proof for OSHA to go to rulemaking (M6:21). Perry noted that the cotton dust standard used a 5% cross shift decrement in lung function as an indicator (M6:21). Infante noted the Perry result showing residual problems at 0.5 mg/m^3 (M9:25). The committee was asked by Infante if a 10% decrement in FEV_1 was a material impairment of health (M9:25). Infante also asked if 10% of the population experienced this effect, would intervention be needed (M9:25).

Newman explained that a decrement of 10% in FEV_1 would be significant (M9:25). White thought there were too many unanswered questions about the risk assessment (M9:26). Burch was opposed to basing a risk assessment on four studies in auto plants (M9:26). More on the non-cancer respiratory risk assessment is in Chapter Two, Health Issues.

Additional resources about risk assessment include Kamrin *et al, Reporting on Risk, A Handbook for Journalists and Citizens* (1995) and handouts of White and Perry (White, 1998; Perry, 1998). Additional references related to this Chapter are found in Attachment #6.

5.5 CONCERNS AND LIMITATIONS

5.5.1 Size of Business

Fine indicated that he believes the data from auto plants can be generalized to other similar processes (M2:2). Burch was concerned that the risk assessment done by Perry was based only on one sector of the economy (M6:39). Burch noted that not all exposure, and not all people are alike (M6:39).

Wegman explained it would be nice to know all the different exposures and forms of exposure in a variety of industries but we do not have that information (M6:41). He urged action on what is available (M6:41).

Frederick cited his almost monthly experiences in small plants where employers will not listen to health and safety complaints if they are in compliance with OSHA standards (M6:40). He questioned what happened in plants without unions (M6:41).

Cox noted that small business provisions can be included in standards (M3:15). He provided examples such as size exemptions, delayed start up and a thirty day per year exposure trigger (M3:15).

PMPA and PMA, two trade organizations representing small business, sought input regarding respiratory illnesses in companies their organizations represent. Companies responded based on either a review of their own records or best recollection (PMPA, 1999, PMA, 1999). Companies either composed their own letter, or used a form letter, and some provided exposure and related data (PMPA,1999, PMA, 1999). A review of PMPA's approximately 80 letters indicates 1 company with three respiratory complaints, a couple with air quality complaints and almost all without either recordable or other types of respiratory complaints (PMPA, 1999). A few dermatitis cases were noted (PMPA, 1999). Problems were solved by changing the type of MWF, better machine and fluid maintenance and improved ventilation (PMPA, 1999). Almost all companies had serious concerns about the implementation of a potential OSHA standard, citing concerns about cost, the need to hire professional help, local and international competitiveness and the need for more research (PMPA, 1999). A similar pattern was seen in approximately 42 letters from PMA members (PMA, 1999). More information on small business is found in the section, "Other Issues" provided below.

5.5.2 The Americans with Disabilities Act (ADA)

There was concern that an action by an employer who is complying with an OSHA regulation, such as medical surveillance, may be violating the ADA. Chastain explained that if an employer takes any action expressly required by another federal law or regulation, the employer does not violate the ADA (M8:13). She explained it is more difficult to defend the action if the employer acts on his own volition beyond what is expressly required, or if the agency issues a guideline or recommendation instead of a regulation (M8:13).

An example was given of an action such as an employer stating, after receiving medical surveillance data, that an individual is not qualified for a job for health reasons (M8:13). According to Chastain, if the testing was based on the requirements of an OSHA standard, the employer does not have to prove direct

threat (M8:13). It is already determined to be job related and reasonable accommodation may still be a question (M8:13). If an action not to hire was based on voluntary approaches by industry, it would be more difficult to defend (M8:13).

5.5.3 Other Issues

The limitations of voluntary action and the limitations of the data on which decisions were made were concerns of the committee. Sheehan was concerned about the limits of Product Stewardship to be self policing (M5:24). Sheehan noted that voluntary action is potentially confusing as one tries to determine which voluntary standard to use and when (M6:35).

A study on Motivating Safety in the Workplace, conducted by the Insurance Research Council (IRI) found that when employees are committed to safe work practices, owners see less of a problem (IRI, 1995). For small businesses, 59% see the cost of worker's compensation as the most important reason to improve workplace safety, followed by 51% believing it is the right thing to do, 33% seeing that it increases long term profitability, and 31% acting because of state and federal safety rules (IRI, 1995). Additional information on related issues can be found in the IRI report (IRI, 1995).

Kushner was concerned about the OSHA IMIS dataset showing that 75% of workplaces are below 0.5 mg/m^3 (M2:2). Teitelbaum and others were concerned about reporting on OSHA 200 logs (M5:27). Sherman noted the inadequacy of the OSHA 200 log and how if a disease has a non-occupational version, it is less apt to be recorded on the log (M5:27). Burch noted that many managers have difficulty filling out the logs (M5:28).Mirer noted the disparity between OSHA 200 logs and SENSOR data reports (M6:37). Chapter Two Health Issues has more information on this topic.

Clearer definitions of recordable occupational disease were needed according to Teitelbaum and Wegman (M5:27-28). White explained the development of a new OSHA recordkeeping standard and thought a list of diseases that are presumptively reportable could include those related to MWFs (M5:28).

The potential for lawsuits was brought up at various times by different committee members. Mirer provided an example of a lawsuit and thought suppliers, tool makers and fluid managers were at risk (M6:24). Lick questioned if companies really wanted to deal with product liability suits (M6:30). An article in the Wall Street Journal provides an example of this approach (Palmer, 1998).

5.6 LINKAGE OF DISCUSSIONS TO OSHA ACTION

NIOSH advocates a single Recommended Exposure Limit for all four types of MWFs, according to Fine (M2:1). According to NIOSH, it is prudent to lower exposure to all types of MWFs since evidence shows negative health endpoints with each of the four types of fluid (M2:1). NIOSH states a recommended exposure limit of 0.4 mg/m^3 thoracic or 0.5 mg/m4 "total" (Fine, 1997). Reducing exposure is prudent because it will decrease the number of new

cases of asthma, respiratory symptoms and acute pulmonary function changes (Fine, 1997). Exposure reduction to the PEL will likely decrease the risk of chronic airway disease and may affect either the risk of HP or the ability of affected individuals to return to work (Fine, 1997). An additional rationale is the concern about cancer based on substantial evidence prior to 1970 (Fine, 1997).

Howell highlighted the importance of voluntary, consensus standards and their role bringing the best practices forward (M4:5). Howell urged the committee to look at this as a viable approach that can be done more quickly and effectively than regulation (M4:5). Howell thought a voluntary program including analysis of hazards in the workplace, knowing the signs and symptoms of disease, engineering controls and fluid management would be more effective than waiting for a standard (M6:24).

O'Brien thought only a standard would work (M6:31).Frederick thought OSHA could act quickly and develop a standard for the committee to review (M6:40). Shortell explained that many progressive employers are managing fluids well but there are many who do not know what is going on and a standard would be for them (M7:23). Shortell noted that employers would not be trying to reduce exposure if they did not think there were health effects (M6:40).

Howell explained that there are health effects associated with MWFs but that he believed these effects are not solely due to the MWF itself but that operational factors also are involved (M7:32). Howell did not believe that the information presented by Perry's presentation in October showed that the effects rise to the level of significance that OSHA would hold meaningful in terms of a standard (M7:32).

White cited OSHA success with voluntary programs such as the meat packing agreement and workplace violence (M5:27). Cox gave examples of companies that had taken action without a standard (M3:15). Burke urged voluntary action as faster and better (M6:27). Burke thought actions such as the ORC document and pressure from the Big 3 on suppliers of fluids and products could go a long way (M6:30).

Infante noted that any voluntary agreement would require a target limit, air sampling, a time line, medical surveillance, training and fluid management (M6:31-32). Any ancillary actions such as respirator use would have to follow existing standards (M6:32).

Mirer noted that no other standard development process has been based on so much data (M4:3). Mirer thought it was most important to have engineering controls, fluid management and medical surveillance, and any PEL would not be as important except to determine if controls are working (M5:15). Mirer noted that if an environment was below a PEL, other program elements may still be needed (M6:24). Mirer suggested considering 95-99% compliant as good enough (M3:11). McGee was willing to consider 1.0 mg/m^3 on old equipment and 0.5 mg/m^3 on new equipment (M3:12).

Teitelbaum was concerned about the issue of action levels (M7:31). He acknowledged the difficulties of sampling and analysis (M7:31). He suggested a PEL of 0.5 mg/m^3 for 45 days and action level of the same exposure but 30 days

(M7:31). Mirer explained that different triggers could be used for medical surveillance and industrial hygiene surveillance (M7:31).

Mirer noted that a tripartite manual and catalog of engineering controls is essential for MWFs, whether or not cooperative compliance is adopted (M6:23). Mirer described his idea for an OSHA Special Emphasis Program for MWFs (M7:35).

Mirer stressed the importance of correct on-site consultation (M7:35). Anderson noted that special emphasis programs get information right out to the appropriate SIC codes (M7:36). Anderson explained that demand for consultation services outstrips available services (M7:36). Cox thought these services need more publicity (M7:36).

Mirer explained that the MWFSAC's product could be used as an OSHA best practices guideline or regulation (M7:35). Wegman recommended that any products of the committee be in the form of a guideline that OSHA could use as either a guideline or standard (M5:30).

Mirer noted that the styrene agreement only occurred when OSHA put styrene on its priority list (M6:31). The general duty clause is used as back up (M6:32). Mirer thought that it was to the fluid formulators' advantage to have a standard so customers will understand why a fluid management program is necessary (M5:26). He thought that without a standard, managers will alter the fluid instead of getting at the root cause of problems (M5:26).

A determination of risk is needed before any regulatory action, according to Burch (M3:13). Burch noted the difficulties of convincing a company to use its limited capital expenditure money to do something without a return on investment (M4:6). Burch warned that we should avoid trying to regulate stupidity (M5:3). Burch thought workman's compensation may have more clout than OSHA to make companies do what is right (M5:30).

Burch suggested allowing union negotiations to set limits (M3:12). Shortell explained that there should not be one standard for unionized workers and another for non-unionized (M3:12).

Lick noted that if a regulation does not make sense, it will not make a difference (M3:16). Lick and Shortell pointed out the machine tool manufacturers' comments that without regulation there would be no pressure to enclose (M6:30,40). Lick thought a standard was the way to change the behaviors he saw in small business (M4:6). Lick wanted to also figure out a way to limit the overuse of biocides (M5:15).

There was discussion of how appropriate voluntary agreements between OSHA and stakeholders would be. Cox noted that organizations can not sign for members (M6:24). White explained that an agreement like the lead battery one would be impossible with MWFs due to the number of companies involved (M6:24). McGee thought there were too many companies involved for anything voluntary and White and Burke agreed that OSHA may find it all too difficult (M6:24,30). Shortell thought that trying to set up agreements with 100,000 employers would be too difficult (M6:40). White did not think the options shown in the OSHA video on partnerships could be used for MWFs due to the number of

facilities involved (M7:26).

Related to systems management, Teitelbaum suggested that when everybody knows what has to be done, it should be all right to write a work practice document without data that explicitly shows the method works (M3:14). Teitelbaum recommended guidelines for physicians to diagnose MWF diseases (M5:30). Teitelbaum cited a study of the compliance with the ethylene oxide standard and was concerned that a standard is needed (M3:16). Teitelbaum doubted that OSHA would not set a standard based on dermatitis (M3:13). Teitelbaum explained that any regulatory action directed at just a particular material or substance was not going to be helpful to protect workers from MWFs (M5:20).

Newman noted that Burke provided information showing that mid size industry could not take care of MWFs themselves (M6:31). Lick explained that the machine tool manufacturers indicated that they needed a regulatory driver while the representatives from mid size business wanted voluntary actions (M6:39). Lick thought regulation drives improvement and noted how Grob and other companies responded to the European standards (M6:39).

White thought OSHA's power was very limited (M6:39). He was very concerned about the impact on mid size business, noting that the two companies represented had a long way to go to meet the NIOSH PEL (M6:39). White explained that the auto industry is already committed and small industry may not have much of a problem (M6:39). He thought there was enough pressure to develop a rational voluntary approach (M6:39). White explained that the ORC document was intended to be more useful than an OSHA standard and the document could be a catalyst for effective action (M8:6).

5.7 COMMITTEE DECISIONS AND RATIONALE

The committee addressed the issue of the need for a Permissible Exposure Limit, PEL.

The majority (12) opinion was that an MWF PEL as an 8 hour time weighted average was needed (M9:25). O'Brien cited the inappropriateness of the TLV for mineral oil mist with no additives (M9:25). This TLV was based on the health effect of lipid pneumonia and did not represent MWFs used today (M9:25). Wegman was concerned that the current Particulates Not Otherwise Classified (PNOC) designation was inadequate (M9:25). Newman cited the number of health effects that cause material impairment of health, burdening the American worker (M9:25).

The minority (Cox, Burch, Howell) opinion was that OSHA needed to prove by a risk assessment that a new PEL was needed (M9:25). Cox noted that a PEL probably was needed (M9:25). Howell thought there should be a lower exposure guide for metal removal fluid mist (M9:25). The lack of significant risk and the linkage of many problems with operational factors and not MWFs were

given as rationale (M7:32). A voluntary approach was stressed.

After making the decision that a PEL was necessary, the committee determined what level to recommend.

The majority (10) viewed that the evidence pointed to 0.5 mg/m^3 (M9:26). O'Brien explained that 0.4 mg/m^3 measured as thoracic particulate was a better surrogate (M9:26). Members cited studies on diminished lung function and the NIOSH Criteria Document (M9:26-27). Members urged that the value be based on an OSHA Risk Assessment (M9:26-27). Mirer, Teitelbaum, Day, Newman and Wegman noted that a PEL of 0.5 mg/m^3 will not completely protect health (M9:26-27). Wegman emphasized that a PEL will not protect the skin (M9:27).

The minority (White, Howell, Lick) viewed the value as either between 0.5 and 1.0 mg/m^3*, or 1.0 mg/m*^{3} (M9:26-27). They also urged that the value be based on an OSHA Risk Assessment (M9:26-27). Howell and White recommended a voluntary application of these values (M9:26-27). Howell stressed the importance of fluid management and noted that a PEL of 0.5 mg/m^3 alone cannot protect against vapor or biological entities (M9:26-27).

Two members (Cox, Burch) did not have an opinion on what value should be proposed (M9:26-27).

Four members (Cox, Howell, O'Brien, Sheehan) viewed that a higher PEL could be listed for straight fluids (M9:26-27). Sheehan and Howell based their opinion on the health data, while O'Brien and Cox recognized the feasibility issues (M9:26-27). Lick noted that a dual standard would be difficult to address in plants with multiple fluid types (M9:27).

The committee determined if an action level is needed.

The majority (12) stated there should be an action level (M9:27). The rationale for an action limit includes concerns about the variability of exposure levels in industrial processes and of sampling techniques. A random sample as high as one half the PEL predicts that exposures greater than the PEL will occur. Triggers are needed for sampling as well as other actions such as medical surveillance in order to protect workers.

The minority (Howell) stated that there should not be an action level (M9:27). Sampling and analytical problems at lower than the PEL were cited. Voluntary approaches were emphasized.

Two members (Burch, Cox) had no comment (M9:27).

After determining that there should be an action level, the committee decided

what that level should be.

The majority (8) viewed that 0.25 mg/m^3 should be used as the action level (M9:27). This opinion was based on the traditional statistical approach of using half the PEL value (M9:27). Mirer noted an earlier vote on best practice for exposure assessment listing the action level as half the PEL (M9:27). Mirer explained that an action level detects and prevents over-exposure (M9:27). Sheehan was concerned about whether the sampling and analytical method could address values in this range (M9:27).

A minority (3- O'Brien, Wegman, Teitelbaum) viewed that the committee should not "tie OSHA's hands" (M9:27). O'Brien, Teitelbaum and Wegman were concerned about residual risk at 0.25 mg/m^3 and Wegman asked that OSHA figure out better ways of addressing this issue (M9:27).

Howell had another minority view and thought the number should reflect the limits of the sampling and analytical method (M9:27).

Lick expressed a different minority opinion, noting that the action level *should be 0.5 mg/m^3,* since the action level becomes a *de facto* PEL (M9:27). Lick also noted the concerns about the sampling and analytical method and that without other components, a PEL and/or action level would fail (M9:27). There was some general consensus that OSHA should identify alternate triggers for action instead of an action level (clarification at tenth meeting).

Burch and Cox did not comment on the value proposed for an action level (M9:27).

The committee discussed the question of whether there should be a short term exposure limit, STEL (M9:28).

The majority (12) viewed that there was inadequate evidence to support a STEL (M9:28). Members were concerned about short term high exposures (M9:28). They noted anecdotal evidence of complaints of respiratory irritation for short term high exposures (M9:28). The concept of real time monitoring to determine short term exposures was supported by members to provide information on these conditions (M9:28). Burch noted that short run operations with a lot of opening and closing of doors produce peak exposures while continuous operations would have less of a problem with peak exposures (M9:28).

Three members (Teitelbaum, Day, McGee) had no opinion or comment (M9:28).

The committee members discussed if more than a PEL is necessary (M9:28-

29). They discussed the importance of systems management of the MWFs and medical surveillance as supporting components (M9:28-29).

All members (15) noted the importance of including more than an exposure limit in any OSHA action concerning MWFs (M9:28-29). Howell explained that the combination of systems management and medical surveillance would accomplish more than a PEL (M9:29). White, Cox, Howell and Burch noted that a regulatory approach should not be used.

All members (15) clearly viewed that systems management is essential (M9:28-29). White noted that a PEL would go a long way to improve current conditions, but systems management was needed to protect against problems such as dermatitis (M9:28). Burch noted that endotoxin could not be addressed with a PEL, but systems management would reduce this problem (M9:29). Mirer explained that design criteria for equipment, process control to reduce misting, and fluid management should be the three major components of systems management and also urged the inclusion of general ventilation (M9:29). White, Cox, Howell and Burch noted that a regulatory approach should not be used.

There was some debate, but no consensus, about whether the specifics of systems management should be laid out by OSHA (M9:28-29). O'Brien urged complete flexibility while Sheehan and alternate member, Shortell, urged defined, quantitative criteria (M9:29). Newman suggested defined criteria with some flexibility built in for emerging technological improvements (M9:29).

The majority (11) stated that medical surveillance was needed (M9:28-29). White, Newman and Mirer noted that medical surveillance would capture problems not addressed by a PEL and systems management (M9:28-29). Mirer recommended active medical surveillance and noted that there will still be problems of under-reporting of health problems (M9:29).

The minority (Cox, Howell, Burch, White) was not against all medical surveillance but did not support the best practices version of a medical surveillance program. Cox urged a common sense approach to medical surveillance especially for small business (M9:29). Howell, Burch, Cox and White cautioned against using medical surveillance as part of a regulation (M9:28-29). The ORC version of a voluntary medical monitoring program was put forth as an alternative by some of those in the minority.

The committee discussed the form of action OSHA should take.

All members agreed that OSHA should act to address the issue of MWFs (M9:33-35). *The majority (11) voted that an OSHA standard for MWFs is needed* (M9:33-34). Anderson, O'Brien, Sheehan, and Wegman stated that the standard should include a PEL, systems management and medical surveillance (M9:33-34). O'Brien viewed that the specifics of the systems management should be in a

non-mandatory appendix (M9:33). Mirer explained that the most critical parts of a standard are the PEL and exposure monitoring portions (M9:35).

Members provided some rationale for choosing a standard (M9:33-35). Mirer noted the wide range of epidemiological studies (M9:35). Mirer explained that the 0.5 mg/m^3 value was determined by Morton Corn, former Assistant Secretary of Labor for OSHA, while Corn served on a GM health advisory board (M9:35). Mirer stated that a standard is needed for exposure reduction, medical surveillance and the commitment to spend the money needed to accomplish these objectives (M9:35).

McGee noted that a standard would promote compliance by employers and employees (M9:33). Day cited his own experience noting that employers only pay attention to standards (M9:34). Teitelbaum urged OSHA to provide a special emphasis program and cited inadequate MSDSs for MWFs (M9:35). Alternate member Shortell noted the difficulty linking stakeholders and OSHA for the development of any voluntary negotiation, and that employers only take standards seriously (M9:35). Lick opined that in time, a guideline might work, but at this time, only a standard would accomplish what is needed in industry (M9:33).

The minority (Burch, Cox, Howell, White) voted that OSHA should publish guidelines for MWFs instead of a standard (M9:33-34). Howell and White noted the complexity of promulgating a standard on MWFs (M9:34). Burch explained that OSHA would have to prove a clear cut risk for a standard (M9:34). White opined that although the whole compilation of health effects is compelling, only a few studies can be used in risk assessment (M9:34). Howell and White explained that a guideline could be implemented much quicker than a standard (M9:33-34). White noted that industry has shown in the ORC document that it is willing to act (M9:34). Howell urged adoption of a non-regulatory approach for users and product stewardship by suppliers (M9:33). The cost burden of a standard concerned White (M9:34). Burch urged sensible action, acknowledging that good employers will follow a guideline, while the bad ones will play the odds of an OSHA inspection (M9:34). Howell and White urged partnerships and cooperative efforts, and Cox provided examples of such in his organization (M9:34). Burch noted that over time, purchases of new machine tools will result in lower exposures (M9:34).

The issue of interim guidelines was discussed but not resolved by a vote (M9:33-35). Howell, Day and Sheehan thought interim guidelines until a standard is promulgated would be a good idea (M9:33-35). Sheehan opined that the committee could release its report as guidelines if OSHA does not act in a timely manner (M9:33-35). White suggested guidelines with the threat of a standard if guidelines did not work, and gave examples of guidelines that work (M9:34-35).

Teitelbaum and Mirer strongly disagreed with interim guidelines (M9:34-35). Mirer explained that OSHA resources needed for standard promulgation would be used to develop the guideline (M9:35). Mirer urged the committee to

disregard the time it takes to develop a standard (M9:35). Lick explained that OSHA could contract someone to develop a guideline (M9:35).

CHAPTER SIX
Deliberations Related to Best Practice: Systems Management of Metalworking Fluids

6.1 GENERAL INFORMATION

Chapter Three of this MWFSAC report discusses the technological feasibility of controlling MWFs. As noted in the earlier chapter, the Systems Work Group defined the role of a systems approach as managing the fluid, integrating and controlling systems that result in exposure control and enhanced MWF and machining performance (M8:3). The Systems Work Group noted the multiple purposes of MWFs, and the overlapping, and sometimes conflicting responsibilities of those employed to manage the fluid, produce useful products, operate the facility and protect the health and safety of employees (Systems, 1999). A systems approach can overcome these conflicts and provide for continuous improvement (Systems, 1999).

The discussions explained in Chapter Three are focused on ways of reducing exposure. The emphasis of this earlier chapter was divided between fluid management and exposure control technologies such as enclosure and ventilation, and the technological feasibility of these actions. Chapter Six addresses how to put together a systems management program for MWFs. Chapter Nine addresses training which must integrate into Systems Management.

The systems work group was charged with finding speakers and resources related to systems management. This work group and the committee as a whole helped provide the basic approach to systems management outlined later in this chapter.

Many individuals and groups outside of the MWFSAC have invested their time and money developing ways of managing the MWF environment. Some MWFSAC committee members have been involved in this work. A very detailed and useful product of these efforts was developed by individuals and groups representing industries that are MWF suppliers and users. This product is the ORC Management of the Metal Removal Fluid Environment. The first edition of this document was explained to the MWFSAC in late 1997. With input from the committee and others, this document was revised and a draft second edition was presented by a group of speakers at the eighth meeting in February, 1999. A CD/web version was presented to the committee at the ninth meeting in May, 1999.

6.2 SPEAKERS AND PRESENTATIONS

Committee member, Dr. Hank Lick, provided an overview of systems management (M2:15-17). Another committee member, Frank White discussed the development of the ORC Guide (M2:16). Dr. James d'Arcy, General Motors described how to use the ORC Guide (M8:6-7). Darrell Matthias, ORC, explained how the document can be used. Dr. John Howell, committee member and Dr.

Daniel Goon, Castrol, addressed issues related to product stewardship (M5;23). Dr. William Watt, Chrysler Corporation presented information on facilities and equipment. Ike Tripp, Etna, addressed fluid management principles (M8:8). Michelle Lantz, Caterpillar Corp., discussed systems management committees (M8:10). Dan Broghammer, Deere, and Greg Williams, Caterpillar, discussed fluid delivery and filtration. Tom Slavin, Navistar, addressed training and safety issues.

6.3 BACKGROUND INFORMATION

Howell outlined the actions an enlightened employer would take with MWFs (7:26). A systems approach would be used: workers would be trained about the fluids, the supplier would have a product stewardship program, and an ORC outreach program would exist (M7:26). Fluids would be properly selected and appropriate concentrations used, monitored and managed (M7:26). Good industrial hygiene practice would be followed, and all machines would be locally exhausted (M7:26). Exposure monitoring and medical management would be done (M7:26). Additional details of what is included in systems management is provided in Chapter Three of this document.

6.4 REVIEW OF AVAILABLE INFORMATION

6.4.1 Experiences and Resources Related to Systems Management

d'Arcy and Mattheis described the organization and structure of the ORC document, CD, and the web based version using hypertext (M8:6,12; M9:5). The website has 70+ interlinked pages with a 271 page print version (M9:6). Searching is possible with the web and CD versions (M9:9). Mattheis noted the intention to have the document available free on the Internet, and at cost in CD-ROM format (M8:10; 9:6). Mattheis stated the only limitation was that information be copied in its entirety and not sold commercially (M9:6). Continuous updating will be done (M8:11).

Mattheis hoped to develop a question and answer bulletin board with an expert panel (M8:11). MWF manager certification programs are being discussed along with training seminars and other outreach efforts (M8:11). More on these issues is found in Chapter Nine.

d'Arcy stressed the importance of active management of the very complex fluid environment (M8:6). d'Arcy highlighted the quick start chapter of the ORC document which describes how to navigate the document (M8:6; M9:6). He noted other chapters on the fluids, management, health issues, facilities and equipment, employees, management programs and quality assurance (M8:6).

d'Arcy explained that the document was designed for the janitor as well as the plant engineer (M8:6). d'Arcy noted that the reading level was viewed as sixth grade level (M8:12). A question and answer format is used and self assessment checklists are available (M8:6). Tools for improvement are provided (M8:6). The document is a dynamic guideline and will be modified to include new information (M8:6).

Howell highlighted fluid topics covered in the document, such as fluid use

and selecting fluid suppliers (M8:7). Howell noted descriptions and functions of the fluid and some typical compositions (M8:7). A flow chart of the manufacturing process describes potential problems with the fluids such as contamination and microbial growth (M8:7). Howell noted how fluids can get out of control and potentially cause increased occurrences of dermatitis (M8:7).

Howell explained that the second part of the chapter on fluids addresses how to choose a fluid supplier and supplier support (M8:7). He noted characteristics of a good supplier who will provide good systems product quality and technical support, and be ISO 9001 or QS 9000 certified (M8:7). The supplier must provide the appropriate fluids for the specific operations in a shop (M8:7). Compatibility between other machine related fluids and metal removal fluid is important (M8:7). Another selection criterion is the ability of the supplier to provide a fluid management program if the user needs an externally provided one (M8:7). Other supplier attributes include: a customer support program, and a product stewardship program (M8:7).

Howell noted that health, safety and environmental characteristics were the first selection criteria for a fluid, followed by compatibility and performance characteristics (M8:7). Howell noted new information available such as misting characteristics, raw materials used and the toxicity of the whole fluid as used compared to components (M8:7). Howell explained how fluid life can be extended by proper fluid selection (M8:7).

Tripp explained how the ORC document addresses management of the fluid (M8:8). He stressed looking at individual components and the entire process including effects of previous operations (M8:8). Tripp highlighted sections on managing the fluid in use, renewing or changing over systems and dealing with environmental concerns (M8:8).

Tripp outlined important management components including: a designated responsible person in charge, proper cleaning and disinfecting of machines, high water quality for water based fluids, and on-going maintenance of machines to prevent leaks and contaminants (M8:8). He stressed how proper management could lengthen tool life and this means less time changing tools resulting in less exposure during tool changes (M8:8).

Tripp stated critical fluid parameters to consider such as: concentration, stability, lubricity, foaming, microbial concentration, vulnerability to tramp oils, and extent of contamination (M8:8). He noted that the ORC guide provides checklists and other ways to assess these parameters (M8:8). He provided examples of tests such as refractive index, alkalinity, and conductivity (M8:8). Observations such as appearance and odor are important for operators to report (M8:8). He shared an example of a log to record important variables (M8:8). Tripp noted other potential contaminants such as airborne dust (M8:8). Tripp explained that the operator has to be considered to reduce any potential for dermal or respiratory effects (M8:8).

Tripp explained a system renewal or change out and stressed that every part of the system must be cleaned to avoid reintroducing contaminated coolant (M8:8). The environmental section of the ORC document addresses

pretreatment and disposal of the spent fluid (M8:8). The document reviews airborne emissions of volatile organics and particulates (M8:8).

Howell discussed the health effects section of the ORC document, noting that it was not designed to take the place of the NIOSH Criteria Document and was not a summary of the medical effects literature (M8:9). The chapter includes routes of exposure for operators and others, limited information on health effects, prevention of these effects, and discusses MSDSs (M8:9).

Watt provided an overview of how the ORC document addresses facilities and equipment (M8:9). Information is provided for those building a new facility, updating an existing facility or using their current facility (M8:9). Ideal building characteristics, ventilation, and enclosure design are addressed (M8:9).

Broghammer discussed additional design considerations for fluid delivery systems and the differences between self contained vs. central fluid systems (M8:9). Williams described the importance of fluid filtration and what the document provides to address this issue (M8:9).

Slavin discussed the ORC document and training (M8:9). More information on this is given in Chapter Nine of this MWFSAC report on training. Slavin also addressed other issues such as machine safety and personal protective equipment (M8:9,10).

d'Arcy spoke on how the document deals with exposure assessment which includes both a qualitative and quantitative assessment (M8:10). Baseline and periodic sampling and a planned exposure reduction program should be implemented (M8:10). More information on exposure assessment is provided in Chapter 7 of this MWFSAC report.

d'Arcy explained that an exposure limit alone would not ensure elimination of health effects, especially if HP is considered (M8:10). The ORC document recommends everyone be below 2 mg/m^3 with 1 mg/m^3 as a target (M8:10).

Mattheis discussed medical surveillance and monitoring, noting that the document may include what was developed by MWFSAC (M8:10). More information on medical surveillance is in Chapter Eight in this MWFSAC report.

Lantz explained that the first approach in actual managing was to put together a committee representing different groups in the work place (M8:10). She recommended including: maintenance, operators, safety, chemical management, operations and manufacturing, machine tool designers and waste treatment (M8:10).

Goon spoke about ILMA Product Stewardship and how it integrates into the other issues that have been discussed (M8:11). Other information he and Howell provided can be found in Chapters Three and Nine of this MWFSAC report. Howell outlined ILMA's Product Stewardship activity (M7:32). There was an implementation task force consisting of three companies which conducted a pilot of a draft program (M7:32). Results of this program are expected in late 1999. ILMA has 100 member companies that produce MWFs which is about 75% of the US production of MWFs (M4:4).

6.4.2 Additional Resources

The systems group recommended resources in addition to the ORC document (M8:5). These resources include: the ANSI B-11 Mist Control document, NIOSH Criteria Document, and the ACGIH Ventilation Manual (M8:5). Howell cited the National Center for Manufacturing Sciences Metalworking Fluids Optimization Guide (M8:7). Literature about microorganisms and MWFs can be obtained from Biosan, Warren, MI. Handouts of Lick, Gauthier and Burke also provide supplementary information (Lick, 1997; Gauthier, 1997; Gauthier, 1999; Burke, 1998). Additional references are found in Attachment #6.

6.5 CONCERNS AND LIMITATIONS

6.5.1 Size of Business

Burch thought the ORC document for systems management was valuable for small business and was encouraged by the use of CD-ROMs and websites (M8:12). He thought the hypertext web version would be useful in obtaining information quickly, especially in crisis situations (M8:12). He noted that small business does not always access information like this, or like the OSHA consultation program, as much as it should due to lack of knowledge or lack of time (M8:12). Burch explained that the document begins to present a system that any size business could integrate into their operations (M8:12).

Sheehan asked if the ORC document would prevent the poor decisions evident in a small business site visited by the group (M8:12). She was concerned about the impact of the document in preventing situations in which suppliers were victimizing small business (M8:12). Cox thought the document was a fine teaching tool and may prevent the poor decisions seen in the plant visited in Cleveland (M8:12). Howell thought it would not solve all problems, but that combining the document, the web version, education, outreach and stewardship could go a long way to changing behavior (M8:12).

Burch noted that other issues were at work besides what is addressed in the document, such as some workers not wanting to report problems because of fear of job transfer and reduced pay (M8:12). Burch explained that in a small business because of lower pay, there is less incentive to stay in a job with, e.g., irritation, if you know there is another job in a cleaner shop for as much or better pay (M8:12). Burch noted that in small business, workers complain to the president, not a medical department (M8:12). The president has an incentive to improve the situation so as not to lose the worker to a competitor (M8:12).

Cox noted that no matter what action the MWFSAC takes, the ORC document is a great document and he would push for its availability to his membership (M8:12). Cox agreed with Kushner that health and safety go hand in hand with product quality and profit (M8:12). The smart businessman knows that you can replace a machine easier than skilled labor (M8:12). Cox thought it should be read by the owner and foreman in a small shop (M8:12). Cox noted that these facilities do not have anything available now (M8:12).

6.5.2 Assessment and Accountability

Committee members were concerned about how the quality of a systems

management program can be determined. More information on these concerns are in Chapters Three and Seven of this MWFSAC report. Members were also concerned about accountability of suppliers and users.

White noted that assessing a fluid management program would be similar to assessing a health and safety program (M7:23). He challenged the group to come up with criteria that determine effectiveness (M7:23). Criteria were incorporated into a qualitative assessment tool that is part of Chapter Seven of this report.

Mirer gave an example of a NIOSH HHE that demonstrated that a poor systems management program did not protect workers (M8:5). He was concerned that this poor program would meet any OSHA or ISO proposed program (M8:5). Mirer was concerned that the ORC document does not help with the assessment of which products are going to be good or not good from a health standpoint (M8:13).

Wegman was concerned that the checklists presented in the ORC document are a beginning, but are not enough to determine the adequacy of a fluid management program (M8:8). He noted the linkage of systems management to the medical surveillance program which has the fluid management program as a trigger (M8:8). He noted that as stated, this is an audit, but not an audit that determines if the program has reached or exceeded the threshold of a good management program (M8:8).

Howell explained that the supplier is accountable for providing education and outreach to customers (M8:12). Howell noted that no one is going to check the supplier except themselves (M8:12). Goon explained that the ILMA product stewardship group was working on the issue of accountability (M8:12).

Sheehan questioned who is responsible in the team format recommended for systems management (M8:12). Lantz noted that people should be responsible for their own well-being to report problems and find someone to help (M8:12). Lantz viewed that the employer is responsible to provide a work environment and team to solve the problem (M8:12). Lantz thought that the team peer pressure was useful for behavioral change (M8:12). Cox explained that the ultimate responsibility was the owner's (M8:12).

6.5.3 Is the ORC Document Enough for Systems Management?

Cox commented that the ORC document was a stand alone document to assist different size businesses in the management of MWFs (M8:7). White noted that the document is stand alone (M8:7).

O'Brien complimented ORC on the quality of the document (M8:7). He disagreed with the document being stand alone because the Disease section is written to be inoffensive instead of complete (M8:7). White admitted the limitations in the document in areas such as medical surveillance and exposure levels, noting that these issues would evolve (M8:7). Howell explained that ORC did not want to duplicate the NIOSH Criteria Document (M8:7).

6.5.4 Health Issues Related to Systems Management

The relationship between systems management and health effects is outlined in Chapters Two and Three of this MWFSAC report. Information discussing what additional health information, other than what is outlined in the ORC document, is needed in a systems management program is provided here.

Newman noted that one of the goals of managing the fluid is to control the health effects and recommended more emphasis on relating any systems management program and health (M8:8,11). He noted simple medical terms like "cough" should be used in training workers and clarifying effects (M8:11). Sheehan and Lantz agreed on a focus on symptoms so workers report health problems (M8:12).

Newman advised against listing other factors that could cause health effects because they understate the health effects a systems management program is trying to prevent (M8:8). Lantz agreed that the operator's health and safety as well as teamwork need more emphasis in the ORC document (M8:8).

O'Brien viewed that the 2 mg/m^3 time weighted average stated in the ORC document as an acceptable limit, had no basis (M8:11). He noted that it was inconsistent with ILMA's own recommendation of this value for a peak (M8:11). O'Brien explained that 2 mg/m^3 as a peak value is roughly equivalent to 0.5 mg/m^3 as a time weighted average (M8:11).

Anderson recommended including MSDS's under technical support provided by suppliers (M8:7). Information provided by suppliers about the toxicity of individual components and aerosol generating potential of the fluids would be useful (M8:7). Mirer appreciated the fluid suppliers removing problem ingredients, but was concerned with what was remaining (M8:13).

Teitelbaum questioned the use of terms in the ORC document, recommending that physicians peer review it (M9:6). Teitelbaum recommended avoidance of the term "healthy fluid" which he thought implied a healthy environment (M8:8). Teitelbaum noted that the "integrity of the fluid" would be a better term (M8:8). Lick indicated the extensive peer review the document received from all who were involved in its production (M9:6). Teitelbaum recommended review by the American Thoracic Society or the American College of Occupational Medicine (M9:8).

White agreed with Frederick and Newman that the section of the ORC document defining causes of skin irritation was not adequate (M8:9). White noted the difficult balance between providing adequate health information and making the information useful to the reader (M9:7).

6.5.5 Other Issues Needed in a Systems Management Program Document

Burch recommended more clarity about which advice in a systems management program applies to which type of fluid (M8:8). This would reduce confusion in shops (M8:8).

Mirer recommended making ORC's checklists more performance or objective oriented (M8:11). Terms need to be clearly defined in a program, according to Frederick (M8:9). White noted that the ORC document needed to do a better job of defining terms such as "high mist level" (M8:9).

Newman agreed that the ORC document was a strong one and a powerful teaching tool for some groups in industry but did not think it was written at a level for workers (M8:11). Newman and Sheehan thought the level was as a trainer's manual (M8:11).

6.6 LINKAGE OF DISCUSSIONS TO OSHA ACTION

White hoped OSHA would embrace the ORC document and noted that industry would rather have a voluntary compliance program than regulation (8:7). He explained that with the ORC document industry has shown that it is willing to do something (M9:34). If the voluntary approach would not work, some combination may be appropriate (8:7). d'Arcy viewed the ORC consensus document approach as more valuable than a rigid regulation which could not incorporate new information (8:6).

Teitelbaum explained his concern was an evidence question and if one believes voluntary approaches will work, it needs to be proven (M8:11). He cited OSHA court cases that have required statistical evidence (M8:11).

Lantz noted that the ORC document can help protect the greatest number of people from threats to their health and safety from working with MWFs or in the MWF environment (M8:10). Lantz emphasized that OSHA should provide information found in the ORC document to get information out to the shop floor (M8:10). It is essential to teach people to be proactive so they can recognize a fluid problem and know who can help them solve it, according to Lantz (M8:10).

Howell noted that the ORC document contains elements of recommended practice that mirrors what OSHA would recommend if it promulgated a standard or guideline (M9:8). He explained that the ORC document would get us further down the road than anything OSHA will do (M9:8).

O'Brien noted that the production of the document was due to the threat of regulation (8:7). Mattheis agreed that without potential regulatory action by OSHA, the ORC document would not exist (M8:10). Mattheis explained the limits of OSHA in protecting worker health citing the focus on inspections of large workplaces (M8:10). Mattheis was concerned about how to reach smaller workplaces who have very little systems management (M8:10). Mattheis noted that the impact of OSHA can be much greater than just inspections (M8:10). Mattheis agreed that the document is not stand alone but needs the help and input of industry, government and labor (M8:10). Mattheis urged the development of alliances to help distribute the information needed to improve these workplaces (M8:10).

White emphasized the importance of partnership and suggested that MWFSAC go beyond the charter to take advantage of useful products such as the ORC document (M8:11). He noted that if action can be taken without a standard, or in preparation for a standard, or as part of a standard, it should be considered (M8:11). White explained it could take until 2005 for any standard to be implemented (M9:5). The ORC guide provides an opportunity for the health and safety community to act to reduce risk now (M9:6).

Mirer explained that the combination of the ORC document, other industry

consensus documents, and the NIOSH Criteria Document provide a significant package for compliance assistance.

Shortell cautioned against viewing the ORC Document as a committee document (M9:8). It would take too much time to change the May,1999 version of the ORC document to make it acceptable to the whole committee (M9:8).

Mirer recommended a short form summary of what was presented in the ORC document (M8:11). He suggested including fluid management, enclosure and ventilation issues (M8:11). He recommended developing 10 to 12 key recommendations for MWF management into a document that could be included in a guideline or standard (M8:11).

6.7 COMMITTEE DECISIONS AND RATIONALE

No formal vote was taken to accept or reject the ORC Guide to Controlling the Metal Removal Fluid Environment. The general consensus was that for most topics, other than health issues or defining an exposure limit, the document was a very useful contribution to systems management of the MWF environment. Chapters Two and Five of this committee report provide the committee's assessment of the health issues and exposure limit. Concerns still remained on how to assess a systems management program's quality.

The committee decided to cite the ORC Document as a definitive resource for systems management. The committee summarized the following pages as the basis for OSHA to include in either a guideline or standard. The best practice for systems management of MWFs includes:

1. *Management commitment* demonstrated through policy, and resource allocation.
2. A *competent individual* placed in charge of a systems management program.
3. An *established, on-going relationship with a reputable fluid supplier* that includes: proper selection of MWFs, as needed substitution of MWFs as a control strategy, effective and complete MSDSs, on-going consultation and product stewardship.
4. An *MWF team* consisting of, but not limited to: the systems manager, machine operators, supervisors, maintenance, plant engineers, ventilation engineers, industrial hygienists, safety engineers, medical staff, environmental engineers, and machine tool designers. For different size facilities, it is recognized that individuals in each of these disciplines may not be on staff. Individual staff members may have multiple responsibilities that include or relate to these disciplines. Teams should reflect these disciplines and/or responsibilities, and use the available company expertise to maximize effective MWF systems management. Both management and employees should be represented on the team.
5. *Written, followed and documented standard operating procedures* for fluid selection, use, water quality, cleaning, filtration and biocides.

6. *Written, followed and documented standard operating procedures* for: daily and weekly fluid measurement, charting of fluid variables, action when variables trend outside of established limits, handling of crises.
7. A *written, followed and documented standard reporting procedure* for everyone in the MWF environment to report technical and/or health problems.
8. *Written, followed and documented standard operating procedures* for exposure assessment, exposure control and environmental control.
9. *Training* of all individuals in the MWF environment about their role in MWF management, symptoms of potential health problems, and the above listed standard operating and reporting procedures.
10. *Recordkeeping* should include information collected about: fluid variables, crises actions, exposure data, exposure control documentation, reported health effects and environmental data. Employee health information should be handled in accordance with existing OSHA regulations. Records of all other information noted above should be easily accessible and aid employees and managers in the continuous improvement of the MWF environment.

CHAPTER SEVEN
Deliberations Related to Best Practice: Exposure Assessment

7.1 GENERAL INFORMATION

Exposure assessment was discussed primarily at the seventh, eighth and ninth meetings and was discussed at other meetings. An Exposure Assessment Work Group was developed and the product of their work and an *ad hoc* work group is found at the end of this chapter. Exposure assessment includes the use of exposure limits, representative sampling strategies, initial and as needed repeat monitoring, statistical treatment of data, provisions for determining the need and termination of monitoring, standardized monitoring procedures with defined accuracy and precision, evaluation of controls and employee notification (Exposure Assessment Work Group, 1999). Exposure assessment can also employ qualitative assessment tools. This chapter focuses on exposure assessment, more on typical exposures can be found in Chapters Two and Three.

7.2 SPEAKERS AND PRESENTATIONS

Dr. James d'Arcy, General Motors, spoke on his research on comparing methods, the development of the ASTM method, and how the ORC Document addresses exposure assessment (M8:10). Committee member, Dr. Dennis O'Brien provided an overview of air sampling and presented information for his NIOSH colleague, Dr. Robert Glaser (M7:12). Committee member, Dr. Frank Mirer provided a systems approach to exposure assessment (M2:12-13). Greg Piacitelli and Dr. Karl Sieber, NIOSH, discussed sampling methods in their presentations on the NIOSH Small Business Study. Dr. Daniel Goon, Castrol noted some sampling issues during a panel discussion. Dr. Eugene White discussed endotoxin sampling during the ninth meeting. The exposure assessment work group provided a recommendation on quantitative exposure assessment and an ad hoc work group provided a recommendation on qualitative exposure assessment that the committee reviewed. These two items are at the end of this chapter.

7.3 BACKGROUND INFORMATION

The evaluation of the work environment is done using exposure assessment, which can include qualitative and quantitative evaluations of exposure. The committee determined that the critical health concerns were non-malignant respiratory effects and dermatitis, followed by cancer. As such, the focus of exposure assessment for MWFs is on the inhalation and dermal routes of entry. Air quality can be assessed qualitatively and quantitatively while the dermal route is usually assessed qualitatively.

O'Brien explained that air sampling addresses toxins that enter via the inhalation route (M7:12). O'Brien noted that air sampling is done to determine the

health risk and relate these results to dose-response (M7:12). Air sampling is also done to comply with regulations and monitor the performance of engineering controls (M7:12). Mirer explained that exposure assessment is a trigger to determine if any employer action such as more sampling, improved ventilation or medical surveillance is needed (M8:6). Howell noted that exposure assessment can relieve an employer of other obligations (M8:6). Sampling helps identify the high hazard jobs or tasks so we can determine ways to reduce these exposures (M7:12).

O'Brien stated for most air measurements, a known volume of air is drawn into a collection device by a pump and the contaminant is collected into or onto a medium (M7:12). The medium, such as a filter for aerosols (dusts and mists) or charcoal for gases, is analyzed in the laboratory (M7:12). Other options are available for gases and some direct reading light scattering instruments can be used for aerosols (M7:12). Diagrams and pictures of sampling equipment can be found in handouts (O'Brien, 1998; Piacitelli, 1998).

O'Brien highlighted air sampling rules such as having a defined and low limit of detection, collecting the appropriate amount of contaminant, and using the proper medium and correct flowrate (M7:12-13). He noted that some sampling strategies address identifying the maximum risk employee for each work operation (M7:13). He described homogeneous exposure groups (HEG) as those employees who would not have a significant difference from one another in their exposures because of the exposure mechanism (M7:13). Representative sampling can be done on some members of a HEG to represent the group (M7:13). Factors such as work hours and machine operating hours are variables to consider, according to Howell (M8:6).

The best air sampling protocol, according to O'Brien is full-period, consecutive sampling and next best is a full shift single sample (M7:13). Of less quality is partial period sampling, and grab sampling is the least desirable approach (M7:13). Time weighted averages (TWAs) are calculated from full-period, consecutive samples by multiplying each concentration by its time period, summing these and dividing by the total time (M7:13). Mirer explained that for a typical filter, sampling is done for eight hours (M2:12).

According to O'Brien, a ceiling limit is a level that is not to be exceeded at any point during the day (M7:13). A grab sampler or direct reading instrument may be able to detect excursions above a ceiling value with measurements taken during the period of maximum or peak exposure (M7:13). If 11 to 13 random grab samples are taken during the day, one would be 95% sure of collecting at least one sample in the top 20% of the exposure range (M7:13).

O'Brien explained that the frequency of sampling for regulatory purposes is usually based on an action level that is approximately half of the PEL (M7:13). Situations above the PEL may require quarterly sampling, while those between the action level and PEL may be done every 6 months, and below the action level, less frequently, if at all (M7:13). Mirer explained if one random sample on one day is above the action level, it is predicted that on any given day, exposures above the PEL will occur (M7:13).

Mirer noted the difference between area samples and personal samples, and that area values are usually higher than personal (M2:12). O'Brien recommended taking samples during different seasons (M7:13).

Sampling and analytical methods have different abilities to detect the substance of interest, d'Arcy described the limit of detection (LOD) as three times the standard deviation of the blank values (M7:17). The limit of quantification (LOQ) is ten times the standard deviation of the blank values (M7:17).

O'Brien described the importance of particle size and respiratory deposition in the ultimate toxicity of an aerosol (M7:13). O'Brien described the ISO/ACGIH definitions for particle size (M7:13). Particles that can reach any part of the respiratory tract are defined as inhalable (M7:13; ACGIH, 1999). Those that can enter the trachea and reach the airways and lung are called thoracic (M7:13; ACGIH, 1999). Particles less that can reach the air exchange region are respirable (M7:13; ACGIH,1999). The equations that describe the three particulate mass fractions and tables noting collection efficiencies by size are found in the ACGIH TLV booklet (ACGIH, 1999)

7.4 REVIEW OF AVAILABLE INFORMATION

7.4.1 Experiences and Resources Related to Qualitative Exposure Assessment

d'Arcy described qualitative exposure assessment, noting the importance of answering the questions who is exposed, where and how they are exposed and what controls exist (M8:10). Mirer described information gathering at a plant, e.g. previous sampling records, floor plans, ventilation system diagrams and testing results (M2:12).

Dermal exposure can only be assessed qualitatively and work practices are a key component (M8:10). Qualitative observations may lead to quantitative exposure assessment (M8:10). Qualitative exposure assessment is part of the ORC Document's approach, according to d'Arcy (M8:10).

7.4.2 Experiences and Resources Related to Quantitative Exposure Assessment

7.4.2.1 *Concepts in Quantitative Exposure Assessment for MWF Environments*

The work area, according to the exposure assessment work group, is the immediate vicinity of the MWF using processes and equipment and includes immediately adjacent areas which are not separated by a physical barrier to the motion of air (M8:24). Mirer defined direct exposure as that from a specific machine to that machine's operator, and indirect exposure to anyone else due to carry - over from work stations (M2:12). He described exposure as the sum of the machine source, the fluid recirculation system, the air cleaner recirculation, and the carry over (M2:12). Mirer explained that small particles can drift away from the generation point and may pass through an air cleaner while larger particles are controlled well by enclosure (M2:12)

Mirer suggested measuring exposure at a station when 1)nothing is running, 2)no production but the fluid is running, 3)production is occurring. He described information gathering at a plant, e.g. previous sampling records, floor

plans, ventilation system diagrams and testing (M2:12).

According to d'Arcy, the ORC Document recommends exposure monitoring when there is a respiratory complaint (M8:10). Baseline and periodic sampling and a planned exposure reduction program should be implemented, according to d'Arcy (M8:10)

As noted in Chapter Five, there are a variety of voluntary consensus standards on sampling and analysis and other activities related to MWFs. Since fluid management affects exposure, some integration between exposure assessment and measurement of fluid is needed. Fluid management involves sampling but this is not traditionally viewed as exposure assessment. Measuring fluid variables such as bacteria, pH, and hardness are discussed in Chapters Three and Six.

7.4.2.2 "*Total" Particulate Sampling and Analysis*

Total particulate can mean all of the particles collected on a filter including MWFs and background aerosol, as well as meaning samples collected with a closed face sampling cassette, according to O'Brien (M7:18). For this report, "total" particulate refers to a sample taken with a closed face filter sampling cassette whose filter has only been analyzed gravimetrically. This "total" has not been extracted and as such may contain background aerosol. This "total" has not been size segregated.

The total particulate method is based on the NIOSH 0500 method. d'Arcy found in his comparative study, a coefficient of variation for the NIOSH 0500 method that was much higher than what is stated in the NIOSH method (M4:3). An article by Wilsey (1996), looks at the relationship between "total" and inhalable particulate for MWFs.

Mirer stated that the total particulate method has advantages such as ease of measurement and minimal analysis (M2:12). He explained that exposure gradients from near field (close to the source) to far field (far from the source) are less with total particulate sampling (M2:12). Mirer noted that bacterial levels correlate with total particulate (M2:12).

7.4.2.3 *Extraction Methods of Analysis*

Some companies have used a variation of the total particulate method that involves extraction. In these methods, the filter is weighed before and after use. After the second weighing, the filter is extracted with a solvent or multiple solvents. The filter is dried and re-weighed. The difference between the second and third weights is viewed as MWFs or oil mist. Extractables just include the fluids, according to d'Arcy (M4:3). Lick noted that the extractable method was developed to separate out the issue of tobacco smoke and other non MWF particulate (M4:2).

d'Arcy described his study comparing the three methods used by the American auto industry (M7:16). Area sampling was used for the comparison to reduce the variability due to worker's activities (M7:16) Triplicate samples were collected by each method and sampling was designed so all four types of fluids

were sampled at each company (M7:16). Each analytical method used gravimetric techniques comparing before and after weights of a filter (M7:17). One method followed NIOSH 0500 and just performed before and after total weights (M7:17). Another method did these weights and extracted the filter with toluene, while the third method used trichloroethylene instead of toluene as the extraction solvent (M7:17). Each of the extraction methods weighed the filter a third time (after extraction) and used the difference between the second and third weights as MWFs (M7:17). d'Arcy noted that none of the methods came close to the published value for coefficient of variation of the NIOSH 0500 method (M7:17). Due to the intra-method variability, little inter-variability could be discerned (M7:17).

As a result of this work, there was an interest in improving the method for sampling and analyzing MWFs (M7:17). A group of AAMA, NIOSH, ILMA, OSHA, university and small business representatives worked with two different contract labs to develop the method (M7:17). The goals were to improve the specificity of the method, improve sensitivity and to correlate with health effects (M7:17). The group looked at the compositional variety of the fluids and decided against using a specific chemical assay and focused on a gravimetric/extraction method (M7:17).

The group wanted to be able to compare with historical data (M7:18). Teflon was chosen for the filter media to improve sensitivity, although this sensitivity has yet to be proven (M7:18).The extraction methods used by two of the auto companies using toluene and trichloroethylene only obtained non-polar components, according to d'Arcy (M7:17). A solvent mixture of methylene chloride, toluene and dichloromethane was developed to obtain polar and non-polar components (M7:18). The ASTM PS42-97 was developed from this group's efforts.

NIOSH is currently evaluating the ASTM PS 42-97 method. Glaser provided early results to determine characteristics of the method (M7:18-19). Of the MWF samples tested, 99.4% were soluble in the ternary blend of solvents (M7:19). One fluid, "Glacier" formerly made by Monsanto, now by Solutia Inc. was not soluble (M7:19). Limits of quantification have been calculated and most were less than 0.2 mg/m^3, but two were equal to or greater than 0.4 mg/m^3, the NIOSH thoracic REL (M7:19).

d'Arcy highlighted the specificity of the ASTM PS42 -97 method (M8:10). The sensitivity and limit of quantification are not an improvement on other methods, according to d'Arcy (M8:10). Having each lab determine its own limit of detection and limit of quantification is an improvement, according to d'Arcy (M7:19).

The ORC Document incorporated the ASTM PS42-97 method (M8:10). Piacitelli explained that the NIOSH Small Business Study used the ASTM PS 42-97 method (M4:1).

Mirer stated that oil mist is typically 80% of the total particulate (M2:12). d'Arcy explained that he found a ratio of 0.8 for extractable/total in his comparative study of the methods used in the auto industry (M4:3). Sieber noted

a ratio of 0.7 for extractable/total in the NIOSH Small Business Study and this ratio was based on averaging the individual ratios (M4:3).

7.4.2.4 *Size Selective Sampling*

Size selective sampling refers to any sampling that segregates portions of the aerosol by size. Most size selective sampling done today determines one or more of the inhalable, thoracic or respirable fractions. Analysis of the collected sample can include gravimetric analysis, extraction or other chemical analysis.

Piacitelli explained that in the NIOSH Small Business Study, they conducted thoracic sampling using a BGI cyclone followed by a Teflon filter (M4:l). O'Brien noted that this sampler can be used as either a thoracic sampler or respirable sampler depending on the flowrate used (M7:13). For the thoracic sampling, NIOSH used both the NIOSH 0500 and ASTM 42-97 methods for analysis of the filter (M4:1). A Marple impactor was used to determine inhalable, thoracic and respirable fractions (M4:1). The stages of the Marple impactor were only analyzed for total mass on each stage (M4:1).

Individual ratios of thoracic/total ranged from 0.2 to 7.4 in the NIOSH Small Business Study, according to Sieber (M7:16). He attributed the variation to sampling variability (M7:16). Using a trimmed mean (5%-95%) method, the ratio of thoracic/total was 0.6 (M7:16).

Sieber viewed thoracic as a logical choice (M7:16). Woskie's study, according to Sieber, showed a geometric mean diameter between 2 and 8 Fm (M7:16). In his study, Robbins found that about 10% of the thoracic particulate was due to cigarette smoke (M5:10). Additional information about size selective sampling can be found in the ACGIH, *Particle Size-Selective Sampling in the Workplace* (1985).

7.4.2.5 *Use of Direct Reading Instruments*

Real time or direct reading aerosol instruments are based on the interaction of the particles with light. The interaction in the most commonly used instruments is light scattering. The more particles in the air, the more scattering. The instrument reads out a concentration in either particle number or concentration. The instruments are calibrated using a standard dust or more appropriately by using side by side sampling with a gravimetric method.

These instruments can be used in multiple sites to develop a map of area concentrations. O'Brien explained that a real time or direct reading instrument can be run throughout the day at one site to determine peaks and averages (M7:15).

d'Arcy explained that real time monitors are thoracic monitors because their design precludes detection of particles larger than 10 Fm since these sizes do not scatter light well (M7:18). The TSI and MIE instruments have peak scattering at 4 Fm, according to d'Arcy (M7:18). At 10 Fm, the scattering would be equal to or less than 5% (M7:18). Correlation between total and direct reading instruments is complicated by this size response factor (M7:18).

Piacitelli explained that in the NIOSH Small Business Study, they used a

direct reading instrument to assess the areas with the highest exposures (M4:1). They used a Grimm light scattering device (M4:1).

7.4.2.6 *Endotoxin Measurement*

Endotoxins are explained in Chapter Two. Endotoxin can be measured in air by analyzing filter samples or in fluid by assaying the fluid. E. White explained the ASTM PS 94-98 method for measuring endotoxin which includes: personal air sampling using a glass fiber filter, extraction, and the Limulus amebocyte lysate (LAL) assay for analysis (M9:1,3). The lysate used in the analysis has a proenzyme which converts to an enzyme in the presence of endotoxin (M9:1). Amino acids in the lysate convert to a peptide, para-nitroaniline in the presence of the enzyme (M9:1). The peptide is produced in proportion to the endotoxin present, and is measured colorimetrically (M9:1).

E. White explained that the LAL test is very sensitive, i.e., endotoxin can be measured in very small quantities, but it has false positives and false negatives (M9:1). According to E. White and Goon, the method has a low selectivity and the analytical kits used were not designed for environmental analysis, but for the pharmaceutical industry to test drugs and medical equipment to qualitatively assess if items were sterile (M9:1,4).

According to E. White, inter-laboratory comparisons of endotoxin data are not really valid due to variations in the analytical method (M9:1-2). The methods are fragile and operator dependent (M9:1-2). E. White noted that a round robin study of the ASTM PS 94-98 method is underway using identical sources of reagents and used MWFs (M9:3). The focus of the round robin study is to acquire reliable quantitative data to have a robust consensus standard method (M9:3).

E. White noted that endotoxin assays should be included in exposure assessment to help define the MWF condition (M9:5). E. White explained that endotoxin gives an indication of how many gram-negative bacteria are present, and combined with the total microbial count, can determine potential problems (M9:5).

Howell stated that if a regulatory standard was written today, endotoxin testing probably would not be included because more information is needed (M9:5). After the round robin studies, investigations on changes in endotoxin in aging fluids, animal and human studies are completed in a year or two, endotoxin measurement should be included, according to Howell (M9:5).

E. White believed that the endotoxin connection with MWFs can be elucidated through collaboration (M9:3). He stressed the need for airborne endotoxin exposure assessments and epidemiological studies done through collaboration among government, industry and academe (M9:3).

7.4.2.7 *Other Quantitative Assessment Methods*

Microorganisms and endotoxin can be measured in the fluid and in the air. The evaluation of these variables in fluids are discussed in Chapter Six, Systems Management.

Goon noted the problems with analyzing endotoxin explaining that is used due to a living source of the standard, the standard can shift (M5:24).

Electrostatic precipitators have been studied by the University of North Carolina team as a way to address volatilization (M7:14). A thorough analysis of this work is provided in Leith's article (Leith, 1996a).

Additional references are cited in Chapter Eight, Medical Surveillance and are also found in Attachment #6.

7.4.3 Measurements done in the Different Studies

NIOSH has used gravimetric and some infrared methods in its earlier studies, according to O'Brien (M7:14).

Piacitelli explained that the NIOSH Small Business Study used a variety of methods to assess the environment including: the NIOSH 0500 method, the ASTM PS 42-97 extraction method, thoracic sampling, impactor sampling, an electrostatic precipitator and a direct reading light scattering device (M4:1). Vapor sampling was not done (M4:1). Piacitelli explained that for the NIOSH 0500 method, they used a Teflon filter (M4:1).

The GM/UAW studies used impactors and gravimetric analysis, according to O'Brien (M7:14). According to Mirer, the studies by Kennedy, Greaves, Robbins and Rosenman as well as Kriebal use total particulate (M7:20).

7.4.4. Additional Information from the NIOSH Criteria Document

Chapter seven of the NIOSH Criteria Document provides information on the sampling and analysis of MWFs (NIOSH, 1998). A compilation of methods used at the time the document was written is found in Table 7-1 of the Criteria Document (NIOSH, 1998). Details about thoracic samplers are found in section 7.2.2 (NIOSH, 1998). A discussion of biases such as sampler inlet bias is found in sections 7.2.3 through 7.2.5 (NIOSH, 1998). Definitions of terms used in the determination of precision and accuracy are found in sections 7.2.6 through the end of the NIOSH Criteria Document chapter seven (NIOSH, 1998). The discussions of the committee used the NIOSH information as a baseline and added new information to the material available on exposure assessment for MWFs.

7.5 CONCERNS AND LIMITATIONS

7.5.1 Size of Business

Mirer recommended that OSHA send out a manual to small and medium size businesses on how to do air sampling and exposure assessment (M7:20). There was concern about the cost of sampling and analysis for small business and this is addressed in Chapter Four, Economic Feasibility. Letters from some small businesses indicate a concern about hiring professionals to do air sampling (PMPA,1999; PMA 1999). Some members noted that many small facilities would not need to do air sampling if a good qualitative assessment tool was available.

7.5.2 Sampling Problems

Each sampling and analytical method has its limitations. O'Brien noted that NIOSH has an accuracy criteria of +/- 25% of the true mean, 95% of the time which translates to a coefficient of variation of less than 12.8% (M7:14).

Mirer explained problems such as particle entry losses and evaporation (M2:12). The cassette method may under-sample according to O'Brien (M7:15). The "total" particulate sampler has been viewed by many aerosol scientists as inadequate to measure inhalable aerosol, according to Sheehan (M7:16). Other inhalable samplers collect more due to better inlet design and weighing of the whole device not just the filter (M7:16). A variety of articles by Vincent and Baron and others addressing the limitations of aerosol sampling are found in the *American Industrial Hygiene Association Journal, Applied Environmental and Occupational Hygiene* and *Aerosol Science and Technology.*

Mirer cited Leith's work stating that half the oil evaporates from the filter (M2:12). Mirer noted that Leith's data shows that the vapor phase is about equivalent to the particulate because Leith stated that about half of the total evaporated (M7:20).

O'Brien explained that gravimetric analysis is simple and consistent historically but subject to evaporation and is not specific (M7:14). It discriminates against dry machining methods (M7:14).

O'Brien explained that extraction differentiates MWFs from dust and is historically consistent with some datasets (M7:15). It is limited depending on the solvents used and is more expensive (M7:15). Sheehan and Howell hoped that if a fluid formulator had a fluid that could not be easily extracted by the ASTM PS42-97 method, the manufacturer would indicate this in their literature (M7:21).

According to O'Brien, infrared has calibration problems (M7:15). Impactors cost more and the sample is split, lessening sensitivity (M7:15). Precipitators are not well known (M7:15).

Direct reading instruments cost more and are more complex. Some limitations of light scattering according to O'Brien are: difficulty standardizing the response of the instrument and concerns about size, shape and refractive index effects (M7:14).Teitelbaum thought it may take more skill to assess a peak value than a TWA (M7:14). A well calibrated direct reading instrument may be acceptable, based on Abrams work, according to Mirer (M7:20).

O'Brien noted that people have unrealistic expectations of the accuracy and precision of instruments (M7:15). He noted variability during the day and Mirer thought the variability in exposures is much greater than the variability due to the method (M7:15,21). Mirer thought that the amount collected by any method is about 1/5 to 1/10 what the operator really receives (M4:3).

Lick disagreed with Mirer's estimates (M4:3). Lick stressed the importance of limiting variability (M4:3). A minor shift in results around 0.5 mg/m^3 could cost millions of dollars, according to Lick (M4:3). As the exposure limit drops, variability becomes more important (M3:4).

d'Arcy agreed with Lick and noted that if the coefficient of variation is 0.2, it is very difficult to prove you are less than 0.5 mg/m^3 (M4:3). d'Arcy showed results of a study he did of the GM contract labs (M7:17). In this study, he

submitted 20 blind blanks to each lab (M7:17). The three labs produced LOQs of 0.18, 0.25 and 0.34 mg/m^3 while the NIOSH 0500 predicts an LOQ of 0.12 (M7:17). d'Arcy noted that the 0500 method was developed for nuisance dust with a PEL of 15 mg/m^3 and that the lowest concentration recommended for the 0500 method is 0.75 mg/m^3 (M7:17) By pushing below what the method was designed to do, we cannot expect the same quality, according to d'Arcy (M7:17) The NIOSH 0500 method needs to be re-evaluated for lower concentrations (M7:17)

7.5.3 Background Values

Mirer emphasized the importance of knowing what to measure, and that cross contamination can be a health and measuring problem (M2:12). Mirer explained that assembly areas can receive some of the cross contamination depending on location and workplace layout (M2:12). Assembly areas are not zero and should be measured (M2:12). Outdoor levels are also a concern, according to Burch (M2:12).

Mirer noted that the background levels in the NIOSH Small Business Study were very low compared to data collected in auto plants (M4:2). A UAW/GM study showed the average background level of MWFs when only flumes were running was 0.11 mg/m^3 as total particulate. Another survey showed workers with exposures of about 0.5 mg/m^3 when their machine was not operating and only surrounding machines affected the exposure (M7:20). Another study Mirer showed, measured exposure and then shut off the ventilation (M7:20). It showed that ventilation reduced exposure to background values but that background values were around 0.5 mg/m^3 (M7:20). Mirer emphasized the importance of assessing direct exposure plus the background to fully evaluate the effectiveness of controls (M7:20).

O'Brien estimated background as 0.1 mg/m^3 if production is off and flumes were off (M7:20). In EPA non-attainment areas, outside particulate levels can be 0.07 mg/m^3, according to O'Brien (M7:20). Mirer noted outdoor averages of 0.03 mg/m^3 with excursions to 0.07 mg/m^3 (M7:20).

Additional information is provided in the handout on Air Sampling for Source Identification (UAW, 1999). The *Occupational Exposure Sampling Strategy Manual* is an additional resource (Leidel *et al,* 1977).

7.5.4 Appropriate Metric for the Health Effects

O'Brien explained that if cancer was the basis of a regulation, inhalable full shift samples would be the air monitoring method (M7:11,17). If any regulation was based on respiratory effects, he viewed that thoracic particulate would be the monitoring method (M7:11). d'Arcy agreed, noting that we should also consider the respirable portion (M7:17). O'Brien thought thoracic sampling both as full shift and peak should be considered (M7:15)

Wegman stated it was not clear to him that the respiratory effects that have been identified are linked to respirable or thoracic particulate (M7:11). He

stated we do not know how asthma gets triggered and we do not know the route of entry for the agent that causes HP (M7:11).

Sieber noted that total particulate sampling is more common and widely available for use than thoracic (M7:16). d'Arcy thought there were enough thoracic samplers available (M7:18).

Sieber viewed that the health effects were better related to thoracic (M7:16). Previous studies showed a very high correlation between thoracic and total, according to Sieber (M7:16).

Robins explained that both the bacterial particulate and thoracic particulate fit the health effects well in his study (M5:9). O'Brien noted that bacterial testing or endotoxin testing may be a way to also determine the effectiveness of a fluid management program (M5:9). Robins viewed the endotoxin testing as very expensive and difficult (M5:9).

O'Brien explained that the values in the NIOSH Small Business study for area and personal samples were not that different (M7:15). Sieber explained that these values were not statistically significantly different (M7:16). O'Brien opined that the mist size may make exposure homogeneous in a shop (M7:15). Burch noted that OSHA regulates personal exposure, not plant area levels (M7:14). O'Brien viewed area sampling as a useful supplement to personal sampling (M7:15).

Mirer viewed that there was no health basis for using extractables (M7:20). There is no health basis for concern about vapor, according to Mirer (M7:20). Howell agreed with Mirer that all the epidemiological studies used thoracic particulate without extraction (M7:88).

O'Brien noted that in the Small Business study, a peak of 2 mg/m^3 corresponded to a TWA of 0.5 mg/m^3 (M7:14). O'Brien explained that peak values may be associated with respiratory responses (M7:14).

7.5.5.Other Issues

Who does the sampling was discussed in the context of exposure assessment as well as cost. More on this topic is in Chapter Four on economic feasibility. Recommendations were made to have industrial hygienists set up a sampling program and workers at a plant could conduct sampling. Burch was concerned that OSHA had a bias against employers doing their own sampling (M7:21). Teitelbaum noted that if people other than industrial hygienists were taking samples, training would be essential (M7:25).

Sampling strategies are discussed below. Additional information on sampling statistics is provided in Leidel, 1977.

7.6 LINKAGE OF DISCUSSIONS TO OSHA ACTION

Mirer viewed any standard as feasibility limited not analytically limited (M7:20). Mirer stated it did not matter what method was used just that the method is consistent (M4:3). Mirer thought if the thoracic is used, the analysis should be for total mass since it represents what actually gets to the lung target (M4:3). Mirer thought due to the relationship between total and extractable, if a

standard is based on extractable it should be adjusted down (M7:20). Mirer viewed the extractable method as appropriate if other particle sources are present (M8:24). Mirer noted the historical value of the total particulate and thought the thoracic sampler was too expensive (M8:24).

Mirer thought having a statistically valid air sampling program could be an innovative compliance issue (M7:21). If an employer had good reason to believe he was in compliance, but had one or two OSHA samples out of compliance, that this could be taken into account in the enforcement (M7:22).

Howell recommended giving the widest choice possible to allow users to choose how to get the best information (M7:22). Mirer did not have a problem with this (M7:22). Howell noted the importance of using air sampling to evaluate the effectiveness of controls (M7:21). As a result, Howell viewed the ASTM method as best practice because it allows measurement of total but also helps define the source of the problem by measuring extractable (M7:21).

There was concern noted in other sections of this report about the ability of any method to effectively measure an action level of 0.25 mg/m^3. O'Brien thought that with a limit of quantification usually less than 0.2 mg/m^3, an action level of this value or 0.25 mg/m^3 could be measured (M7:19).

Mirer explained that an air sample is an index of exposure, not a complete exposure determination (M7:20). Howell, Teitelbaum and Mirer agreed that at best, any method is just an indicator because of the complex, dynamic nature of the fluid (M8:26).

In response to the various concerns of the committee, the Exposure Assessment Work Group presented a draft recommendation (M8:23). Their draft provided the opportunity to use one of four sampling and analytical methods: total, thoracic, extractable or a direct reading instrument (M8:23). Ratios were given to show the relationships between different methods (M8:23). As proposed, an employer would be in compliance if 95% of samples in an exposure group are within the PEL (M8:23). Substantial changes in production would be a trigger for additional monitoring (M8:23).

The draft document provided recommended relationships between a PEL, action level and STEL (M8:23). Wegman, Howell and Anderson viewed there was not enough health data to support a STEL and that simply using a multiplier times the PEL was not appropriate (M8:23).

Mirer noted that the work group's recommendation was flexible (M8:24). Frederick recommended a data call in from OSHA in increments of five years, this could be used to determine the effectiveness of an OSHA standard (M8:24). Sherman requested that the exposure assessment group provide a rationale for a 30 year recordkeeping requirement (M8:25).

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7.7 COMMITTEE DECISIONS AND RATIONALE

Recommendations for best practices quantitative exposure assessment and exposure monitoring were proposed to the full committee by an exposure assessment working group. A written text was reviewed by the full committee at the May meeting.

The importance of fluid management and the potential difficulties for small business to do exposure assessment were appreciated by the group. As a result, an ad *hoc* work group drafted a qualitative observational assessment to integrate with quantitative requirements.

The full committee unanimously endorsed the written recommendation as a best practice for exposure monitoring for workers exposed to metal working fluids, with some reservations regarding the action level recorded in the transcript and summarized below. The full committee unanimously endorsed the observational checklist. The committee did not separately vote on this proposal as an enforceable OSHA regulatory text.

The exposure assessment group accepted the NIOSH criteria document Chapter 7, "Sampling and Analytical Methods," as the starting point for determining best practices for exposure assessment. This information was supplemented by extensive additional work including the NIOSH small business study, and the development of ASTM-PS42. The NIOSH criteria document recommends a limit based on the thoracic fraction analyzed by gravimetric methods. NIOSH proposes that the thoracic size fraction would be 80% of the total particulate fraction.[1]

The text for exposure monitoring consisted of "boiler plate" OSHA standard language, derived from the formaldehyde standard (29 CFR 1910.1048), with new ideas for changes from the standard practice highlighted in the committee draft and in the attached text. These issues included: omission of a STEL or excursion limit; statistical compliance evaluation; definition of qualitative observations which would constitute objective evidence for initial determination of the need for initial monitoring; and provision for multiple air sampling and analytical methods as appropriate.

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[1] The exposure assessment group noted that "total" particulate is actually a misleading term. "Total" means a sample collected with a 37 mm closed face filter cassette, or equivalent. The cover is now known to exclude large particles, and in some cases may radically understate the true exposure. Paradoxically, "inhalable" particulate collected with an open faced sampler may exceed "total" by 3-fold in some environments, which "total" exceeds "thoracic" by only 20%.

The written recommendation is attached.

The discussion and vote did not directly address the value for the PEL.

Key issues in the recommendation follow.

7.7.1. Method of Analysis. The Committee recommends that an employer could rely on samples analyzed by extraction methods to demonstrate compliance with the PEL, or to determine the need for additional engineering or other controls. Extraction analysis would be permitted where the employer could demonstrate there were sources of particulate other than MWF processes in the work area where the sample was collected. The Committee also agrees that it would be desirable to allow employers to use the cheaper gravimetric method, or direct reading instruments to demonstrate compliance. The Exposure Assessment group noted that the extraction method would permit the employer to stop the process at the weighing (gravimetric stage) if these results demonstrated compliance.

The Full Committee and the Exposure Assessment Group maintain a range of views on the appropriate method of analysis.

The consensus of the exposure working group was that side by side samples analyzed by extractable methods would not provide a higher exposure value than the gravimetric samples, and likely would provide a lower exposure value than gravimetric samples. The extent of the deviations is not known, but the consensus was that it could be substantial in areas where dry grinding or other exposure sources were present. Some argued that the respiratory effects studies used for exposure response assessment were based on exposures measured by gravimetric analysis (of thoracic samples) and so a health based standard should reflect the analytical method. In addition, gravimetric analysis was known to be substantially cheaper than extraction methods. Others argued for the specificity of extraction methods, and possible improved analytical precision of the method. They noted that extraction methods could also provide a total gravimetric result.

The consensus of the exposure assessment working group was that exposure assessment using a properly calibrated direct reading instrument (real-time aerosol monitor) was highly desirable and yielded data on both short term exposures and sources which would not be provided by standard filter sampling methods. Such measurements were to be encouraged. However, the group was divided on the availability of equipment and persons trained to interpret the results, and felt it could not require such measurement methods.

7.7.2. Size Selective Sampling. The Committee recommends that the PEL be stated as either a total particulate sample, or a thoracic fraction sample at 80% of the total particulate level.

The NIOSH criteria document recommends a limit based on the thoracic fraction for protection against respiratory effects. NIOSH proposes that the thoracic size fraction would be 80% of the total particulate fraction[2]. Thus, the recommendation was 0.5 mg/m^3 total particulate and 0.4 mg/m^3 thoracic.

The consensus of the full committee was that a thoracic fraction was more appropriate for a standard to prevent respiratory effects, and that an inhalable fraction would be more appropriate for a standard to prevent cancer effects. However, neither thoracic nor inhalable sampling devices are commonly used in current industrial hygiene practice. Thoracic sampling would be more costly. The quantitative relationship between total and thoracic will be variable, depending on exposure circumstance. Principally, close to exposure sources with large sized particulate emissions, inhalable and total samples will exceed thoracic by a larger amount than samples collected farther away.

7.7.3 Action Limit. The majority of the Committee recommends an action limit of 1/2 the PEL for the purposes of triggering continuing monitoring.

The rationale for the action limit for exposure assessment, which is common to all OSHA chemical exposure standards, lies in the variability of exposure levels in all studied industrial processes. A random sample as high as ½ the PEL, collected from a work area, predicts that exposures over the PEL will occur. Continuing air sampling would be needed to determine with certainty that PEL compliance was achieved. In addition, continuing exposure surveillance in a work area where exposures are close to the PEL should be maintained to insure that controls do not deteriorate and exposures increase to exceed the PEL.

A minority of Committee felt that an action limit of 0.25 mg/m^3 would impose a very large amount of continuing air sampling, and that this value posed analytical accuracy problems by gravimetric and extraction methods, but not when using direct reading instruments.

7.7.4. Short Term Exposure Limit. The committee as a whole did not recommend a short-term exposure limit. Discussion was divided on this issue, although the ultimate vote was unanimous.

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[2] The exposure assessment group noted that "total" particulate is actually a misleading term. "Total" means a sample collected with a 37 mm closed face filter cassette, or equivalent. The cover is now known to exclude large particles, and in some cases may radically understate the true exposure. Paradoxically, "inhalable" particulate collected with an open faced sampler may exceed "total" by 3-fold in some environments, which "total" exceeds "thoracic" by only 20%.

The prevailing view was that existing sampling methods would not support short-term exposure measurements based on a 30 minute STEL as high as 2.0 mg/m^3 In addition, it was felt that studies directly showing additional adverse effects of short term high exposures were not sufficient to support such a recommendation. Further, it was argued that evidence was insufficient to support a conclusion that a STEL would furnish additional feasible protections beyond those of a TWA exposure limit.

The minority view was that a STEL would be needed to protect workers if an exposure limit of 0.5 mg/m^3 were adopted, because material impairment to health has been observed among workers exposed to levels less than the TWA. They argued that available studies did not measure peak exposures within that TWA, but that other evidence supported conclusions that the peaks were there. A substantial fraction of the observed respiratory effects of MWF appear to be reactive airway responses. By analogy to many other substances, and also in the experience of respiratory physicians, it would be likely that peak exposures or excursions were important in causing these effects. Proponents of the STEL noted that the ACGIH recommends excursion limits as a general practice:

> *Excursions in worker exposure may exceed the TLV-TWA for no more than 30 minutes during a workday, and under no circumstances should they exceed the TLV-TWA, provided that the TLV-TWA is not exceeded.*

7.7.5 Statistical Compliance. The Committee recommends a statistical compliance scheme as a departure from existing OSHA regulatory practice.

The committee intended to address a feasibility concern with this new approach. The concern is whether a few outlier samples would trigger installation of additional engineering controls in a work area which was generally well controlled. It is intended that an employer could rebut an OSHA citation for a PEL (or Action Level) violation by showing that 95% of samples within a homogeneous exposure group were in compliance. This would apply to the most highly exposed homogeneous exposure group in the work area. This is largely a quantification in regulatory text for a practice which already exists in the field. It was suggested that OSHA take this concept in to account in feasibility determination.

The consensus did not intend that OSHA would have to show that 5% of samples were out of compliance.

7. 7.6 Exception from Initial Monitoring

The committee recommends that a clear meaning be given to the existing allowance for use of "objective data" to determine that initial monitoring not be required. The committee recommends a checklist approach in which qualitative observations of the production process and systems approach could be used to

predict whether exposures above the action level or PEL are foreseeable.

The committee believes that many small, low volume, or well-ventilated machining operations do not create exposures above an appropriate exposure limit. By providing detailed observations which could be used to support a determination, the committee believes that employers who maintain such operations will be able to avoid the effort of collecting air samples to confirm that no further action is necessary. This provision would primarily benefit small employers with few professional industrial hygiene resources. However, it will also benefit employers with isolated machining operations which support other production activities.

The exposure assessment and ad hoc qualitative assessment groups developed a checklist which is provided after the quantitative exposure assessment document. The committee believes that this checklist represents the general consensus of the MWF community on the observations which would trigger the need for quantitative exposure assessment. It is supported by the observations and experience of the team which conducted the NIOSH Small Business study. The committee concedes that this checklist should be validated in the field, and that alternative weighting of responses may be plausible. Issues of concern for some members of the committee included: wording, weighting, validity and recordkeeping requirements. The committee further notes that an employer would not be required to use this checklist as the sole objective evidence that quantitative exposure assessment was not needed.

The quantitative exposure assessment best practice and the qualitative checklist are found on the following pages.

Best Practices Description for Monitoring and Analysis of MWF Exposures[1]

(c) Permissible Exposure Limit (PEL).[2]

(1) TWA. The employer shall assure that no employee is exposed to an airborne concentration of MWF which exceeds 0.X mg MWF per cubic meter of air (0.X mg/m^3) (or 0.8 [0.X]MG MWF PER CUBIC METER OF AIR (0.X MG/M3) MEASURED AS THORACIC FRACTION) as an 8-hour TWA.

(3)ACTION LEVEL. THE ACTION LEVEL FOR THE PURPOSE OF INITIATION OR TERMINATION OF MONITORING WILL BE ½ THE PEL AS A TWA.[3]

(d) METHOD OF ANALYSIS

(1) THE EMPLOYER MAY MEASURE EMPLOYEE EXPOSURE USING THE FOLLOWING METHODS:

1

Note: Text was derived from the OSHA Formaldehyde standard. Appropriate substitutions of MWF and mass levels were made in the Formaldehyde text. CHANGES FROM THE ORIGINAL STANDARD TEXT ARE IN CAPS. Deletions from the original standard text are not shown.

The PEL is arbitrarily described as "O.X mg/m^3" without stating the PEL. The STEL found in the Formaldehyde standard has been omitted based on discussions in the Committee Recommendations. This proposal assumes that there might be different action levels (or triggers by another name) for training, medical surveillance or other purposes than for monitoring exposure.

This proposal allows for 3 different analytical methods, and for the use of a properly calibrated real time aerosol monitor. The proposal retains the 80% conversion factor for closed face total to thoracic fraction proposed by NIOSH. The proposal permits employers to rely on total aerosol analyzed by extraction methods if they can demonstrate there are sources of particles in the work area unrelated to MWF emissions.

2

Effective dates are not contained in this section. Phase in periods might be different for new and existing equipment, or for different sized workplaces.

3

Medical surveillance or training might be triggered by different exposure levels than the action level for monitoring. The need for an action level for exposure monitoring is derived from knowledge of time and analytical variation of exposure measurements.

(i) TOTAL GRAVIMETRIC;

(ii) TOTAL EXTRACTABLE IF THE EMPLOYER CAN DEMONSTRATE THAT A WORK AREA HAS SOURCES OF PARTICULATE EMISSIONS UNRELATED TO MWF EMITTING PROCESSES;

(iii) THORACIC GRAVIMETRIC; OR

(iv) REAL TIME AEROSOL MONITORING CONSISTENT WITH PARAGRAPH (d)(2) OF THIS SECTION.

(2) REAL TIME AEROSOL MONITOR. (i) THE EMPLOYER MAY RELY ON SAMPLING RESULTS FROM A REAL TIME AEROSOL MONITOR IF THE INSTRUMENT IS CALIBRATED AGAINST SAMPLES COLLECTED AND ANALYZED BY ONE OF THE OTHER METHODS DESCRIBED IN PARAGRAPH (C) OF THIS SECTION IN THE WORK AREA WHERE THE SAMPLES ARE COLLECTED.

(ii) IF THE EMPLOYER CAN DEMONSTRATE THAT A WORK AREA HAS SOURCES OF PARTICULATE EMISSIONS UNRELATED TO MWF EMITTING PROCESSES, THE EMPLOYER MAY RELY ON EXTRACTION ANALYSES TO CALIBRATE REAL TIME AEROSOL MONITORS.

(3) REPRESENTATIVE SAMPLING. (i) AN EMPLOYER SHALL BE DEEMED IN COMPLIANCE WITH THE REQUIREMENTS OF PARAGRAPH (C) IF THE EMPLOYER CAN DEMONSTRATE BY A STATISTICALLY VALID REPRESENTATIVE AIR SAMPLING SCHEME THAT 95% OF AIR SAMPLES WITHIN EACH HOMOGENEOUS EXPOSURE GROUP ARE WITHIN THE PEL OR ACTION LEVEL. HOMOGENEOUS EXPOSURE GROUP MEANS EMPLOYEES PERFORMING ESSENTIALLY IDENTICAL TASKS AT ESSENTIALLY IDENTICAL WORK STATIONS.[4]

(ii) When an employee's exposure is determined from representative sampling, the measurements used shall be representative of the employee's full exposure to MWF.

(iii) Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts. A WORK AREA FOR THE PURPOSES OF THIS SECTION IS THE IMMEDIATE VICINITY OF METALWORKING PROCESSES AND ASSOCIATED

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[4] Employees within the homogeneous exposure group would be deemed to have the same exposure as the representative sample.

EQUIPMENT, WHERE PRODUCTION ACTIVITIES, MAINTENANCE, SERVICE, AND IN PROCESS INSPECTION ARE PERFORMED, AS WELL AS IMMEDIATELY ADJACENT AREAS WHICH ARE NOT SEPARATED FROM DIRECT EXPOSURE BY PHYSICAL BARRIERS TO MOVEMENT OF AIR.

(e) Exposure monitoring.

(1) General. (i) Each employer who has a workplace covered by this standard shall monitor employees to determine their exposure to MWF.

(ii) Exception. Where the employer documents, using objective data, that the presence of MWF EMITTING PROCESSES or MWF-releasing products in the WORK AREA cannot result in airborne concentrations of MWF that would cause any employee to be exposed at or above the action level under foreseeable conditions of use, the employer will not be required to measure employee exposure to MWF. THE EMPLOYER MAY RELY ON THE METHODS AND OBSERVATIONS IN THE NON-MANDATORY APPENDIX TO DETERMINE WHETHER INITIAL MONITORING IS NEEDED.[5]

(2) Initial monitoring. (i) The employer shall identify all employees who may be exposed at or above the action level and accurately determine the exposure of each employee so identified.

(ii) Unless the employer chooses to measure the exposure of each employee potentially exposed to MWF, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

(iii) The initial monitoring process shall be repeated each time there is a SUBSTANTIAL change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to MWF.

(iv) If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with MWF exposure, the employer shall promptly monitor the affected employee's exposure. Consideration should be given to other than airborne mechanisms of exposure.

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[5] Use of the checklist would relieve an employer from citation for failure to conduct initial monitoring, and periodic monitoring, if OSHA were to enter the workplace and collect samples which exceeded the action level. However, the employer could still be cited for violation of all other requirements of the standard triggered by exposure level if the action level or PEL were exceeded.

(3) Periodic monitoring. (i) The employer shall periodically measure and accurately determine exposure to MWF for employees shown by the initial monitoring to be exposed at or above the action level.

(ii) If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

(4) Termination of monitoring. The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation.

(5) Accuracy of monitoring. Monitoring shall be BY A METHOD AT LEAST AS ACCURATE, AS NIOSH 0500 OR ASTM PS-42 at the 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of MWF at the TWA and the STEL and to within plus or minus 35 percent for airborne concentrations of MWF at the action level.[6]

(6) Employee notification of monitoring results. Within 15 days of receiving the results of exposure monitoring conducted under this standard, the employer shall notify the affected employees of these results. Notification shall be in writing, either by distributing copies of the results to the employees or by posting the results. If the employee exposure is over the PEL, the employer shall develop and implement a written plan to reduce employee exposure to or below the PEL, and give written notice to employees. The written notice shall contain a description of the corrective action being taken by the employer to decrease exposure.[7]

(7) Observation of monitoring. (i) The employer shall provide affected employees AND their designated representatives an opportunity to observe any monitoring of employee exposure to MWF required by this standard.

(ii) When observation of the monitoring of employee exposure to MWF requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the clothing and equipment to the observer, require

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[6] The Committee believes it is better to specify methods which meet the generally applied criteria for accuracy of monitoring, rather than state statistical criteria which are not readily understood by employers and employees.

[7] Where representative sampling is used, each employee within a homogeneous exposure group shall be provided the notifications applicable to that group.

the observer to use such clothing and equipment, and assure that the observer complies with all other applicable safety and health procedures.

Self Assessment Checklist

The purpose of this qualitative self assessment is to determine the need for quantitative air monitoring of employee exposures to metalworking fluid mist. The questions in this checklist are organized by three classifications. The answers to the "A" questions are critical. The answers to the "B" questions are important and the answers to the "C" questions denote recommended actions. In summary:

"A" questions refer to **critical** elements. For example: Has responsibility for MWF management been assigned?

"B" questions are **important** elements. For example: Are machine enclosures maintained in operating condition?

"C" questions denote **recommended** practices. For example: Are machines maintained in clean condition?

The results are calculated as follows:

For **"A"** questions, an answer of "no" to any of the questions results in a requirement to conduct representative quantitative air monitoring of employee exposures to metal working fluid mist.

For **"B"** questions, if at least seventy five percent ($75%) of the answers to the "B" questions are answered "yes" there is no need for employee exposure monitoring. A response rate of fifty to seventy four percent (50-74%) "yes" on the important questions is "marginal" and quantitative employee exposure monitoring is **recommended** for a representative number of workers in the areas reflective of the deficient elements. A response rate of less then fifty percent (<50%) "yes"on the important questions indicates that representative employee exposure monitoring for metal working fluid mist should be conducted.

"Yes" answers to the **"C"** questions are often good indicators of the quality of the overall metal working fluid exposure conditions in the facility. Answers to these questions are not used to determine the need for employee exposure monitoring.

[Note: Much of the material included in this checklist was adapted from similar checklists in the ORC Guide to Controlling the Metal Removal Fluid Environment.]

Metalworking Fluid Exposure Management Checklist

Plant:_____ Operation:_____

Department:_____ Bay/Column:_____

Date: _____ Completed by_____

Instructions: Place a check in the appropriate boxes below. If "No" is checked, make comments and recommend corrective actions if possible. If an item does not apply to the plant/department/operation, check the "NA" box.
Detail corrective actions or comments in the space provided.

Importance	Element	Yes	No	NA	Comments
Metalworking Fluid (MWF) Management					
A	1. Does a single designated and properly trained person have overall responsibility for MWF management?				
A	2. Are metalworking fluid management responsibilities and testing protocols specified in a written plan?				
B	3. Are coolant systems routinely monitored (at least weekly) and test results documented for MWF concentration, pH, microbial levels, tramp oil, suspended particulate, etc.?				
A	4. Are fluid system additions (inc. biocides) controlled by a designated person and recorded?				
C	5. Are system clean-outs routinely scheduled and follow standard operating procedures?				
C	6. Are systems thoroughly cleaned (e.g. power washing and rinsing) before recharging with fresh fluid?				
B	7. Are MWF filtration equipment routinely checked and maintenance recorded?				

C	8. Are coolant sumps covered with solid material or a moderate foam blanket to contain a mist?				
C	9. Is there a process in place to check regularly for MWF leaks and spills?				
Worker Training and Hazard Communication					
B	1. Are Material Safety Data Sheets readily available for all MWFs used in the immediate work area?				
A	2. Have employees been given effective information and have been trained on potential health effects, including toxicity, and safe handling of MWFs used in their work area?				
B	3. Are written records maintained of all worker training?				
B	4. Is there a written health and safety program that provides for systematic, periodic identification of potential hazards related to employee exposure to MWFs?				
C	5. Has air monitoring been conducted in the past 12 months for determining ambient levels of MWF aerosol?				
A	6. Do identified employees or their representatives actively participate in the company's MWF management and control programs?				
Housekeeping					
B	1. Are floors or other non-work surfaces free of MWF residue that may indicate uncontrolled emissions?				
B	2. Is there no evidence of MWFs condensing on building structures (e.g., trusses, columns or pipes)?				

B	3. Are fluid sumps, trenches and the surrounding floor free of cigarette butts, cups or other trash?				
C	4. Are MWF and oil spills or leaks cleaned up promptly?				
B	5. Are machine interiors, exteriors and the surrounding floor free of chip accumulations that can interfere with proper MWF circulation?				
B	6. Is the area free of sulfurous odors after a prolonged machine shut-down (e.g., on Monday mornings)?				
B	7. Is the general air free of visible "haze" during machining?				
Machining Operations					
B	1. Are the majority of machines (75%) operated with metal removal rates of less than 5 cubic inches per minute?				
B	2. Are the majority of machines (75%) operating for short production runs (e.g., less than 4-6 hours) between tool set-ups?				
B	3. Is a high-pressure or high-velocity coolant application method prohibited on any machine without full enclosure?				
B	4. Is there less than 1 machine per 50 ft^2 which is routinely operated?				
Ventilation and Exposure Control					
B	1. Are exhaust ventilation hoods routinely tested to ensure proper system performance?				
C	2. Is written documentation maintained or local exhaust hood maintenance and repair?				
B	3. Are mist collectors properly designed and maintained (e.g., per ANSI B 11 TR 2-1997)?				

B	4. Is a written record available for mist collector maintenance (e.g., filter changes)?				
B	5. Is recirculation of exhaust air (which includes fresh make-up air) used?				
B	6. Is natural ventilation (e.g., opening outside doors/windows) utilized wherever feasible?				
B	7. Are man-cooling fans, if present, placed or directed so as not to interfere with the exhaust ventilation?				
B	8. Is the flow of MWF at each operation interrupted or cycled off when machining or grinding is not occurring?				
A	9. Have new machine tools purchased in the last 12 months been selected with appropriate enclosures and ventilation that minimizes release of the MWF aerosol into the workplace atmosphere?				
B	10. Are machine enclosures (full or partial) in place and in good condition for at least 75% of the machinery?				
A	11. Do machine enclosures prevent visible aerosol emissions?				
B	12. Is exhaust ductwork from machine tool enclosures designed and maintained per recognized specifications (e.g., ANSI B11 TR 2-1997)?				
B	13. Is there a written plan for implementing engineering and work practice controls to reduce and maintain employee exposure levels to below 0.5 mg/m^3?				
Work Practices and Personal Protection					

B	1. Is there a written plan which describes job duties and any required use of personal protective equipment?				
B	2. If respiratory protection is provided, has the OSHA Respiratory Protection Standard (29 CFR 1910.134) been complied with?				
B	3. Are employees observed using required personal protective equipment (e.g., safety glasses, gloves, respirators, etc.)?				
B	4. Do employees avoid using rags contaminated with metallic debris, such as swarf and chips?				
B	5. Do employees wash hands with mild soap and warm water before breaks and meals?				
B	6. Do employees change work clothing if it becomes soaked with metal removal fluids during the work shift?				
B	7. Is compressed air prohibited for cleaning machine tools and parts?				
Medical Surveillance and Health Outcomes					
A	1. Is periodic medical surveillance available to all employees who are currently exposed to MWF?				
B	2. Is a medical removal program available for all employees who develop MWF illnesses such as dermatitis, asthma and hypersensitivity pneumonitis?				
A	3. Have no employees at this facility developed signs or symptoms of adverse health effects due to MWF such as dermatitis, asthma or hypersensitivity pneumonitis in the last 12 months?				

B	4. Are OSHA 200 Forms available for the past five years?				

CHAPTER EIGHT
Deliberations Related to Best Practice: Medical Monitoring and Surveillance

8.1 GENERAL INFORMATION

Medical monitoring and surveillance was discussed primarily at the fifth, seventh, eighth and ninth meetings. A panel of physicians addressing non-malignant respiratory disease focused on different needs and approaches to address medical monitoring and surveillance. The Health Work Group was charged with developing a best practice document for medical monitoring and surveillance. Although most of the attention was devoted to non-malignant respiratory effects, the group developed strategies for addressing dermatitis as well. Various editions of this document were discussed and the final version is provided at the end of this chapter.

8.2 SPEAKERS AND PRESENTATIONS

A medical panel consisting of Dr. Kevin Fennelly and Dr. Cecile Rose, both of National Jewish Research and Medical Center, along with committee members, Dr. Lee Newman, Dr. David Wegman and Dr. Henry Anderson addressed the committee (M5:7). They fielded committee questions on respiratory disease and MWFs, and medical monitoring and surveillance. The Health Work Group developed a medical surveillance program that could be either part of a regulation or guideline, and provided extensive input to discussions. Dr. Gordon Reeve, Ford Motor Company, and committee member Ken Kushner provided information on the use of passive surveillance at their companies (M6:1-5). Darryl Mattheis discussed medical surveillance in his description of the ORC Document. More on many of the issues discussed by these speakers is found in Chapter Two. Active discussion and development of the recommendations on medical surveillance began at the fifth meeting of the committee.

8.3 BACKGROUND INFORMATION

The panel of physicians explained that medical monitoring is screening individuals and referring cases to physicians for treatment (M5:7). Monitoring is an individual based activity, while surveillance is population based (M6:25). Medical surveillance goes beyond medical monitoring (M5:7). Medical surveillance helps provide indicators of problems not shown by individual cases (M5:7). Wegman explained that surveillance can elucidate patterns of disease in a population and not just identify cases (M5:7). Medical surveillance can be a safety net so ideally people with early stages of disease can be found and treated (M5:7). Both monitoring and surveillance can help identify work areas that need prevention efforts, according to Newman (M5:7).

Wegman explained that passive surveillance uses existing records that have been collected for a different reason (M6:25). Active surveillance is the

development of records specifically designed to track symptoms and disease related to exposure (M6:25). Passive surveillance can help guide identification of problem areas, according to Wegman (M8:22).

8.4 REVIEW OF AVAILABLE INFORMATION

8.4.1 The NIOSH Criteria Document

Medical monitoring is discussed in section 9.4 of the NIOSH Criteria Document (NIOSH, 1998). It cites that the major objective of the recommended medical monitoring is the early identification of workers who develop symptoms of MWF-related conditions such as asthma, HP and dermatitis (NIOSH, 1998). Early identification can result in exposure control and minimization of recurrence of symptoms or exacerbation of disease (NIOSH, 1998). It notes that priority should be given to those with highest risk (NIOSH, 1998). Training workers about identifying symptoms and reporting them is needed (NIOSH, 1998). Qualifications of medical personnel and testing frequency and scheduling recommendations are provided (NIOSH,1998). Questionnaires, spirometry and skin examination are included as recommended tests (NIOSH, 1998). Details on medical exams, reporting, employer action and follow up are found 9.4.4-9.4.8 of the Criteria Document (NIOSH,1998).

The NIOSH Criteria Document for Metalworking Fluids provided the committee with a comprehensive baseline for its consideration of a medical surveillance program. The documentation and recommendations in the criteria document were supplemented by literature provided to the committee by members of the committee and by invited experts.

8.4.2 Discussions Related to Components of a Medical Surveillance Program for MWFs

Wegman and Rose explained that surveillance would include baseline and follow-up testing using a questionnaire and pulmonary function testing (M5:7). Rose thought diffusing capacity might be included as part of the spirometry exam but warned that a qualified lab is needed (M5:7). Rose also recommended considering a baseline radiograph (M5:7). In addition, Fennelly suggested paying attention to upper airway and skin symptoms (M5:7). Infante questioned if case identification guidelines should be included (M5:31).

Rose explained that for HP and other sensitization reactions, the exposure had to be much lower than existing PELs or TLVs (M5:7). She noted the importance of using surveillance tools such as questionnaires (M5:7). A well designed questionnaire and surveillance can capture information, according to Newman (M5:7). Anderson thought that respiratory complaints can help flag problems (M5:7). Rose noted that in HP, the symptoms precede any discernible radiographic or spirometric abnormalities (M5:7).The Government Options Work Group reported that the Michigan SENSOR program uses questionnaires (M5:26). Mirer recommended using a questionnaire similar to what the SENSOR program uses (M5:26). Wegman hoped that the Health Work Group would at

least address the type of questionnaire used (M5:31).

Return to work was discussed in the context of medical surveillance. Fennelly explained that there is a lot of overlap between the concerns about returning to work with HP and with asthma (M5:7). Newman recommended that if someone is returning to their work environment, serial exams documenting recurrence or exacerbation are needed (M5:7). These tests would include a questionnaire, spirometry, peak flow for asthma and skin screening for dermatitis (M5:7). Wegman noted that return to work may be difficult for OSHA to address (M5:7).

As a result of discussion, a program, according to the Health Work Group should include: a definition of who is included, baseline medical components, frequency, triggers, sentinel events, use of data and evaluation of surveillance and a questionnaire (M5:31). Pulmonary function and skin exams should be included (M5:31).

8.4.3 Development of a Medical Monitoring and Surveillance Document

An initial draft of the Health Work Group's Medical Monitoring and Surveillance Document was provided at the sixth meeting (M6:25). Eligibility was based on exceedance of some level, e.g., PEL, or presence of symptoms associated with MWFs even if below a PEL (M6:25). A baseline medical exam would include a questionnaire, physical exam and baseline spirometry and there would be follow-up periodic medical monitoring, e.g., annually (M6:25). At a minimum, the follow-up would include a questionnaire and certain findings on a questionnaire may trigger further medical testing (M6:25). Substantial cross shift pulmonary function changes may trigger further diagnostic exams (M6:25). Exceedance of a PEL in a homogeneous exposure zone may trigger medical monitoring for all workers in this group even if individuals were not above the PEL (M6:25).

In the early stages, the work group was trying to identify medical removal triggers and related issues (M6:25). The work group wanted to relate their program to exposure, and fluid management issues, and determine ways of exempting areas from medical monitoring (M6:25). Howell suggested dividing out those already exhibiting a history of medical problems in a given work place and then extend appropriate testing to others in the area (M6.26).

A new draft of the Health Work Group's Medical Monitoring and Surveillance document was reviewed at the seventh meeting (M7:28-30). The program included: baseline medical monitoring, periodic medical monitoring, medical surveillance, medical removal, incentives and evaluation of the medical surveillance (M7:29). The trigger for baseline medical monitoring would be working in an area above an action level for 30 days per year (M7:29). The 30 day value was an arbitrary choice made by the Health Work Group (M7:29). Another trigger would be working in an area whose MWF management program does not meet set criteria, even if exposure is less than the action level (M7:29). A third trigger would be that a physician determines the presence of an MWF

related condition (M7:29). A fourth trigger would be a veteran worker with previous history of work in an area where the PEL was exceeded for greater than 30 days/year for a minimum of 5 years (M7:29). A special criteria would be working in an area where a sentinel event occurred (M7:29).

For the draft discussed at the seventh meeting, Wegman explained that the baseline exam would include a questionnaire that is similar to the American Thoracic Society's questionnaire and would include respiratory symptoms, work history, smoking, and demographic data (M7:29). The exam would include a physical exam of lung and skin and baseline pulmonary function (M7:29). For the special criteria category, only a questionnaire would be used (M7:29). Minimal periodic medical monitoring would be required for those working in areas where the MWF management program does not meet minimum criteria, or the exposures are between the action level and PEL but the program meets the criteria (M7:29). The minimal periodic monitoring would include a questionnaire (M7:29). The routine periodic medical monitoring would be for those working in areas with exposures between the action level and PEL and the fluid management program does not meet minimum criteria, or those working in areas with exposures above the PEL and the fluid program meets minimum criteria (M7:29). These exams would include a questionnaire and simple spirometry and would be annual exams (M7:29).

According to the draft discussed at the seventh meeting, enhanced periodic monitoring is triggered by an indicated need from periodic or baseline monitoring (M7:29). Those using respirators to reduce exposure to MWF would need enhanced periodic monitoring (M7:29). If abnormalities are found on exams, enhanced monitoring would be needed (M7:29). Those working in areas designated positive on surveillance exams would need enhanced monitoring (M7:29). Other triggers would include abnormal health events such as allergy to MWFs or sickness greater than 3 days due to respiratory disease (M7:29). An unexplained febrile illness occurring more than two times within 6 months would also trigger enhanced monitoring (M7:29). The discretion of the physician can trigger enhanced monitoring (M7:29). Enhanced periodic monitoring adds cross-shift FEV_1 and FVC along with environmental evaluation to the routine monitoring requirements (M7:29). The enhanced exams would be annual unless there are abnormal findings (M7:29).

As noted in the seventh meeting draft, for the surveillance component for the employees in periodic medical monitoring, the data would be grouped and a criteria used to prompt action that otherwise would not occur based on individuals (M7:29). Medical removal triggers would include new asthma or a cross-shift drop in FEV_1 or FVC or 10 % on three successive exams conducted at monthly intervals (M7:29). Other triggers would be a diagnosis of or exacerbation of asthma, diagnoses of HP or work-associated contact dermatitis (M7:29). A return to work protocol would include an environmental review and for some disorders a minimal removal time (M7:29).

In the seventh meeting draft, the criteria for ceasing medical surveillance

would be documentation of exposures below the PEL for more than 11 months and the MWF management program exceeds minimum criteria (MT:30).Triggers that put individuals in medical monitoring also return to normal (M7:30). The pulmonary function data collected for surveillance could be assessed by NIOSH within the first 10 years of implementation (M7:30). NIOSH would determine if the pulmonary function data collection is achieving the intended goal and if not, recommend that OSHA discontinue this testing requirement and only require questionnaires (M7:30).

In the seventh meeting draft, tables and figures were provided, including a flow chart (M7:30). Some clarifications were needed on the document. Wegman clarified that if someone under the special criteria has an abnormal questionnaire they move into a baseline exam, but if they have a normal questionnaire, they are out of the medical monitoring program (M7:30). Wegman explained that new onset of symptoms referred to results from a questionnaire, not physician diagnosis (M7:30). Wegman clarified that the seventh meeting document requires a baseline questionnaire and pulmonary function test if the fluid management program does not meet minimum criteria (M7:30). This requirement is independent of air concentration (M7:30). Wegman clarified work history and noted that for veteran employees with 5 or more years of exposure, only a baseline evaluation would be done unless there are abnormalities (M7:30). Wegman explained that NIOSH would determine the sunsetting of the pulmonary function testing based on the overall data set, not on a case by case basis (M7:30). Wegman explained that section lA, 1D refers to individuals who currently work for the company but do not work with MWFs (M7:31). He noted that baseline means the first testing (M7:31).

Comments from the committee on the seventh meeting draft included many compliments on this draft. White questioned if it would be practical in many facilities and if a drop of $FEV_{1.0}$ of 10% is valid (M7:30). Howell liked the inclusion of a fluid management trigger (M7:30). Howell questioned the use of contact dermatitis as a sentinel event since there may be very different reasons why it would appear than, e.g., respiratory symptoms (M7:30)

Recommendations for improvement of the seventh meeting draft included: improving the flow chart, removing dermatitis as a trigger or developing a different logic route, working on the dermatitis issue, explaining why triggers were chosen, justifying the criteria used in their recommendation, reviewing the new respirator standard's questionnaire, and developing the rationale for the 30 days per year (M7:30). When air sampling was done, and how frequently, needed to be clarified along with a definition of work area (M7:30). These last issues including a definition for work area are included in Chapter Seven on Exposure Assessment (M7:30).

At the eighth meeting, the Health Work Group provided an updated version of the medical surveillance document (M8:13). Anyone exposed to MWF above a defined action limit for 30 or more days per year or working with an inadequate fluid management program would be eligible for a baseline exam

consisting of a questionnaire, pulmonary function test and limited physical exam (M8:13). Normal exam results lead into one of three levels of periodic monitoring depending on the environment (M8:13). Abnormal baseline results send the worker into enhanced periodic monitoring (M8:13). Surveillance exams of a group can also lead into monitoring (M8:13). Environmental review can trigger monitoring and excessively abnormal medical test results can result in a more involved medical exam needs (M8:13). A physician diagnosis of a MWF related condition can place one in surveillance (M8:13). Any worker with a history of working in an area where the PEL was exceeded for greater than 30 days for a minimum of two years will receive a baseline exam (M8:13). If the exam is normal, the individual is removed from the program (M8:13). This approach finds those who may have been affected by MWFs earlier in their work life (M8:13). The questionnaire would focus on respiratory and dermal issues using part of a standard questionnaire (M8:13-14). The pulmonary function testing would include FEV_1 and FVC and their ratio determined using standard procedures (M8:14). The physical would focus on the skin and some guidance would be given for it (M8:14) The questionnaire, pulmonary function test and physical would be the baseline exam (M8:14).

As stated in the eighth meeting draft, a combination of below the action level and an inadequate fluid management program would trigger the minimum periodic medical monitoring (M8:14). A combination of between the action level and PEL, plus an adequate fluid management program would also need minimum periodic medical monitoring (M8:14). Minimum periodic monitoring consists of an annual questionnaire (M8:14). Areas between the action level and the PEL, and with an inadequate fluid management system, would need routine periodic monitoring (M8:14). Areas above the PEL and with an adequate fluid management system would also need routine periodic monitoring (M8:14). Routine periodic monitoring consists of an annual questionnaire and pulmonary function test (M8:14). Enhanced monitoring was for those areas with exposure greater than the PEL and the fluid management is inadequate (M8:14). Regardless of environmental conditions or fluid management, those individuals with abnormal baseline exams (e.g., low pulmonary function test measurements, baseline defined symptom abnormalities) would be in the enhanced category (M8:14). Any individual with an abnormal baseline questionnaire alone would be given the questionnaire again in six-months, and if the same result occurs, the individual would be placed in the enhanced category (M8:14). Abnormal minimum or routine periodic exam including new symptoms, cross shift drop or physician diagnosed MWF related disease would place the worker in the enhanced category (M8:14). The enhanced monitoring is done annually and includes routine monitoring plus cross-shift $FEV_{1.0}$ and FVC on site, and a physical exam of the skin by an appropriate health care professional (M8:14). Two annual cycles of stable results removes the worker from enhanced monitoring and places the worker in a category based on environmental conditions (M8:14). Minimal or routine periodic would be done annually (M8:14).

Enhanced periodic would be done annually but if the results are unchanged on resurvey, it would be done monthly or semiannually, or a physician can determine that more than annual testing is needed (M8:14).

For the eighth meeting draft, an approach was developed for population results (M8:14). If population results of periodic medical monitoring indicated a problem with the group, this result would trigger enhanced monitoring for the group (M8:14). Abnormalities including unusual values for a whole group or three individuals for cross shift drops in FEV_1 or FVC, a loss in annual $FEV_{1.0}$ or FVC or new onset of symptoms (M8:14). Sentinel events would include diagnosed conditions of asthma, HP or contact dermatitis associated with exposure to MWFs (M8:14). Triggers and sunsetting were similar to the earlier draft. How to get out of medical surveillance was provided in the eighth meeting version.

Clarifications about the eighth meeting draft were given that 30 days exposure did not mean sampling for 30 days but that someone works in this environment more than 30 days (M8:14). Airborne levels without reduction for respirator use would be used (M8:14). Simple respiratory function and simple spirometry were synonyms (M8:14). Population changes only changed the monitoring, while sentinel events triggered an investigation (M8:14). There was an effort to include smoking status as part of the way symptoms were interpreted (M8:17). The changes in lung function noted in the table on page 3 of draft 6 (eighth meeting draft) of the medical surveillance document would not usually occur in a smoker, according to Anderson (M8:17).

Howell noted that without the fluid management approach, the work group's product would look like any normal medical surveillance program and including the fluid management aspect can make the program less burdensome (M8:15,17). Wegman urged development of criteria for the fluid management so there would be reasonable relief from spirometry testing while protecting the workers' health (M8:15).

Burch was concerned with how small business could accomplish what was presented in this draft and more on this issue is provided in the issues and concerns section of this chapter (M8:15). White noted that as a best practice document, the proposed medical surveillance program is elegant, limited and targeted although some of the triggers could be debated (M8:15). Burch noted one burden was the complexity of the 8 pages of the program (M8:16).

Some discussion of improvements and corrections of the eighth meeting document were noted such as making the program more user friendly, determining how to handle someone with dermatitis so these individuals would not have to take a pulmonary function test, and exempting workplaces with no risk (M8:15,17). Other concerns were the development of algorithms for asthma and HP to help physicians discriminate between the two, and how to conduct an investigation of a sentinel event (M8:14). Other issues of concern about the draft reviewed at the eighth meeting included: how to handle skin and colo-rectal cancer, who should conduct the testing, medical record retention, and how to encourage companies to also do passive surveillance (M8:22).

A revised version of the Health Work Group's Medical Monitoring and Surveillance Document (draft #8) was discussed at the ninth meeting (M9:9). The document was similar in content to the version reviewed at the eighth meeting (M9:9). Some improvements were recommended by Sherman to provide better decision links (M9:9). Wegman noted a change that was needed on the draft description of the time interval for baseline test (M9:9). The revision should state: for current employees - within six months of starting a medical surveillance program; for new employees - within two weeks of starting the job (M9:9). Another item to change was the eligibility could be 30 days working in an environment where the sample indicates that the exposure is at this, or greater than this level (M9:9). Wegman noted that depending on the outcome of the Exposure Assessment Group, the eligibility trigger could be as soon as you document an area is over the PEL (M9:9). The work group decided that if an abnormal spirometry test result occurred, a repeated spirometry test should be done within two months (M9:9). If an abnormal symptom was found, the symptom survey would be repeated within two months (M9:9). Wegman noted the term dermatitis will be used throughout instead of skin disease and, "dermatologist" will be replaced with "physician familiar with occupational skin disease" (M9:9).

Wegman clarified that the word volunteer on page 4, IV C (2) (c) of the version discussed at the ninth meeting, referred to employees in the sentinel event area (M9:9). These individuals will be asked to participate in a survey (M9:9). Mirer clarified that OSHA only requires that testing be offered to designated employees and Sherman agreed (M9:9).

Continuing with the changes in the ninth meeting edition, individuals can be returned to areas below the action level but at the discretion of a physician for areas between the action level and PEL (M9:9). Wegman explained that worker removal would be for a maximum of a year (M9:10). White clarified that a shorter time may be listed for dermatitis (M9:10).

Wegman wanted to include non-mandatory guidance for searching for change among groups of individuals (M9:10). Mirer recommended using economic protection language from the formaldehyde standard for medical removal protection benefits (M9:10).

Newman explained algorithms 1 and 2 as part of the ninth meeting draft of the document (M9:10). These are guidelines for physicians (M9:11).

Other than the algorithms, diagrams were removed from this draft. Wegman explained that the fluid management triggers were removed from the ninth meeting edition due to lack of a defined evaluation scheme for fluid management (M9:10). Wegman noted that a good fluid management program only dropped out a questionnaire (M9:10). There was discussion of dropping from enhanced to basic periodic monitoring with a good fluid management program (M9:10).

8.4.4 Passive Medical Surveillance

Kushner noted that the worker's compensation carriers for some of his plants did not classify claims by industry type or track diseases (M8:16). He explained a data source he found called NCCI which is a national compensation group that gathers data but they did not classify by industry or disease (M8:16). Kushner found a private service that reviews health care claims for employees and families and provides information on inpatient and outpatient health care (M8:16). Any diagnosis can be accessed (M8:16). Reeve provided information from Ford at the sixth and seventh meetings and most of this was discussed in Chapter Two on Health Issues. Kushner also provides some surveillance data at the sixth meeting and this is noted in Chapter Two. Additional information is in Kushner's handout from the tenth meeting (Kushner, 1999).

8.4.5 Other Sources of Information

Many of the items discussed in this chapter relate to Chapter Two on Health Effects. An additional resource is an article by Bai *et al* entitled Questionnaire Items that Predict Asthma and Other Respiratory Conditions in Adults (1998). Additional references are found later in this Chapter in the section on rationale and in the proposed medical surveillance document as well as in Attachment #6.

8.5 CONCERNS AND LIMITATIONS

8.5.1 Size of Business

The appropriateness of the different versions of the medical surveillance document was debated. Wegman explained that the program was developed by the Health Work Group to be appropriate for small or large business (M5:31). Cox questioned how practical the seventh meeting version of the medical surveillance document would be for small business (M7:30). Burch explained that with the methylene chloride standard, the companies he represents could avoid medical surveillance by changing solvents (M8:15). With MWFs, as stated in the eighth meeting version, there would be no option (M8:15).

Mattheis noted a very simple approach for small business would be to have employees with a health problem inform their employer (M8:10) Potential problems could be outlined (M8:10). ORC may use the program developed by the MWFSAC Health Work Group (M8:10).

Wegman thought the draft provided at the eighth meeting would not be too burdensome because it only included pulmonary function tests and a questionnaire (M8:15). He viewed the program as reasonable if a problem such as asthma or HP exists (M8:16). Wegman noted that pulmonary function tests for e.g., 29 workers would not be burdensome (M8:16). Wegman agreed that cross, shift testing would be burdensome but a need for these tests would indicate an out of control situation (M8:16). The Health Work group did not think that the program as presented in the eighth meeting would be affected by business size (M8:22). They noted that the mechanisms for delivery may be different (M8:22).

White explained that as best practice, the program could be done by a

large company, but questioned how to adapt it to small companies (M8:16). Howell questioned how burdensome it would be for small business, noting whatever is set for a PEL or action level would also influence the burden (M8:17). How a different PEL for different fluids would affect medical surveillance concerned Howell; this would affect different industries in different ways depending on fluid type used (M8:22).

Burch stated that he did not see how the medical surveillance could work for a small business with no resources (M8:15). Even if no one had a serious problem, the infrastructure would have to be put in place (M8:15). Burch noted that a big industry can have someone track the medical data, while a small company cannot (M8:23). Burch urged the group to make this process do-able for small business with the goal of identifying people at risk so small business can take care of those employees with their limited resources (M8:16). Burch wanted to see the health effects in his industry group before requiring this type of effort (M8:15)

Cox explained a scenario in a small business in which an employee develops a cough, rash or any symptom and goes to a physician (M8:16). Any follow-up required by the physician as well as the original exam are covered by insurance (M8:16). Estimating this employee's exposure to MWFs when his job covers many areas would be difficult (M8:16).

Anderson did not think the program was very burdensome (M8:16). If exposures are low, no one is sick and the business is not having any trouble, only a periodic questionnaire is required (M8:16). Anderson stressed that the questionnaires could be very useful to help characterize lost work day problems and solve them (M8:16). Anderson questioned if Burch could guarantee that no one in small business has been sick due to MWFs (M8:16). Anderson thought that the questionnaire would help with awareness of problems (M8:16). Mirer wanted to know what percentage of facilities already do the testing, lessening the additional burden (M7:31)

Kushner explained that small and middle sized business would like to be able to identify MWF related respiratory disease in their workplaces (M8:16). Kushner believed these cases would be small or else they would be more obvious in data sources such as OSHA 200 logs, self-reported cases to medical and workman's compensation (M8:16).

8.5.2 Effectiveness and Validity of Test Methods

Fennelly noted that more validation of the measurement tools is needed (M5:8). Wegman recommended focusing on the potential yield of any test (M5:8). Hoffman noted that medical tests need to be reliable, valid, repeatable and accurate (M5:10).

Rose noted that the effectiveness of questionnaires has not been proven (M5:7). Hoffman explained that questionnaires need to be validated, or one should use an existing validated questionnaire such as the American Thoracic Society's or the Medical Research Council's instruments (M5:10). Newman

explained that the questionnaire should include questions from already developed questionnaires with established reliability (M8:15). The Health Work Group hoped to have a product with the best reliability and validity without being onerous (M8:15). Wegman noted that an American Thoracic Society (ATS) questionnaire plus additional questions from, e.g., the International Union Against Tuberculosis and Lung Disease, which has good questions on asthma, may be appropriate (M8:15). Wegman explained that there is not any questionnaire for HP (M8:15). Wegman stated that it may be impossible to validate such a questionnaire (M8:15).

Newman was concerned about the rare asymptomatic individual or someone who denies the relationship between symptoms and work (M5:7). Newman questioned if a questionnaire would detect this individual, but he and Rose agreed that some of the baseline testing probably would (M5:7). Anderson questioned who would evaluate questionnaires (M5:87).

Burch thought that baseline tests may have some merit, but questioned the value of questionnaires (M5:8). Later, Burch thought questionnaires might be very useful for small business (M5:8). Other benefits of questionnaires were noted by Howell and Rose (M5:8). Individuals with TB, fungal disease and Mycobacterial diseases could be found and helped (M5:7). Shortell thought the questionnaires may be more useful than the medical tests (M5:8).

Rose noted that asthma and HP may not be very different in a surveillance program but are handled differently in medical management (M5:8). The common denominator of removal from cause is needed in both, according to Rose (M5:8).

8.5.3 Triggers

Triggers were discussed by the committee in the context of debating the merits of the Medical Surveillance Program proposed by the Health Work Group. Specific triggers are noted in the section above on the development of the program.

The committee needs to provide the triggers for OSHA, according to Wegman (M5:8). Compared to agents like lead, MWFs do not have clear triggers, according to White (M5:8). Teitelbaum cautioned that an airborne exposure concentration may not work as a trigger (M5:8). White stated that there has to be some exposure trigger for baseline testing and Wegman agreed (M5:8). Wegman explained that some characterization of exposure or some supplemental information would drive the initial eligibility for a baseline medical test (M6:25). White noted that if an action level was the trigger instead of a PEL, many more tests would be needed (M6:25).

Other issues discussed included the use of individual cases pointing to a need to check other cases in a group and loss claims or hospitalizations or a certificate to go back to work acting as a trigger (M5:7). If the work environment improves, more workers would be in a low risk group and less testing would be needed according to Newman (M5:8).

8.5.4 Training

Cox, Wegman and Newman agreed that information dissemination was a problem (M5:8). Information on medical surveillance, in general, along with testing, symptoms and diagnosis are needed by medical personnel (M5:8). Newman and Lick noted that any medical surveillance program should include education (M5:31). Fennelly explained that education of workers, management and medical staff is a necessary component of any medical surveillance program (M5:8). More on education and training is discussed in Chapter Nine.

8.5.5 Use of Data

Lick emphasized that we need to know how the data would be used (M5:8). He was concerned that it would just be stored and not used effectively (M5:8,15). Wegman agreed with Lick, noting the committee needs to recommend how the data are used (M5:16). White explained that we need to know what to do with the information so it will allow us to intervene and protect workers (M5:8).

Wegman stated that nothing has been done with OSHA required medical surveillance data (M5:8). Wegman noted that capturing health information may be difficult as shown by Reeve (M7:29) Claims data analysis for hospitalization and general medical care utilization is rapidly evolving and there may be a way of identifying risk in the future (M7:29).

8.5.6 Separating MWF Related Symptoms or Disease from Background Levels

Kushner expressed his concern about the natural background level of asthma and how would workers with asthma unrelated to MWFs be handled in the proposed medical surveillance program (M8:15). Kushner did not see the burden in the questionnaire or pulmonary function test, but because respiratory disease is so prevalent, some people who have exposure to MWFs will be identified in medical surveillance although their illness is not related to MWF exposure (M8:16). Wegman agreed that this is a problem and noted that HP is not just related to MWFs (M8:15). Wegman stated a medical surveillance system that includes questionnaires and spirometry will focus on and find those asthmatics who don't know their problem is work related (M8:17).

Wegman explained that being asthmatic did not mean the individual will react to MWFs (M8:15). Medical monitoring appropriate for the environment will show whether the person is reacting and requires additional monitoring or medical removal (M8:15). Asthmatics would not be in monitoring forever (M8:15). Newman added that the first tier of medical monitoring would flag an asthmatic and the second tier would identify if it was work related (M8:15). Teitelbaum explained that pre-existing asthma would not trigger a group action unless the condition deteriorated due to MWFs (M8:15). Teitelbaum noted that some asthmatics will probably react to MWFs and may voluntarily leave this workplace (M8:15).

8.5.7 Other Issues

Burch recommended consideration of what the appropriate reaction of an employer should be to a prospective employee's respiratory problems noted on the baseline test (M6:25). Sheehan felt that the baseline test would identify pre-existing disease and protect the current employer from responsibility due to exposure at another workplace (M8:30). Wegman noted that his group had not discussed using a baseline test to exclude someone from a job (M9:10). Wegman explained there is no condition that *de novo* would exclude an individual from the MWF environment, if they could pass a pre-placement medical exam (M9:10).

Related to this issue, Burch was concerned about the fairness of the approach that employers have requirements while employees are volunteers for medical testing (M9:10). Sherman and Mirer clarified that OSHA has written that medical exams will be "made available" (M9:10).

How cancer would change medical surveillance was noted in a general discussion of the implications of cancer being a main health endpoint (M7:10). Anderson explained that more surveillance would be needed (M7:10). Howell suggested including cancer history as part of a questionnaire (M7:11). Medical testing may include colo-rectal exams and there would be a question on the level of medical professional needed (M7:11).

Recordkeeping and similar issues were discussed. Sherman noted that the retention of record is linked to the type of disease (M8:22). Mirer thought the re-review of data idea was excellent and should be applied to other provisions of any standard (M7:31).

The cost of medical testing and surveillance are discussed in Chapter Four. The discussion of symptoms versus disease is found in Chapter Two. A discussion of who would pay for tests and the differences between insurance carriers' interpretations of coverage of diagnostic tests vs. screening tests was noted by Burch, Wegman and Mirer (M8:22).

Smoking cessation as part of a medical surveillance document was discussed, and smoking history would be included in questionnaires (M7:30). More on smoking is found in Chapter Two on Health Issues.

Burch was concerned about ADA regulations and this topic is discussed more fully in Chapter Five (M7:31). Burch recommended determining if a questionnaire is considered a medical exam under the ADA (M9:10).

8.6 LINKAGE OF DISCUSSIONS TO OSHA ACTION

Wegman thought the committee needs to advise OSHA about the type and frequency of medical exams and other tests (M5:8). Sherman noted that the committee needs to provide a rationale for the frequency of testing since it is more frequent than usual OSHA regulations (M8:15). Teitelbaum noted that the frequency was not out of step with standards such as the lead standard (M8:15). Teitelbaum explained that the Health Work Group was very careful to note that all tests could be done by an appropriate health care professional until the problem reaches a diagnosis stage (M8:15). Licensing becomes an issue with a

diagnosis (M8:15).

Who to include is a question. Newman noted that HP can occur in offices as well as on the line (M5:8). Newman stated that medical surveillance is a safety net to help prevent health effects (M8:11).

White explained that industry will question the benefit and cost of medical surveillance (M7:30). Lick noted that he did not like medical surveillance, but without it how are you going to dispute the problems presented by labor (M6:41).

8.7 COMMITTEE DECISIONS AND RATIONALE

The committee provided extensive input into the Health Work Group's Medical Monitoring and Surveillance Document. No formal vote was taken, however the general consensus was that it was a comprehensive, best practice document. There were reservations about how small business would accomplish the actions provided in the document. The final version of the committee's Best Practice for Medical Monitoring and Surveillance is at the end of this chapter.

As indicated in section 8.5, the committee was concerned that medical surveillance data should be used. The committee recommends that annually, with the assistance of the Bureau of Labor Statistics (BLS), OSHA will identify a nationally representative sample of plants covered by the MWF rule. These plants will provide OSHA surveillance results without personal identifiers. These surveillance results will be forwarded to NIOSH for a review of the MWF surveillance findings and a report prepared for general distribution. Any plant identified through surveillance analysis to have a potential health problem not evident on the plant's OSHA 200 logs, will be informed in accordance with established policies.

The Health Work Group developed a rationale for including medical surveillance in a standard. The rationale is provided in the remaining paragraphs of this section, followed by the best practice document for medical surveillance.

There are established health effects from exposure to MWFs that warrant medical surveillance as an integral component of an OSHA action or rule. These health effects are asthma, HP and dermatitis (Greaves, 1995a & b; Sprince, 1997; Kennedy, 1999; Kennedy, 1989; Kriebel, 1997; Fox, 1999; Kreiss, 1997: MMWR,1996). There is sufficient medical evidence for each of these conditions provided in the NIOSH Criteria Document and the general medical literature which has been provided to the committee. Each of these health effects is a significant risk and represents material impairment of health. These adverse health effects have been demonstrated to occur throughout the industry. Studies and testimony provided to the committee demonstrate these diseases in large and small industry and associated with all types of fluids.

There are other health conditions related to MWF exposure for which the evidence is still evolving. These include cancer at various anatomical sites, other forms of respiratory disease and respiratory infections. These health effects are a significant risk and represent material impairment of health and are detailed in Chapter Two.

There is evidence that the adverse health effects may be mitigated so that the risk is reduced and impairment of health is minimized or eliminated. Since control of MWF exposures below the recommended PEL and appropriate systems management of the MWF environment cannot eliminate all material impairment or harm for the lung or skin, an active medical surveillance program is an essential component of a rule. Active medical surveillance mitigates risk in at least three ways:

1. Regular monitoring of workers exposed above the PEL will identify those experiencing early evidence of respiratory impairment or dermatitis and allow prevention of progression of the effects.
2. Regular monitoring of workers exposed above the action level, but below the PEL will provide a "safety net" to identify the subpopulation of individuals who may experience early evidence of respiratory impairment or dermatitis at lower levels of exposure and allow prevention of progression of the effects.
3. Active medical surveillance can help identify work areas that need intervention attention.

Active medical surveillance through routine survey questionnaires and simple spirometry, can detect asthma at an earlier stage than determined by self-report or physician diagnosis. Active medical surveillance through routine survey questionnaires, pulmonary function tests, and other laboratory tests, can detect HP at an earlier stage than determined by self-report or physician diagnosis. Active medical surveillance through routine survey questionnaires, can detect dermatitis at an earlier stage than determined by self-report or physician diagnosis.

Active medical surveillance allows early detection of adverse health outcomes and leads to better health outcomes. Key characteristics of an effective medical surveillance program are that the elements are beneficial to the worker, simple to administer, non-invasive, cost effective, and acceptable to workers, physician and employer (Halperin, 1992; Teutsch, 1994; Rutstein, 1983; Mullan, 1991; Halperin, 1985; Balmes, 1991; Mastrangelo, 1997; Meredith, 1994; Ross, 1997; Gannon, 1993; Roos, 1996; Rosenman, 1997; Timmer, 1993; Reilly, 1995). With these considerations in mind, the following elements of an active medical surveillance program were incorporated.

Questionnaires eliciting history and symptoms of respiratory illness, including asthma and HP, have been demonstrated to be effective tools for the detection of respiratory disease in general, and occupational respiratory disease in particular (Jones, 1992; Abramson, 1991; Venables, 1993; Donoghue, 1993; Ferris, 1978; Smith, 1989; Toren, 1993; Samet, 1978; Brodkin, 1993; Burney, 1989; Burney, 1996). These questionnaires are of demonstrated utility in identifying pre-existing and co-existing non-occupational causes of respiratory illness. Such questionnaires have been demonstrated to have reasonably high

sensitivity, specificity and reliability and validity. They are simple, efficient, and inexpensive to adminster and are non-invasive as well as acceptable to workers, physicians and employers with appropriate privacy protection.

Simple spirometry complements questionnaire information and both supplements and confirms respiratory disease in general and occupational respiratory disease in particular (Smith, 1989; Hankinson, 1999; American Thoracic Society, 1995; American Thoracic Society, 1991; Kennedy, 1999; Becklake, 1993; Becklake, 1992, Oxman, 1993). When used as baseline tests they provide an objective reference point for subsequent comparisons. These tests have demonstrated utility in identifying occupational as well as preexisting or co-existing non-occupational causes of respiratory illness and in providing an objective measure of disease severity and impairment. These tests are readily available, well standardized, and when administered by a NIOSH certified technician provide reliable data on respiratory status for interpretation. Such tests have been demonstrated to have reasonably high sensitivity, specificity and reliability and validity. They are simple, efficient, and inexpensive to administer and are non-invasive as well as acceptable to workers, physicians and employers with appropriate privacy.

The combination of a dermatologic questionnaire and physical examination of the skin constitute the standard of practice for early detection of both occupational and non-occupational dermatitis (Adams, 1990; Marks, 1992; Nethercott, 1994). They are simple, efficient, and inexpensive to administer and are non-invasive as well as acceptable to workers, physicians and employers with appropriate privacy.

Studies have demonstrated that all workers who are exposed to MWFs are at potential risk of the above health effects. Consequently, both initial and ongoing surveillance of exposed workers is indicated. Cases of MWF-related respiratory and skin illnesses have occurred within 30 days of first exposure. Exposure has been defined as work with MWFs at or above the action level for 30 days or more in accordance with established OSHA procedures. Delaying eligibility until 30 days increases the likelihood of identifying only those individuals with exposure-related disease. Basic periodic medical surveillance should be required no more frequently than annually. The rate of development of abnormal symptoms or pulmonary function in the general population can be detected with this frequency of testing. While abnormalities may develop in the year between annual tests, it is expected that unapparent disease will be efficiently detected at this interval and that individuals with more obvious disease or illness will seek medical attention which will trigger enhanced surveillance through the sentinel event response. When an abnormality has been detected, resurveying within a minimum of two months of detection of the abnormality is prudent practice and allows sufficient time for acute non-occupational illnesses to resolve.

In order to improve likelihood of detecting adverse health effects in the highest risk individuals enhanced periodic monitoring is indicated for those who show evidence of abnormality or have experienced prolonged exposure above

the PEL. Eligibility for enhanced periodic monitoring, however, is contingent upon demonstrating the repeatability of the abnormality. This is in keeping with standard medical practice and reduces the likelihood of inappropriate action on transient non-work related illnesses or laboratory error. In the presence of abnormality, increased periodicity of testing is justified in order to mitigate material impairments of health. The frequency recommended is consistent with the known natural history of MWF health effects.

Cross shift simple spirometry, as an added component of enhanced medical surveillance, provides a specific measure of work-relatedness (Bernstein, 1993; Newman, 1995; Chan-Yeung, 1995; Chan-Yeung, 1996; Venable, 1997; Wagner, 1998, Milton, 1998; Rose, 1998). This information would not be obtained in any other fashion. An acute drop in $FEV_{1.0}$ or FVC following exposure is a sensitive indicator of asthma or HP (Chan-Yeung, 1995; Rose, 1998). A cross-shift decrement of 10% or greater is unlikely to occur by chance and in exposed workers is indicative of an acute work-related respiratory health effect which should be immediately resurveyed. From a health perspective it would be inappropriate to delay such resurveying for more than one month. Repeated abnormality on cross-shift spirometry testing is strong indication of a work-related disease warranting special examination because it is essential to intervene before irreversible damage occurs.

Even a single case of occupational respiratory disease or dermatitis is important as a sentinel event. Sentinel events are a well-recognized indicator of potential presence of a hazard to the remainder of a workforce which may be amenable to control before other workers are affected (MMWR, 1996; Rutstein,1989; Mullah, 1991; Bernstein, 1993). A sentinel event may indicate a failure in fluid management and occupational hygiene controls. Thus, any single sentinel event warrants a series of response actions for the individually affected worker, for all other workers in that environment, and for the environment itself.

Medical removal protection and multiple physician review are important components of an effective medical surveillance program, more so for MWFs than for several other chemical agents for which OSHA has provided this provision. Diagnosis of MWF related respiratory illness depends heavily on employee's accounts of symptoms or time course of objective signs of illness. The proposed standard requires, and occupational medical practice frequently employs temporary removal from exposure as a diagnostic tool, to see whether the illness resolves on removal from exposure. Temporary restrictions may be needed while controls are installed, and in a few instances permanent restrictions may also be necessary to protect individuals with advanced illness. Employees will be reluctant to reveal this information if they fear it will lead to job restriction and attendant loss of self-esteem or compensation. The committee heard direct testimony on this point and there is extensive evidence of this from personal experience of some committee members. Machining jobs were also recognized to be the higher paying and higher skilled jobs in many MWF using facilities, which would provide incentives for employees not to disclose symptoms. Medical

removal protection is needed for maximum effectiveness of medical surveillance. Multiple physician review is another best practice, mirroring procedures from the general health care system. An example of regulatory text for medical removal protection and multiple physician review is provided in Attachment #10.

Medical Monitoring and Surveillance for Non-Malignant Respiratory and Skin Disorders

Goals of Proposed Medical Surveillance Program:

Assumption: Control of MWF exposures below a PEL of 0.5 mg/m^3 will reduce but not eliminate all impairment or material harm to the lungs or skin due to MWF exposure.

Goals:

1. Regular monitoring of workers exposed above the PEL will identify those experiencing early evidence of respiratory impairment or dermatitis and allow prevention of progression of the effects [1]

2. Regular monitoring of workers exposed above the AL, but below the PEL will provide a "safety net" to identify the subpopulation of individuals who may experience early evidence of respiratory impairment or dermatitis at lower levels of exposure and allow prevention of progression of the effects [2]

3. The demands of an effective medical surveillance system will provide an incentive to eliminate exposure circumstances that require medical surveillance, thus eliminating the need for continuation of the surveillance system.

Proposed Medical Surveillance System

I. Baseline Medical Examination

A. Content of Baseline Medical Exam
1. Questionnaire [3-5]
2. Baseline Simple Spirometry tests administered by NIOSH certified spirometry technician [6]
3. Physical Exam of the skin by appropriate health care professional [7]

B. Eligibility
1. **Currently Exposed:** Currently work where exposure is >Action Level for 30 days per year
2. **Previously Exposed:** Currently ***unexposed*** workers who, during the period of employment with the current employer have a history of ***previous*** work in an area where the PEL was exceeded >30 days per year for a minimum of two years.

C. Timing
1. New employees shall be examined within 2 weeks of assignment to MWF work area
2. Current employees not previously examined should be examined within 6 months of the implementation of the programs' implementation.

D. Response to results of baseline medical examination of previously exposed
a. If results are normal then no further action needed
b. If results of any of the three Baseline Medical Exam tests are abnormal, then enroll in Enhanced Periodic Medical Monitoring until those results are stable for

two consecutive re-surveys.

II. Periodic Medical Monitoring Program

A. Basic Periodic Medical Monitoring
1. Eligibility Criteria
   a. Currently work in an area >Action Level and < PEL
   b. Basic Medical Examination normal
2. Content of Basic Periodic Medical Examination
   a. Follow-up questionnaire for changes in respiratory or dermatitis symptoms
3. Performed annually in the absence of any abnormality

B. Enhanced Periodic Medical Monitoring
1. Eligibility Criteria
   a. Currently work in an area > PEL
   b. Abnormal Basic Medical Examination or follow-up examination
2. Content of Enhanced Periodic Medical Examination
   a. Basic Medical Monitoring program (Follow-up questionnaire for changes in respiratory or dermatitis symptoms)
   b. Cross-shift simple spirometry
3. Performed annually in the absence of any abnormality

III. Actions Resulting from Medical Surveillance Examination Outcomes

A. Definition of Baseline Examination Abnormality
1. A worker in the current MWF exposure environment who is found to have abnormal respiratory or dermatitis symptoms or abnormal simple spirometry tests on baseline exam.

ACTION:
Abnormal test results need to be replicated. Abnormal symptoms should be resurveyed within no more than two months of initial baseline exam. If abnormality persists, enter into Enhanced Periodic Medical Examination Program

B. Definition of Basic Periodic Medical Examination Abnormality
1. New onset, or increase in, abnormal symptoms.

ACTION:
Respiratory symptom abnormalities need to be resurveyed within two months. If symptoms are replicated then enter into Enhanced Periodic Medical Examination.

C. Definition of Enhanced Periodic Medical Examination Abnormality
1.New onset, or increase in, abnormal symptoms
2.Cross-shift Drop in FEV_1 or FVC of 10% or greater

ACTIONS:

a. Respiratory symptom abnormalities need to be resurveyed within six months. If symptom abnormalities are replicated then referral for Special Examination shall be made
b. Cross-shift drop abnormality needs to be resurveyed within one month. If same or greater cross-shift drop is documented then referral for Special Examination shall be made. **NOTE:** Special examinations are to be performed by Qualified Physician following the specified algorithms (see appendix) or their equivalent.
c. Conduct environmental review of work area and implement appropriate follow-up action. At a minimum, the environmental review shall include
    i. For respiratory symptoms, supplemental exposure monitoring of the affected job.
    ii Review of the Fluid Management Program to evaluate potential factors that may be contributing to the abnormality.
    iii Review the engineering and administrative controls, work practices and personal protective equipment being used on the affected job.

IV. Sentinel Events

A. Definition

Sentinel event is a disease diagnosis in one individual which is considered sufficient, alone, to indicate need to examine a work setting to determine whether other individuals similarly exposed are at risk of the same disease.

Potential sentinel event is a report of respiratory or skin problems by a worker exposed to MWF who reports the problem to the appropriate supervisor or health care professional.

B. Sentinel events related to MWF exposures

1. Respiratory
    a. New onset asthma or new asthma attacks diagnosed in a currently exposed worker(s)
    b. Hypersensitivity Pneumonitis is diagnosed in any worker in the facility
2. Skin
    a. Dermatitis due to MWF is diagnosed.

C. Sentinel Event Response action

1. Sentinel event investigation in the work area where the individual worked
2. Health evaluation
    a. All employees in the Sentinel Event Area are requested to participate
    b. Respiratory sentinel events
    Volunteers are provided with a medical examination following the algorithm (see Appendix A) or its equivalent.
    c. Skin sentinel events
    Volunteers are referred to a physician familiar with occupational skin disease.
3. Environmental evaluation
    a. Conduct an evaluation of the work area to determine if there is a correctable exposure circumstances that might have caused or contributed to the sentinel event and take appropriate follow-up action. Such an evaluation shall include, at a minimum:

b. For respiratory events, supplemental exposure monitoring of the affected job(s) and representative samples of similar jobs in the work area; if the sentinel event is hypersensitivity pneumonitis, then assessment of bioaerosols should be added to the monitoring of airborne exposures.
c. A comprehensive review of the Fluid Management Program to determine whether fluid system factors, changes or upsets may have contributed to the event.
d. A review of the engineering and administrative controls, work practices and personal protective equipment being used in the affected job(s) and similar jobs in the affected area and an evaluation to determine if supplemental controls, practices or equipment can reduce exposures potentially related to the event.

4. If event meets criteria for a *potential sentinel event*
   a. The individual is referred for enhanced periodic monitoring to be performed as soon as possible, within two weeks of report.
   b. Confirmed sentinel event follows from results of enhanced periodic monitoring exam or qualified physician diagnosis.

V. Medical Removal

A. Causes for medical removal for an employee working with MWF
1. Diagnosis of new onset ***asthma*** in a pattern related to exposures to MWF or diagnosed as due to exposure to MWF
2. Diagnosis of exacerbation of ***asthma*** (asthma attacks) in a pattern related to exposures to MWF or diagnosed as due to exposure to MWF
3. Diagnosis of ***hypersensitivity pneumonitis*** in a worker exposed to MWF
4. Diagnosis of dermatitis due to MWF

B. Return to work protocol
1. After remediation of identified problems in environmental controls
2. For respiratory conditions, after minimum of 2 weeks (longer duration at discretion of physician)
3. For skin conditions, after recovery from dermatitis as certified by the diagnosing physician
4. Return to work in area where exposures are < action level or to areas > action level at the discretion of the diagnosing physician.

C. Medical removal protection
1. An employee on medical removal will have earnings, seniority and other employment rights and benefits maintained

VI. Multiple Physician Review

A. Right to seek a second medical opinion after a special examination or other required medical diagnostic examination.

B. If results differ physicians should attempt to resolve any disagreement.

C. If quick resolution is not possible then a third opinion is sought by physician agreed to by first two

D. Third physician's recommendations are acted on unless employer and employee agree to act on recommendation of one of the first two.

E. An alternative method to multiple physician review can be agreed to by the employee and employer so long as the alternative is expeditious and at least as protective of the employee

VII. Criteria to Cease Medical Surveillance The following need to be documented

A. < AL for > 11 months

B. No subsequent sentinel events

C. Current medical surveillance findings have been stable for the past two cycles

VIII. Definitions

AL = Action Level
A time-weighted exposure level equivalent to ½ of the PEL

Asthma
Asthma diagnosed by a physician or asthma-like symptoms (see below)

Asthma and Hypersensitivity Pneumonitis Evaluation Algorithms (See attached)

Cross-shift drop
Simple spirometry measurement before shift starts and then repeated after a minimum of six hours. Percent drop is calculated as (Pre-shift - Post-shift)/(Pre-shift).

Simple Spirometry
Ventilatory function tests which collect, at a minimum, measurements of Forced Expiratory. Volume in one second (FEV_1 and Forced Ventilatory Capacity (FVC). Results recorded are FEV_1, FVC, and FEV_1/FVC.

Tests are collected according to most current criteria of American Thoracic Society: American Thoracic Society. Standardization of spirometry: 1994 update. Amer Rev Respir Dis. (1995) 152:1107-36

Baseline Simple Spirometry Abnormalities

Percent of Predicted (FEV_1)	<	75%
Percent of Predicted (FVC)	<	75%
FEV_1/FVC	<	70%

Percent Predicted based on age, gender, race and ethnicity models: Hankinson JL, Odencrantz JR, Fedan KB. Spirometric reference values from a sample of the general U.S. population. Amer J Respir Crit Care Med (1999) 159:179-187

Physical Exam

A complete physical examination with emphasis on the skin and the respiratory system

Questionnaire Content Areas

MWF medical surveillance questionnaire will be used to trigger evaluation and help guide in clinical assessment of possible MWF-related illness; information would be included in materials shared with clinician conducting clinical assessment

Initial questionnaire:

- 1.0 Identifiers, contact information, employer, and demographics
- 2.0 Report of recent respiratory infection symptoms
- 3.0 Respiratory questions: Asthma symptoms, bronchitis symptoms
  - 3.1 Relation of symptoms to work or other activities/environments
  - 3.2 New onset or recent worsening of symptoms
  - 3.3 Physician diagnosed asthma or bronchitis
  - 3.4 Other causes of asthma/bronchitis
- 4.0 Respiratory/Systemic questions: Hypersensitivity pneumonitis
  - 4.1 Relation of symptoms to work or other activities/environments
  - 4.2 New onset or recent worsening of symptoms
  - 4.3 Physician diagnosed hypersensitivity pneumonitis, interstitial lung disease or pneumonia
  - 4.4 Other causes of hypersensitivity pneumonitis
- 5.0 Skin questions: rash and skin symptoms
  - 5.1 Relation of symptoms to work or other activities/environments
  - 5.2 New onset or recent worsening of symptoms/rashes
  - 5.3 Physician diagnosed contact, allergic dermatitis
  - 5.4 Other causes/contributing factors to dermatitis
- 6.0 Smoking (American Thoracic Society, Ferris 1978)
- 7.0 Physician-diagnosed MWF disease (yes no)
- 8.0 Additional questions for purposes of guiding future modifications in OSHA medical surveillance recommendations: e.g., non-actionable questions regarding rectal cancer and skin cancer

Follow-up questionnaire will be designed to target evolution of symptoms; content would emphasize change in symptoms since person's last survey

- 1.0 Identifiers, updated contact information and demographics
- 2.0 Report of respiratory infection symptoms since last survey
- 3.0 New or worsening Asthma symptoms, bronchitis symptoms
  - 3.1 Relation of symptoms to work or other activities/environments
  - 3.2 New onset or recent worsening of symptoms
  - 3.3 Physician newly diagnosed asthma or bronchitis
  - 3.4 Other causes of asthma\bronchitis
- 4.0 New or worsening Respiratory/Systemic symptoms suggestive of Hypersensitivity pneumonitis
  - 4.1 Relation of symptoms to work or other activities/environments
  - 4.2 New onset or recent worsening of symptoms

4.3 New Physician diagnosed hypersensitivity pneumonitis, interstitial lung disease or pneumonia
4.4 Other causes of hypersensitivity pneumonitis
5.0 New or worsening Skin questions: rash and skin symptoms
5.1 Relation of symptoms to work or other activities/environments
5.2 New onset or recent worsening of symptoms/rashes
5.3 New Physician diagnosed contact, allergic dermatitis
5.4 Other causes/contributing factors to dermatitis
6.0 Updated Smoking (American Thoracic Society, Ferris 1978)
7.0 New Physician-diagnosed MWF disease (yes no)
8.0 Additional questions for purposes of guiding future modifications in OSHA medical surveillance recommendations: e.g., non-actionable questions regarding rectal cancer and skin cancer

Respiratory symptoms collected using:

1) The currently recommended American Thoracic Society symptom questionnaire: Ferris BG. Epidemiology standardization project: Section C. Questionnaires. Amer Rev Respir Dis (1978) 118(part 2):10-27.

2) Supplemented by asthma questions derived from:
Abramson MJ, Hensley MJ., Saunders NA, Wiodarczyk JH. Evaluation of a new asthma questionnaire. J Asthma (1991) 28:129-139.
Venables KM, Farrer N, Sharp L, Graneek B J, Newman-Taylor AJ. Respiratory symptoms questionnaire for asthma epidemiology: validity and reproducibility. Thorax (1993) 48:214-219.
Donoghue AM. Respiratory symptoms questionnaire for asthma epidemiology: validity and reproducibility (letter) Thorax (1993) 48:871.
Kennedy SM, Chan-Yeung M, Teschke K, Karlen B. Change in airway responsiveness among apprentices exposed to metalworking fluids. Amer J Respir Crit Care Med (1999) 159:87-93

Dermatitis symptoms collected

An MWF medical surveillance questionnaire will be used to trigger evaluation and help guide in clinical assessment of possible MWF-related illness; information would be included in materials shared with clinician conducting clinical assessment

Initial and follow-up questions will be based on the NIOSH adaptation of the questions for hand dermatitis (eczematous dermatitis) for NHANES IV which in turn were adapted from National Health Interview Survey - Occupational Health Supplement 1988

Respiratory Symptom Abnormalities

a) ***Simple Bronchitis*** in a non-smoker
Defined by positive answers to American Thoracic Society questionnaire to:
"Do you usually cough as much as 4 to 6 times a day more than 4 days out of the

week"

or

"Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week?"

b) ***Chronic Bronchitis*** in a cigarette smoker

Defined by positive answers to American Thoracic Society questionnaire either to:

"Do you usually cough like this on most days for 3 consecutive months or more during the year?" and an indication that this has happened for at least 2 years.

or

"Do you usually bring up phlegm like this on most days for 3 consecutive months or more during the year?" and an indication that this has happened for at least 2 years.

c) ***Asthma-Like Symptoms****:*

A definition of asthma-like symptoms will be based on an adaptation of questions drawn from Venables, et al, Donoghue, and Kennedy et al. The Venables study would indicate a positive answer to 2 or 3 of the 9 questions would qualify as evidence of asthma-like symptoms. Once the questions are adapted, a similar rule would be provided.

Venables questions:

1. If you run, or climb stairs fast do you ever
   a. Cough?
   b. Wheeze?
   c. Get tight in the chest?
2. Is your sleep ever broken by
   a. Wheeze?
   b. Difficulty with breathing?
3. Do you ever wake up in the morning (or from sleep if a shift worker) with
   a. Wheeze?
   b. Difficulty with breathing?
4. Do you ever wheeze
   a. If you are in a smokey room?
   b. If you are in a very dusty place?

Donoghue suggests the addition of three questions to the Venables questions

1. On holidays are the problems you answered "yes" to, better, worse, or unchanged?
2. On weekends are the problems you answered "yes" to, better, worse, or unchanged?
3. On Mondays are the problems you answered "yes" to, better, worse, or unchanged?

Kennedy supplemented each of the ATS (Ferris) respiratory symptom questions with "Is there any thing or situation which makes your (...'symptom') worse

(and if so, describe)?"

d) Dermatitis symptom abnormalities

A definition of dermatitis symptom abnormalities will be based on an adaptation of questions drawn from the NHANES IV NIOSH adaptation.

IX. Non-mandatory guidance (to be included in an appendix)

A. Maintenance work is included in the concept of MWF exposure

B. Longitudinal change in pulmonary function can be used as a trigger for more enhanced medical surveillance or for special medical examination

$10% drop or $350 mlsl in FEV or FVC from baseline

C. Sickness absences for respiratory illnesses can be used as a trigger for more enhanced medical surveillance or for special medical examination

Sickness Absence $3 days due to respiratory disease or hospitalized for a respiratory disease.

Sickness absence for unexplained febrile illness $2 times within 6 months

Questions for Hand Dermatitis (Eczematous Dermatitis) for NHANES IV
Adapted from National Health Interview Survey - Occupational Health Supplement 1988

* 1a. During the past 12 months, that is since (month date) a year ago, have you had dermatitis, eczema, or other red, inflamed skin rash?

_____Yes
_____ No (Go to end)
_____ Don't know (Go to end)

lb. During the past 12 months, on about how many days altogether did you have this skin condition? Include days when you used treatment for the condition.

_____Every day
_____Days

* lc. Do you have this skin condition today?

_____Yes
_____No

* 2. What parts of the body were affected by this skin condition? (Mark all that apply)

_____Hands _____Head, face or neck
_____Arms _____Other body area (specify)_____

3a. During the past 12 months, did you use any prescription medications or other treatments prescribed by a doctor for your skin condition?

_____Yes
_____No
_____Don't know

3b. Did you use any over-the-counter or non-prescription medications or treatments for your skin condition?

_____Yes
_____No
_____Don't know

* 4a. Did this skin condition you had in the past 12 months result from chemicals or other substances which got on your skin?

_____Yes
_____No (Go to end)
_____Don't know (Go to end)

* 4b. What chemicals or other substances were these?

_____

* 4c. Were you at work or your job or business when you got these substances on your skin?

_____Yes
_____No (Go to end)
_____Don't know (Go to end)

4d. During the past 12 months, did you miss at least a full day from work because of your skin condition?

_____Yes
_____No
_____Don't know

4e. During the past 12 months, have you stopped working at a job or changed jobs because of your skin condition?

_____Yes
_____No
_____Don't know

4f. During the past 12 months, did you report your skin condition to your employer as a work-related illness or injury?

_____Yes
_____No
_____Don't know

4g. During the past 12 months, was a worker's compensation claim filed for your skin condition?

_____Yes
_____No
_____Don't know

*** Key Questions**

CHAPTER NINE
Deliberations Related to Best Practice: Training and Information Outreach

9.1 GENERAL INFORMATION

The committee discussed the issue of training and information outreach as a part of many different discussions. The Cooperation and Comparisons Work Group and its renamed version, the Training and Information Infrastructure Work Group (referred to as the Training Work Group in this chapter) identified useful sources of information and training. Many of the efforts are cooperative ones among different industries and between industry and labor.

9.2 SPEAKERS AND PRESENTATIONS

Darrell Mattheis, ORC, provided information about that organization's activities as well as the ORC document as a training tool. Committee member, Dr. John Howell explained the ILMA Product Stewardship Program. Tom Hanlon, United Technologies, as a member of the audience was invited to speak about websites (M6:36). Speakers on other issues addressed training as well. These speakers included: Dr. Cecile Rose, National Jewish Research and Medical Center; Dr. Daniel Goon, Castrol; Dr. Ed Stein, OSHA; Stephen Gauthier, a machinist at a large manufacturing facility on the East Coast; Thomas Slavin, Michelle Lantz, Caterpillar; and John Burke, Eaton Corp.

9.3 BACKGROUND INFORMATION

Training is a common requirement in OSHA standards and guidelines. The recent Industrial Truck Standard was cited by many members as an example of a comprehensive approach to training. Training is a major component of the Hazard Communication Standard. Stein explained that the recommendations in early OSHA and NIOSH work about dermatitis emphasized the need for training (M5:28). NIOSH also recommends training of employees who use MWFs (NIOSH, 1998).

9.4 REVIEW OF AVAILABLE INFORMATION

9.4.1 Experiences and Resources Related to the Need for Training and Information Outreach

Committee members noted the importance of training. Lick explained that inadequate training has led to over-reaction and worsened problems (M2:15). Howell noted that salesmen often do not have the expertise to aid customers with their MWF program (M4;4).

Education of users at all levels will have the best payoff, according to Howell (M5:16). Howell thought that initial expenditures for education and awareness should occur before engineering controls (M4:8).

Education has to be part of medical surveillance according to Lick and

Newman (M5:31). Rose indicated that HP diagnosis is not covered adequately in many medical schools (M5:5). Wegman noted that better training of medical personnel on MWF related problems is needed to effectively address medical surveillance (M5:8). Rose stated that patients do not always know what symptoms to pay attention to and report in a questionnaire (M5:7).

Burch reported that the Cooperation and Comparison/Training and Information Infrastructure Work group listed the following groups as needing training: small businesses segmented by number of employees, operators, supervisors, senior management on the shop floor, unions, worker's compensation carriers, OSHA compliance officers, OSHA operating management, health and safety professionals, apprentices, trade associations, physicians (including primary care), compensation carriers and trade schools (M5:30; 8:3,20). Lick reported that the Systems Work Group added: suppliers, MWF managers, and tool makers to the list and stressed the importance of training compliance officers (M5:29; 8:1). Gauthier recommended not only teaching the new machinist about machining, but about MWFs as well (M8:19).

9.4.2 Existing, Developing and Needed Programs

9.4.2.1 0RC

Reports were made to the committee about the progress made by ORC in the area of training and information outreach (M5:30; 8:9). Mattheis explained that ORC is working with ILMA, AAMA and the Chemical Manufacturer's Association to develop a series of nationwide one day seminars for 1999 (M6:36). Low cost, one day seminars at universities with help from government funding and planning were recommended by Mattheis (M9:6). In addition, train the trainer programs are anticipated (M6:36). According to Mattheis, ORC planned to have education and outreach programs organized in every state by working together with OSHA, NIOSH, organized labor, universities and the business community (M9:6). Mattheis stressed the need to include labor and mid and small size business in ORC's development of education and outreach (M6:36). Local and national associations, local health department and other organizations could help provide participants and ORC would help with these efforts (M8:6). The seminars would include health issues but focus on fluid management and use the ORC Guide (M9:6).

The ORC document can be used as a centerpiece for outreach, training and education spearheaded by industry and White hoped labor as well (M8:6). Cox noted that it would be an excellent training tool (M8:7). Newman agreed that the document was a powerful teaching tool (M8:11). Newman thought it was more of a trainer's manual and recommended using simple terms like cough so workers would recognize if they had a problem (M8:11). According to Howell, the ORC document expands on what is needed by the Hazard Communication Standard, explaining what symptoms to expect and how workers can protect themselves (M:9:8).

9.4.2.2 *ILMA Product Stewardship*

Howell explained that ILMA's product stewardship program, ILMA MWFPSG at different times during the committee's deliberations (M4:4; 5:31). He explained that the program was finalized and a training session was provided in early May, 1999 (M9:11). Companies who participate will be committed to providing customers information and training on how to properly use MWFs in the workplace (M9:11). It is ILMA's view that products are safe as formulated and when used and managed as directed (Howell, 1998). Members reformulate when new health and safety data indicate it is prudent to do so (Howell, 1998).

The objectives of ILMA's program are: to demonstrate member companies' commitment to manufacturing and marketing safe and effective products; to enhance the safety and health of our own and our customer's employees; to develop sound, scientific peer reviewed data and to protect the environment (Howell, 1998). Additional goals include: development of educational materials; identification and addressing of potential data gaps; evaluation of potential risks; identification of work place factors affecting exposure; and development of a comprehensive product stewardship program (Howell, 1998).

A detailed written program for potential member companies has been put together (MWFPSG, 1999). The document "walks" the member through the program and provides a self assessment checklist and an extensive resource list (MWFPSG, 1999).

Wegman suggested that ILMA provide fluid specific training materials for customer's employees to avoid errors customers may make by developing their own training materials (M6:35). Howell noted that Burke's ideas for labeling and education would be taken back to the ILMA MWFPSG[SM] (M6:35).

Training, product stewardship and dissemination of information are essential and Howell thought they could accomplish more in a shorter time than other options (M6:24). Howell viewed that the supplier was accountable for providing education and outreach to customers (M8:12). Product stewardship is also noted in Chapters Three and Six.

9.4.2.3. *Medical Professionals*

Wegman noted the importance of having a trained medical person involved in medical surveillance (M8:20).The Training Work Group noted the difficulty of providing information to physicians, especially family doctors (M8:20). Shortell noted that a very clear message to physicians about HP is needed (M5:30).

Teitelbaum explained that the best way to reach occupational physicians was through peer reviewed journal articles and teaching (M5:30). Wegman thought some materials about MWFs and disease should be sent to physicians by the employer (M8:20). Burch noted that his organization had prepared a form for ADA for workers to take to physicians (M8:20). Sherman explained that some OSHA standards require the employer to provide information to physicians (M8:20). Anderson stated that the best teachable moment for physicians is when they are about to see a patient (M8:20). Anderson recommended that any

employer form should not be too complex (M8:20). Cox explained that the Training Work Group did not want to make decisions for physicians but wanted to make sure physicians knew the relation between symptom, disease and MWF exposure (M8:20).

Anderson explained that a list of physicians by specialty can be obtained due to licensure (M8:20). He recommended targeting physicians who are seeing these patients, physicians who have a relationship with employers, and to use the OSHA consultation program (M8:20).

9.4.2.4 *Industrial Hygienists and Safety Professionals*

Kushner noted that health and safety professionals have done a poor job of communicating risk to employees and employers (M6:39). O'Brien was concerned that industrial hygienists do not know much about MWF systems management (M7:11). Lick disagreed noting that training can be accomplished through short courses (M7:11). According to Lick, industrial hygienists and safety engineers can be reached through their professional societies which offer conferences, and professional development courses (M5:30).

9.4.2.5 *Courses and Websites*

Burke explained that the Society for Manufacturing Engineers (SME) and the Society of Tribologists and Lubrication Engineers already have training courses that could be adapted to a certification standard (M6;30). Lick also noted courses by SME and other organizations and thought some vendors may view this as an entrepreneurial opportunity (M5:30).

Hanlin explained that the National Metal Finishing Resource Center has a listserve and people can send in questions and give responses (M6:36). He noted his company has an intranet MWF information resource with applications specifically for his company (M6:36). The intranet has hyperlinks to various sources including email links to individuals in the company that can help address specific problems (M6:36). White noted that many companies have intranet sites and this is a useful resource for distributing information within companies (M6:36). Day noted that all unions have websites and that they link to other sources (M6:36).The ILMA webpage provides a wide range of information, according to Howell (M4:4). Day noted OSHA's web page which includes presentations available for respiratory protection and fork trucks (M9:11).

The Cooperation and Comparisons/Training work group wanted to have a committee website separate from OSHA due to concerns about bias (M6:36). The work group recommended information such as members, links to organizations, charter, contacts at OSHA, minutes and linkage to the docket (M8:21). A bibliography would also be useful (M8:21). Sheehan volunteered West Chester University as a location for this website.

9.4.2.6 *Labor/Industry Cooperative Efforts*

The Chrysler/UAW training document on MWFs was received by the group

(M6:23). Mirer explained that this booklet integrated with Hazard Communication training (M8:21). Current train the trainer activities do not usually include MWFs, according to Day, although he has incorporated MWFs into his training (M5:30). Gauthier provided some training materials that he has successfully used (M8:20).

Day includes MWF within the construct of the OSHA 30 hour courses which allow additional modules to be taught along with basic requirements (M9:11). Day explained OSHA local offices have resources as well as NIOSH (M9:11). Day noted that he distills out information from the NIOSH Criteria Document because this document is too involved for workers to read (M9:11).

9.4.2.7 *Other Programs and Ideas*

The Cooperations and Comparisons work group provided information on the SHARP program in Washington State (M3:15). This program provides a document *Metalworking Fluids: A Resource for Employers and Health and Safety Personnel in Washington State* (1997). The document summarizes health effects, components, and provides a self assessment tool for industry (Washington State, 1997).

Burch noted that some ISO activities on health and safety include training (M5:30). O'Brien stated that a new outreach program is starting at the NIOSH Morgantown office (M5:30; 6:36).

PMPA has a manufacturing fundamentals book for new hires that addresses MWF safety (M8:20). Other industry trade groups may also provide resources to their members.

Burke recommended training and certification of fluid specifiers and handlers (M6:29). He also suggested on-site manuals (M6:29). Mattheis explained that a proactive, thorough on-going educational program unlike any ever seen is needed (M5:24).

9.4.3 Material Safety Data Sheets

Teitelbaum was concerned about the adequacy of MSDSs (M1:2). He provided examples of ones he thought were inadequate (M5:21). He noted comments such as no harmful effects and that asthma and HP were not mentioned (M5:21).

Goon was concerned that Teitelbaum was judging formulators using an MSDS from a supplier to fluid formulators (M5:21). Goon felt that an MSDS is the wrong place to look for complete formulation information because manufacturers are not obligated to give this information (M5:21). Companies are concerned about proprietary information but will provide this information one-on-one, according to Goon (M5:21). Lick was concerned that only big companies can pressure formulators to do this (M5:22). Goon and Lucke agreed that the quality of MSDSs are poor in general in industry (M5:21). Howell noted that the quality varied among industries (M9:13).

Lick noted that the ANSI format is the appropriate one to use for MSDSs (M5:22; 9:13). An initial summary should be used and the format should be

consistent and uniform (M9:13). Howell explained that only those components 1% or more of the total had to be listed on an MSDS (M5:22).

Burch agreed with Teitelbaum's ongoing concern about MSDSs (M9:13). He noted that small business takes the information from the MSDS and assumes it is accurate and trains from it (M9:13). Better MSDSs will result in better training (M9:13). He thought the MSDS was written more for legal protection than training (M9:13). Day cautioned against using MSDSs as the core of training (M9:13). Workers need to know how to read MSDSs but training to the chemical requires more information than an MSDS (M9:13). Lick noted common misconceptions about MSDSs such as thinking that it is appropriate to train from them (M9:13).

Additional references are cited in other Chapters and are also found in Attachment #6.

9.4.4 What Should be Included in Training

Burch reported for the Cooperation and Comparisons/Training and Information Infrastructure work group (M19). The group recommended that any training include: identification of the problem, development of goals, assembling of a program and materials, implementation and evaluation of the program, and improvement as needed (M8:19). The group noted that many of these components are part of Hazard Communication and other OSHA standards (M8:19). The recent industrial truck operating standard was cited because it provides for more specific training that reflects the work site and the previous experiences and training of the worker (M8:19). A training needs assessment should be done (M8:20). The frequency could follow the industrial truck standard and should involve an assessment of behavior to determine a need for training (M8:20). Training has to be fluid specific (M8:20). Checklists are good and retraining when conditions, risks, fluids change or at least annually would be appropriate (M8:20).

According to the Cooperation and Comparisons/Training and Information Infrastructure work group, training should be symptom driven and the symptoms linked to specific potential diseases (M8:20). Linkage of symptoms and disease to specific actions to take by the individual being trained is important (M8:20). Wegman urged explaining the work-relatedness of symptoms (M9:12).

The work group explained that any training would depend on the fluid, exposures and risk (M8:2). The approach and content would be different depending on the audience (M8:20). The issue of long term risks has to be addressed and how the fluids have changed over time (M8:20). Anderson explained that it was important to include information about cancer in training, especially regarding minimizing skin contact (M7:10).

Wegman suggested a preamble in the training section that identifies the health endpoints of concern which would guide most of the training effort (M8:20). Despite any disagreements on the relation of MWFs and symptoms, workers have to be trained on any relevant symptoms that are work related (M9:12). Mirer noted that whatever OSHA puts in a preamble of a standard or

guideline would have to be addressed in training (M8:21). Any reputable statistically significant study has to be addressed (M8:21).

The Training Work Group recommended records such as training materials, attendance logs and evaluations checklists (M8;21). A three year retention may be appropriate and Sherman noted that as new training materials are developed they can replace the old ones (M8:21). Any recordkeeping should be done in a way to meet multiple uses by the employer (8:21).

The Training Work Group recommended integration of training under Hazard Communication (M9:11). Burch noted that the training document would supplement Hazard Communication unless the committee recommended training separate from this standard as part of a regulation (M9:12). Howell cited the Hazard Communication section H of 1910.1200, noting that what was emphasized by Wegman and Burch was included already (M9:12).

Burke recommended including information on: off work activities that cause problems, personal hygiene, good work practices and recognizing warning signs of disease (M6:30). Personal protective equipment training, as needed, could be included stated Burke (M6:30).

Sheehan urged the development of prototype training programs/ resources like the Chrysler/UAW booklet, so everyone does not have to start from scratch (M8:2). Lantz recommended warning individuals of special risks and cited her success with this approach (M8:12).

Gauthier thought that a comprehensive training program was needed and urged worker involvement in all actions (M8:18). His program was 40 minutes long and well received by workers (M8:18). Gauthier recommended not only teaching the new machinist about machining, but about MWFs as well (M8:19).

Day recommended some generic information for all audiences and more specific information for certain audiences (M9:11). How to recognize symptoms or an outbreak and what to do are important (M9:11). He did not know if everyone could buy into the same program (M9:11). Burch noted that there may be a variety of messages depending on the level of the audience, the type and size of plant, the fluids used, etc. (M9;11).

An improved delivery system is needed with existing documents made into how-to documents with bullet points for quick reading (M5:29). Lantz noted that in training sessions she distills the information into a few slides of do's and dont’s as bullet points (M8:12). She urged quicker dissemination of the material to those who need it (M8:12). Lantz noted that it is important to teach people to be proactive so they can recognize a fluid problem and know who can help them solve it (M8:10).

Training on fluids management was discussed in the context of reviewing the ORC document. Slavin noted the importance of training but explained that the size of the system would dictate what would be included in training (M8:9). Training should included: machine safety, hazard communication, recognition of health effects and how to protect oneself according to Slavin (M8:9). How to recognize if a ventilation system is not working properly is important (M8:9).

Proper addition and dilution of fluids and components must be understood (M8:9). Procedures for getting something fixed should be known by operators (M8:9).

9.5 CONCERNS AND LIMITATIONS

9.5.1 Size of Business

Burch explained that different training should be provided for different groups and different size businesses (M8:20). Certain basic concepts would be covered in any training with some specialized topics depending on system size, according to Slavin (M8:9).

Cox thought the ORC document was a fine teaching tool for small business (M8:12). He thought it should be read by the owner and foreman (M8:12).

Burch noted that training materials are held by many small businesses for the duration of employment (M8:21). These records document employee performance (M8:21).

Burch explained that for some small businesses, the OSHA on site consultants have made mistakes that were very costly (M9:13). As a result, some businesses do not have that much faith in these programs (M9:13).

9.5.2 Other Issues

McGee was concerned with Burke's recommendation for certification and wanted to know who would require uniform labeling and training and certification (M6:30). Burke thought that the MWF formulator trade associations should do the labeling and wanted a group of stakeholders to work out the certification and training issues (M6:30).

Howell noted that it would be difficult for one segment of the MWF community to provide all the information needed for training (M9:11). Besides the bias issue, no one has the whole perspective, according to Howell (M9:11)

Teitelbaum was concerned about workers who deny symptoms (M9:12). He worried about workplaces which discourage or penalize workers for reporting medical problems (M9:12).

9.6 LINKAGE OF DISCUSSIONS TO OSHA ACTION

Mattheis explained that a regulation without a strong education component would not work (M5:24). Burke recommended voluntary training for employees and that this training could help employees check on other employees (M6:30). Burke recommended certification with continuing education requirements (M6:30). Lick suggested considering forcing people to get training (M5:29).

NIOSH recommends training of workers to detect and report hazardous situations and to know how to protect themselves (NIOSH,1998). Good hygiene and housekeeping should be taught along with how to identify health effects associated with MWFs (NIOSH,1998).

9.7 COMMITTEE DECISIONS AND RATIONALE

At the fifth meeting, the committee voted unanimously to recommend to OSHA that prevention of illnesses from MWFs be included as one of the priorities for Susan Harwood targeted training grants in the next cycle (M5:30).

At the seventh meeting, the committee voted on the motion: that OSHA a) consider and respond to the committee's request to develop a targeted training program or programs which make use of training grants, but potentially other mechanisms and b) direct resources toward its on-site consultation program in both of these: i) in the area of MWF and issues of implementation of MWF programs and ii) providing advice and assistance with respect to MWFs (M7:37). All members were in favor of this motion (M7:38).

As a result of committee discussions the Cooperation and Comparisons/ Training and Information Infrastructure Work Group provided a summary of what should be included in a best practice training program.

The committee voted on its acceptance of what was provided by the training work group. *The majority (14) voted for acceptance of this best practices document and one member (Burch) abstained.*

Throughout many discussions of other issues, the importance of training was emphasized. Everyone involved with MWFs needs to know the potential health hazards involved, how to recognize signs and symptoms of disease, how fluids can be managed and are mismanaged, and how exposure can be controlled and contamination reduced. This coupled with the other best practices can reduce the deleterious effects of MWFs.

BEST PRACTICES FOR TRAINING

The committee identified that training has to be well organized, integrated into the existing requirements of the OSHA Hazard Communication Standard, and be specific to the individual circumstances of each facility. Although there are some common denominators, most training has to be geared to a specific audience. The committee recommended the following outline. The first two sections, A and B include items that should be part of all training and combined with the specific training as noted for specific groups.

A. Organization of Training Should Include:

1. A definition of audience and needs
2. The development of goals
3. High quality program materials
4. A determination of the frequency of training
5. Program implementation
6. Evaluation of the effectiveness of training and skill performance of employees assigned responsibilities for fluid management.
7. Program continuous improvement (M8:19-20).

B. Generic Training for Any Audience Should Include:

1. A description of MWFs and how MWFs become contaminated.
2. A description of good fluid maintenance practices.
3. Elements of the MWF Management Program for the facility, including the names of personnel responsible for the Program.
4. Recognition of symptoms and signs associated with exposure to MWFs and the added importance of symptoms when they appear in more than one worker.
5. In priority order, steps workers and other individuals can take to reduce exposures to MWFs.
6. Requirements of an OSHA Standard (if any).

C. Specific Employee/Apprentice Training Should Include in Addition to A & B:

1. How to reduce one's own exposure and maintain this reduction.
2. What to do and whom to contact if the individual has a MWF related symptom or determines that exposure control systems are not functioning adequately.
3. Information that is specific to the fluid and MWF system size (M8:2,20;9; 11).
4. Specific training to address behaviors that increase exposure to or contaminate MWFs.
5. The use of employee experiences with MWFs.
6. Specific training about the activities the individual has to do related to MWFs e.g. measurement of fluid concentration, pH, etc.
7. How to do any needed recordkeeping for MWFs.

C. Specific Employee/Apprentice Training Should Include in Addition to A & B (continued):

8. Integration with training required by the Hazard Communication Standard (M9:11).

D. Specific Training for Medical Professionals/Insurance Carriers Should Include:

1. How to recognize any symptoms related to MWFs, determine if symptoms are work related and link symptoms to specific potential diseases (M8:20).
2. How to diagnose and treat the symptoms and/or disease.
3. The significance of identifying more than one worker from a site with symptoms associated with MWF exposure and the needed response actions.
4. Procedures for medical removal.

E. Specific Training for Industrial Hygienists and Safety Professionals Should Include:

1. How to recognize any symptoms related to MWFs, determine if symptoms are work related and link symptoms to specific potential diseases (M8:20).
2. How to encourage employee reporting of symptoms etc.

3. The significance of identifying more than one worker from a site with symptoms associated with MWF exposure and the needed response actions.
4. How to qualitatively and quantitatively assess exposure.
5. How to compare to exposure limits.
6. How to identify fluid and mist problems and identify solutions.
7. How to develop a systems management team.
8. How to design and evaluate enclosure and ventilation systems for MWFs.
9. How to select and maintain mist collectors.
10. Additional sampling techniques such as bioaerosols, fluid parameters.
11. How to develop a MWF management program.
12. How to identify and change behaviors of employees and managers that lead to increased exposure.
13. How to do any needed recordkeeping for MWFs.
14. How to train employees about MWFs.

F. Specific Training for Supervisors/Managers Should Include:

1. How to recognize any symptoms related to MWFs, determine if symptoms are work related and link symptoms to specific potential diseases (M8:20).
2. How to encourage employee reporting of symptoms etc.
3. The significance of identifying more than one worker from a site with symptoms associated with MWF exposure and the needed response actions.
4. How to identify fluid and mist problems and identify solutions.
5. How to develop a systems management team.
6. How to develop an MWF management program.
7. Specific training about the activities the individual has to do related to MWFs, e.g., measurement of fluid concentration, pH, etc.
8. How to identify and change behaviors of employees and managers that lead to increased exposure.
9. How to do any needed recordkeeping for MWFs.
10. Procedures for medical removal.

G. Specific Training for Engineers Should Include:

1. How to identify fluid and mist problems and identify solutions.
2. How to develop a systems management team.
3. How to develop an MWF management program.
4. How to design overall fluid systems to minimize exposure and reduce fluid problems.
5. How to design enclosure and ventilation systems for MWFs.
6. How to select and maintain mist collectors.
7. How to minimize water and outdoor air pollution from MWFs.
8. Specific training about the activities the individual has to do related to

MWFs, e.g., measurement of fluid concentration, pH, etc.

9. How to do any needed recordkeeping for MWFs.

H. Specific Training for OSHA Compliance Officers/Managers Should Include:

1. How to recognize any symptoms related to MWFs, determine if symptoms are work related and link symptoms to specific potential diseases (M8:20).
2. The significance of identifying more than one worker from a site with symptoms associated with MWF exposure and the needed response actions.
3. How to qualitatively and quantitatively assess exposure.
4. How to compare to exposure limits.
5. How to identify fluid and mist problems and identify solutions.
6. Additional sampling techniques such as bioaerosols, fluid parameters.
7. How to identify and change behaviors of employees and managers that lead to increased exposure.
8. How to interpret any needed recordkeeping for MWFs.

Appropriate training, as described in B and C in the above Best Practice, should be conducted 1) at the time of initial assignment; 2) when a new and significantly different physical or health hazard is introduced into the workplace, and 3) when new ways of protecting against recognized hazards or new engineering controls are introduced into the plant. Evaluation of the effectiveness of training should be conducted either annually or, in the alternative, periodically as appropriate to the facility. Retraining should be conducted as necessary.

Sample language for a training and education requirement for MWF, based on the HAZWOPER Standard (29 CFR 1910.120) is included in Attachment #10 of this report. Until such time that a standard is developed, training suggested in this Chapter could be accomplished under the requirements of the OSHA Hazard Communication Standard. The committee recommends that the items in B and C be included in any standard. The committee recognizes that some elements of the training could be accomplished under the OSHA Hazard Communication Standard.

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Note: these references were cited in the report, additional references can be found in Attachment #6 and the Committee Docket list in Attachment #7.

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