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TESTIMONY OF

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In the Public Hearings on the
Proposed Amendments to 30 CFR Part 11

NATIONAL INSTITUTE FOR OCCUPATIONAL

SAFETY & HEALTH

MY NAME IS EINAR HORNE AND I AM HERE REPRESENTING THE OCCUPATIONAL HEALTH & SAFETY PRODUCTS DIVISION (OH&SP) OF 3M COMPANY.

INTRODUCTION

FOR MANY YEARS, 3M HAS BEEN A MANUFACTURER OF CERTAIN TYPES OF RESPIRATORS. FOR EXAMPLE, 3M MANUFACTURES CHEMICAL-CARTRIDGE RESPIRATORS, PARTICULATE FILTER RESPIRATORS, POWERED AIR PURIFIERS, AND SUPPLIED-AIR RESPIRATORS, ALL OF WHICH CAN BE USED FOR PROTECTION AGAINST NON-TOXIC DUSTS, TOXIC DUSTS AND TOXIC VAPORS. CONSEQUENTLY, 3M IS DIRECTLY AFFECTED BY THE 30 CFR 11 REGULATION RELATED TO RESPIRATOR TESTING, CERTIFICATION, SELECTION AND USE. FURTHER, AS A MANUFACTURER OF RESPIRATORY DEVICES WE ARE ACUTELY CONCERNED THAT CHANGES TO EXISTING STANDARDS, POLICIES & PRACTICES IMPROVE THE QUALITY AND EFFECTIVENESS OF PERSONAL PROTECTIVE DEVICES.

THEREFORE, IN RESPONSE TO THE INVITATION FOR INTERESTED PARTIES TO SUBMIT COMMENTS CONCERNING THE CONSULTANT'S REPORT AND POSSIBLE AMENDMENT OF 30 CFR 11, WE OFFER THE FOLLOWING VIEWS FOR THE PURPOSE OF AIDING IN THE DEVELOPMENT OF AN APPROPRIATE AND FEASIBLE REGULATION WHICH WOULD ADEQUATELY PROTECT EMPLOYEES WHO ARE REQUIRED BY OSHA STANDARDS TO USE NIOSH APPROVED RESPIRATORY DEVICES.

MY TESTIMONY TODAY WILL ADDRESS THOSE AREAS IDENTIFIED IN THE NOTICE FOR THESE HEARINGS, PUBLISHED IN THE FEDERAL REGISTER ON WEDNESDAY, JUNE 18, 1980 (45 FED. REG. 41219). SPECIFICALLY, I SHALL DISCUSS BOTH THE PROPOSED CHANGES TO 30 CFR 11 THAT WERE OUTLINED BY NIOSH AND THE CONSULTANT'S REPORT.

OVERVIEW

ONE OF OUR MAJOR CONCERNS WITH THE EXISTING 30 CFR 11 REGULATION IS THAT ITS

RESPIRATOR APPROVAL SYSTEM IS BASED LARGELY UPON TEST METHODS DEVELOPED IN THE 1930'S THAT WERE DESIGNED TO MEASURE THE EFFECTIVENESS OF RESPIRATORS DURING THAT ERA. NIOSH SIMPLY TOOK BUREAU OF MINES' TESTS, PERSONNEL AND PHILOSOPHY INTO THE DECADE OF THE 1970'S. EVEN THE APPROVAL NUMBERING SYSTEM WAS CONTINUED. IN RECENT YEARS THERE HAVE BEEN SIGNIFICANT SCIENTIFIC DISCOVERIES AND DEVELOPMENTS WITHIN THE RESPIRATOR INDUSTRY. TODAY, NEW AND INNOVATIVE RESPIRATORY PRODUCTS, HAVING THE ABILITY TO GREATLY IMPROVE EMPLOYEE RESPIRATORY PROTECTION AND ACCEPTANCE, ARE READY FOR THE MARKETPLACE. NONETHELESS, BECAUSE THE CURRENT APPROVAL SYSTEM IN 30 CFR 11 IS TECHNICALLY OUTDATED AND INAPPLICABLE TO TODAY'S RESPIRATORS, THESE NEW AND IMPROVED PRODUCTS ARE NOT RECEIVING NIOSH APPROVAL. 3M HAS TESTIFIED IN TWO PREVIOUS 1977 HEARINGS THAT THE ENTRANCE OF NEW RESPIRATOR PRODUCTS INTO THE MARKETPLACE IS BEING RESTRICTED.

CONTINUED ADHERENCE TO THIS OLD APPROVAL SYSTEM TENDS TO HAVE A CHILLING EFFECT ON THE INCENTIVE TO CONTINUE TO DESIGN AND DEVELOP NEW AND BETTER RESPIRATORY PRODUCTS -- WHY DESIGN A NEW PRODUCT IF IT CANNOT POSSIBLY RECEIVE NIOSH APPROVAL?

FURTHER, THE ADVENT OF NEW AND MORE ENCOMPASSING REGULATIONS BY OSHA, EPA, AND OTHER GOVERNMENTAL AGENCIES RESTRICTING EMPLOYEE EXPOSURE TO POTENTIAL OR KNOWN TOXIC SUBSTANCES HAS INCREASED THE USE OF EMPLOYEE RESPIRATORY PROTECTION DEVICES. THE NEED TO AMEND, UPDATE AND REPROMULGATE (THE TESTING AND CERTIFICATION PROCESS OF 30 CFR 11) TO REFLECT THE CURRENT STATE-OF-THE-ART IN THE RESPIRATORY INDUSTRY IS OBVIOUS. A NEW APPROVAL SYSTEM MUST CONTAIN THE FLEXIBILITY TO EVALUATE INNOVATIVE PRODUCTS, WITH THE ULTIMATE GOAL OF PROVIDING THE AMERICAN WORKER THE BEST RESPIRATORY PROTECTION AVAILABLE.

IT IS ON THIS BASIS AND WITH THIS GOAL AS OUR OBJECTIVE, THAT 3M HAS DEVELOPED AND SUBMITS THE FOLLOWING COMMENTS:

DISCUSSION

THE CONSULTANTS ARE TO BE CONGRATULATED FOR THEIR EXCELLENT ANALYSIS OF THE PRESENT NIOSH TESTING AND CERTIFICATION FUNCTION. THEY HAVE ESTABLISHED A BASE FROM WHICH A WORKABLE SYSTEM OF CERTIFICATION AND FIELD AUDIT OF RESPIRATORY PROTECTION DEVICES SHOULD BE RAPIDLY BUILT.

3M AND OTHER RESPIRATOR MANUFACTURERS HAVE HAD DISCUSSIONS LIKE THIS ONE WITH NIOSH BEFORE. WHILE THIS IS THE FIRST ONE HELD SINCE DR. ROBBINS TOOK OVER AS DIRECTOR, THE IDEA AND NEED ARE NOT NEW. HE IS TO BE CONGRATULATED FOR HIS APPROACH TO THE REGULATION ANALYSIS THROUGH THE USE OF A PANEL OF EXPERTS. WE WERE PLEASED TO SEE THE RECOMMENDATIONS OF THE EXPERTS DR. ROBBINS ASSIGNED, BECAUSE THEY ONCE AGAIN BROUGHT FORTH AN OPPORTUNITY TO RECOMMEND MUCH NEEDED CHANGES TO THE METHODS PRESENTLY USED FOR APPROVING RESPIRATORS.

THE CONSULTANT'S REPORT WENT INTO GREAT DETAIL IN REGARD TO THE SUBJECT OF LIABILITY THAT NIOSH SHARES WITH THE MANUFACTURER, AND A CONCERN WAS EXPRESSED ABOUT THE LIABILITY AND RESPONSIBILITY OF "NIOSH CERTIFIED LABORATORIES".

THE LIABILITY ARGUMENT THAT THE NIOSH CONSULTANTS PUT FORTH IS PERSUASIVE, BUT INCOMPLETE. MANUFACTURERS OF NIOSH APPROVED PRODUCTS GET SUED, AND I SUGGEST THERE ARE MANY CASES OUTSTANDING TODAY. AS A PRACTICAL MATTER, NIOSH IS NOT SUED FOR GIVING APPROVALS.

THE NIOSH APPROVAL CERTIFICATION IS NOT LOOKED ON AT 3M AS A SHARING OF RESPONSIBILITY FOR PRODUCT PERFORMANCE. I'M CONFIDENT OTHER MANUFACTURERS

OF PERSONAL PROTECTIVE EQUIPMENT WOULD PROJECT SIMILAR FEELINGS. THE APPROVAL IS LOOKED UPON AS A MARKETPLACE NECESSITY DUE TO RECOMMENDED OSHA RESPIRATOR PROGRAM REQUIREMENTS FOR USE OF ONLY NIOSH APPROVED PRODUCTS AS OUTLINED IN CHAPTER III OF THE MAY 24, 1979 EDITION OF THE INDUSTRIAL HYGIENE FIELD OPERATIONS MANUAL. IF THE PERSONAL PROTECTIVE EQUIPMENT MANUFACTURER TAKES THE PROFITS AND GAINS FROM SALES OF A PERSONAL PROTECTIVE EQUIPMENT DEVICE, HE SHOULD TAKE THE RISKS. BUT THEN NO MANUFACTURING COMPANY SHOULD OBTAIN MARKETING ADVANTAGES BECAUSE OF DESIGN SPECIFICATIONS IN THE LAW, AS IS THE CASE TODAY WITH EXISTING 30 CFR 11 REGULATIONS. ?

REPEAT UNDERLINED

IN LATE 1977 PUBLIC MEETINGS WERE HELD IN WASHINGTON, D.C. WITH RESPECT TO AMENDING THE CERTIFICATION REQUIREMENTS FOR RESPIRATORY PROTECTION DEVICES AS CONTAINED IN 30 CFR PART 11. AT THIS MEETING EXTENSIVE TESTIMONY WAS ELICITED FROM GOVERNMENTAL AGENCIES, USERS OF RESPIRATORY PROTECTION DEVICES, MANUFACTURERS OF THESE DEVICES, AND ACADEMIC INSTITUTIONS. ALL PARTIES TESTIFYING AGREED THAT EXTENSIVE CHANGES IN THE CERTIFICATION PROCEDURES WERE DESPERATELY NEEDED IN ORDER TO ASSURE THAT THE AMERICAN WORKER HAS THE MOST ADVANCED AND BEST OCCUPATIONAL PROTECTIVE DEVICES AVAILABLE. NEVERTHELESS, IN SPITE OF THE OVERWHELMING NEED EXPRESSED FOR CHANGES IN 30 CFR PART 11 AT THESE HEARINGS, THE CONTROLLING GOVERNMENTAL AGENCY STATED IN THEIR CONCLUSION THAT PROMULGATION OF THE AMENDMENTS WOULD REQUIRE THE NORMAL THREE TO FIVE YEARS. TO DATE NO ACTION ON THAT HEARING HAS OCCURRED AND ALMOST THREE YEARS HAVE GONE BY.

WE ASK TO HAVE INCLUDED, AS PART OF THIS TESTIMONY, ALL 3M TESTIMONY THAT WAS SUBMITTED TO NIOSH DURING THE LAST HEARING ON NOVEMBER 29-30, DECEMBER 1, 1977.

WE SUBMIT THAT IT IS INCONCEIVABLE THAT DELAYS SUCH AS THESE IN ISSUING REGULATIONS CAN BE ALLOWED TO OCCUR.

IN ORDER FOR POSITIVE CHANGES IN RESPIRATORY PROTECTIVE DEVICE APPROVAL TO BE CONSUMMATED, THE NEGATIVE ASPECTS OF THE EXISTING SYSTEM MUST BE IDENTIFIED AND BROUGHT FORWARD. TO DO THIS WE HAVE THOROUGHLY STUDIED THE HISTORY OF THE RESPIRATOR APPROVAL SYSTEM IN THE U.S. AS PRACTICED BY THE BUREAU OF MINES AND NIOSH. ONE FACT STANDS OUT: NIOSH CONTINUED THE BUREAU OF MINES TESTS, APPROVAL NUMBERING SYSTEMS, PERSONNEL AND PHILOSOPHY WITHOUT MODERNIZATION. THIS INCLUDES TESTS FOR APPROVALS THAT ARE NOT ACCURATE, NOT REPRODUCIBLE OR ADEQUATELY DEFINED. THESE TESTS HAVE BEEN ESTABLISHED WITHOUT A DETERMINED TEST VARIATION, AND ARE DESIGNED FOR 1930-1940 ERA INSTRUMENTATION. THE PAINT SPRAY TESTS, LEAD FUME TESTS AND SILICA MIST TESTS ARE ALL EXAMPLES. EVEN MORE DISASTROUS FOR INNOVATIVE NEW PRODUCTS HAS BEEN THE CARRY OVER AND USE OF A DESIGN PHILOSOPHY OF RESPIRATOR APPROVAL RATHER THAN A PERFORMANCE-ORIENTED PHILOSOPHY. DESIGNATION BY DESIGN CLASS SUCH AS REUSABLE, REPLACEABLE AND SINGLE-USE IS EVEN MORE OBSCURE BECAUSE OF THE LACK OF ACCEPTABLE DEFINITIONS.

UNDER THE PRESENT SYSTEM OF TESTING AND APPROVALS, MANUFACTURERS ARE FORCED TO SUBMIT PRODUCTS THAT WILL PASS TESTS THAT MAY OR MAY NOT GUARANTEE PROTECTION TO THE USER. IT IS POSSIBLE THAT THE EXISTING NIOSH TESTING DOES MORE HARM THAN GOOD BASED ON THE FACT THAT THE TESTS HAVE LITTLE, IF ANY, CORRELATION TO ACTUAL FIELD CONDITIONS.

ONE MIGHT ASK WHY AN INNOVATIVE RESPIRATOR MANUFACTURER WOULD WANT TO SUBMIT HIS PRODUCT INTO THIS EXISTING NIOSH SYSTEM VOLUNTARILY. MANUFACTURERS DO IT TODAY BECAUSE OF OSHA HEALTH STANDARDS AND OSHA ENFORCEMENT. IF OSHA INSPECTORS DO NOT SEE NIOSH APPROVED PRODUCTS, THEY CITE AND PROPOSE A FINE

FOR THE EMPLOYER. SUBMISSION FOR APPROVALS IS NOT DONE BECAUSE NIOSH TESTING GUARANTEES WORKER PROTECTION, REDUCES OR ELIMINATES LIABILITY OF THE MANUFACTURER, OR IS TIMELY. EXISTING NIOSH APPROVALS ARE A MARKETING DEVICE HAVING LITTLE OR NO TRUE MERIT.

3M MARKETS BOTH APPROVED AND UNAPPROVED RESPIRATORS SUCCESSFULLY AND AGGRESSIVELY. WE DO THIS BECAUSE OUR THOROUGH LABORATORY AND FIELD TESTING DATA TELL US THAT THE PRODUCT PROTECTS THE WORKER WHEN CORRECTLY USED. WE SELL NON-APPROVED PRODUCTS BECAUSE MARKET STUDIES AND FIELD EVALUATIONS SHOW THAT USER NEED EXISTS, EVEN THOUGH THE DESIGN SPECIFICATIONS AND TESTS IN THE EXISTING 30 CFR 11 REGULATIONS DO NOT ALLOW CERTIFICATION. IN ADDITION, IN MANY CASES THERE IS NO APPROVAL SCHEDULE FOR THE SPECIALIZED RESPIRATORS REQUIRED BY WORKERS FOR THEIR PROTECTION IN SPECIFIC ENVIRONMENTS.

DISCUSSIONS WITH NIOSH AND BUREAU OF MINES OFFICIALS HAVE MADE IT OBVIOUS THAT THEY FEEL THEY CANNOT LEGALLY CHANGE OR ADD TO 30 CFR 11 AND APPROVE DEVICES THAT FALL OUTSIDE THE EXISTING DESIGN CRITERIA IN A REASONABLE TIME FRAME.

① FOR THESE BASIC REASONS WE THINK NIOSH SHOULD DEVELOP PERFORMANCE CRITERIA FOR RESPIRATORS.

NIOSH RESPIRATOR STANDARDS INTENDED TO INSURE THE ACHIEVEMENT OF SPECIFIC GOALS SHOULD BE BASED ON PERFORMANCE CRITERIA AND NOT ON DESIGN SPECIFICATIONS. NIOSH SHOULD SPECIFY THE PROBLEMS TO BE SOLVED AND NOT THE DETAILED PRESCRIPTION FOR SOLVING THEM. FOR EXAMPLE, FACEFIT PROTECTION LEVEL SHOULD BE SPECIFIED INSTEAD OF FOUR POINT SUSPENSION. BUT, NIOSH MUST INCLUDE VALID QUANTITATIVE MEANS FOR DETERMINING WHETHER THE REQUIRED PERFORMANCE HAS BEEN ACHIEVED.

BY SPECIFYING THE PERFORMANCE CRITERIA IN FUNCTIONAL TERMS FOR THE USER, THE

PURPOSE OF 30 CFR 11 WILL BE CLEAR, AS WILL BE THE LEVEL OF RESPIRATOR PERFORMANCE REQUIRED TO ACHIEVE IT.

THE MANUFACTURERS TRYING TO MEET THE NEED CAN THEN SEARCH, WITH MINIMUM RESTRAINT, FOR INNOVATIVE SOLUTIONS TO RESPIRATOR USER PROBLEMS. THE RESTRAINTS ON TECHNOLOGY ARE THEN ONLY LIMITED TO THOSE THAT ARE ACTUALLY RELEVANT TO THE USER. PERFORMANCE CRITERIA ARE ALSO LESS PRONE TO SERVE AS OBSTACLES TO A FAIR, COMPETITIVE MARKETPLACE, SINCE THEY ARE LESS LIKELY TO PROTECT ESTABLISHED TECHNOLOGIES AGAINST POTENTIALLY MORE PRODUCTIVE NEW ONES.

EVALUATION OF PERFORMANCE IS NECESSARY. THEREFORE, NIOSH SHOULD PUBLISH DETAILED PROCEDURES FOR WELL-DEFINED TESTS. A FEW OF THE VALID TESTS NOW IN EXISTENCE IN 30 CFR 11 SHOULD BE RETAINED, BUT IN EVERY CASE COMPLETE EQUIPMENT DESCRIPTIONS AND TEST PROCEDURES, AS WELL AS TEST VARIABILITIES, REQUIRE DEFINITION.

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IT WILL ALSO BE NECESSARY, IN DEFINING TESTING FOR PERFORMANCE CRITERIA, TO LEAVE THE SYSTEM OPEN-ENDED SO THAT AS INNOVATIVE TECHNOLOGY OR UNIQUE NEW EQUIPMENT COMES ALONG, NEW MEANS FOR EVALUATING PRODUCT PERFORMANCE EFFECTIVENESS ARE PERMITTED.

NIOSH AND THE PRIVATE SECTOR MUST WORK COOPERATIVELY IN DEVELOPING AND PUBLISHING APPROPRIATE, DETAILED PERFORMANCE TESTS OF KNOWN RELIABILITY.

ONE USABLE MEANS TO CONTROL PRODUCT PERFORMANCE IS THE ABILITY OF ONE COMPETITOR TO TEST ANOTHER'S PRODUCT WITH METHODS THAT ARE REPRODUCIBLE AND OF KNOWN VARIABILITY. ONLY THEN CAN SUBSEQUENT DISCUSSIONS BE MEANINGFUL. IF FIELD AUDITS ARE EVER TO BE USEFUL, TESTS MUST BE AS UNIFORM AS POSSIBLE SO THAT DISPUTES CAN BE RESOLVED BASED ON TRULY PARALLEL DATA.

THE QUANTITATIVE FIT TEST CONTROVERSY PRESENTLY BEING ENCOUNTERED IN INDUSTRY WITH OSHA ON THE LEAD STANDARD IS AN EXAMPLE OF THE NEED TO HAVE NIOSH PUBLISH DETAILED PERFORMANCE TESTS. THERE IS NO DEFINED FIT TEST METHOD THAT CAN BE USED BY INDUSTRY. YET, IF NIOSH HAD FOLLOWED UP ON THEIR SPONSERED LOS ALAMOS RESEARCH WITH A TEST PROTOCOL, A SYSTEM MIGHT EXIST AND FIT FACTORS COULD BE ASSIGNED TO EACH RESPIRATOR BY THE MANUFACTURER IF HE SO DESIRED.

NIOSH MUST BE ABLE TO ADAPT NEW TESTS, REGARDLESS OF OPERATIONAL APPROACH, TO APPROVE NEW DEVICES THAT CANNOT BE TESTED AND APPROVED UNDER EXISTING SPECIFIED, DESIGN-ORIENTED TEST METHODS. IT SHOULD NOT BE THE INTENT OF NIOSH TO REQUIRE UNNECESSARY TESTS, OR TO EXCLUDE NEW DEVICES FROM APPROVAL CONSIDERATION, BECAUSE AN EXISTING, SPECIFIED APPROVAL TEST OR REQUIREMENT IS NOT DIRECTLY APPLICABLE TO THAT NEW DEVICE.

ONCE NIOSH HAS DEFINED PERFORMANCE CRITERIA AND RELIABLE TEST METHODS TO COMPARE PERFORMANCE TO THE CRITERIA, MANUFACTURERS SHOULD CONDUCT THE TESTS AND CERTIFY THAT THEIR PRODUCTS MEET THE PUBLISHED NIOSH REQUIREMENTS. NIOSH SHOULD AUDIT FIELD SAMPLES TO VERIFY MANUFACTURER'S CLAIMS.

AT THIS POINT IT IS OBVIOUS THAT 3M RECOMMENDS ALTERNATIVE #4 DESCRIBED IN THE JUNE 18, 1980 FEDERAL REGISTER. WE REJECT THE OTHERS FOR REASONS I WILL DISCUSS LATER.

OPTION #4, THE SELF-CERTIFICATION ALTERNATIVE, WOULD COMBINE THE BEST OF THE LISTED AVAILABLE ALTERNATIVES. 3M RECOMMENDS THE FOLLOWING:

1. NIOSH WOULD DEVELOP AND MAINTAIN PERFORMANCE CRITERIA USING THE BEST STATE-OF-THE-ART METHODS. THESE WOULD BE PROMULGATED AND PUBLISHED IN THE FORMAL RULEMAKING PROCEDURE. MANUFACTURERS WOULD USE THESE

PERFORMANCE SPECIFICATIONS AND TEST METHODS TO EVALUATE THEIR PRODUCTS. PRODUCTS MEETING THE APPROPRIATE SPECIFICATIONS WOULD BE MANUFACTURER CERTIFIED AS MEETING THE MINIMUM REQUIREMENTS.

2. NIOSH WOULD ALLOW MANUFACTURERS TO SUBMIT SAMPLES TO VALIDATE TESTS BETWEEN NIOSH AND THE MANUFACTURER, BUT NIOSH AUDIT OF THE MANUFACTURERS' FACILITIES IS UNNECESSARY.
3. NIOSH SHOULD HAVE A CONTINUING PROGRAM TO DEVELOP IMPROVED TEST EQUIPMENT AND TESTING METHODS. IT IS IMPORTANT THAT NIOSH REPLACE CURRENT TESTING TECHNIQUES AND EQUIPMENT. NIOSH SHOULD KEEP MANUFACTURERS INFORMED OF ANY IMPROVED TECHNIQUE.
4. PRIOR TO DISTRIBUTION AND SALE, THE MANUFACTURER WOULD NOTIFY NIOSH OF ITS INTENT AND THE GEOGRAPHIC AREA INTO WHICH THE PRODUCT WOULD BE SOLD. THE MANUFACTURER WOULD INCLUDE A DESCRIPTION OF THE PRODUCT AND ITS INTENDED USE. THIS NOTIFICATION WOULD ALLOW NIOSH TO EXERCISE ITS OPTION TO PURCHASE THE PRODUCT AND PERFORM ITS OWN EVALUATION, IF IT IS FELT NECESSARY TO VERIFY THAT THE PRODUCT IN FACT MEETS THE PERFORMANCE REQUIREMENTS.
5. IF NIOSH FINDS PROBLEMS THROUGH ITS OWN EVALUATIONS OR BASED ON USER COMPLAINTS, WE FEEL ADEQUATE PROVISIONS EXIST IN THE LAW TODAY TO HANDLE ENFORCEMENT OF ITS FINDINGS. AFTER DISCUSSION OF ITS FINDINGS WITH THE MANUFACTURER AND AGREEMENT OF FACT, NIOSH COULD REQUEST VOLUNTARY ACTION SUCH AS CORRECTION OF THE PROBLEM, STOP SALE, RECALL, ETC., DEPENDING ON THE NATURE OF THE PROBLEM. IF THE MANUFACTURER DOES NOT TAKE ACCEPTABLE ACTION, NIOSH COULD USE LEGAL PROCEDURES TO PREVENT DISTRIBUTION OF SUBSTANDARD PRODUCTS.

6. OSHA WOULD ACCEPT THE MANUFACTURER'S CERTIFICATION OF DEVICES AS LABELED.
7. THE FIELD AUDITS BY NIOSH WOULD ALLOW SUFFICIENT RESPONSE TIME TO A MANUFACTURER TO CORRECT ANY PROBLEMS DISCOVERED IN NIOSH EVALUATIONS.
8. IF NIOSH DOES CONDUCT FIELD AUDITS AND DESIRES TO DISTRIBUTE TEST RESULTS, ONLY CONFORMANCE AND NON-CONFORMANCE SHOULD BE STATED. NOT NUMBERS, AS NUMBERS CAN OFTEN BE MISINTERPRETED. MANUFACTURERS MUST BE INFORMED OF NON-CONFORMANCE PRIOR TO ANY DATA DISTRIBUTION. AS A CROSS CHECK ON THE SYSTEM, NIOSH MUST BE REQUIRED TO PRESENT EVIDENCE OF CONTROLLED TESTING BEFORE A NON-CONFORMANCE PUBLICATION IS DISTRIBUTED. A SYSTEM TO HANDLE FAILURES SHOULD BE PROPOSED AND DEBUGGED.
9. NIOSH SHOULD NOT UNDERTAKE TO WIDELY PUBLICIZE NEGATIVE RESULTS OF TESTS PERFORMED FOR ANYTHING BUT MAJOR HAZARD DEFECTS, AND ONLY AFTER CONSULTING WITH THE MANUFACTURER. BAD PRESS BY NIOSH FOR A POOR BUT INSIGNIFICANT TEST RESULT COULD CAUSE IRREPARABLE DAMAGE TO ALL MANUFACTURERS AND COULD WIPE OUT A SMALL MANUFACTURER.
10. NIOSH POLICY SHOULD BE STRUCTURED SO NIOSH PERSONNEL PARTICIPATION ON CONSENSUS STANDARD MAKING COMMITTEES, SUCH AS THE AMERICAN NATIONAL STANDARDS INSTITUTE, IS ENCOURAGED. IT WILL HELP GET IMPROVED CRITERIA INTO THE SYSTEM FASTER. BROAD PARTICIPATION BY ALL AFFECTED PARTIES IS ESSENTIAL IN THE SELECTION OF THE STRATEGY FOR SOLVING PROBLEMS AND THE CHOICE OF THE LEVEL OF PERFORMANCE TO BE REQUIRED. MUCH IS LOST WHEN NIOSH PERSONNEL ARE NOT PART OF THE REASONING FOR ESTABLISHING CONSENSUS CRITERIA.
11. NIOSH NEED NOT SPONSOR RESEARCH ON NEW DEVICES. WITH THE NUMBER OF

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MANUFACTURERS IN SAFETY AND HEALTH, MARKET FORCES WILL BRING FORTH NEEDED PRODUCTS SO LONG AS PERFORMANCE CRITERIA ARE NOT SO CONFINING AS TO PREVENT INNOVATIVE PRODUCTS ENTERING THE MARKET PLACE. THE PRIVATE SECTOR IS BETTER SUITED FOR RESEARCH THAN NIOSH.

THE SELF-CERTIFICATION METHOD WOULD ALLOW FREQUENT ASSESSMENT OF THE PRODUCT IN THE FIELD BY NIOSH. IT WILL CORRECTLY PLACE THE BURDEN OF DESIGNING, PRODUCING AND TESTING RELIABLE DEVICES ON THE MANUFACTURER.

BY PLACING THE PRIMARY RESPONSIBILITY ON THE MANUFACTURER FOR CERTIFICATION, NIOSH COULD USE ITS RESOURCES TO DEVELOP BETTER, MORE PERTINENT PERFORMANCE SPECIFICATIONS AND TEST METHODS TO EVALUATE THEM. NIOSH HAS NOT PERFORMED THIS FUNCTION ADEQUATELY IN THE PAST, AND THE SELF-CERTIFICATION ALTERNATIVE WOULD ALLOW RESOURCES TO BE DIVERTED, CONCENTRATED, AND UTILIZED IN THIS MANNER. ADVANTAGES OF OPTION #4 ARE:

1. IT REDUCES THE NEED FOR CONTINUED EXPANSION OF NIOSH FACILITIES AND PERSONNEL AS THE NUMBER OF APPROVALS GROW.
2. IT BRINGS NEW PRODUCTS TO MARKET EARLIER.
3. IT ALLOWS NIOSH TO CONCENTRATE ON THE AUDIT OF PRODUCTS THAT MAY BE MORE REPRESENTATIVE THAN SELECTED, SUBMITTED SAMPLES.
4. AS MANUFACTURERS ACCEPT THE RESPONSIBILITY FOR TESTING, THEIR RESOURCES WILL BE USED TO DEVELOP NEW AND MORE REALISTIC TEST METHODS.
5. IT PREVENTS NIOSH FROM BEING USED AS A DEVELOPMENT LABORATORY BY MANUFACTURERS.
6. CHANGES TO A PRODUCT DON'T NEED SUBMISSION AS LONG AS THE MANUFACTURER CERTIFIES CONFORMANCE TO PERFORMANCE CRITERIA.

7. AS APPROVAL TIME AND SUBMITTAL EXPENSE IS REDUCED, MANUFACTURERS WOULD BE ENCOURAGED TO PRODUCE A WIDER RANGE OF SPECIFIC PRODUCTS THAT WOULD AFFORD THE END USER A BETTER SELECTION AND REDUCED COST.
8. IT INCREASES PRODUCTIVITY AS IT REDUCES COST OF APPROVALS - BOTH TO MANUFACTURERS AND NIOSH.
9. IT WILL IMPROVE THE WORKING RELATIONSHIP BETWEEN NIOSH AND MANUFACTURERS. INNOVATION, COMFORT, EFFICIENCY AND ECONOMY WOULD BE ENCOURAGED.
10. IN THE CASE OF A MAJOR DEFECT BEING DISCOVERED IN THE USER'S PRODUCT, IT IS THE MANUFACTURER'S RESPONSIBILITY, NOT NIOSH'S. THE RESPONSIBLE MANUFACTURER MUST LOCATE AND INFORM THEIR CUSTOMERS OF THE PROBLEM.
11. OPTION #4 HAS THE FURTHER ADVANTAGE THAT AN ELEMENT OF TRUST AND MATURITY MUST BE ESTABLISHED AMONG NIOSH, OSHA AND THE MANUFACTURER THAT THE NEEDS OF THE USER WILL BEST BE MET BY THIS TYPE OF SYSTEM. THOSE THAT SOW SEEDS OF DISSENT AND MISINFORMATION ABOUT THE MANUFACTURERS' TRUE INTENT WILL BE FORCED TO BRING FORTH THEIR DATA THAT CAN BE EXAMINED ON THE BASIS OF TECHNICAL FACT - NOT THROUGH ENDLESS, EXPENSIVE LEGAL CONTROVERSIES THAT SERVE NO GOOD PURPOSE. OR, AS HAS BEEN THE CASE, WITHOUT ANY DATA FROM THEIR OWN EXPERIENCE.

Exceptions to Prod did not

DISCUSSION OF THE OTHER CERTIFICATION OPTIONS THAT NIOSH HAS PRESENTED IS IMPORTANT. ALL THINGS BEING EQUAL, OPTION 1, CONTINUING AS WE PRESENTLY ARE DOING, BUT WITH REVISED ADMINISTRATIVE AND TEST CRITERIA AREAS, IS COMPLETELY UNACCEPTABLE.

THE PRESENT SYSTEM HAS BEEN AND IS BEING, ABUSED BY THOSE INVOLVED IN THE CERTIFICATION PROCESS. 30 CFR 11, AS IT IS BEING ADMINISTERED, APPEARS TO

BE AUTOCRATICALLY DESIGNED TO ESTABLISH AN ADVERSARY ROLE BETWEEN THE APPROVING AGENCY AND MANUFACTURERS OF DEVICES. THIS IS A ROLE NEITHER THE U.S. MANUFACTURER, GOVERNMENT OR USER CAN AFFORD TO ALLOW TO CONTINUE. I MIGHT ADD THAT ONLY IN THE U.S. DOES THIS ADVERSARY ROLE EXIST. IN MANY OTHER COUNTRIES THE GOVERNMENTAL APPROVING AGENCY COOPERATES WITH LOCAL MANUFACTURERS OF EQUIPMENT, EVEN TO THE LEVEL OF COOPERATION THAT MAKES IT ALMOST IMPOSSIBLE FOR IMPORTED PRODUCTS TO BE APPROVED.

*level of cooperation
requirement one year*

FURTHER, THE PRESENT SYSTEM OF THE MSHA/NIOSH APPROVAL OF A DEVICE DOES NOT GUARANTEE END USER UTILITY OR SAFETY. AS WE HAVE TESTIFIED IN THE PAST, THE FACT THAT A RESPIRATOR MEETS A TEST REQUIREMENT IS ONLY A VERY MINOR PART IN AN EFFECTIVE USER RESPIRATOR PROGRAM. MATCHING THE PROPER DEVICE TO THE HAZARD, INSURING PROPER FIT TO WORKERS, MATCHING FILTRATION PERFORMANCE TO REAL WORK SITUATIONS, ETC., SHOULD NOT BE OVERSHADOWED BY AN INFLEXIBLE, ARTIFICIAL TEST METHOD THAT STOPS INNOVATION.

THE MAIN REASON AN EMPLOYER-USER WANTS AN MSHA/NIOSH APPROVED PRODUCT IS, QUITE SIMPLY, THAT THEY DON'T WANT A HASSLE FROM OSHA. HOWEVER, ON PAGE 13 OF THE OSHA OPERATIONS MANUAL, CHAPTER III, SUBPART E, AND I QUOTE, "MSHA/NIOSH WILL PROVIDE A TEST SCHEDULE FOR ANY RESPIRATOR AGAINST ANY SPECIFIC CONTAMINANT. THE USE OF UNAPPROVED RESPIRATORS, EVEN IN SPECIAL USE SITUATIONS, IS UNACCEPTABLE UNLESS APPROVAL IS PENDING BEFORE NIOSH."

THIS IS NOT AND HAS NOT BEEN THE CASE WITH THE EXISTING MSHA/NIOSH APPROVAL SYSTEM. 30 CFR 11 IS UNWORKABLE AS IT DOES NOT ALLOW NEW, BETTER WORKER PROTECTIVE DEVICES TO REACH THE MARKETPLACE FAIRLY.

OVER THE LAST TEN MONTHS NIOSH HAS BEEN DOING A POORER JOB IN COMMUNICATING THE STATUS OF APPROVAL TESTING WITH MANUFACTURERS THAN EVER BEFORE. THEY PRESENTLY WILL NOT ALLOW WITNESSING OF TESTS AND WILL NOT DISCUSS THE STATUS

OF SUBMITTED PRODUCTS.

ON WITNESSING OF TESTS:

- A. NIOSH MUST BE AUDITED.
- B. ERRORS HAVE BEEN MADE BY NIOSH IN TESTING. (9920 - Failed)
- C. THERE IS NO PRESSURE ON TEST TECHNICIANS IF THINGS ARE DONE CORRECTLY, SO IT IS NOT A PROBLEM TO WATCH THEM TEST.
- D. NIOSH CAN ESTABLISH GROUND RULES OF WHAT A WITNESS TO THE TEST CAN AND CANNOT DO.

PERHAPS THE MOST IRRITATING ASPECTS OF EXISTING NIOSH POLICY IS ITS POSITION OF REFUSING TO DISCUSS THE STATUS OF CERTIFICATION TESTING. WHEN A PRODUCT IS OFFICIALLY SUBMITTED AND DELIVERED TO MORGANTOWN, IT'S AS IF EVERYTHING DISAPPEARED INTO A BLACK HOLE.

Re: 125 RECENTLY 3M EXPERIENCED AT LEAST A FOUR MONTH DELAY BETWEEN THE ACTUAL APPROVAL TESTING AND RECEIPT OF THE LETTER OF CERTIFICATION. (WE DO NOT UNDERSTAND WHY NIOSH WOULD WANT TO DELAY INTRODUCTION OF AN APPROVED PRODUCT TO THE MARKET. IF AND WHEN QUESTIONS ARISE ABOUT A SUBMITTED PRODUCT, WE ARE CONFIDENT THAT A TEN MINUTE TELEPHONE CALL WILL OFTEN SOLVE THE PROBLEM. PROBLEMS SHOULD BE SOLVED AS EXPEDITIOUSLY AS POSSIBLE.

IN SUMMARY, OPTION #1 SHOWS NO IMMEDIATE RELIEF THAT HELPS EITHER USER OR MANUFACTURER.

OPTION #2, AS OUTLINED, IS SUBJECT TO THE SAME OBJECTIONS AS WE HAVE STATED AGAINST THE FIRST OPTION.

LET'S DISCUSS SOME RECENT NIOSH-ISSUED GUIDELINES, AS THEY PROVIDE CLUES AS

TO THE MANNER IN WHICH A NIOSH-ONLY APPROVAL SYSTEM WOULD WORK AND BE ADMINISTERED.

ON JUNE 19 AND JUNE 20, 1980, TWO DOCUMENTS WERE PUBLISHED BY NIOSH AS "GUIDELINES" THAT ARE CLOSELY RELATED TO THE "FIELD AUDIT" SYSTEM THAT WAS PROPOSED FOR DISCUSSION AT THIS HEARING. THE FIRST ONE, CONCERNING STOP SALE AND RECALL OF PRODUCTS, HAS NEVER BEEN SUBJECT TO PUBLIC REVIEW. THE SECOND, REGARDING AN APPEALS PROCEDURE, HAS BEEN COMMENTED ON IN A NUMBER OF NIOSH HEARINGS SINCE 1974. BOTH SUBJECTS ARE IMPORTANT AND THEY SHOULD EITHER PROPERLY BECOME A PART OF 30 CFR 11 WITH A PUBLIC HEARING OR BE DROPPED. THESE GUIDELINES CANNOT BE ALLOWED TO BE ACCEPTED AS STANDARD NIOSH APPROVAL OPERATING PROCEDURES WITHOUT THOROUGH COMMENT AND REVIEW. THE SAME IS TRUE OF A PROCESS BY NIOSH, OR BY ANY AGENT OF NIOSH, CONCERNING FIELD AUDITS OF SAMPLES UTILIZING GUIDELINES NOT REVIEWED PUBLICLY.

IN ADDITION TO THESE "VOLUNTARY GUIDELINES", NIOSH USES MANY OTHER "GUIDELINES" FOR RESPIRATOR TESTS THAT HAVE NEVER BEEN PUBLISHED AND SUBJECTED TO PUBLIC REVIEW. THE LATEST OF THESE IS A DECISION NOT TO APPROVE DUST RESPIRATORS FOR ASBESTOS, EVEN THOUGH THE RESPIRATOR MEETS THE TEST REQUIREMENTS AND THE LAW. IT IS IMPORTANT THAT NIOSH PERSONNEL BE REQUIRED TO CONSISTENTLY FOLLOW CORRECT RULEMAKING PROCEDURES.

REQUIREMENTS OR CHANGES TO REQUIREMENTS FOR CERTIFICATION MUST BE SUBJECT TO PUBLIC HEARING AND REVIEW. ANY OUTSIDE LABORATORY DATA SYSTEM SET UP BY NIOSH MUST BE SUBJECT TO SPECIFIC CROSS CHECKS FOR DATA VALIDATION AND STRINGENT PUBLISHED RULES FOR INFORMATION RELEASE. ADVERSE DATA WOULD HAVE TO BE CONFIDENTIAL AND NOT BE DISCLOSED BY ANYONE, INCLUDING PRIVATE LABORATORIES ACTING ON BEHALF OF NIOSH, UNTIL A THOROUGH REVIEW OF THE DATA HAS BEEN HELD WITH THE MANUFACTURER. TODAY THIS PROCEDURE DOES NOT EXIST.

IN 1972 AND 1973 EARLY RELEASE BY LOS ALAMOS OF INCOMPLETE TEST INFORMATION FROM NIOSH CONTRACTED RESEARCH WAS HARMFUL TO THE 3M COMPANY RESPIRATOR PROGRAM.

AS IN THE CASE OF OPTION #1, 3M FEELS OPTION #2 IS UNWORKABLE. TO GIVE MORE POWER OR TO AGREE TO THE POWER LEVEL OF THE EXISTING NIOSH/MSHA SITUATION THAT IS UNWORKABLE IS NOT ACCEPTABLE. IN CASE YOU MISSED OUR POINT, THE PRESENT SYSTEM IS SLOW, INACCURATE, ARBITRARY, INEFFECTIVE AND INFLEXIBLE. LESS, NOT MORE, POWER OF CERTIFICATION SHOULD BE ALLOWED THE EXISTING MSHA/NIOSH SYSTEM AND THEIR RESPONSIBILITIES MORE CLOSELY DEFINED.

3M FEELS THAT OPTION #3, PRIVATE LABORATORY CERTIFICATION, WILL ONLY INTRODUCE ANOTHER LEVEL OF CONFUSION AND EXCUSE FOR DELAY TO THE PRESENT APPROVAL COMMUNICATION PROBLEMS. ALSO, OUTSIDE CERTIFIED LABORATORIES WOULD RESULT IN DISAGREEMENT AS TO CONFORMANCE OR NON-CONFORMANCE. UNCERTIFIED LABORATORIES WOULD BE WORSE. IF LABORATORIES ARE TO BE CERTIFIED BY NIOSH, MANUFACTURERS WHO ALREADY HAVE EQUIPMENT AND EXPERTISE CANNOT BE EXCLUDED FROM CERTIFIABLE STATUS.

THE CONSUMER PRODUCT SAFETY COMMISSION WAS SUGGESTED BY THE CONSULTANTS AS A POSSIBLE MODEL FOR NIOSH TO FOLLOW IN THE AREA OF HEALTH AND SAFETY PRODUCT TESTING AND CONTROL. WE DO NOT AGREE WITH THIS RECOMMENDATION. 3M EXPERIENCE WITH THE CONSUMER PRODUCT SAFETY COMMISSION (AEROSOL SPRAY ADHESIVE CASE) IS EVIDENCE THAT POWER TO BAN A PRODUCT WITHOUT MANDATORY SAFEGUARDS REQUIRING FULL EVALUATION AND CRITICAL REVIEW OF DATA RESULTS IN SEVERE HARDSHIP TO THE USERS, AND EXTENSIVE EXPENSE AND FINANCIAL LOSS TO THE MANUFACTURER. THE RESULTS OF ERRORNEOUS ACTIONS BY FEDERAL AGENCIES ARE LONG TERM CONSEQUENCES. LAWSUITS CONTINUE OVER SIX YEARS AFTER THE CONSUMER PRODUCT SAFETY COMMISSION WITHDREW THE SPRAY ADHESIVE BAN THAT WAS

BASED ON EVIDENCE WHICH COULD NOT BE VERIFIED.

THE WIDELY-PUBLICIZED CONSUMER PRODUCT SAFETY COMMISSION NATIONAL NETWORK FOR OBTAINING DATA ON UNSAFE PRODUCTS HAS WEAKNESSES THAT CAN EASILY RESULT IN MISLEADING CONCLUSIONS. ANY DATA COLLECTING SYSTEM THAT DOES NOT INCORPORATE PROCEDURES FOR VERIFYING INFORMATION AT THE SOURCE IS SUBJECT TO QUESTION. UNVERIFIED DATA THAT ARE EXTRAPOLATED TO SUPPOSEDLY NATIONWIDE STATISTICS IS EVEN MORE QUESTIONABLE.

TO SUPPORT OUR POSITION, WE REFERENCE A REPORT TO SENATOR JOHN TOWER FROM THE COMPTROLLER GENERAL OF THE UNITED STATES NUMBER B-139310. THE REPORT IS UNDATED, BUT IS IN RESPONSE TO SENATOR TOWER'S REQUEST DATED APRIL 29, 1974. THE REPORT IS ATTACHED, BUT WILL NOT BE READ.

WE BELIEVE THAT IT IS ADVISABLE FOR NIOSH TO PERIODICALLY TEST SAFETY EQUIPMENT OBTAINED THROUGH NORMAL COMMERCIAL CHANNELS. WE ALSO KNOW THAT THE RESULTS OF THOSE TESTS MUST BE HANDLED BY WELL-STRUCTURED, MANDATORY PROCEDURES. THIS WILL PREVENT EMBARRASSMENT TO NIOSH, UNACCEPTABLE DELAYS IN CORRECTING ERRORS, UNNECESSARY CONCERN ON THE PART OF THE PUBLIC, AND UNWARRANTED EXPENSE TO SAFETY EQUIPMENT MANUFACTURERS.

THE NEED FOR SUBMISSION OF OPERATING (USE) AND MAINTENANCE MANUALS TO NIOSH DOES NOT EXIST. THE MANUFACTURER HAS A RESPONSIBILITY TO PROVIDE THE CUSTOMER WITH TECHNICAL DATA TO EFFECTIVELY USE AND MAINTAIN SPECIFIC PRODUCTS. THE AMOUNT OF DATA FOR PROPER PRODUCT USE VARY CONSIDERABLY AND MUST BE ESTABLISHED BY PROFESSIONAL, TECHNICAL AND LEGAL STAFFS. SOME MANUALS REQUIRE DETAILED ASSEMBLY, USE, AND MAINTENANCE INSTRUCTIONS. BECAUSE CERTAIN TYPES OF PERSONAL PROTECTIVE EQUIPMENT ARE PRODUCT SPECIFIC, EACH MANUFACTURER MUST DEVELOP HIS OMI MANUALS. 3M EXPERIENCE SHOWS THAT A CONCERTED EFFORT IS REQUIRED TO PRODUCE A MANUAL THAT GIVES THE CUSTOMER

WHAT IS NEEDED TO OBTAIN SATISFACTORY USE OF THE PRODUCT. EXPERIENCE ALSO SHOWS THAT AS A PRODUCT IS USED, MORE IS LEARNED FROM FIELD TRIALS AND CUSTOMER SERVICE. CONSEQUENTLY, CHANGES TO MANUALS AND USE INSTRUCTIONS ARE INITIATED WHERE NEEDED TO KEEP MANUALS UPDATED FOR PROPER PRODUCT USE AND TO PREVENT MISUSE. IT WOULD BE A DISSERVICE TO THE USERS OF RESPIRATORY PROTECTIVE EQUIPMENT TO BE FORCED TO WAIT FOR MANUAL CHANGES WHILE NIOSH REVIEWS AND APPROVES THEM. IN ADDITION, NIOSH IS NOT IN A POSITION TO APPROVE OR DISAPPROVE A MODIFICATION OF A MANUAL WITHOUT CONSULTATION WITH THE MANUFACTURER, AND WITHOUT ENTERING INTO DEVELOPMENT RESEARCH TO DETERMINE THE EFFICACY OF A CHANGE. THIS IS NOT A PROPER ACTIVITY (RESEARCH TO SOLVE A PARTICULAR PROBLEM FOR A MANUFACTURER) OF NIOSH.

THERE CERTAINLY WOULD BE NO OBJECTION TO PROVIDING NIOSH WITH COPIES OF MANUALS, POSTERS, MAINTENANCE AND DATA SHEETS, SELL SHEETS, ETC. FOR THEIR RECORDS, BUT NOT AS A PART OF APPROVAL.

IT SEEMS TO 3M THAT THE LITERATURE DESCRIBED IN THIS SECTION IS SIMILAR TO THE MANUALS AND SUPPORTING RECORDS REQUIRED FOR QUALITY CONTROL PLANS. NIOSH HAS ACKNOWLEDGED THAT THIS REQUIREMENT DOES NOT CONTRIBUTE TO THE CURRENT TESTING AND CERTIFICATION PROGRAM, AND RECOMMENDS THAT THIS REQUIREMENT BE ELIMINATED. LIKEWISE, WE RECOMMEND THAT THIS PROPOSAL BE DROPPED AT THIS POINT.

IN REGARD TO THE OTHER SPECIFIC AREAS ABOUT WHICH NIOSH REQUESTED COMMENTS, MOST ANSWERS ARE SIMPLE. GROUP TESTING OF RESPIRATORS IS UNACCEPTABLE AS IT IS AN UNNECESSARY RESTRAINT OF TRADE. TO FORCE ALL MANUFACTURERS TO GO AT THE SAME PACE TO MAKE IT MORE CONVENIENT FOR NIOSH TESTING IS NOT ACCEPTABLE. NIOSH MUST EITHER TEST EFFICIENTLY OR GET MORE PEOPLE JUSTIFIED IN THEIR BUDGET IF THEY ARE TO CONTINUE TO TEST.

WE AGREE WITH NIOSH THAT THEY NO LONGER TRY TO MAKE AN IN DEPTH REVIEW AND APPROVE QUALITY CONTROL PLANS. THE PRODUCT QUALITY LIMITS THAT NIOSH SETS DEFINE QUALITY LEVELS. IN THE REAL WORLD THERE ARE NO 100% CERTAINTIES AS SO MANY VARIABLES EXIST OVER WHICH NO CONTROLS ARE POSSIBLE. NIOSH MUST BE SURE THEY SAMPLE AND STATISTICALLY REVIEW FIELD AUDITS OF PRODUCTS.

IN REGARD TO CHANGES TO APPROVED DEVICES, THE PRESENT SYSTEM IS INDISCRIMINATE AND PLACES MEANINGLESS BURDEN ON BOTH MANUFACTURER AND NIOSH.

3M'S VIEWS IN SUMMARY

1. AUTOCRATIC ADMINISTRATIVE ACTIVITIES BEING PERPETRATED AT NIOSH AND THE CURRENT CONCEPT OF DESIGN SPECIFICATION MUST BOTH BE ABANDONED.
PERFORMANCE CRITERIA FOR PRODUCTS SHOULD BE JOINTLY ESTABLISHED BY NIOSH AND INDUSTRY.
2. REPRODUCIBLE TEST METHODS, WHICH CAN BE USED TO JUDGE WHETHER PRODUCTS MEET PERFORMANCE CRITERIA, SHOULD BE DEVELOPED AND AGREED UPON BY NIOSH AND INDUSTRY.
3. SELF-CERTIFICATION BY MANUFACTURERS SHOULD BE EMPLOYED. NIOSH AND MANUFACTURERS WOULD THEN HAVE MORE CONFIDENCE IN EACH OTHER. PROBLEMS OF NIOSH LIABILITY AND USE OF NIOSH AS A DEVELOPMENT LABORATORY WOULD BE ELIMINATED.
4. THE REMOVAL OF QUALITY ASSURANCE PLANS AS A REQUIREMENT FOR CERTIFICATION IS A GOOD START TOWARD THE ABOVE SYSTEM.
5. THE IDEA OF MANUALS, ETC., BEING SUBMITTED FOR APPROVALS IS COUNTERPRODUCTIVE TO THE IDEA OF ELIMINATING QUALITY ASSURANCE PLANS.

WE SINCERELY HOPE THAT THESE COMMENTS WILL ASSIST YOU IN PROMULGATING A NEW

SYSTEM WHICH WILL EMPHASIZE A TESTING AND CERTIFICATION PROGRAM BASED ON RESPIRATOR PERFORMANCE AND WHICH WILL BE ABLE TO ACCOMMODATE AND ENCOURAGE THE INTRODUCTION OF NEW AND INNOVATIVE PRODUCTS. WE SUBMIT THAT THESE GOALS CAN BE ACHIEVED WITHOUT SACRIFICING WORKER PROTECTION, AND IF NOT ACCOMPLISHED, WILL ULTIMATELY HAVE A MOST SEVERE NEGATIVE IMPACT UPON ALL THOSE WORKERS WHO DEPEND UPON OUR PROFESSIONAL EXPERTISE TO PROVIDE THEM THE BEST RESPIRATORY PROTECTION POSSIBLE.

THANK YOU.

RESPECTFULLY SUBMITTED,

EINAR D. HORNE
TECHNICAL DIRECTOR
OCCUPATIONAL HEALTH & SAFETY
PRODUCTS DIVISION
3M COMPANY
ST. PAUL, MINNESOTA 55101

DATED: JULY 21, 1980

/lw

MY NAME IS EINAR HORNE AND I AM HERE REPRESENTING THE OCCUPATIONAL HEALTH & SAFETY PRODUCTS DIVISION (OH&SP) OF 3M COMPANY.

INTRODUCTION

FOR MANY YEARS, 3M HAS BEEN A MANUFACTURER OF CERTAIN TYPES OF RESPIRATORS. FOR EXAMPLE, 3M MANUFACTURES CHEMICAL-CARTRIDGE RESPIRATORS, PARTICULATE FILTER RESPIRATORS, POWERED AIR PURIFIERS, AND SUPPLIED-AIR RESPIRATORS, ALL OF WHICH CAN BE USED FOR PROTECTION AGAINST NON-TOXIC DUSTS, TOXIC DUSTS AND TOXIC VAPORS. CONSEQUENTLY, 3M IS DIRECTLY AFFECTED BY THE 30 CFR 11 REGULATION RELATED TO RESPIRATOR TESTING, CERTIFICATION, SELECTION AND USE. FURTHER, AS A MANUFACTURER OF RESPIRATORY DEVICES WE ARE ACUTELY CONCERNED THAT CHANGES TO EXISTING STANDARDS, POLICIES & PRACTICES IMPROVE THE QUALITY AND EFFECTIVENESS OF PERSONAL PROTECTIVE DEVICES.

THEREFORE, IN RESPONSE TO THE INVITATION FOR INTERESTED PARTIES TO SUBMIT COMMENTS CONCERNING THE CONSULTANT'S REPORT AND POSSIBLE AMENDMENT OF 30 CFR 11, WE OFFER THE FOLLOWING VIEWS FOR THE PURPOSE OF AIDING IN THE DEVELOPMENT OF AN APPROPRIATE AND FEASIBLE REGULATION WHICH WOULD ADEQUATELY PROTECT EMPLOYEES WHO ARE REQUIRED BY OSHA STANDARDS TO USE NIOSH APPROVED RESPIRATORY DEVICES.

MY TESTIMONY TODAY WILL ADDRESS THOSE AREAS IDENTIFIED IN THE NOTICE FOR THESE HEARINGS, PUBLISHED IN THE FEDERAL REGISTER ON WEDNESDAY, JUNE 18, 1980 (45 FED. REG. 41219). SPECIFICALLY, I SHALL DISCUSS BOTH THE PROPOSED CHANGES TO 30 CFR 11 THAT WERE OUTLINED BY NIOSH AND THE CONSULTANT'S REPORT.

OVERVIEW

ONE OF OUR MAJOR CONCERNS WITH THE EXISTING 30 CFR 11 REGULATION IS THAT ITS

RESPIRATOR APPROVAL SYSTEM IS BASED LARGELY UPON TEST METHODS DEVELOPED IN THE 1930'S THAT WERE DESIGNED TO MEASURE THE EFFECTIVENESS OF RESPIRATORS DURING THAT ERA. NIOSH SIMPLY TOOK BUREAU OF MINES' TESTS, PERSONNEL AND PHILOSOPHY INTO THE DECADE OF THE 1970'S. EVEN THE APPROVAL NUMBERING SYSTEM WAS CONTINUED. IN RECENT YEARS THERE HAVE BEEN SIGNIFICANT SCIENTIFIC DISCOVERIES AND DEVELOPMENTS WITHIN THE RESPIRATOR INDUSTRY. TODAY, NEW AND INNOVATIVE RESPIRATORY PRODUCTS, HAVING THE ABILITY TO GREATLY IMPROVE EMPLOYEE RESPIRATORY PROTECTION AND ACCEPTANCE, ARE READY FOR THE MARKETPLACE. NONETHELESS, BECAUSE THE CURRENT APPROVAL SYSTEM IN 30 CFR 11 IS TECHNICALLY OUTDATED AND INAPPLICABLE TO TODAY'S RESPIRATORS, THESE NEW AND IMPROVED PRODUCTS ARE NOT RECEIVING NIOSH APPROVAL. 3M HAS TESTIFIED IN TWO PREVIOUS 1977 HEARINGS THAT THE ENTRANCE OF NEW RESPIRATOR PRODUCTS INTO THE MARKETPLACE IS BEING RESTRICTED.

CONTINUED ADHERENCE TO THIS OLD APPROVAL SYSTEM TENDS TO HAVE A CHILLING EFFECT ON THE INCENTIVE TO CONTINUE TO DESIGN AND DEVELOP NEW AND BETTER RESPIRATORY PRODUCTS -- WHY DESIGN A NEW PRODUCT IF IT CANNOT POSSIBLY RECEIVE NIOSH APPROVAL?

FURTHER, THE ADVENT OF NEW AND MORE ENCOMPASSING REGULATIONS BY OSHA, EPA, AND OTHER GOVERNMENTAL AGENCIES RESTRICTING EMPLOYEE EXPOSURE TO POTENTIAL OR KNOWN TOXIC SUBSTANCES HAS INCREASED THE USE OF EMPLOYEE RESPIRATORY PROTECTION DEVICES. THE NEED TO AMEND, UPDATE AND REPROMULGATE (THE TESTING AND CERTIFICATION PROCESS OF 30 CFR 11) TO REFLECT THE CURRENT STATE-OF-THE-ART IN THE RESPIRATORY INDUSTRY IS OBVIOUS. A NEW APPROVAL SYSTEM MUST CONTAIN THE FLEXIBILITY TO EVALUATE INNOVATIVE PRODUCTS, WITH THE ULTIMATE GOAL OF PROVIDING THE AMERICAN WORKER THE BEST RESPIRATORY PROTECTION AVAILABLE.

IT IS ON THIS BASIS AND WITH THIS GOAL AS OUR OBJECTIVE, THAT 3M HAS DEVELOPED AND SUBMITS THE FOLLOWING COMMENTS:

DISCUSSION

THE CONSULTANTS ARE TO BE CONGRATULATED FOR THEIR EXCELLENT ANALYSIS OF THE PRESENT NIOSH TESTING AND CERTIFICATION FUNCTION. THEY HAVE ESTABLISHED A BASE FROM WHICH A WORKABLE SYSTEM OF CERTIFICATION AND FIELD AUDIT OF RESPIRATORY PROTECTION DEVICES SHOULD BE RAPIDLY BUILT.

3M AND OTHER RESPIRATOR MANUFACTURERS HAVE HAD DISCUSSIONS LIKE THIS ONE WITH NIOSH BEFORE. WHILE THIS IS THE FIRST ONE HELD SINCE DR. ROBBINS TOOK OVER AS DIRECTOR, THE IDEA AND NEED ARE NOT NEW. HE IS TO BE CONGRATULATED FOR HIS APPROACH TO THE REGULATION ANALYSIS THROUGH THE USE OF A PANEL OF EXPERTS. WE WERE PLEASED TO SEE THE RECOMMENDATIONS OF THE EXPERTS DR. ROBBINS ASSIGNED, BECAUSE THEY ONCE AGAIN BROUGHT FORTH AN OPPORTUNITY TO RECOMMEND MUCH NEEDED CHANGES TO THE METHODS PRESENTLY USED FOR APPROVING RESPIRATORS.

THE CONSULTANT'S REPORT WENT INTO GREAT DETAIL IN REGARD TO THE SUBJECT OF LIABILITY THAT NIOSH SHARES WITH THE MANUFACTURER, AND A CONCERN WAS EXPRESSED ABOUT THE LIABILITY AND RESPONSIBILITY OF "NIOSH CERTIFIED LABORATORIES".

THE LIABILITY ARGUMENT THAT THE NIOSH CONSULTANTS PUT FORTH IS PERSUASIVE, BUT INCOMPLETE. MANUFACTURERS OF NIOSH APPROVED PRODUCTS GET SUED, AND I SUGGEST THERE ARE MANY CASES OUTSTANDING TODAY. AS A PRACTICAL MATTER, NIOSH IS NOT SUED FOR GIVING APPROVALS.

THE NIOSH APPROVAL CERTIFICATION IS NOT LOOKED ON AT 3M AS A SHARING OF RESPONSIBILITY FOR PRODUCT PERFORMANCE. I'M CONFIDENT OTHER MANUFACTURERS

OF PERSONAL PROTECTIVE EQUIPMENT WOULD PROJECT SIMILAR FEELINGS. THE APPROVAL IS LOOKED UPON AS A MARKETPLACE NECESSITY DUE TO RECOMMENDED OSHA RESPIRATOR PROGRAM REQUIREMENTS FOR USE OF ONLY NIOSH APPROVED PRODUCTS AS OUTLINED IN CHAPTER III OF THE MAY 24, 1979 EDITION OF THE INDUSTRIAL HYGIENE FIELD OPERATIONS MANUAL. IF THE PERSONAL PROTECTIVE EQUIPMENT MANUFACTURER TAKES THE PROFITS AND GAINS FROM SALES OF A PERSONAL PROTECTIVE EQUIPMENT DEVICE, HE SHOULD TAKE THE RISKS. BUT THEN NO MANUFACTURING COMPANY SHOULD OBTAIN MARKETING ADVANTAGES BECAUSE OF DESIGN SPECIFICATIONS IN THE LAW, AS IS THE CASE TODAY WITH EXISTING 30 CFR 11 REGULATIONS. ?

REPEAT UNDERLINED

IN LATE 1977 PUBLIC MEETINGS WERE HELD IN WASHINGTON, D.C. WITH RESPECT TO AMENDING THE CERTIFICATION REQUIREMENTS FOR RESPIRATORY PROTECTION DEVICES AS CONTAINED IN 30 CFR PART 11. AT THIS MEETING EXTENSIVE TESTIMONY WAS ELICITED FROM GOVERNMENTAL AGENCIES, USERS OF RESPIRATORY PROTECTION DEVICES, MANUFACTURERS OF THESE DEVICES, AND ACADEMIC INSTITUTIONS. ALL PARTIES TESTIFYING AGREED THAT EXTENSIVE CHANGES IN THE CERTIFICATION PROCEDURES WERE DESPERATELY NEEDED IN ORDER TO ASSURE THAT THE AMERICAN WORKER HAS THE MOST ADVANCED AND BEST OCCUPATIONAL PROTECTIVE DEVICES AVAILABLE. NEVERTHELESS, IN SPITE OF THE OVERWHELMING NEED EXPRESSED FOR CHANGES IN 30 CFR PART 11 AT THESE HEARINGS, THE CONTROLLING GOVERNMENTAL AGENCY STATED IN THEIR CONCLUSION THAT PROMULGATION OF THE AMENDMENTS WOULD REQUIRE THE NORMAL THREE TO FIVE YEARS. TO DATE NO ACTION ON THAT HEARING HAS OCCURRED AND ALMOST THREE YEARS HAVE GONE BY.

WE ASK TO HAVE INCLUDED, AS PART OF THIS TESTIMONY, ALL 3M TESTIMONY THAT WAS SUBMITTED TO NIOSH DURING THE LAST HEARING ON NOVEMBER 29-30, DECEMBER 1, 1977.

WE SUBMIT THAT IT IS INCONCEIVABLE THAT DELAYS SUCH AS THESE IN ISSUING REGULATIONS CAN BE ALLOWED TO OCCUR.

IN ORDER FOR POSITIVE CHANGES IN RESPIRATORY PROTECTIVE DEVICE APPROVAL TO BE CONSUMMATED, THE NEGATIVE ASPECTS OF THE EXISTING SYSTEM MUST BE IDENTIFIED AND BROUGHT FORWARD. TO DO THIS WE HAVE THOROUGHLY STUDIED THE HISTORY OF THE RESPIRATOR APPROVAL SYSTEM IN THE U.S. AS PRACTICED BY THE BUREAU OF MINES AND NIOSH. ONE FACT STANDS OUT: NIOSH CONTINUED THE BUREAU OF MINES TESTS, APPROVAL NUMBERING SYSTEMS, PERSONNEL AND PHILOSOPHY WITHOUT MODERNIZATION. THIS INCLUDES TESTS FOR APPROVALS THAT ARE NOT ACCURATE, NOT REPRODUCIBLE OR ADEQUATELY DEFINED. THESE TESTS HAVE BEEN ESTABLISHED WITHOUT A DETERMINED TEST VARIATION, AND ARE DESIGNED FOR 1930-1940 ERA INSTRUMENTATION. THE PAINT SPRAY TESTS, LEAD FUME TESTS AND SILICA MIST TESTS ARE ALL EXAMPLES. EVEN MORE DISASTROUS FOR INNOVATIVE NEW PRODUCTS HAS BEEN THE CARRY OVER AND USE OF A DESIGN PHILOSOPHY OF RESPIRATOR APPROVAL RATHER THAN A PERFORMANCE-ORIENTED PHILOSOPHY. DESIGNATION BY DESIGN CLASS SUCH AS REUSABLE, REPLACEABLE AND SINGLE-USE IS EVEN MORE OBSCURE BECAUSE OF THE LACK OF ACCEPTABLE DEFINITIONS.

UNDER THE PRESENT SYSTEM OF TESTING AND APPROVALS, MANUFACTURERS ARE FORCED TO SUBMIT PRODUCTS THAT WILL PASS TESTS THAT MAY OR MAY NOT GUARANTEE PROTECTION TO THE USER. IT IS POSSIBLE THAT THE EXISTING NIOSH TESTING DOES MORE HARM THAN GOOD BASED ON THE FACT THAT THE TESTS HAVE LITTLE, IF ANY, CORRELATION TO ACTUAL FIELD CONDITIONS.

ONE MIGHT ASK WHY AN INNOVATIVE RESPIRATOR MANUFACTURER WOULD WANT TO SUBMIT HIS PRODUCT INTO THIS EXISTING NIOSH SYSTEM VOLUNTARILY. MANUFACTURERS DO IT TODAY BECAUSE OF OSHA HEALTH STANDARDS AND OSHA ENFORCEMENT. IF OSHA INSPECTORS DO NOT SEE NIOSH APPROVED PRODUCTS, THEY CITE AND PROPOSE A FINE

FOR THE EMPLOYER. SUBMISSION FOR APPROVALS IS NOT DONE BECAUSE NIOSH TESTING GUARANTEES WORKER PROTECTION, REDUCES OR ELIMINATES LIABILITY OF THE MANUFACTURER, OR IS TIMELY. EXISTING NIOSH APPROVALS ARE A MARKETING DEVICE HAVING LITTLE OR NO TRUE MERIT.

3M MARKETS BOTH APPROVED AND UNAPPROVED RESPIRATORS SUCCESSFULLY AND AGGRESSIVELY. WE DO THIS BECAUSE OUR THOROUGH LABORATORY AND FIELD TESTING DATA TELL US THAT THE PRODUCT PROTECTS THE WORKER WHEN CORRECTLY USED. WE SELL NON-APPROVED PRODUCTS BECAUSE MARKET STUDIES AND FIELD EVALUATIONS SHOW THAT USER NEED EXISTS, EVEN THOUGH THE DESIGN SPECIFICATIONS AND TESTS IN THE EXISTING 30 CFR 11 REGULATIONS DO NOT ALLOW CERTIFICATION. IN ADDITION, IN MANY CASES THERE IS NO APPROVAL SCHEDULE FOR THE SPECIALIZED RESPIRATORS REQUIRED BY WORKERS FOR THEIR PROTECTION IN SPECIFIC ENVIRONMENTS.

DISCUSSIONS WITH NIOSH AND BUREAU OF MINES OFFICIALS HAVE MADE IT OBVIOUS THAT THEY FEEL THEY CANNOT LEGALLY CHANGE OR ADD TO 30 CFR 11 AND APPROVE DEVICES THAT FALL OUTSIDE THE EXISTING DESIGN CRITERIA IN A REASONABLE TIME FRAME.

① FOR THESE BASIC REASONS WE THINK NIOSH SHOULD DEVELOP PERFORMANCE CRITERIA FOR RESPIRATORS.

NIOSH RESPIRATOR STANDARDS INTENDED TO INSURE THE ACHIEVEMENT OF SPECIFIC GOALS SHOULD BE BASED ON PERFORMANCE CRITERIA AND NOT ON DESIGN SPECIFICATIONS. NIOSH SHOULD SPECIFY THE PROBLEMS TO BE SOLVED AND NOT THE DETAILED PRESCRIPTION FOR SOLVING THEM. FOR EXAMPLE, FACEFIT PROTECTION LEVEL SHOULD BE SPECIFIED INSTEAD OF FOUR POINT SUSPENSION. BUT, NIOSH MUST INCLUDE VALID QUANTITATIVE MEANS FOR DETERMINING WHETHER THE REQUIRED PERFORMANCE HAS BEEN ACHIEVED.

BY SPECIFYING THE PERFORMANCE CRITERIA IN FUNCTIONAL TERMS FOR THE USER, THE

PURPOSE OF 30 CFR 11 WILL BE CLEAR, AS WILL BE THE LEVEL OF RESPIRATOR PERFORMANCE REQUIRED TO ACHIEVE IT.

THE MANUFACTURERS TRYING TO MEET THE NEED CAN THEN SEARCH, WITH MINIMUM RESTRAINT, FOR INNOVATIVE SOLUTIONS TO RESPIRATOR USER PROBLEMS. THE RESTRAINTS ON TECHNOLOGY ARE THEN ONLY LIMITED TO THOSE THAT ARE ACTUALLY RELEVANT TO THE USER. PERFORMANCE CRITERIA ARE ALSO LESS PRONE TO SERVE AS OBSTACLES TO A FAIR, COMPETITIVE MARKETPLACE, SINCE THEY ARE LESS LIKELY TO PROTECT ESTABLISHED TECHNOLOGIES AGAINST POTENTIALLY MORE PRODUCTIVE NEW ONES.

EVALUATION OF PERFORMANCE IS NECESSARY. THEREFORE, NIOSH SHOULD PUBLISH DETAILED PROCEDURES FOR WELL-DEFINED TESTS. A FEW OF THE VALID TESTS NOW IN EXISTENCE IN 30 CFR 11 SHOULD BE RETAINED, BUT IN EVERY CASE COMPLETE EQUIPMENT DESCRIPTIONS AND TEST PROCEDURES, AS WELL AS TEST VARIABILITIES, REQUIRE DEFINITION. DK

IT WILL ALSO BE NECESSARY, IN DEFINING TESTING FOR PERFORMANCE CRITERIA, TO LEAVE THE SYSTEM OPEN-ENDED SO THAT AS INNOVATIVE TECHNOLOGY OR UNIQUE NEW EQUIPMENT COMES ALONG, NEW MEANS FOR EVALUATING PRODUCT PERFORMANCE EFFECTIVENESS ARE PERMITTED.

NIOSH AND THE PRIVATE SECTOR MUST WORK COOPERATIVELY IN DEVELOPING AND PUBLISHING APPROPRIATE, DETAILED PERFORMANCE TESTS OF KNOWN RELIABILITY.

ONE USABLE MEANS TO CONTROL PRODUCT PERFORMANCE IS THE ABILITY OF ONE COMPETITOR TO TEST ANOTHER'S PRODUCT WITH METHODS THAT ARE REPRODUCIBLE AND OF KNOWN VARIABILITY. ONLY THEN CAN SUBSEQUENT DISCUSSIONS BE MEANINGFUL. IF FIELD AUDITS ARE EVER TO BE USEFUL, TESTS MUST BE AS UNIFORM AS POSSIBLE SO THAT DISPUTES CAN BE RESOLVED BASED ON TRULY PARALLEL DATA.

THE QUANTITATIVE FIT TEST CONTROVERSY PRESENTLY BEING ENCOUNTERED IN INDUSTRY WITH OSHA ON THE LEAD STANDARD IS AN EXAMPLE OF THE NEED TO HAVE NIOSH PUBLISH DETAILED PERFORMANCE TESTS. THERE IS NO DEFINED FIT TEST METHOD THAT CAN BE USED BY INDUSTRY. YET, IF NIOSH HAD FOLLOWED UP ON THEIR SPONSORED LOS ALAMOS RESEARCH WITH A TEST PROTOCOL, A SYSTEM MIGHT EXIST AND FIT FACTORS COULD BE ASSIGNED TO EACH RESPIRATOR BY THE MANUFACTURER IF HE SO DESIRED.

NIOSH MUST BE ABLE TO ADAPT NEW TESTS, REGARDLESS OF OPERATIONAL APPROACH, TO APPROVE NEW DEVICES THAT CANNOT BE TESTED AND APPROVED UNDER EXISTING SPECIFIED, DESIGN-ORIENTED TEST METHODS. IT SHOULD NOT BE THE INTENT OF NIOSH TO REQUIRE UNNECESSARY TESTS, OR TO EXCLUDE NEW DEVICES FROM APPROVAL CONSIDERATION, BECAUSE AN EXISTING, SPECIFIED APPROVAL TEST OR REQUIREMENT IS NOT DIRECTLY APPLICABLE TO THAT NEW DEVICE.

ONCE NIOSH HAS DEFINED PERFORMANCE CRITERIA AND RELIABLE TEST METHODS TO COMPARE PERFORMANCE TO THE CRITERIA, MANUFACTURERS SHOULD CONDUCT THE TESTS AND CERTIFY THAT THEIR PRODUCTS MEET THE PUBLISHED NIOSH REQUIREMENTS. NIOSH SHOULD AUDIT FIELD SAMPLES TO VERIFY MANUFACTURER'S CLAIMS.

AT THIS POINT IT IS OBVIOUS THAT 3M RECOMMENDS ALTERNATIVE #4 DESCRIBED IN THE JUNE 18, 1980 FEDERAL REGISTER. WE REJECT THE OTHERS FOR REASONS I WILL DISCUSS LATER.

OPTION #4, THE SELF-CERTIFICATION ALTERNATIVE, WOULD COMBINE THE BEST OF THE LISTED AVAILABLE ALTERNATIVES. 3M RECOMMENDS THE FOLLOWING:

1. NIOSH WOULD DEVELOP AND MAINTAIN PERFORMANCE CRITERIA USING THE BEST STATE-OF-THE-ART METHODS. THESE WOULD BE PROMULGATED AND PUBLISHED IN THE FORMAL RULEMAKING PROCEDURE. MANUFACTURERS WOULD USE THESE

PERFORMANCE SPECIFICATIONS AND TEST METHODS TO EVALUATE THEIR PRODUCTS. PRODUCTS MEETING THE APPROPRIATE SPECIFICATIONS WOULD BE MANUFACTURER CERTIFIED AS MEETING THE MINIMUM REQUIREMENTS.

2. NIOSH WOULD ALLOW MANUFACTURERS TO SUBMIT SAMPLES TO VALIDATE TESTS BETWEEN NIOSH AND THE MANUFACTURER, BUT NIOSH AUDIT OF THE MANUFACTURERS' FACILITIES IS UNNECESSARY.
3. NIOSH SHOULD HAVE A CONTINUING PROGRAM TO DEVELOP IMPROVED TEST EQUIPMENT AND TESTING METHODS. IT IS IMPORTANT THAT NIOSH REPLACE CURRENT TESTING TECHNIQUES AND EQUIPMENT. NIOSH SHOULD KEEP MANUFACTURERS INFORMED OF ANY IMPROVED TECHNIQUE.
4. PRIOR TO DISTRIBUTION AND SALE, THE MANUFACTURER WOULD NOTIFY NIOSH OF ITS INTENT AND THE GEOGRAPHIC AREA INTO WHICH THE PRODUCT WOULD BE SOLD. THE MANUFACTURER WOULD INCLUDE A DESCRIPTION OF THE PRODUCT AND ITS INTENDED USE. THIS NOTIFICATION WOULD ALLOW NIOSH TO EXERCISE ITS OPTION TO PURCHASE THE PRODUCT AND PERFORM ITS OWN EVALUATION, IF IT IS FELT NECESSARY TO VERIFY THAT THE PRODUCT IN FACT MEETS THE PERFORMANCE REQUIREMENTS.
5. IF NIOSH FINDS PROBLEMS THROUGH ITS OWN EVALUATIONS OR BASED ON USER COMPLAINTS, WE FEEL ADEQUATE PROVISIONS EXIST IN THE LAW TODAY TO HANDLE ENFORCEMENT OF ITS FINDINGS. AFTER DISCUSSION OF ITS FINDINGS WITH THE MANUFACTURER AND AGREEMENT OF FACT, NIOSH COULD REQUEST VOLUNTARY ACTION SUCH AS CORRECTION OF THE PROBLEM, STOP SALE, RECALL, ETC., DEPENDING ON THE NATURE OF THE PROBLEM. IF THE MANUFACTURER DOES NOT TAKE ACCEPTABLE ACTION, NIOSH COULD USE LEGAL PROCEDURES TO PREVENT DISTRIBUTION OF SUBSTANDARD PRODUCTS.

6. OSHA WOULD ACCEPT THE MANUFACTURER'S CERTIFICATION OF DEVICES AS LABELED.
7. THE FIELD AUDITS BY NIOSH WOULD ALLOW SUFFICIENT RESPONSE TIME TO A MANUFACTURER TO CORRECT ANY PROBLEMS DISCOVERED IN NIOSH EVALUATIONS.
8. IF NIOSH DOES CONDUCT FIELD AUDITS AND DESIRES TO DISTRIBUTE TEST RESULTS, ONLY CONFORMANCE AND NON-CONFORMANCE SHOULD BE STATED. NOT NUMBERS, AS NUMBERS CAN OFTEN BE MISINTERPRETED. MANUFACTURERS MUST BE INFORMED OF NON-CONFORMANCE PRIOR TO ANY DATA DISTRIBUTION. AS A CROSS CHECK ON THE SYSTEM, NIOSH MUST BE REQUIRED TO PRESENT EVIDENCE OF CONTROLLED TESTING BEFORE A NON-CONFORMANCE PUBLICATION IS DISTRIBUTED. A SYSTEM TO HANDLE FAILURES SHOULD BE PROPOSED AND DEBUGGED.
9. NIOSH SHOULD NOT UNDERTAKE TO WIDELY PUBLICIZE NEGATIVE RESULTS OF TESTS PERFORMED FOR ANYTHING BUT MAJOR HAZARD DEFECTS, AND ONLY AFTER CONSULTING WITH THE MANUFACTURER. BAD PRESS BY NIOSH FOR A POOR BUT INSIGNIFICANT TEST RESULT COULD CAUSE IRREPARABLE DAMAGE TO ALL MANUFACTURERS AND COULD WIPE OUT A SMALL MANUFACTURER.
10. NIOSH POLICY SHOULD BE STRUCTURED SO NIOSH PERSONNEL PARTICIPATION ON CONSENSUS STANDARD MAKING COMMITTEES, SUCH AS THE AMERICAN NATIONAL STANDARDS INSTITUTE, IS ENCOURAGED. IT WILL HELP GET IMPROVED CRITERIA INTO THE SYSTEM FASTER. BROAD PARTICIPATION BY ALL AFFECTED PARTIES IS ESSENTIAL IN THE SELECTION OF THE STRATEGY FOR SOLVING PROBLEMS AND THE CHOICE OF THE LEVEL OF PERFORMANCE TO BE REQUIRED. MUCH IS LOST WHEN NIOSH PERSONNEL ARE NOT PART OF THE REASONING FOR ESTABLISHING CONSENSUS CRITERIA.
11. NIOSH NEED NOT SPONSOR RESEARCH ON NEW DEVICES. WITH THE NUMBER OF

subject about

MANUFACTURERS IN SAFETY AND HEALTH, MARKET FORCES WILL BRING FORTH NEEDED PRODUCTS SO LONG AS PERFORMANCE CRITERIA ARE NOT SO CONFINING AS TO PREVENT INNOVATIVE PRODUCTS ENTERING THE MARKET PLACE. THE PRIVATE SECTOR IS BETTER SUITED FOR RESEARCH THAN NIOSH.

THE SELF-CERTIFICATION METHOD WOULD ALLOW FREQUENT ASSESSMENT OF THE PRODUCT IN THE FIELD BY NIOSH. IT WILL CORRECTLY PLACE THE BURDEN OF DESIGNING, PRODUCING AND TESTING RELIABLE DEVICES ON THE MANUFACTURER.

BY PLACING THE PRIMARY RESPONSIBILITY ON THE MANUFACTURER FOR CERTIFICATION, NIOSH COULD USE ITS RESOURCES TO DEVELOP BETTER, MORE PERTINENT PERFORMANCE SPECIFICATIONS AND TEST METHODS TO EVALUATE THEM. NIOSH HAS NOT PERFORMED THIS FUNCTION ADEQUATELY IN THE PAST, AND THE SELF-CERTIFICATION ALTERNATIVE WOULD ALLOW RESOURCES TO BE DIVERTED, CONCENTRATED, AND UTILIZED IN THIS MANNER. ADVANTAGES OF OPTION #4 ARE:

1. IT REDUCES THE NEED FOR CONTINUED EXPANSION OF NIOSH FACILITIES AND PERSONNEL AS THE NUMBER OF APPROVALS GROW.
2. IT BRINGS NEW PRODUCTS TO MARKET EARLIER.
3. IT ALLOWS NIOSH TO CONCENTRATE ON THE AUDIT OF PRODUCTS THAT MAY BE MORE REPRESENTATIVE THAN SELECTED, SUBMITTED SAMPLES.
4. AS MANUFACTURERS ACCEPT THE RESPONSIBILITY FOR TESTING, THEIR RESOURCES WILL BE USED TO DEVELOP NEW AND MORE REALISTIC TEST METHODS.
5. IT PREVENTS NIOSH FROM BEING USED AS A DEVELOPMENT LABORATORY BY MANUFACTURERS.
6. CHANGES TO A PRODUCT DON'T NEED SUBMISSION AS LONG AS THE MANUFACTURER CERTIFIES CONFORMANCE TO PERFORMANCE CRITERIA.

7. AS APPROVAL TIME AND SUBMITTAL EXPENSE IS REDUCED, MANUFACTURERS WOULD BE ENCOURAGED TO PRODUCE A WIDER RANGE OF SPECIFIC PRODUCTS THAT WOULD AFFORD THE END USER A BETTER SELECTION AND REDUCED COST.
8. IT INCREASES PRODUCTIVITY AS IT REDUCES COST OF APPROVALS - BOTH TO MANUFACTURERS AND NIOSH.
9. IT WILL IMPROVE THE WORKING RELATIONSHIP BETWEEN NIOSH AND MANUFACTURERS. INNOVATION, COMFORT, EFFICIENCY AND ECONOMY WOULD BE ENCOURAGED.
10. IN THE CASE OF A MAJOR DEFECT BEING DISCOVERED IN THE USER'S PRODUCT, IT IS THE MANUFACTURER'S RESPONSIBILITY, NOT NIOSH'S. THE RESPONSIBLE MANUFACTURER MUST LOCATE AND INFORM THEIR CUSTOMERS OF THE PROBLEM.
11. OPTION #4 HAS THE FURTHER ADVANTAGE THAT AN ELEMENT OF TRUST AND MATURITY MUST BE ESTABLISHED AMONG NIOSH, OSHA AND THE MANUFACTURER THAT THE NEEDS OF THE USER WILL BEST BE MET BY THIS TYPE OF SYSTEM. THOSE THAT SOW SEEDS OF DISSENT AND MISINFORMATION ABOUT THE MANUFACTURERS' TRUE INTENT WILL BE FORCED TO BRING FORTH THEIR DATA THAT CAN BE EXAMINED ON THE BASIS OF TECHNICAL FACT - NOT THROUGH ENDLESS, EXPENSIVE LEGAL CONTROVERSIES THAT SERVE NO GOOD PURPOSE. OR, AS HAS BEEN THE CASE, WITHOUT ANY DATA FROM THEIR OWN EXPERIENCE.

Exceptions to Prod did not

DISCUSSION OF THE OTHER CERTIFICATION OPTIONS THAT NIOSH HAS PRESENTED IS IMPORTANT. ALL THINGS BEING EQUAL, OPTION 1, CONTINUING AS WE PRESENTLY ARE DOING, BUT WITH REVISED ADMINISTRATIVE AND TEST CRITERIA AREAS, IS COMPLETELY UNACCEPTABLE.

THE PRESENT SYSTEM HAS BEEN AND IS BEING, ABUSED BY THOSE INVOLVED IN THE CERTIFICATION PROCESS. 30 CFR 11, AS IT IS BEING ADMINISTERED, APPEARS TO

BE AUTOCRATICALLY DESIGNED TO ESTABLISH AN ADVERSARY ROLE BETWEEN THE APPROVING AGENCY AND MANUFACTURERS OF DEVICES. THIS IS A ROLE NEITHER THE U.S. MANUFACTURER, GOVERNMENT OR USER CAN AFFORD TO ALLOW TO CONTINUE. I MIGHT ADD THAT ONLY IN THE U.S. DOES THIS ADVERSARY ROLE EXIST. IN MANY OTHER COUNTRIES THE GOVERNMENTAL APPROVING AGENCY COOPERATES WITH LOCAL MANUFACTURERS OF EQUIPMENT, EVEN TO THE LEVEL OF COOPERATION THAT MAKES IT ALMOST IMPOSSIBLE FOR IMPORTED PRODUCTS TO BE APPROVED.

Level of Quality Required are poor.

FURTHER, THE PRESENT SYSTEM OF THE MSHA/NIOSH APPROVAL OF A DEVICE DOES NOT GUARANTEE END USER UTILITY OR SAFETY. AS WE HAVE TESTIFIED IN THE PAST, THE FACT THAT A RESPIRATOR MEETS A TEST REQUIREMENT IS ONLY A VERY MINOR PART IN AN EFFECTIVE USER RESPIRATOR PROGRAM. MATCHING THE PROPER DEVICE TO THE HAZARD, INSURING PROPER FIT TO WORKERS, MATCHING FILTRATION PERFORMANCE TO REAL WORK SITUATIONS, ETC., SHOULD NOT BE OVERSHADOWED BY AN INFLEXIBLE, ARTIFICIAL TEST METHOD THAT STOPS INNOVATION.

THE MAIN REASON AN EMPLOYER-USER WANTS AN MSHA/NIOSH APPROVED PRODUCT IS, QUITE SIMPLY, THAT THEY DON'T WANT A HASSLE FROM OSHA. HOWEVER, ON PAGE 13 OF THE OSHA OPERATIONS MANUAL, CHAPTER III, SUBPART E, AND I QUOTE, "MSHA/NIOSH WILL PROVIDE A TEST SCHEDULE FOR ANY RESPIRATOR AGAINST ANY SPECIFIC CONTAMINANT. THE USE OF UNAPPROVED RESPIRATORS, EVEN IN SPECIAL USE SITUATIONS, IS UNACCEPTABLE UNLESS APPROVAL IS PENDING BEFORE NIOSH."

THIS IS NOT AND HAS NOT BEEN THE CASE WITH THE EXISTING MSHA/NIOSH APPROVAL SYSTEM. 30 CFR 11 IS UNWORKABLE AS IT DOES NOT ALLOW NEW, BETTER WORKER PROTECTIVE DEVICES TO REACH THE MARKETPLACE FAIRLY.

OVER THE LAST TEN MONTHS NIOSH HAS BEEN DOING A POORER JOB IN COMMUNICATING THE STATUS OF APPROVAL TESTING WITH MANUFACTURERS THAN EVER BEFORE. THEY PRESENTLY WILL NOT ALLOW WITNESSING OF TESTS AND WILL NOT DISCUSS THE STATUS

OF SUBMITTED PRODUCTS.

ON WITNESSING OF TESTS:

- A. NIOSH MUST BE AUDITED.
- B. ERRORS HAVE BEEN MADE BY NIOSH IN TESTING. (9920 - Failed)
- C. THERE IS NO PRESSURE ON TEST TECHNICIANS IF THINGS ARE DONE CORRECTLY, SO IT IS NOT A PROBLEM TO WATCH THEM TEST.
- D. NIOSH CAN ESTABLISH GROUND RULES OF WHAT A WITNESS TO THE TEST CAN AND CANNOT DO.

PERHAPS THE MOST IRRITATING ASPECTS OF EXISTING NIOSH POLICY IS ITS POSITION OF REFUSING TO DISCUSS THE STATUS OF CERTIFICATION TESTING. WHEN A PRODUCT IS OFFICIALLY SUBMITTED AND DELIVERED TO MORGANTOWN, IT'S AS IF EVERYTHING DISAPPEARED INTO A BLACK HOLE.

12/20/75 RECENTLY 3M EXPERIENCED AT LEAST A FOUR MONTH DELAY BETWEEN THE ACTUAL APPROVAL TESTING AND RECEIPT OF THE LETTER OF CERTIFICATION. [WE DO NOT UNDERSTAND WHY NIOSH WOULD WANT TO DELAY INTRODUCTION OF AN APPROVED PRODUCT TO THE MARKET. IF AND WHEN QUESTIONS ARISE ABOUT A SUBMITTED PRODUCT, WE ARE CONFIDENT THAT A TEN MINUTE TELEPHONE CALL WILL OFTEN SOLVE THE PROBLEM. PROBLEMS SHOULD BE SOLVED AS EXPEDITIOUSLY AS POSSIBLE.

IN SUMMARY, OPTION #1 SHOWS NO IMMEDIATE RELIEF THAT HELPS EITHER USER OR MANUFACTURER.

OPTION #2, AS OUTLINED, IS SUBJECT TO THE SAME OBJECTIONS AS WE HAVE STATED AGAINST THE FIRST OPTION.

LET'S DISCUSS SOME RECENT NIOSH-ISSUED GUIDELINES, AS THEY PROVIDE CLUES AS

TO THE MANNER IN WHICH A NIOSH-ONLY APPROVAL SYSTEM WOULD WORK AND BE ADMINISTERED.

ON JUNE 19 AND JUNE 20, 1980, TWO DOCUMENTS WERE PUBLISHED BY NIOSH AS "GUIDELINES" THAT ARE CLOSELY RELATED TO THE "FIELD AUDIT" SYSTEM THAT WAS PROPOSED FOR DISCUSSION AT THIS HEARING. THE FIRST ONE, CONCERNING STOP SALE AND RECALL OF PRODUCTS, HAS NEVER BEEN SUBJECT TO PUBLIC REVIEW. THE SECOND, REGARDING AN APPEALS PROCEDURE, HAS BEEN COMMENTED ON IN A NUMBER OF NIOSH HEARINGS SINCE 1974. BOTH SUBJECTS ARE IMPORTANT AND THEY SHOULD EITHER PROPERLY BECOME A PART OF 30 CFR 11 WITH A PUBLIC HEARING OR BE DROPPED. THESE GUIDELINES CANNOT BE ALLOWED TO BE ACCEPTED AS STANDARD NIOSH APPROVAL OPERATING PROCEDURES WITHOUT THOROUGH COMMENT AND REVIEW. THE SAME IS TRUE OF A PROCESS BY NIOSH, OR BY ANY AGENT OF NIOSH, CONCERNING FIELD AUDITS OF SAMPLES UTILIZING GUIDELINES NOT REVIEWED PUBLICLY.

IN ADDITION TO THESE "VOLUNTARY GUIDELINES", NIOSH USES MANY OTHER "GUIDELINES" FOR RESPIRATOR TESTS THAT HAVE NEVER BEEN PUBLISHED AND SUBJECTED TO PUBLIC REVIEW. THE LATEST OF THESE IS A DECISION NOT TO APPROVE DUST RESPIRATORS FOR ASBESTOS, EVEN THOUGH THE RESPIRATOR MEETS THE TEST REQUIREMENTS AND THE LAW. IT IS IMPORTANT THAT NIOSH PERSONNEL BE REQUIRED TO CONSISTENTLY FOLLOW CORRECT RULEMAKING PROCEDURES.

REQUIREMENTS OR CHANGES TO REQUIREMENTS FOR CERTIFICATION MUST BE SUBJECT TO PUBLIC HEARING AND REVIEW. ANY OUTSIDE LABORATORY DATA SYSTEM SET UP BY NIOSH MUST BE SUBJECT TO SPECIFIC CROSS CHECKS FOR DATA VALIDATION AND STRINGENT PUBLISHED RULES FOR INFORMATION RELEASE. ADVERSE DATA WOULD HAVE TO BE CONFIDENTIAL AND NOT BE DISCLOSED BY ANYONE, INCLUDING PRIVATE LABORATORIES ACTING ON BEHALF OF NIOSH, UNTIL A THOROUGH REVIEW OF THE DATA HAS BEEN HELD WITH THE MANUFACTURER. TODAY THIS PROCEDURE DOES NOT EXIST.

IN 1972 AND 1973 EARLY RELEASE BY LOS ALAMOS OF INCOMPLETE TEST INFORMATION FROM NIOSH CONTRACTED RESEARCH WAS HARMFUL TO THE 3M COMPANY RESPIRATOR PROGRAM.

AS IN THE CASE OF OPTION #1, 3M FEELS OPTION #2 IS UNWORKABLE. TO GIVE MORE POWER OR TO AGREE TO THE POWER LEVEL OF THE EXISTING NIOSH/MSHA SITUATION THAT IS UNWORKABLE IS NOT ACCEPTABLE. IN CASE YOU MISSED OUR POINT, THE PRESENT SYSTEM IS SLOW, INACCURATE, ARBITRARY, INEFFECTIVE AND INFLEXIBLE. LESS, NOT MORE, POWER OF CERTIFICATION SHOULD BE ALLOWED THE EXISTING MSHA/NIOSH SYSTEM AND THEIR RESPONSIBILITIES MORE CLOSELY DEFINED.

3M FEELS THAT OPTION #3, PRIVATE LABORATORY CERTIFICATION, WILL ONLY INTRODUCE ANOTHER LEVEL OF CONFUSION AND EXCUSE FOR DELAY TO THE PRESENT APPROVAL COMMUNICATION PROBLEMS. ALSO, OUTSIDE CERTIFIED LABORATORIES WOULD RESULT IN DISAGREEMENT AS TO CONFORMANCE OR NON-CONFORMANCE. UNCERTIFIED LABORATORIES WOULD BE WORSE. IF LABORATORIES ARE TO BE CERTIFIED BY NIOSH, MANUFACTURERS WHO ALREADY HAVE EQUIPMENT AND EXPERTISE CANNOT BE EXCLUDED FROM CERTIFIABLE STATUS.

THE CONSUMER PRODUCT SAFETY COMMISSION WAS SUGGESTED BY THE CONSULTANTS AS A POSSIBLE MODEL FOR NIOSH TO FOLLOW IN THE AREA OF HEALTH AND SAFETY PRODUCT TESTING AND CONTROL. WE DO NOT AGREE WITH THIS RECOMMENDATION. 3M EXPERIENCE WITH THE CONSUMER PRODUCT SAFETY COMMISSION (AEROSOL SPRAY ADHESIVE CASE) IS EVIDENCE THAT POWER TO BAN A PRODUCT WITHOUT MANDATORY SAFEGUARDS REQUIRING FULL EVALUATION AND CRITICAL REVIEW OF DATA RESULTS IN SEVERE HARDSHIP TO THE USERS, AND EXTENSIVE EXPENSE AND FINANCIAL LOSS TO THE MANUFACTURER. THE RESULTS OF ERRORNEOUS ACTIONS BY FEDERAL AGENCIES ARE LONG TERM CONSEQUENCES. LAWSUITS CONTINUE OVER SIX YEARS AFTER THE CONSUMER PRODUCT SAFETY COMMISSION WITHDREW THE SPRAY ADHESIVE BAN THAT WAS

BASED ON EVIDENCE WHICH COULD NOT BE VERIFIED.

THE WIDELY-PUBLICIZED CONSUMER PRODUCT SAFETY COMMISSION NATIONAL NETWORK FOR OBTAINING DATA ON UNSAFE PRODUCTS HAS WEAKNESSES THAT CAN EASILY RESULT IN MISLEADING CONCLUSIONS. ANY DATA COLLECTING SYSTEM THAT DOES NOT INCORPORATE PROCEDURES FOR VERIFYING INFORMATION AT THE SOURCE IS SUBJECT TO QUESTION. UNVERIFIED DATA THAT ARE EXTRAPOLATED TO SUPPOSEDLY NATIONWIDE STATISTICS IS EVEN MORE QUESTIONABLE.

TO SUPPORT OUR POSITION, WE REFERENCE A REPORT TO SENATOR JOHN TOWER FROM THE COMPTROLLER GENERAL OF THE UNITED STATES NUMBER B-139310. THE REPORT IS UNDATED, BUT IS IN RESPONSE TO SENATOR TOWER'S REQUEST DATED APRIL 29, 1974. THE REPORT IS ATTACHED, BUT WILL NOT BE READ.

WE BELIEVE THAT IT IS ADVISABLE FOR NIOSH TO PERIODICALLY TEST SAFETY EQUIPMENT OBTAINED THROUGH NORMAL COMMERCIAL CHANNELS. WE ALSO KNOW THAT THE RESULTS OF THOSE TESTS MUST BE HANDLED BY WELL-STRUCTURED, MANDATORY PROCEDURES. THIS WILL PREVENT EMBARRASSMENT TO NIOSH, UNACCEPTABLE DELAYS IN CORRECTING ERRORS, UNNECESSARY CONCERN ON THE PART OF THE PUBLIC, AND UNWARRANTED EXPENSE TO SAFETY EQUIPMENT MANUFACTURERS.

THE NEED FOR SUBMISSION OF OPERATING (USE) AND MAINTENANCE MANUALS TO NIOSH DOES NOT EXIST. THE MANUFACTURER HAS A RESPONSIBILITY TO PROVIDE THE CUSTOMER WITH TECHNICAL DATA TO EFFECTIVELY USE AND MAINTAIN SPECIFIC PRODUCTS. THE AMOUNT OF DATA FOR PROPER PRODUCT USE VARY CONSIDERABLY AND MUST BE ESTABLISHED BY PROFESSIONAL, TECHNICAL AND LEGAL STAFFS. SOME MANUALS REQUIRE DETAILED ASSEMBLY, USE, AND MAINTENANCE INSTRUCTIONS. BECAUSE CERTAIN TYPES OF PERSONAL PROTECTIVE EQUIPMENT ARE PRODUCT SPECIFIC, EACH MANUFACTURER MUST DEVELOP HIS OMI MANUALS. 3M EXPERIENCE SHOWS THAT A CONCERTED EFFORT IS REQUIRED TO PRODUCE A MANUAL THAT GIVES THE CUSTOMER

WHAT IS NEEDED TO OBTAIN SATISFACTORY USE OF THE PRODUCT. EXPERIENCE ALSO SHOWS THAT AS A PRODUCT IS USED, MORE IS LEARNED FROM FIELD TRIALS AND CUSTOMER SERVICE. CONSEQUENTLY, CHANGES TO MANUALS AND USE INSTRUCTIONS ARE INITIATED WHERE NEEDED TO KEEP MANUALS UPDATED FOR PROPER PRODUCT USE AND TO PREVENT MISUSE. IT WOULD BE A DISSERVICE TO THE USERS OF RESPIRATORY PROTECTIVE EQUIPMENT TO BE FORCED TO WAIT FOR MANUAL CHANGES WHILE NIOSH REVIEWS AND APPROVES THEM. IN ADDITION, NIOSH IS NOT IN A POSITION TO APPROVE OR DISAPPROVE A MODIFICATION OF A MANUAL WITHOUT CONSULTATION WITH THE MANUFACTURER, AND WITHOUT ENTERING INTO DEVELOPMENT RESEARCH TO DETERMINE THE EFFICACY OF A CHANGE. THIS IS NOT A PROPER ACTIVITY (RESEARCH TO SOLVE A PARTICULAR PROBLEM FOR A MANUFACTURER) OF NIOSH.

THERE CERTAINLY WOULD BE NO OBJECTION TO PROVIDING NIOSH WITH COPIES OF MANUALS, POSTERS, MAINTENANCE AND DATA SHEETS, SELL SHEETS, ETC. FOR THEIR RECORDS, BUT NOT AS A PART OF APPROVAL.

IT SEEMS TO 3M THAT THE LITERATURE DESCRIBED IN THIS SECTION IS SIMILAR TO THE MANUALS AND SUPPORTING RECORDS REQUIRED FOR QUALITY CONTROL PLANS. NIOSH HAS ACKNOWLEDGED THAT THIS REQUIREMENT DOES NOT CONTRIBUTE TO THE CURRENT TESTING AND CERTIFICATION PROGRAM, AND RECOMMENDS THAT THIS REQUIREMENT BE ELIMINATED. LIKEWISE, WE RECOMMEND THAT THIS PROPOSAL BE DROPPED AT THIS POINT.

IN REGARD TO THE OTHER SPECIFIC AREAS ABOUT WHICH NIOSH REQUESTED COMMENTS, MOST ANSWERS ARE SIMPLE. GROUP TESTING OF RESPIRATORS IS UNACCEPTABLE AS IT IS AN UNNECESSARY RESTRAINT OF TRADE. TO FORCE ALL MANUFACTURERS TO GO AT THE SAME PACE TO MAKE IT MORE CONVENIENT FOR NIOSH TESTING IS NOT ACCEPTABLE. NIOSH MUST EITHER TEST EFFICIENTLY OR GET MORE PEOPLE JUSTIFIED IN THEIR BUDGET IF THEY ARE TO CONTINUE TO TEST.

WE AGREE WITH NIOSH THAT THEY NO LONGER TRY TO MAKE AN IN DEPTH REVIEW AND APPROVE QUALITY CONTROL PLANS. THE PRODUCT QUALITY LIMITS THAT NIOSH SETS DEFINE QUALITY LEVELS. IN THE REAL WORLD THERE ARE NO 100% CERTAINITIES AS SO MANY VARIABLES EXIST OVER WHICH NO CONTROLS ARE POSSIBLE. NIOSH MUST BE SURE THEY SAMPLE AND STATISTICALLY REVIEW FIELD AUDITS OF PRODUCTS.

IN REGARD TO CHANGES TO APPROVED DEVICES, THE PRESENT SYSTEM IS INDISCRIMINATE AND PLACES MEANINGLESS BURDEN ON BOTH MANUFACTURER AND NIOSH.

3M'S VIEWS IN SUMMARY

1. AUTOCRATIC ADMINISTRATIVE ACTIVITIES BEING PERPETRATED AT NIOSH AND THE CURRENT CONCEPT OF DESIGN SPECIFICATION MUST BOTH BE ABANDONED. PERFORMANCE CRITERIA FOR PRODUCTS SHOULD BE JOINTLY ESTABLISHED BY NIOSH AND INDUSTRY.
2. REPRODUCIBLE TEST METHODS, WHICH CAN BE USED TO JUDGE WHETHER PRODUCTS MEET PERFORMANCE CRITERIA, SHOULD BE DEVELOPED AND AGREED UPON BY NIOSH AND INDUSTRY.
3. SELF-CERTIFICATION BY MANUFACTURERS SHOULD BE EMPLOYED. NIOSH AND MANUFACTURERS WOULD THEN HAVE MORE CONFIDENCE IN EACH OTHER. PROBLEMS OF NIOSH LIABILITY AND USE OF NIOSH AS A DEVELOPMENT LABORATORY WOULD BE ELIMINATED.
4. THE REMOVAL OF QUALITY ASSURANCE PLANS AS A REQUIREMENT FOR CERTIFICATION IS A GOOD START TOWARD THE ABOVE SYSTEM.
5. THE IDEA OF MANUALS, ETC., BEING SUBMITTED FOR APPROVALS IS COUNTERPRODUCTIVE TO THE IDEA OF ELIMINATING QUALITY ASSURANCE PLANS.

WE SINCERELY HOPE THAT THESE COMMENTS WILL ASSIST YOU IN PROMULGATING A NEW

SYSTEM WHICH WILL EMPHASIZE A TESTING AND CERTIFICATION PROGRAM BASED ON RESPIRATOR PERFORMANCE AND WHICH WILL BE ABLE TO ACCOMMODATE AND ENCOURAGE THE INTRODUCTION OF NEW AND INNOVATIVE PRODUCTS. WE SUBMIT THAT THESE GOALS CAN BE ACHIEVED WITHOUT SACRIFICING WORKER PROTECTION, AND IF NOT ACCOMPLISHED, WILL ULTIMATELY HAVE A MOST SEVERE NEGATIVE IMPACT UPON ALL THOSE WORKERS WHO DEPEND UPON OUR PROFESSIONAL EXPERTISE TO PROVIDE THEM THE BEST RESPIRATORY PROTECTION POSSIBLE.

THANK YOU.

RESPECTFULLY SUBMITTED,

EINAR D. HORNE
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