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Testimony Before the National Institute for
Occupational Safety and Health

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Occupational Safety and Health Administration

In the Matter of
Testing and Certification Program for
Personal Protective Equipment and Hazard Measuring Instruments

(Corrected Copy)

THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION WELCOMES THIS OPPORTUNITY TO PROVIDE TESTIMONY CONCERNING THE IMPROVEMENT OF THE NIOSH TESTING AND CERTIFICATION PROGRAM FOR RESPIRATORS.

WE HAVE LONG BELIEVED THAT SEVERAL CHANGES TO THE TESTING AND CERTIFICATION PROGRAM ARE NECESSARY TO ENSURE THAT THIS NATION'S WORKERS CAN HAVE CONFIDENCE THAT THE RESPIRATORS THEY WEAR ARE ADEQUATE AND RELIABLE.

AS I AM SURE YOU ALREADY KNOW, OSHA STANDARDS PRESCRIBE THE USE OF RESPIRATORS ONLY WHEN ENGINEERING CONTROLS ARE NOT FEASIBLE, DURING INSTALLATION OF ENGINEERING CONTROLS, OR IN EMERGENCIES. AT THIS TIME, A LARGE WORKER POPULATION RELIES ON RESPIRATORS FOR PROTECTION AND, AS MORE HEALTH STANDARDS ARE PROMULGATED BY OSHA, THE NUMBER OF WORKERS WHO MUST RELY ON RESPIRATORS FOR SOME PERIOD OF TIME WILL, OF NECESSITY, INCREASE. THE RECENT STANDARD REGULATING EXPOSURE TO LEAD SPECIFIES A PERIOD OF 10 YEARS BEFORE PRIMARY LEAD PRODUCTION COMPANIES MUST REDUCE EXPOSURES BY ENGINEERING CONTROLS. THIS MEANS THAT ALL EMPLOYEES OF THESE COMPANIES MUST RELY SOLELY ON RESPIRATORS FOR PROTECTION FROM LEAD UNTIL FEBRUARY 1989. IT IS THUS OBVIOUS THAT GOOD RESPIRATORY PROTECTION IS NOW, AND WILL CONTINUE TO BE, A VERY IMPORTANT ELEMENT IN PROTECTING WORKER HEALTH.

UP TO NOW THE NIOSH/MSHA RESPIRATOR TESTING AND CERTIFICATION PROGRAM IN 30 CFR 11 HAS BEEN THE ONLY ASSURANCE OF ADEQUATE QUALITY AND PERFORMANCE OF RESPIRATORS. OSHA BELIEVES THAT IT IS NOW NECESSARY TO BROADEN THIS RESPIRATOR TESTING PROGRAM AND DEAL WITH RECOGNIZED DEFICIENCIES.

AT THIS TIME OSHA DOES NOT WISH TO STATE A REFERENCE FOR ANY OF THE FOUR PROGRAM ALTERNATIVES DESCRIBED IN THE NOTICE OF THIS MEETING, BUT RATHER TO FOCUS ON THE NECESSARY CRITERIA FOR AN EFFECTIVE RESPIRATOR PROGRAM. IT IS OUR FEELING THAT IF SPECIFIC PROGRAM OPERATIONAL CRITERIA ARE DEVELOPED, ANY OF THE ALTERNATIVES CAN BE EFFECTIVE PROVIDED THAT FUNDING IS AVAILABLE TO IMPLEMENT THE PROGRAM.

OSHA BELIEVES THAT THE CURRENT 30 CFR PART 11 MUST BE REVISED TO ESTABLISH STATE-OF-THE-ART PERFORMANCE TESTING PROCEDURES AND CRITERIA. IT WILL ALSO BE NECESSARY TO MODIFY THE PERFORMANCE TESTING PROCEDURES AND CRITERIA TO KEEP PACE WITH TECHNOLOGY. HOWEVER, IN VIEW OF STATEMENTS IN THE FEDERAL REGISTER NOTICE FOR THIS MEETING, AN IMPORTANT DISTINCTION MUST BE DRAWN. THE PURPOSE OF RESEARCH IS NOT TO REFLECT THE CURRENT STATE OF KNOWLEDGE OR TO DISCOVER THE

STATE-OF-THE-ART; IT IS TO ADVANCE THE STATE-OF-THE-ART AND AND TO IMPROVE ON CURRENT KNOWLEDGE. THEREFORE, THERE NEED NEVER BE A DELAY AWAITING RESEARCH RESULTS TO DEVELOP PERFORMANCE SPECIFICATIONS THAT REFLECT THE CURRENT STATE-OF-THE-ART. ADDITIONAL RESEARCH IS ALWAYS LAUDABLE, BUT SOME OF THESE RESPIRATOR TESTING ISSUES HAVE AWAITED RESOLUTION LONG ENOUGH ALREADY. WE NEED TO PROCEED PROMPTLY WITH AN IMPROVED TESTING PROGRAM. IN THOSE INSTANCES WHERE RULEMAKING IS NECESSARY, THERE WILL OF COURSE BE THE USUAL PROCEDURAL DELAY, BUT WE BELIEVE THERE ARE IMPROVEMENTS WHICH CAN BE MADE TO THE EXISTING PROGRAM IMMEDIATELY IN THAT THEY WILL NOT REQUIRE RULEMAKING.

FIRST, WE FEEL IT IS NECESSARY TO INCREASE INSPECTION AND TESTING FREQUENCY OF RESPIRATORS. ACCORDING TO CURRENT PRACTICE, NIOSH PURCHASES APPROVED RESPIRATORS ON THE OPEN MARKET AND TESTS THEM TO DETERMINE WHETHER THE DEVICES ARE, IN FACT, IN AN APPROVED CONDITION. BECAUSE NIOSH HAS INDICATED THAT THEY HAVE A LIMITED BUDGET FOR PURCHASING SUCH EQUIPMENT, ONLY A SMALL NUMBER OF RESPIRATORS CAN BE TESTED EACH YEAR. TO ALLEVIATE THIS SITUATION RESPIRATOR MANUFACTURERS COULD BE REQUIRED TO PROVIDE A SPECIFIED NUMBER OF THEIR RESPIRATORS AS PART OF THEIR APPLICATION FOR APPROVAL. TO PRESERVE THE RANDOMNESS OF CHOICE OF UNITS, THE APPROVING AGENCY MUST BE ABLE TO CHOOSE

WHICH SPECIFIC UNITS ARE TO BE TESTED. ONE METHOD OF DOING THIS WOULD BE FOR THE MANUFACTURER TO ISSUE REIMBURSEMENT PURCHASE COUPONS TO THE APPROVING AGENCY WHICH WOULD THEN OBTAIN SAMPLES FOR TESTING FROM ANY DISTRIBUTOR IT CHOOSES USING THE COUPON AS PAYMENT. ^{also NIOSH's} OSHA'S FIELD STAFF COULD ASSIST THE APPROVING AGENCY IN SECURING THE RESPIRATORS FOR TESTING BY MAKING THESE "PURCHASES" AT DISTRIBUTORS THROUGHOUT THE COUNTRY. TO INCREASE TESTING BY GETTING THE MAXIMUM USE OF EXISTING TESTING EQUIPMENT, NIOSH COULD HIRE PART-TIME HELP AND IN-HOUSE CONTRACTORS TO TEST RESPIRATORS OR SOME OF THE TESTING COULD BE EXPANDED TO A TWO-SHIFT BASIS.

RESPIRATORS THAT HAVE HAD THE APPROVAL CERTIFICATE AMENDED SHOULD BE COMPLETELY RETESTED. IF THE MODIFIED RESPIRATOR QUALIFIES FOR APPROVAL, IT SHOULD RECEIVE A NEW APPROVAL NUMBER.

THERE ARE SEVERAL CHANGES TO 30 CFR PART 11 THAT OSHA BELIEVES ARE DESIRABLE AND THAT DO NOT REQUIRE ADDITIONAL SUPPORTING RESEARCH. FOR INSTANCE, DURATION OF RESPIRATOR APPROVALS CAN BE ESTABLISHED WITHOUT WAITING FOR NEW TESTING CRITERIA. UNDER THE CURRENT PROGRAM, A RESPIRATOR APPROVED 40 YEARS AGO CAN STILL BE USED TODAY. THIS PRACTICE CURTAILS INCENTIVE FOR INNOVATION IN TECHNOLOGY AND CAN ALSO, AS YOU POINT OUT, RESULT IN CONFUSING

Supports periodic recertification

SITUATIONS. THE DURATION OF APPROVAL SHOULD BE SPECIFIC BUT VARIED WITH DIFFERENT TYPES OF RESPIRATORS. LONGER DURATIONS SHOULD BE GRANTED FOR MORE COMPLICATED OR EXPENSIVE EQUIPMENT SINCE USERS ARE NOT LIKELY TO REPLACE THE EQUIPMENT AS OFTEN. AN ALTERNATIVE IS TO LIMIT EACH APPROVAL TO FIVE YEARS, AND AFTER THAT PERIOD, SUBJECT EACH APPROVAL TO YEARLY REVIEWS TO DETERMINE WHETHER AN EXTENSION IN APPROVAL SHOULD BE GRANTED. THIS ALTERNATIVE, HOWEVER, APPEARS ADMINISTRATIVELY UNTENABLE.

WE WOULD LIKE TO POINT OUT THAT THE SITUATION DESCRIBED IN THE SECTION OF THE NOTICE ON DURATION OF APPROVAL REPRESENTS A VIOLATION OF THE BASIC PREMISE STATED UNDER "CHANGES TO APPROVED DEVICES" THAT CONTINUED APPROVAL WOULD ONLY BE FOR MODIFICATIONS THAT DO NOT AFFECT FORM, FIT, OR FUNCTION. DISSIMILAR VERSIONS OF A DEVICE SURELY MUST INCORPORATE SOME CHANGE OF FORM, FIT, OR FUNCTION WITH THE EXCEPTION OF DIFFERENT COLORS. CLEARLY WITH NO DIFFERENCE OF FORM, FIT, OR FUNCTION THERE SHOULD NOT BE ANY DANGER REGARDLESS OF WHICH UNIT IS CHOSEN FOR USE. RESPIRATORS AS DIFFERENT AS DESCRIBED IN THAT SECTION SHOULD BE SEPARATELY APPROVED IF THEY PASS THE REQUISITE TESTS.

A STOP-SALES-AND-RECALL PROCEDURE SHOULD BE FORMALLY ESTABLISHED. THE CURRENT REGULATIONS HAVE NEITHER PROVISIONS FOR HALTING THE SALES OF A RESPIRATOR NOR FOR A RECALL OF DEFECTIVE DEVICES. THUS, THESE PROCEDURES APPEAR VERY OPEN TO CHALLENGE BY MANUFACTURERS. A STOP-SALES-AND-RECALL REGULATION SHOULD REQUIRE A STATISTICALLY SIGNIFICANT NUMBER OF RESPIRATORS TO BE TESTED TO DETERMINE THE EXTENT OF THE DEFECT. RECALL SHOULD BE LIMITED TO THOSE CASES THAT POSE SOME IMMEDIATE HAZARD TO THE WEARER. IF TESTING REVEALS DEFECTS WHICH LEAD NIOSH TO BELIEVE THAT THE RESPIRATOR SHOULD NOT BE USED, THE APPROVAL SHOULD BE SUSPENDED UNTIL THE RESPONSIBLE DEFECT IS CORRECTED OR A MORE SUITABLE UNIT IS DEVELOPED. A PANEL WHICH CONSISTS OF GOVERNMENT OFFICIALS AND INDEPENDENT RESPIRATOR EXPERTS SHOULD REVIEW EVERY CASE TO DETERMINE WHETHER STOP SALES, RECALLS OR DECERTIFICATION IS NECESSARY.

OSHA DOES NOT AGREE WITH THE POSITION STATED IN THE MEETING NOTICE THAT QUALITY CONTROL PLAN REQUIREMENTS SHOULD BE ELIMINATED FROM 30 CFR PART 11. IN FACT, WE RECOMMEND THAT 30 CFR PART 11 BE REVISED TO ESTABLISH UNIFORM QUALITY CONTROL PLANS. UNDER CURRENT REGULATIONS THE MANUFACTURER IS ALLOWED BROAD DISCRETION REGARDING THE STRINGENCY OF THE QUALITY CONTROL PLAN AND CHOICE OF

FACTORS TO BE INSPECTED. INSTEAD, OF THIS DISCRETION, EACH MANUFACTURER OF A GIVEN TYPE OR STYLE OF RESPIRATOR SHOULD BE REQUIRED TO TEST THE SAME QUALITIES, ITEMS, AND FUNCTIONS.

OSHA AGREES THAT PRODUCT QUALITY CONTROL IS INHERENTLY A MANUFACTURER'S RESPONSIBILITY. HOWEVER, IF NIOSH WERE TO ESTABLISH A SET OF TEST CRITERIA TO USE IN MONITORING A MANUFACTURERS ADHERENCE TO EFFECTIVE QUALITY CONTROL AND TO ENSURE THAT THE PERCENT DEFECTIVE RATE IS LESS THAN A GIVEN VALUE, NIOSH WOULD IN ESSENCE HAVE ITS OWN QUALITY CONTROL PROGRAM. THE CRITERION FOR EACH QUALITY, ITEM, OR FUNCTION SPECIFIED BY NIOSH FOR ITS MONITORING WOULD BY NECESSITY BE ADOPTED BY EACH MANUFACTURER. SUCH NIOSH CRITERIA WOULD BE IMPORTANT ENOUGH THAT THEY SHOULD BE ESTABLISHED BY RULEMAKING IN 30 CFR PART 11.

IN THIS CONTEXT IT IS RELEVANT TO POINT OUT TWO ESSENTIAL USES FOR AN ANALYSIS OF DIMENSIONAL TOLERANCES. THE TOLERANCE SET BY A MANUFACTURER WILL INFLUENCE THE MECHANICS OF THE SAMPLING AND THE INTERPRETATION OF THE SAMPLING IN A QUALITY CONTROL PROGRAM. A CONSIDERATION OF MANUFACTURING TOLERANCES IS A NECESSARY PART OF DESIGNING THE NIOSH MONITORING. IN ADDITION AN ANALYSIS OF THE DIMENSIONAL TOLERANCES MAY AFFECT WHETHER A RESPIRATOR DESIGN SHOULD BE

APPROVED. VARIATIONS IN DIMENSIONS OF A FACEPIECE OR HARNESS PARTS WILL AFFECT THE CONSISTENCY OF FIT ON ANY PERSON AND WILL AFFECT THE RANGE OF POPULATION THAT CAN EXPECT TO BE FITTED.

WE SEE NO REASON WHY FILTERS, CARTRIDGES, AND OTHER COMPONENTS OF RESPIRATORS SHOULD NOT BE INTERCHANGEABLE BETWEEN DIFFERENT MODELS OR EVEN BETWEEN DIFFERENT MANUFACTURERS. SUCH COMPONENTS COULD BE SEPARATELY TESTED AND APPROVED. AT THE SAME TIME IT SHOULD BE A SMALL CHALLENGE FOR MANUFACTURERS TO USE STANDARDIZED FITTINGS, THREADS, SIZES ETC. OR MAKE ADAPTER FITTINGS SO THAT INTERCHANGEABILITY IS PHYSICALLY POSSIBLE. WE BELIEVE THAT SUCH INTERCHANGEABILITY WOULD PROMOTE COMPETITION AND PRODUCT IMPROVEMENT.

IN GENERAL, THE REVISION OR IMPROVEMENT OF THE 30 CFR PART 11 SHOULD BE EVOLUTIONARY RATHER THAN REVOLUTIONARY SO THAT CHANGE CAN BEGIN PROMPTLY. WE DO NOT EXPECT RADICAL OVERNIGHT CHANGES, BUT GRADUAL IMPROVEMENT AND UPDATING OF TESTING CRITERIA AS NEW RESEARCH FINDINGS BECOME AVAILABLE IS ESSENTIAL. WE HOPE THAT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES WILL SET A HIGH PRIORITY FOR AND PROVIDE MORE LEGAL ASSISTANCE TO THE REVISION OF 30 CFR PART 11.

THE REVISED RULES SHOULD INCLUDE CONSIDERATION OF RESPIRATOR DESIGN CRITERIA. ENGINEERING DESIGN IS NOT SYNONYMOUS WITH FAILURE MODE ANALYSIS AND THE TERMS SHOULD NOT BE USED INTERCHANGEABLY. THE THREE ELEMENTS OF THE EVALUATION SUGGESTED-- SOUND ENGINEERING AND SCIENTIFIC PRINCIPLES, CONSTRUCTION OF SUITABLE MATERIALS, AND EVIDENCE OF GOOD WORKMANSHIP--ARE UNACCEPTABLY VAGUE. BECAUSE PERFORMANCE IS THE ONLY ARBITER OF ACCEPTABILITY, REQUIRING SOUND ENGINEERING AND SCIENTIFIC PRINCIPLES IN DESIGN IS UNNECESSARY. CONSTRUCTION OF SUITABLE MATERIALS AND EVIDENCE OF GOOD WORKMANSHIP CAN BE EXPRESSED IN EXPLICIT TERMS OF DIMENSIONS, TEST RESULTS, AND EXACT QUALITATIVE PERAMETERS. A HOSE CLAMP SERVICEABLE AFTER X NUMBER OF HOURS IN AN ACID ENVIRONMENT IS AN EXAMPLE OF A TEST RESULT.

RESPIRATOR DESIGN SHOULD BE BASED ON THE PHYSIOLOGICAL LIMITATIONS OF THE WEARER. THE MAXIMUM BREATHING RESISTANCE AND AIR FLOW PERMITTED FOR EACH TYPE OF RESPIRATOR AS SPECIFIED IN THE 30 CFR 11 MAY NOT HAVE SCIENTIFIC BASIS. UNDER HEAVY WORKLOAD, A 30-MINUTE-SERVICE-LIFE AIR CYLINDER ON A SCBA MAY ONLY LAST 20 MINUTES. IN ADDITION, SOME APPROVED AIR-PURIFYING RESPIRATORS MAY BE PHYSICALLY UNBEARABLE TO WEAR.

THE DESIGN OF A RESPIRATOR SHOULD BE WEARER-ORIENTED AND ERGONOMIC CONSIDERATIONS SHOULD GOVERN THE DESIGN OF THE RESPIRATOR UNIT. DESIGN CRITERIA SHOULD ACCOMMODATE THE VARIOUS GEOMETRIES OF THE HUMAN FACE, ESPECIALLY CONCERNING FACE SIZE AND FEATURES. THE FACEPIECE SHOULD HAVE A RELATIVELY COMFORTABLE FIT. THE RESPIRATOR SHOULD ACCOMMODATE THE WEARING OF EYEGLASSES. THE LOCATION OF FILTERING ELEMENTS AND BREATHING TUBES SHOULD MINIMIZE THE RESTRICTION OF VISION, AND PERMIT NORMAL RANGE OF MOTION. COMPONENTS WHICH NEED FREQUENT SERVICING SHOULD BE READILY ACCESSIBLE. THE RESPIRATOR SHOULD BE EASY TO CLEAN AND INSPECT FOR POTENTIAL DEFECTS.

WHEN SELECTING MATERIALS TO MAKE THE VARIOUS COMPONENTS, THE ENVIRONMENT IN WHICH THE RESPIRATOR IS USED MUST BE CONSIDERED. A RESPIRATOR SHOULD WITHSTAND TEMPERATURE AND HUMIDITY EXTREMES. IT SHOULD RESIST CORROSION, IMPACT, ABRASION AND VIBRATION.

SEVERAL CHANGES SHOULD BE MADE TO THE FILTER TESTING CRITERIA. THE CHEMICAL CARTRIDGES SHOULD BE TESTED AT 80% OR HIGHER RELATIVE HUMIDITY BECAUSE A MAJOR PORTION OF THE CHEMICAL INDUSTRIES ARE LOCATED IN THE HIGH-HUMIDITY GULF COAST AREAS. THE SILICA MIST TEST SHOULD BE REPLACED WITH AN OIL MIST CHALLENGE

AND A CHROMIC ACID MIST CHALLENGE TO MORE EFFECTIVELY REFLECT THE ACTUAL USE PERFORMANCE REQUIREMENTS OF FILTERS. THE LEAD FUME TEST SHOULD BE REPLACED WITH ONE THAT IS MORE PREDICTABLE AND STABLE IN FUME CONCENTRATION AND PARTICLE SIZE, SUCH AS THE USE OF LEAD ACETATE FROM A LIQUID GENERATOR. QUANTITATIVE FIT TESTING STUDIES INDICATE THAT NEGATIVE-PRESSURE ATMOSPHERE SUPPLYING RESPIRATORS OFFER MUCH LESS PROTECTION THAN THEIR POSITIVE-PRESSURE COUNTERPARTS. IT IS A WASTE OF LIMITED RESOURCES TO TEST SUCH EXPENSIVE LOW PERFORMANCE RESPIRATORS. CONSEQUENTLY THE NEGATIVE PRESSURE UNITS SHOULD NO LONGER BE APPROVED.

THE TEST METHODS FOR FILTER MEDIA FOR PARTICULATE MATERIALS MUST BE RECONSIDERED. THE METHOD USED CURRENTLY TO TEST PARTICULATE FILTERS ONLY DETERMINES THE INTEGRATED PENETRATION OVER THE TESTING PERIOD WITH A VERY HIGH AEROSOL CONCENTRATION. CONSIDERING THE TREND OF SETTING LOWER PERMISSIBLE EXPOSURE LIMITS FOR TOXIC SUBSTANCES, THIS METHOD BECOMES LESS AND LESS APPROPRIATE. DURING EMPLOYEE USE THE FILTER MAY NOT LOAD UP AND IMPROVE THE FILTRATION EFFICIENCY. EMPLOYEES THEN WOULD END UP EXPOSED TO MUCH HIGHER THAN PREDICTED LEVELS OF THE FINE PARTICLES WHICH HAVE PENETRATED THROUGH THE FILTER MEDIA.

A TEST METHOD DETERMINING THE INITIAL PENETRATION THROUGH THE FILTER AND RATE OF PENETRATION FALLOFF SHOULD BE DEVELOPED.

CONCERNING THE SORBENT FOR GASES AND VAPORS, IT IS WELL DOCUMENTED THAT THE BREAKTHROUGH TIMES VARY GREATLY. RESPIRATOR CARTRIDGES SHOULD BE TESTED AGAINST A SPECIFIED NUMBER OF GASES OR VAPORS, BUT NOT JUST A SINGLE ONE.

IN REFERENCE TO SPECIAL-USE AIR-PURIFYING RESPIRATORS, CURRENT TESTING METHODS FOR PAINT SPRAY, PESTICIDE, AND MIST RESPIRATORS EMPLOY TESTING AGENTS WHICH HAVE NO RELATION TO THE REAL SUBSTANCE. FOR EXAMPLE, IF A RESPIRATOR PASSES A LEAD FUME AND AN ORGANIC VAPOR TEST IT CAN BE CERTIFIED AS A RESPIRATOR FOR PESTICIDES. ANOTHER EXAMPLE, THERE ARE NO TESTING CRITERIA FOR MERCURY VAPOR CARTRIDGES. MORE REALISTIC TESTING METHODS FOR SUCH SUBSTANCES SHOULD BE DEVELOPED. UNDER CURRENT REGULATIONS A DISPOSABLE RESPIRATOR THAT IS SUBJECTED TO A SINGLE TEST, WHICH IS A SILICA DUST TEST, IS APPROVED FOR PROTECTION AGAINST ASBESTOS, A KNOWN HUMAN CARCINOGEN.

ELECTROSTATIC FILTER MEDIA FOR PARTICULATE FILTRATION IS KNOWN TO BE SEVERELY DEGRADED BY HIGH HUMIDITY AND EXPOSURE TO OIL MISTS. IT ALSO LOSES ITS EFFICIENCY DURING STORAGE. SINCE MECHANICAL FILTER MEDIA, SUCH AS FIBER GLASS, ARE AVAILABLE, ELECTROSTATIC MEDIA SHOULD NO LONGER BE CONSIDERED ACCEPTABLE.

THERE ARE OTHER NOW OBVIOUS PROGRAM CHANGES WHICH MUST AWAIT THE RESULTS OF FURTHER RESEARCH. THIS RESEARCH SHOULD BEGIN AS SOON AS FEASIBLE. THE SHELF-LIFE FOR FILTERS AND SORBENTS MUST BE CONSIDERED. MOST RESPIRATOR FILTERS ARE MADE WITH ELECTROSTATIC ELEMENTS WHICH DEGRADE UPON STORAGE. FURTHERMORE, THE SERVICE LIFE OF SORBENTS, SUCH AS ACTIVATED CHARCOAL, MAY BE SHORTENED IF THEY ARE EXPOSED TO HUMID ENVIRONMENTS. TESTS SHOULD BE CONDUCTED TO DETERMINE THE SHELF LIFE OF FILTERS AND SORBENTS. FILTER ELEMENTS SHOULD BE LABELLED TO INDICATE WHEN THEY ARE NO LONGER SERVICEABLE.

MANY RESPIRATOR MANUFACTURERS PROVIDE ONLY ONE SIZE OF FACEPIECE. ONE SIZE IS NOT LIKELY TO ACHIEVE PROPER FIT FOR INDIVIDUALS WITH WIDELY DIFFERING FACIAL CHARACTERISTICS. AT THE PRESENT TIME WE HAVE NO WAY TO PREDICT ADEQUACY OF FIT BASED ON ANY FACIAL MEASUREMENTS. RESEARCH MUST BE CONDUCTED TO DETERMINE DISTRIBUTION AT FACIAL DIMENSIONS OF THE AMERICAN WORK POPULATION. THERE IS A VERY SERIOUS NEED TO FIND A FACIAL DIMENSION THAT IS A GOOD PROXY FOR FACEPIECE FIT. SUCH A PROXY MEASURE WOULD ALLOW THE SELECTION OF BETTER PANELS FOR FIT TESTING AND ALSO PERMIT THE SELECTION OF A MEANINGFUL SERIES OF PANELS SPECIFICALLY FOR VARIOUS SIZE CATEGORIES.

I WOULD NOW LIKE TO ADDRESS ITEMS DISCUSSED IN THE NOTICE NOT ALREADY COVERED. AT THE PRESENT TIME, THERE IS NO UNIFORMITY IN THE USER INSTRUCTIONS PROVIDED BY THE MANUFACTURERS. A PROPER INSTRUCTION MANUAL SHOULD CONTAIN AT LEAST AN EXPLANATION OF THE CAPABILITIES AND LIMITATIONS OF A RESPIRATOR.

PROPER FITTING AND USE SHOULD BE EXPLAINED AS WELL AS METHODS OF INSPECTIONS, CLEANING, STORAGE, TROUBLESHOOTING, AND SIMPLE REPAIR OF EACH PARTICULAR UNIT. FINALLY, SPARE PARTS SHOULD BE LISTED AND A SIMPLE DIAGRAM PROVIDED.

RESPIRATORS SHOULD BE FIELD TESTED. ESPECIALLY IN THE CASE OF INITIAL APPROVAL TESTING, EVEN IF A RESPIRATOR HAS BEEN WELL DESIGNED AND HAS PASSED ALL PERFORMANCE TESTING CRITERIA, PROBLEMS CAN STILL BECOME EVIDENT DURING FIELD USE. NIOSH SHOULD ISSUE A CONDITIONAL APPROVAL FOR A RESPIRATOR WHICH HAS PASSED ALL PERFORMANCE CRITERIA PENDING SATISFACTORY FIELD TESTING RESULTS. INITIALLY, FIELD TESTING SHOULD BE CONDUCTED ON HIGH PROTECTION RESPIRATORS SUCH AS SCBA, SUPPLIED-AIR, AND POWER AIR-PURIFYING RESPIRATORS. LATER ON, ALL APPROVED RESPIRATORS SHOULD BE SUBJECT TO FIELD TESTING.

OSHA AGREES THAT APPROVAL TESTING SHOULD BE PERFORMED ON REGULAR PRODUCTION UNITS. PROTOTYPE UNITS MAY NOT FAIRLY REPRESENT THE FINAL REGULAR PRODUCTION

UNITS. IF TESTING IS DONE ON PREPRODUCTION UNITS, THEN ONLY A PROVISIONAL APPROVAL SHOULD BE GRANTED.

SECURING USED RESPIRATORS FOR TESTING SHOULD NOT BE EQUATED WITH QUALITY CONTROL. THE MANUFACTURER IS NEVER RESPONSIBLE FOR DEFECTS OF USE AND ABUSE WHICH ARE THE RESULT OF USER ACTIONS. ONLY IN RESPONSE TO A NEW PERFORMANCE CRITERION ON DURABILITY OF RESPIRATORS OR THEIR COMPONENTS WOULD THIS TYPE OF TESTING BE LEGITIMATE. HOWEVER, ESTABLISHING A SINGLE CRITERION APPLICABLE TO ALL USES OF A RESPIRATOR TYPE WOULD BE VERY DIFFICULT.

OSHA HAS OFTEN RECEIVED VARIANCE REQUESTS CONCERNING THE USE OF LIMITED PRODUCTION, SPECIAL-PURPOSE RESPIRATORS. OSHA CANNOT DETERMINE THE EFFECTIVENESS OF THOSE RESPIRATORS. NIOSH OFTEN CLAIMS THAT THE RESPIRATOR USER MUST SUBMIT DETAILED QUALITY ASSURANCE PLANS WHICH ARE NOT FEASIBLE FOR THE SMALL NUMBER OF RESPIRATORS INVOLVED. NIOSH SHOULD GIVE SPECIAL CONSIDERATION TO THE REALISTIC AND PRACTICAL TESTING AND CERTIFYING OF LIMITED PRODUCTION RESPIRATORS.

IF AN INNOVATIVE RESPIRATOR DESIGN HAS BEEN DEVELOPED AND SUBMITTED TO NIOSH FOR TESTING, SOMETIMES NIOSH CANNOT TEST AND CERTIFY THE DEVICE BECAUSE THERE ARE NO CRITERIA AVAILABLE. SPECIAL PROVISIONS SHOULD BE MADE IN THE REVISION OF 30 CFR PART 11 TO ACCOMMODATE NEW DESIGNS IN RESPIRATORS.

OSHA DOES NOT BELIEVE THAT GROUP TESTING OF RESPIRATORS WOULD BE AN IMPROVEMENT. FUNDAMENTALLY IT IS INCONSISTENT TO CLAIM THAT A SYSTEM BASED ON WAITING UNTIL A TIME IN THE FUTURE WILL MAKE A PROGRAM MORE RESPONSIVE. THE RELATIVE TIME OF TESTING DIFFERENT UNITS OF A GIVEN CLASS OR TYPE SHOULD HAVE NO INFLUENCE ON THE SPEED OF THE TESTING AND EVALUATION PROCESS ITSELF. AIR-PURIFYING AND ATMOSPHERE-SUPPLYING RESPIRATORS ARE TESTED BY DIFFERENT PERSONNEL ANYWAY. THE TEST EQUIPMENT IS DESIGNED FOR A SPECIFIC TYPE OF RESPIRATOR. THEREFORE THERE SHOULD BE LITTLE PROBLEM IN TESTING ANY RESPIRATOR AS IT ARRIVES WITHOUT WAITING FOR BATCH PROCESSING.

THE PUBLICATION OF TEST RESULTS WOULD SERVE LITTLE PURPOSE UNDER PRESENT CIRCUMSTANCES BECAUSE THE TEST METHODS ARE NOT REALLY MEANINGFUL. FOR EXAMPLE AIR-PURIFYING RESPIRATORS ARE ONLY TESTED FOR FILTER EFFICIENCY. A RESPIRATOR CAN PROVIDE VERY EFFICIENT PARTICULATE FILTRATION YET BE VERY UNCOMFORTABLE TO WEAR AND NOT FIT A MAJORITY OF WEARERS. WE DO THINK THAT FULL PUBLICATION OF ACTUAL TEST DATA VALUES FOR ALL APPROVED RESPIRATORS CAN BE VERY BENEFICIAL IF THE RESPIRATORS ARE THOROUGHLY EVALUATED BY A COMPLETE REALISTIC TEST REGIMEN.

MANY OF THE EIGHTEEN QUESTIONS RAISED BY THE CONSULTANTS HAVE ALREADY BEEN ANSWERED, BUT A FEW REMAIN FOR COMMENT:

PROVISIONS SHOULD BE MADE FOR USER COMMENTS. AT PRESENT THERE IS NO MECHANISM FOR ACTION BASED ON FEEDBACK FROM THE RESPIRATOR USERS TO NIOSH. ONE WAY TO DO THIS WOULD BE A USER COMMENT CARD ATTACHED TO THE INSTRUCTION MANUAL SO THE USER CAN NOTIFY NIOSH IF THERE IS A REAL OR POTENTIAL DEFECT FOUND IN THE DESIGN AND CONSTRUCTION OF THE RESPIRATOR. NIOSH SHOULD REQUIRE REGISTRATION WITH THE MANUFACTURER OF ANY HIGH PROTECTION-FACTOR RESPIRATORS OR A DEVICE WHICH IS TO BE USED IN AN ENVIRONMENT IMMEDIATELY DANGEROUS TO LIFE OR HEALTH. THE USER COULD THEN BE NOTIFIED BY THE MANUFACTURER PROMPTLY IF A POTENTIAL DEFECT WERE DISCOVERED.

THE CONSULTANTS POSE THE QUESTION OF FURTHER RESEARCH. OSHA BELIEVES THAT RESPIRATORY PROTECTION IS TOO IMPORTANT TO EMPLOYEE HEALTH NOT TO BE A VERY WORTHWHILE TOPIC OF MORE RESEARCH TO IMPROVE WHAT IS IN MANY RESPECTS A FAIRLY BASIC TECHNOLOGY AT PRESENT.

ONE FACTOR IN RESPIRATORY PROTECTION IS RELATIVELY NEW AND OF UNCERTAIN IMPACT ON THE REST OF A RESPIRATORY PROTECTION PROGRAM INCLUDING THE NEED FOR TESTING AND CERTIFYING RESPIRATORS. THIS NEW FACTOR IS QUANTITATIVE FIT TESTING (QNFT). QNFT PROMISES TO GIVE INDIVIDUALLY TAILORED EVALUATION OF THE EFFECTIVENESS OF ANY RESPIRATOR FOR ANY WEARER. THIS WOULD APPEAR TO

DRASTICALLY ALTER ONE OF THE PRESENT BASIC CONCERNS ABOUT RESPIRATORS, THAT IS, ASSURING A MINIMALLY PROTECTIVE RESPIRATOR IN A PREDICTIVE MANNER. THE CLASS PROTECTION FACTORS, THE QUALITY CONTROL PROGRAM, AND UNIT CERTIFICATION ARE IN LARGE MEASURE AN EFFORT TO CONFIDENTLY PREDICT THAT A RESPIRATOR WILL PROTECT.

WE HOPE THESE REMARKS WILL BE USEFUL TO YOU IN EVALUATING WHAT CHANGES TO MAKE TO THE TESTING AND CERTIFICATION PROGRAM. THERE ARE MANY CHANGES THAT OSHA BELIEVES ARE VERY NECESSARY.

THIS CONCLUDES MY PREPARED REMARKS.