NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

STATEMENT OF POSITION OF THE OCCUPATIONAL
HEALTH AND SAFETY PRODUCTS DIVISION MINNESOTA MINING
AND MANUFACTURING COMPANY WITH RESPECT
TO THE NOTICE OF PROPOSED RULEMAKING
42 CFR PART 84

REVISION OF TESTS AND REQUIREMENTS FOR CERTIFICATION
OF RESPIRATORY PROTECTIVE DEVICES

JANUARY 28, 1988
INTRODUCTION

GOOD MORNING. I AM DAVID KOLANDER, THE MARKETING DIRECTOR FOR THE OCCUPATIONAL HEALTH AND SAFETY PRODUCTS DIVISION OF 3M. WE MANUFACTURE AND SELL A BROAD PRODUCT LINE OF RESPIRATORY PROTECTIVE DEVICES.

I AM COMPELLED TO EXPRESS 3M'S DEEP CONCERN REGARDING THE LACK OF SUFFICIENT INFORMATION AND SUPPORTING DOCUMENTATION CONTAINED IN THE AUGUST 27, 1987 FEDERAL REGISTER NOTICE, WHICH SET FORTH THE MANY SIGNIFICANT CHANGES NIOSH IS PROPOSING TO MAKE TO RESPIRATOR CERTIFICATION. BECAUSE NIOSH DID NOT PROVIDE EXTENSIVE INFORMATION ON WHAT IS BEING PROPOSED, AND WHY THE CHANGES ARE BEING PROPOSED, IT IS DIFFICULT FOR 3M AND THE OTHER RESPIRATOR MANUFACTURERS TO PREPARE MEANINGFUL COMMENTS.

3M STILL FEELS STRONGLY THAT THE BEST COURSE OF ACTION IS FOR NIOSH TO RECALL THE PROPOSAL AND REISSUE IT WITH SUPPORTING DOCUMENTATION AND ACCURATE COST ESTIMATES OF COMPLIANCE, PRESENTED IN SUFFICIENT DETAIL TO ALLOW A MEANINGFUL DIALOGUE.

NOW I WILL MOVE TO SPECIFIC CONCERNS 3M HAS ABOUT THE PROPOSAL.
WORKPLACE TESTING

3M BELIEVES THAT WORKPLACE TESTING, AS PROPOSED BY NIOSH, IS A REQUIREMENT THAT IS IMPOSSIBLE TO COMPLY WITH. WHETHER OR NOT THE TESTS ARE CONDUCTED IN MINES, IS IMMATERIAL. IT IS STILL IMPOSSIBLE. ON JANUARY 20, 1988 NIOSH STATED IN THEIR HEARING COMMENTS: "NIOSH IS CURRENTLY PREPARING A DOCUMENT TO PROVIDE PERFORMANCE-BASED GUIDANCE FOR FIELD TESTING. COMMENTS WILL BE SOLICITED ON THIS DRAFT." YOU MAY ASK, AS WE HAVE, WHY NOT INCLUDE THIS DOCUMENT IN THE ORIGINAL PROPOSAL? 3M REQUESTS THAT THE COMMENT PERIOD ON 42 CFR PART 84 BE LEFT OPEN FOR 180 DAYS AFTER THE PUBLICATION OF THE NIOSH "PERFORMANCE-BASED GUIDANCE DOCUMENT FOR FIELD TESTING."

LET ME CLARIFY ONE THING - WORKPLACE TESTING AND EVALUATION OF RESPIRATORS IS SOMETHING THAT 3M SUPPORTS, AND IS CURRENTLY CONDUCTING FOR RESEARCH PURPOSES WITH OUR OWN PRODUCTS TODAY. NEVERTHELESS, GIVEN TODAY'S STATE-OF-THE-ART WORKPLACE TESTING TECHNIQUES AND KNOWLEDGE, IT IS A TASK THAT IS EXTREMELY DIFFICULT TO DO.
1. TESTING LIMITATIONS

THE CHALLENGE IS TO MEASURE SMALL CONCENTRATIONS OF MICROSCOPIC PARTICLES INSIDE RESPIRATORS, WHILE BEING USED IN THE WORKPLACE, ON THE WORKER'S FACE. TODAY, THE ANALYTICAL INSTRUMENTS AVAILABLE FOR WORKPLACE TESTING, WITH THE SENSITIVITY NEEDED TO GIVE ACCURATE MEASUREMENTS, ARE ALL BUT NON-EXISTENT. THERE ARE A FEW COMMON WORKPLACE CONTAMINANTS, SUCH AS LEAD, ZINC, AND ASBESTOS WHICH CAN BE READILY MEASURED. THE VAST MAJORITY, HOWEVER, CANNOT.

ALSO, OUR EFFORTS IN WORKPLACE TESTING HAVE MADE IT VERY CLEAR THAT MOST CONTAMINANTS ARE NOT ISOLATED IN THE WORKPLACE. FOR EXAMPLE, IN A FOUNDRY, WHERE YOU ARE MEASURING SILICA PARTICLES, YOU WILL ALSO FIND PARTICLES OF CARBON, LEAD AND IRON OXIDE IN THE TEST SAMPLES. IN A CHEMICAL PROCESSING PLANT, WHERE YOU ARE ATTEMPTING TO MEASURE BENZENE LEVELS, YOU WILL COMMONLY FIND TRACES OF TOLUENE, XYLINE, AND HEXANE.

ACTUAL WORKPLACES ARE EXTREMELY COMPLEX AND CHALLENGING ENVIRONMENTS TO BE USED FOR CERTIFICATION REQUIREMENTS. WORKPLACE TESTING MAY BE EXTREMELY VALUABLE TO A RESPIRATOR MANUFACTURER IN DETERMINING HOW A RESPIRATOR PERFORMS ON THE JOB, BUT WITH THE INHERENTLY HIGH VARIABILITY ASSOCIATED WITH WORKPLACE TESTING, SUCH RESULTS ARE POORLY SUITED FOR A CERTIFICATION REQUIREMENT. FEW WOULD DISAGREE THAT ANY TEST REQUIREMENT WHICH IS A TENET FOR CERTIFICATION MUST PROVIDE RELIABLE, REPRODUCIBLE RESULTS.
2. PRACTICAL LIMITATIONS

NIOSH HAS TOTALLY IGNORED THE PRACTICAL LIMITATIONS OF WORKPLACE CERTIFICATION. WE HAVE APPROXIMATELY 200 CURRENT RESPIRATORS REQUIRING TESTING. IMAGINE THE PROBLEM OF FINDING 200 WORK SITES WHERE THE EMPLOYERS WILL LET YOU TIE UP 150 WORKERS FOR SEVERAL DAYS TO TEST YOUR RESPIRATORS.

ENVISION THESE SAME EMPLOYERS WHEN 20 RESPIRATOR MANUFACTURERS DESCEND UPON THEM WITH THE SAME REQUEST. PRACTICALLY SPEAKING, IT IS EXTREMELY DIFFICULT TO FIND ONE OR TWO SUITABLE WORK SITES AND COOPERATIVE EMPLOYERS TO EVALUATE PERFORMANCE OF ONE OR TWO RESPIRATORS, MUCH LESS 200.

NIOSH HAS RECENTLY BEEN DIRECTED BY OMB TO SUBMIT A REGULATORY IMPACT ANALYSIS. 3M REQUESTS THAT AS PART OF THIS ANALYSIS, NIOSH SURVEY USERS OF RESPIRATORS TO OBTAIN A MEASURE OF THE PRACTICAL PROBLEMS OF CONDUCTING THOUSANDS OF WORKPLACE CERTIFICATION TESTS.
3. COST LIMITATIONS

ASSUME THAT THE MANY TECHNICAL AND PRACTICAL DIFFICULTIES COULD BE OVERCOME. COMPLEX TECHNICAL STUDIES ALWAYS BRING WITH THEM ANOTHER INHIBITING FACTOR, HIGH COST.

TO MAKE OUR ESTIMATE, WE USED A DRAFT PROTOCOL DEVELOPED BY NIOSH IN 1987 TITLED "EXPERIMENTAL DESIGN AND RESEARCH PROTOCOL TO ASSIGN PROTECTION FACTORS FOR NEGATIVE PRESSURE RESPIRATORS." THE NIOSH PROTOCOL PROPOSES EVALUATING EACH RESPIRATOR AGAINST THREE TO SIX SUBSTANCES. COMBINED WITH 3M'S OWN EXPERIENCE AT EVALUATING RESPIRATORS IN THE WORKPLACE, WE HAVE A FAIRLY RELIABLE ESTIMATE OF COST FOR PERFORMING A SINGLE WORKPLACE STUDY AGAINST A SINGLE SUBSTANCE: $53,000.

THE ESTIMATE INCLUDES SPECIAL ANALYSIS FOR EACH SAMPLE, TRAVEL COSTS AND COSTS OF SHIPPING TEST EQUIPMENT. IT DOES NOT INCLUDE CONTINUING COSTS SUCH AS EMPLOYEE WAGES AND SALARIES. IN ADDITION, APPROXIMATELY ONE PERSON YEAR OF EFFORT IS NEEDED PER TEST. FOR THIS $53,000, WE WOULD OBTAIN APPROXIMATELY 100 TO 150 USABLE DATA POINTS, THE NUMBER REQUIRED TO PROVIDE A RELIABLE ESTIMATE OF RESPIRATOR PERFORMANCE FOR CERTIFICATION.

AT AN ESTIMATED COST OF OVER $50,000 PER WORKPLACE TEST, BRINGING ALL EXISTING RESPIRATORS INTO CONFORMANCE WOULD REQUIRE RESPIRATOR MANUFACTURERS TO SPEND OVER $700 MILLION. THIS ASTRONOMICAL FIGURE DOES NOT INCLUDE THE COST OF CERTIFYING NEW PRODUCTS.

IN THEIR JANUARY 20, 1988 COMMENTS, NIOSH STATES THAT THIS ESTIMATE IS BASED ON A "CRITICAL, BUT INCORRECT, ASSUMPTION... EACH EXPOSURE AGENT FOR WHICH THE RESPIRATOR WOULD PROVIDE PROTECTION (E.G., HUNDREDS OF ORGANIC VAPOR COMPOUNDS) MUST BE TESTED INDIVIDUALLY." IT IS NIOSH WHICH HAS MADE THE INCORRECT ASSUMPTION, AND IGNORED WHAT WAS CLEARLY STATED. SO, LET ME REPEAT. 3M AND THE INDUSTRY HAVE USED THE NIOSH PROTOCOL, WHICH PROPOSES EVALUATING EACH RESPIRATOR AGAINST THREE TO SIX SUBSTANCES, NOT HUNDREDS OF SUBSTANCES.
4. NIOSH COST STUDY QUESTIONNAIRE

IN THEIR JANUARY 20, 1988 STATEMENT, NIOSH SAYS: "IN ACCORDANCE WITH ESTABLISHED REGULATORY PROCEDURES, NIOSH CONTRACTED FOR A STUDY OF COSTS ASSOCIATED WITH THE PROPOSED PART 84 REGULATIONS... QUESTIONNAIRES WERE SENT TO ALL MANUFACTURERS FOR THEIR RESPONSE. ALTHOUGH ALL DID NOT RESPOND, NIOSH RECEIVED ENOUGH INFORMATION TO MAKE AN INFORMED ESTIMATE OF THE COSTS ASSOCIATED WITH THE PROPOSED RULE. THE ESTIMATED COST WAS SUBSTANTIALLY LESS THAN $100 MILLION."

I HAVE CONDUCTED MARKET RESEARCH STUDIES FOR 3M. I HAVE PERSONALLY DESIGNED AND ADMINISTERED DOZENS OF QUESTIONNAIRES, I HAVE REVIEWED HUNDREDS OF QUESTIONNAIRES AND I HAVE STUDIED HUNDREDS OF COMPLETED INDUSTRIAL MARKET RESEARCH STUDIES. I AM WELL-QUALIFIED TO COMMENT ON THE MARKET RESEARCH CONDUCTED FOR NIOSH. I CAN SAY WITHOUT QUALIFICATION, THAT THE DESIGN AND ADMINISTRATION OF THE PROCEDURE, THE QUESTIONNAIRE, THE TREATMENT OF DATA, AND THE FINAL MARKET RESEARCH REPORT, LACKED EVEN THE REMOTEST RESEMBLANCE TO AN ACCEPTABLE MARKET RESEARCH STUDY. AS A PROFESSIONAL RESEARCHER, I WOULD ELECT TO NOT EVEN BE ASSOCIATED WITH IT.

THE CONCLUSIONS NIOSH HAS DRAWN FROM THIS ATTEMPTED MARKET RESEARCH STUDY ARE IRREPARABLY FLAWED AND OF NO VALUE. FOR AN ISSUE AS COMPLEX AS THIS ONE, WITH A UNIVERSE OF ONLY 20 RESPONDENTS, EVEN THE RANK AMATEUR MARKET RESEARCHER, FRESH OUT OF COLLEGE, WOULD QUICKLY CONCLUDE THAT THE INVESTIGATION MUST BE DONE WITH DIRECT PERSONAL INTERVIEWS, NOT WITH A HUGE MAIL QUESTIONNAIRE.
HERE ARE A FEW OF THE OTHER MAJOR FLAWS:

1. THE QUESTIONNAIRE WAS OBVIOUSLY NOT PRE-TESTED, A CARDINAL RULE FOR MAIL QUESTIONNAIRES. SOME QUESTIONS WERE SO CONFUSINGLY WRITTEN, THAT THEY LITERALLY COULD NOT BE ANSWERED. WE STATED THIS IN OUR RESPONSE.

2. NIOSH MADE NO FOLLOW-UP WITH THE NON-RESPONDENTS, TO DETERMINE WHY THEY DIDN'T RESPOND, AND TO ATTEMPT TO VERIFY THAT THE NON-RESPONDENT'S ANSWERS WOULD BE THE SAME AS THE RESPONDENTS. THIS IS ANOTHER CARDINAL RULE IN MAIL QUESTIONNAIRE PROCEDURES.

3. EVEN THOUGH ONLY A FEW MANUFACTURERS RESPONDED, NIOSH THREW OUT SOME OF THEIR ANSWERS, BECAUSE THEY WERE "NOT REPRESENTATIVE." IS IT POSSIBLE THE DATA THEY DISCARDED DID NOT PROVIDE THE ANSWERS NIOSH WANTED TO HEAR?

4. AND HERE IS THE TOPPER! THEY ASKED THE RESPONDENTS TO ESTIMATE COSTS OF WORKPLACE TESTING, BUT GUESS WHAT! THEY DID NOT PROVIDE THE PROTOCOLS TO ALLOW THE RESPONDENTS TO MAKE A REASONABLE ESTIMATE OF TEST PROCEDURES AND COSTS. SOUND FAMILIAR?
I HAVE GONE ON AT LENGTH ABOUT A TOPIC--THE HIGHLY SUSPECT
RESEARCH PROCEDURE USED TO MISREPRESENT THE COSTS OF
WORKPLACE TESTING--THAT YOU MAY CONSIDER AN OVER REACTION.

HOWEVER, I SUBMIT THAT IT IS INDICATIVE OF THE NIOSH
ADMINISTRATION IN ATLANTA, AND THEIR TYPICAL RESPONSE TO OUR
INDUSTRY...DON'T BOTHER US WITH THE FACTS, OUR MIND IS
ALREADY MADE UP. IT IS TIME FOR THE PEOPLE IN ATLANTA TO
ADHERE TO THE FUNDAMENTAL POLICY FOR ALL GOVERNMENT
AGENCIES--BE RESPONSIVE TO YOUR CONSTITUENTS AND ENGAGE IN
MEANINGFUL DIALOGUE WITH THEM.
5. COST IMPACTS

$700 million in new costs would have a drastic impact. Small employers would no longer be able to afford to provide their workers with respiratory protection. Major employers would cut back on discretionary use of respirators.

Finally, it is doubtful that a cost increase of this size could ever be fully borne by the marketplace. Consequently, 3M estimates that it would be forced to undergo a drastic reduction in the categories and types of equipment that it manufactures, if it were to remain in the respirator business at all.

Frankly speaking, if 42 CFR Part 84 were enacted in its present form, the most likely scenario for 3M will be to remain in the industry with existing products until the five year grandfather clause expires, and then simply exit the market.
LABORATORY TESTING

THE PROPOSED CHANGES FOR RESPIRATOR CERTIFICATION ALSO INCLUDE MAJOR REVISIONS IN LABORATORY TESTING. AS WITH WORKPLACE TESTING, 3M FINDS MANY OF THESE PROPOSALS EQUALLY UNACCEPTABLE.

1. SOLID AND LIQUID OIL MIST TEST

FIRST, NIOSH IS PROPOSING THAT ALL PARTICULATE FILTERS MEET BOTH A SOLID AND A LIQUID OIL MIST TEST. IF ADOPTED, FILTER MATERIAL FROM MOST RESPIRATOR MANUFACTURERS, INCLUDING 3M, THAT IS CURRENTLY DESIGNED FOR SOLID AEROSOL TEST CHALLENGES WILL NEED TO BE REDESIGNED TO ALSO MEET A LIQUID OIL MIST TEST CHALLENGE. THESE CHANGES WILL RESULT IN FILTER MATERIALS THAT HAVE A HIGHER BREATHING RESISTANCE AND POORER LOADING CAPACITIES. WORKERS WEARING THESE RESPIRATORS WOULD FIND THEM HARDER TO BREATHE THROUGH, MAKING THEM LESS ACCEPTABLE TO WEAR.

THE LARGE MAJORITY OF PARTICULATES FOUND IN THE WORKPLACE ARE OF THE SOLID TYPE, NOT OF THE OIL MIST TYPE. MOREOVER, IT IS QUITE SIMPLE FOR THE END USER TO DETERMINE WHETHER THE AEROSOL PRESENT IN THE WORKPLACE IS A SOLID OR LIQUID OIL MIST TYPE.

IN THEIR JANUARY 20, 1988 STATEMENT, NIOSH SAYS: "THUS, FOR PUBLIC HEALTH REASONS, NIOSH HAS ADOPTED A LIQUID, AS WELL AS A SOLID AEROSOL TEST...." IF THE PUBLIC HEALTH IS NIOSH'S TRUE MOTIVATION, THEN 3M SUBMITS THAT NIOSH MUST CREATE TWO CATEGORIES OF PARTICULATE FILTER RESPIRATORS - SOLID PARTICULATES AND LIQUID OIL-MIST-CONTAINING PARTICULATES. IN THIS WAY, RESPIRATOR USERS WILL STILL BE ABLE TO OBTAIN RESPIRATORS WITH LOW BREATHING RESISTANCE, THE TYPE PREFERRED BY MOST USERS TODAY.
2. AIR FLOW RATES AND RELATIVE HUMIDITY

A second change proposed by NIOSH would increase the size of current organic vapor cartridge by a factor of four, with corresponding increases in weight and in breathing resistance. Specifically, NIOSH proposes to increase the relative humidity of the air, and double the air flow rates in testing organic vapor cartridges. In order to meet these new test conditions, approximately four times the carbon would be needed, based on current carbon technology.

In their January 20, 1988 statement NIOSH says: "NIOSH is unaware of any published technical data to substantiate this claim..." I suggest they consult with their technical people in Morgantown for a basic review of carbon technology. In the next paragraph NIOSH says: "We believe that the five-year 'grandfather' period... allows ample time to address this requirement."

In other words, there is no published data to show that larger cartridges will be needed, but you have five years to figure out how to comply, because we know it will require larger cartridges. Does NIOSH really believe that the certification procedure can be used to force invention and innovation beyond today's known limits of carbon technology? Although compliance with this proposal would provide a longer respirator service life, it would not increase the protection of the worker while wearing the respirator.

The effect of this proposal, as NIOSH well knows, would be that none of the existing approved organic vapor cartridge systems with half masks or full face masks would be NIOSH certified for use. Every worker now wearing a typical cartridge respirator would be forced to wear the much larger, heavier, chin or front or back mounted style of canisters; in effect moving back to the bulky gas mask concept of the 1930's. This is in direct contrast to the preferences of the end users, where cartridge style respirators are far and away the most widely used of the air purifying gas and vapor respirators.
THESE TWO "SIMPLE" CHANGES IN TEST PROCEDURE COULD ACTUALLY RESULT IN LESS WORKER PROTECTION FROM AVAILABLE RESPIRATORS. IN BOTH OF THESE AREAS, NIOSH HAS TOTALLY IGNORED THE INPUTS AND DOCUMENTS PROVIDED BY THE INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION AND ANSI. BOTH GROUPS HAVE PREVIOUSLY DESCRIBED TO NIOSH IN DETAIL THE EFFECTS OF THESE PROPOSED TEST CHANGES. WE NEED IMMEDIATE AND RESPONSIBLE DIALOGUE ON THIS MATTER, NOT STONE WALLING.
CONCLUSION

IN CONCLUSION, NIOSH HAS MADE A GENUINE EFFORT TO ADDRESS SEVERAL OF THE KNOWN DEFICIENCIES IN THE CURRENT SYSTEM. WE CAN CLEARLY SEE, HOWEVER, THAT SOME OF THE CHANGES RECOMMENDED BY NIOSH WILL MAKE RESPIRATORS EXTREMELY COSTLY AND MUCH LESS ACCEPTABLE TO WORKERS. WE SUBMIT THAT CERTIFICATION REQUIREMENTS AND TEST PROCEDURES SHOULD BE:

1. A MEANINGFUL INDICATOR OF THE DEVICE'S PERFORMANCE IN USE;

2. READILY INTERPRETABLE BY BOTH THE MANUFACTURERS AND THE CERTIFYING AGENCY; AND

3. TESTS THAT WILL PROVIDE RELIABLE, REPRODUCIBLE RESULTS.

MEETING THESE THREE CRITERIA IS TRULY A MONUMENTAL TASK. IT BECOMES AN EVEN GREATER TASK IF THE REGULATORY AGENCY DOES NOT DEVELOP AND MAINTAIN A MEANINGFUL DIALOGUE WITH THOSE SUBJECT TO ITS REGULATIONS. WE STRONGLY RECOMMEND THAT NIOSH TAKE ADVANTAGE OF THE EXPERTISE AVAILABLE IN MORGANTOWN, OTHER GOVERNMENT AGENCIES, INDUSTRY, LABOR, AND RESPIRATOR MANUFACTURERS IN DEVELOPING MEANINGFUL, FEASIBLE, AND RELIABLE TESTS FOR EVALUATING AND CERTIFYING PRODUCT PERFORMANCE. WE BELIEVE A CONSENSUS APPROACH IS THE CORRECT APPROACH.
ONE FINAL POINT. IN MY JOB I TRY TO SPEND 40 PERCENT OF MY TIME IN THE FIELD, OUT OF THE OFFICE. THAT WORKS OUT TO APPROXIMATELY 100 DAYS A YEAR OF CONTACT WITH END USERS OF OUR PRODUCTS—INDUSTRIAL HYGIENISTS, SAFETY DIRECTORS, SAFETY DISTRIBUTORS, AND GOVERNMENT AGENCIES.

NIOSH HAS A DEDICATED, HARD WORKING STAFF LOCATED IN THEIR MORGANTOWN FACILITIES. HOWEVER, IT HAS BEEN MY OBSERVATION AND THAT OF OTHERS IN OUR INDUSTRY, THAT THE ATLANTA STAFF HAS LITTLE KNOWLEDGE OF THE REAL WORLD OF RESPIRATOR USERS. I WOULD LIKE TO USE THIS FORUM TODAY TO EXTEND BOTH AN INVITATION AND A CHALLENGE TO NIOSH TO LEAVE THEIR SHELTERED ENVIRONMENT IN ATLANTA AND SPEND TIME IN THE FIELD WITH SAFETY DIRECTORS, WITH HYGIENISTS, AND WITH RESPIRATOR USERS. TALK TO THE PEOPLE THAT HAVE TO SELECT THE RESPIRATORS, TRAIN THE EMPLOYEES IN THE CORRECT USE OF THE RESPIRATORS, AND IMPLEMENT SOUND RESPIRATOR PROGRAMS. AND TALK TO THE EMPLOYEES THAT WEAR THE RESPIRATORS. THIS TYPE OF CONTACT CAN ONLY STRENGTHEN AND IMPROVE NIOSH'S ABILITY TO DETERMINE SOUND RESPIRATOR POLICIES AND CERTIFICATION REQUIREMENTS.

THANK YOU.